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Centers for Medicare & Medicaid Services
Clinical Diagnostic Laboratory Test Payment System Proposed Rule
MLN Connects National Provider Call
Moderator: Amanda Barnes
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Contents

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

I will now turn the call over to Amanda Barnes. Thank you, you may begin.

Announcements and Introduction

Amanda Barnes: Thank you Crystal. I am Amanda Barnes from the Provider Communications Group here at CMS, and I am your moderator today. I would like to welcome you to this MLN Connects National Provider Call on Clinical Diagnostic Laboratory Test Payment System Proposed Rule.

MLN Connects Calls are part of the Medicare Learning Network®. The Clinical Diagnostic Laboratory Test Payment System Proposed Rule would significantly revise the Medicare payment system for clinical diagnostic laboratory tests and implement a related data collection system. This call will not include a question-and-answer session.

Before we get started, I have a couple of announcements. You should have received a link to today's slide presentation email. If you have not already done so, you may view or download the presentation from the following URL, www.cms.gov/npc. Again, that URL is www.cms.gov/npc. At the left side of the web page, select National Provider Calls and Events, then select the date of today's 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. Registrants will receive an email when these materials are available.

At this time, I would like to turn the call over to Rasheeda Johnson. Rasheeda?

Presentation

Rasheeda Johnson: Thanks Amanda. We'll begin this presentation with an overview of the proposed policy regarding CMS-1621-P, current Clinical Laboratory Fee Schedule. 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, and the payment rates were based on changes — charges to the Medicare program. The fee schedule is updated annually to establish payment amounts for new tests and/or for statutory across-the-board updates. However, there is currently no other mechanism for updating it. Additionally, payments for new tests added to the fee schedule are not implemented in a budget-neutral manner.

Payment for a new test code on the fee schedule established after 1984 is based on either crosswalking, where an existing test or tests on the fee schedule with a similar methodology is used as a basis for the payment, or gapfilling, where a test with no similar methodology is tasked to the Medicare Administrative Contractors to develop a payment.

The CLFS provides payment for approximately 13,000 clinical diagnostic laboratory tests, and Medicare pays approximately $8 billion per year for these tests. Medicare-enrolled laboratories are a mix of national chains that perform a large menu of tests and small regional operations that have a small menu of tests and/or concentrate on specific population, such as serving nursing home residents. Physician offices also perform certain tests that are paid under the fee schedule.

Overview of the Protecting Access to Medicare Act

The Protecting Access to Medicare Act, PAMA. Section 216 of the Protecting Access to Medicare Act of 2014, also known as PAMA, added new section 1834A of the Social Security Act and requires significant changes to the process for pricing clinical diagnostic laboratory tests under the fee schedule.

CMS's proposal for implementing the provisions of the PAMA was displayed in the *Federal Register* on September 25th, 2015, and published on October the 1st. Under PAMA, CMS is required to collect data from applicable laboratories on the payment rates that they receive from private payors and the volume of tests associated with each payment rate.

For certain designated exceptions, PAMA requires that the payment amount for tests on the fee schedule furnished on or after January 1st, 2017, will equal to the weighted median of the private payor rates reported for the test based on the private payor rates and volumes of data collected from the laboratories. The public comment for the proposed rule will close on November 24th, 2015.

Slide 6, who will be required to report? PAMA defines laboratory subject to the new reporting requirements or an applicable laboratory as having the majority of its Medicare revenues paid under the CLFS or the Physician Fee Schedule, PFS.

First, as PAMA does not provide a definition for a laboratory, we propose to use the CLIA — or CLIA definition of laboratory at section 493.2 of the regulations for defining the laboratory portion of the term applicable laboratory. We also propose to define a laboratory as any entity with at least one facility performing laboratory tests and meeting the CLIA definition, which would include a wide variety of organizational structures, including systems with other types of providers and suppliers, such as hospitals. In such situations, the entire organization would be considered a laboratory for data reporting purposes under section 1834A. Proposed to rely on the tax

identification number, the TIN, as a mechanism for defining the entity required to submit payment data to CMS.

Slide 7, majority defined. Next, we address what majority means for the purpose of this provision. We propose to define majority using the commonly understood meaning of majority as more than 50 percent. For a laboratory organization that is comprised of multiple facilities performing laboratory testing that meet the CLIA definition under one parent organization or that includes other types of providers and suppliers all sharing the same TIN, we would consider the organization to be an applicable laboratory if more than 50 percent of the total revenues of the entire organization are received from payment under the CLFS or Physician Fee Schedule.

The proposed definition would exclude the majority of hospital laboratories, which, we believe, is consistent with the intent of the statute. The requirements for majority of the revenues deriving from the CLFS or Physician Fee Schedule in and of itself would exclude most hospitals as the majority of their revenues would be from the IPPS and OPPS. Also, most hospital laboratory services are furnished to hospital inpatients and outpatients. These laboratory services are paid by Medicare as part of bundled or packaged service.

Low expenditure threshold established, slide 8. We also propose to create a low expenditure threshold in order to reduce reporting burden for small laboratories, particularly physician offices. We propose that a laboratory that received less than $50,000 per year from payments under the CLFS be exempt from reporting. A laboratory organization is comprised of multiple facilities performing laboratory tests — testing that meet the CLIA definition under one parent organization or that includes other types of providers and suppliers all sharing a single TIN would have to look at its entire organization to determine whether it meets the $15,000 per year low-volume threshold.

Data Collection and Reporting

What data will be collected by CMS? PAMA requires that applicable laboratories report to CMS the payment rate that was paid by each payor for the testing during the data collection period and the volume of such tests for each such payor for the period. PAMA defines the term private payor as: (a) a health insurer — a health insurance insurer in a group health plan, as such terms are defined in section 2791 of the Public Health Service Act; (b) a Medicare Advantage plan under Part C; (c) a Medicaid managed care organization, as defined in section 1903(m).

We will use the statutory definitions and how those definitions have been applied through regulations for their respective purposes to implement the PAMA provision.

PAMA provides that in cases where an applicable lab has more than one payment rate for the same payor for the same test or more than one payment for rate — for different payors for the same test, applicable laboratories shall report each such payment rate and the volume for the test of each such rate under this subsection.

PAMA also provides that beginning with January 1, 2019, the Secretary may establish rules for — to aggregate reporting in such situations. We propose to preclude any entity that does not meet the definition of applicable laboratory from reporting applicable information to CMS.

What are the data collection and reporting periods, slides 10, 11? PAMA requires that applicable laboratories submit private payor data for clinical diagnostic laboratory tests that are not ADLTs every 3 years. For ADLTs, laboratories must report data annually. For the initial data collection period only, we propose to collect only 6 months of data, July 1 through December 31st, 2015, to reduce burden on laboratories, given the delay in releasing the proposed rule and limit – limited time to prepare for 2016 reporting.

Consistent with this proposal, we also propose that the low-volume threshold for the initial data collection reporting period only would be $25,000. We propose that future data collection periods would be a full calendar year. We also propose a data collection reporting process that would require laboratories to report to CMS the data that they collected for the previous calendar year by April 1 of the current calendar year to determine payment rates that are effective beginning on January 1 of the following calendar year.

How would CMS calculate the new payment amount for tests on the CLFS, slide 12? As previously mentioned, PAMA requires that the payment amount for a test on the fee schedule furnished on or after January 1, 2017, be equal to the weighted median private payor rate reported for the test for the most recent data collection period. The weighted median for each test will be calculated by arraying distribution of all payment rates reported for the reporting period, the test weighted by the volume for which each payor and each laboratory. We propose to calculate the weighted median private payor rate for a test in the manner in which the statute specifies.

How would CMS establish the payment amount for a test when no private data are received for the test? We propose to use gapfilling or crosswalking to price tests for which we receive no private payor.

Sarah Harding will later in this presentation discuss penalties for nonreporting. This ends my portion of the presentation. Before Craig proceeds with the next section on advanced diagnostic laboratory tests, I'll turn the presentation back briefly to Amanda.

Keypad Polling

Amanda Barnes: Thank you Rasheeda. At this time we will pause for a few moments to complete keypad polling. Crystal, we're ready to start.

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 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. Please continue to hold while we complete the polling.

Thank you for your participation. I would now like to turn the call back to Amanda Barnes.

Presentation Continued

Amanda Barnes: Thank you Crystal. Craig, we're ready to resume our presentation.

Craig Dobyski: Thank you Amanda. In this next segment, we're going to be discussing a special category of tests, designated as advanced diagnostic laboratory tests, or ADLTs. We'll begin with the statutory definition of an ADLT.

Advanced Diagnostic Laboratory Tests

PAMA defines ADLTs in two parts. Part 1 is an overarching requirement that applies to all ADLTs. Under this first part, PAMA requires the test to be a clinical diagnostic lab test, which is covered under Medicare Part B, offered and furnished only by a single lab, and only sold for use by the original developing lab or successor owner.

For the second part, PAMA requires the test to meet 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 FDA, or

C. The test meets other similar criteria established by the Secretary.

On this next slide, we will discuss CMS's proposal for implementing Criteria A and also provide some additional detail regarding FDA clearance or approval.

CMS proposed a test qualifying as an ADLT under Criterion A must be molecular pathology analysis of multiple biomarkers of DNA or RNA and predict the development of certain conditions or response to particular therapy. We also propose under Criterion A that the test provide new clinical diagnostic information that cannot be obtained from any other tests or combination of tests. We also clarified that the test may include other assays. For example, in addition to an analysis of a DNA biomarker, an ADLT might also include a component that analyzes protein.

As mentioned previously, Criteria B is FDA clearance or approval. Now the FDA considers CDLT to be medical devices, and they have two distinct application processes for clearing and approving medical devices. To receive FDA clearance, a premarket notification submission must be submitted to the FDA.

Under a premarket notification submission, the submitter must demonstrate that their medical device, in this case CDLT, is substantially equivalent to a medical device that is legally marketed for the same use. A request for FDA approval is typically submitted through a premarket approval application, or PMA. To obtain FDA approval of a device, an applicant must submit a PMA, which contains valid scientific evidence to ensure that the device is safe and effective for its intended use. So as an alternative to Criteria A, the test could also — could qualify as an ADLT if it received FDA clearance or approval.

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. At this time, we are not proposing any additional criteria. However, if we do so in the future, it will be done through notice and comment rulemaking.

New ADLTs vs. existing ADLTs, slide 17. We propose to define a new ADLT as an ADLT for which payment has not been made under the Clinical Lab Fee Schedule prior to January 1st, 2017, while an existing ADLT would be any ADLT that has been paid for under the Clinical Lab Fee Schedule prior to January 1st, 2017. In other words, there will be no new ADLTs until the January 1st, 2017. It is important to understand the distinction between a new ADLT and an existing ADLT, because new ADLTs, at least initially, have a unique payment methodology.

Before we talk about the payment methodology for new ADLTs, we need to discuss the concept of new ADLT initial period. For each new ADLT, the new ADLT initial period is three full calendar quarters. It would begin on the first day of the first full calendar quarter following the day the new ADLT is first performed. For example, if an ADLT is first performed on February 15th, the new ADLT initial period would begin on April 1st and end December 31st.

Payment for ADLTs

Moving on to payment for new ADLTs, slide 19. Payment for new ADLTs is divided into three separate phases — before, during, and after a new ADLT initial period. Before the new ADLT initial period, the local Medicare Administrative Contractor would determine the payment amount for the test. Using the example from the previous slide, where the new ADLT is first performed on February 15th, the period before the initial period would be February 15th through March 31st.

During the ADLT initial period, PAMA requires that new ADLTs be paid based on the actual list charge for the test. Under our proposal, the actual list charge would be the publically 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.

Now, payment for existing ADLTs has two phases — before and after the effective date of PAMA. Prior to the effective date of PAMA, January 1st, 2017, existing ADLTs would be paid based on either crosswalking or gapfilling methodology. Beginning January 1st, 2017, the payment amount for existing ADLTs would be based on the weighted median private payor rate methodology. In other words, beginning January 1st, 2017, payment for existing ADLTs would go right to the weighted median private payor rate. Initial period only applies to new ADLTs.

On slide 21 we discuss the ADLT recoupment provisions. PAMA requires recoupment of payments made during the new ADLT initial period when actual list charge substantially exceeds private payor rate. 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 recouping payment, CMS proposed to recoup the entire difference between the actual list charge and the weighted median private payor rate. In such cases, claims paid during the new ADLT initial period would be repriced using the weighted median private payor rate. However, if the difference between the 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 ADLT, slide 22, outlines ADLT data collection and reporting. As noted earlier, ADLTs have a different data collection and reporting schedule from CDLTs that are not ADLTs. For new ADLTs during the new ADLT initial period, PAMA requires that private payor rates 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 2017, which would be April 1st, and ending the last day of the fourth quarter of 2017, which would be December 31st, the applicable lab would be required to report private payor rates for the new ADLT by the end of the third quarter of 2017, which would be September 30th.

Now for existing ADLTs and new ADLTs after the new ADLT initial period is over, PAMA requires the applicable lab to collect and report private payor rates annually. The data collection period would be conducted annually on a calendar year basis, while the

reporting period would be consistent with all CDLTs and run from January 1st through March 31st, at the conclusion of each data collection period.

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

Other PAMA Provisions

Sarah Harding: Thank you Craig, and thank you for the opportunity to speak to you all today about a few more provisions outlined by the PAMA statute.

On slide 24, this shows that a part of the statute outlining the new Clinical Lab Fee Schedule has to do with coding. Just as a brief background, CMS generally adopts codes established by the American Medical Association CPT Committee. This committee assigns codes to a wide variety of medical services and procedures provided by doctors, suppliers, and other health professionals. These are known to us as level I HCPCS codes. If there are tests that CPT does not assign codes to, CMS has the ability to create level II codes so that Medicare could be billed and paid for those services.

For us, relevant to this rule, are codes for laboratory tests. When CMS creates a level II HCPCS code for a test, it uses what we refer to as a G code. The code starts with a G and is followed by four numbers. A section of PAMA requires that either for new or existing ADLTs, as Craig has just discussed, and also for new or existing clinical diagnostic laboratory tests that have specifically been cleared or approved by the FDA, that the Secretary shall assign unique HCPCS codes. In doing so, CMS will be able to better track information for these tests. In the proposed rule, CMS proposed to use G codes to identify any new or existing ADLTs or CDLTs with FDA clearance or approval. Because this is a coding process already in use by CMS, therefore, we can use it, for it — for these new categories of tests, as defined by PAMA.

The next slide describes the payment reduction limits outlined by PAMA. Generally speaking, this says that the CLFS payment rate cannot decrease more than a certain amount, no matter what the calculated weighted median is. For the first 3 years after PAMA is implemented, which will be 2017, 2018, and 2019, the reduction limit is 10 percent. So, for example, if a test has a national limitation amount, or an NLA, of $100 on the 2016 Clinical Lab Fee Schedule, the payment rate in 2017 cannot be lower than 10 percent of $100, or $10, resulting in a Clinical Lab Fee Schedule rate no lower than $90.

In 2018, the same 10-percent reduction limit would be applied to the 2017 rate, or $90. The 10-percent limit would mean the CLFS rate could be no lower than $81. The same calculation would then take place in 2019. In 2020, however, the reduction limit changes to a maximum of 15 percent. This continues for 2021 and 2022. Beginning in 2023, there will no longer be any phase-in reduction limits. For more detailed

explanations or examples of how this phase-in reduction would work, there are several examples in the proposed rule that you're welcome to refer to.

On our next slide, we talk about the confidentiality of the information that CMS will be receiving. PAMA described confidentiality for the data collected to calculate the CLFS payment rates. It states that CMS and its contractors may not disclose applicable information that would identify either a private payor or a laboratory or any prices charged or payments made to a laboratory. In other words, CMS and its contractors cannot publish the raw data it collects from applicable laboratories. CMS plans to publish only the weighted medians associated with each code once they have been calculated.

PAMA goes on to state that while CMS and its contractors must keep applicable information confidential, there is an exception that allows CMS to share data with the Comptroller General, the Director of the CBO, the HHS Office of Inspector General, MedPAC, or other law enforcement entities, such as the Department of Justice, to review the information.

Overview of the Data Collection System

Finally, we wanted to discuss briefly a system that we are preparing that will be able to collect the vast amounts of applicable information that are outlined in PAMA.

Slide 28 talks about our fee-for-service data collection system. This will be a web-based system that will be able to collect all of the applicable information and keep it secure. Applicable labs will ultimately be able to either upload data from a template that we have — that we provide that you can prepare ahead of time, or else directly enter applicable information into the system. We will be publishing information about the system as it's available, but we do plan to have this system ready at the time we begin collecting applicable information.

Finally, I wanted to speak just a little bit about the process by which labs will sign up for access to the data collection system. We're using a service called EIDM, which is the Enterprise Identification Management system. This is simply an authentication system that many systems at CMS use. It is a way for us to keep our data secure. It's for authentication and both security purposes.

Registering for EIDM is a completely separate process from the system that we are building, and so we urge you to register early for EIDM user names and passwords. You may have used the EIDM credentials with other systems at CMS, but we will still have instructions on just how to register once we are up and running with the system. We simply urge you to register early and not wait until the last minute to register for EIDM, simply because the more people registering, the busier the system gets. When that information is available, we will certainly publish it, along with instructions, user manuals, how tos, and other information to make the process as easy as possible.

Resources

Finally, on slide 30, we have a brief list of resources that are available with additional information on all of the topics we've talked about today. Please take a look if there is still more information that you are seeking regarding PAMA and the proposed rule. If you have comments, please submit them through the formal rulemaking process, which you can find, I believe, through the links associated with the proposed rule on this resource slide.

Thank you very much. I'd like to turn it back over to Amanda.

Additional Information

Amanda Barnes: Thank you Sarah. An audio recording and written transcript of today's call will be posted to the MLN Connects Call website. We will release an announcement in the MLN Connects Provider eNews when these become available.

On slide 32 of the presentation, you will find information and a URL to evaluate your experience with today's call. Evaluations are anonymous, confidential, and voluntary. We hope you take a few moments to evaluate your call experience.

Again, my name is Amanda Barnes, and I'd like to thank our presenters and also thank you for participating in today's MLN Connects Call, Clinical Diagnostic Laboratory Test Payment System Proposed Rule.

Have a great day everyone.

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

-END-


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