Clinical Diagnostic Laboratories to Collect and Report Private Payor Rates Call

Moderated by: Diane Maupai
January 23, 2019 2:00pm

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Announcements & Introduction

Operator: At this time, I would like to welcome everyone to today's Medicare Learning Network® event. 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 will now turn the call over to Diane Maupai, Thank you. You may begin.

Diane Maupai: Thank you. This is Diane Maupai from the Provider Communications Group here at CMS and I'm your moderator today. Welcome to this Medicare Learning Network call Clinical Diagnostic Laboratories Collecting and Reporting Private Payor Rate. This call is a refresher on how to collect and submit required data. CMS will use this data to set Medicare payment rates effective January 1st, 2021.

Before we get started, you received a link to the presentation in your confirmation email. The presentation is available at the following URL is go.cms.gov/npc. Again, that URL is go.cms.gov/npc.

Today's event is not intended for the press and the remarks are not considered on the record. If you are a member of the press, you may listen in and please refrain from asking questions during the question-and-answer session. If you have inquires, contact press@cms.hhs.gov. I'll now turn the call over to Sarah Harding from the Division of Ambulatory Services in CMS.

Presentation

Sarah Harding: Thank you Diane. Good Afternoon. Thank you for joining us today. This call today is, as Diane started to mention is really intended to serve either as a reminder or potentially an introduction of the big pieces of the CLFS private payor data collection and reporting policies that were set forth by the Protecting Access to Medicare Act or PAMA. As you may know, we've entered the second, overall cycle of the new payment procedures for the clinical lab fee schedule. And so, we thought it would be useful to hold this call to highlight some new provisions that have changed since the first PAMA system.

If you reported data to CMS during the first overall cycle, then much of what is going to be on this call will be what you already know. Still we thought, this would be a good opportunity to reach out for laboratories, point you to resource this that are online that had even more information available and also hear from you on any questions that you may have. We'll talk on our end for about 30 minutes and then invite questions from all of you.

So, I'd now like to turn the call over to my colleague Rasheeda Arthur who will highlight several aspects of the data collection and reporting process for the CLFS. Rasheeda?

CLFS Data Collection and Reporting Policies (Part 1)

Rasheeda Arthur: Thanks Sarah. I will begin on slide 3, where I'll do an overview of the CLFS requirement. 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 test also called CDLT under the fees schedule.

CMS's proposal for implementing the provisions PAMA, was displayed in the Federal Register on September the 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 CMS and used to calculate Medicare payment rates.

Continue on slide 5, the definition of applicable laboratory, PAMA requires applicable laboratories to report applicable information to CMS. PAMA also defines an applicable laboratory as having the majority of its Medicare revenues paid under the CLFS or the Physician Fee Schedule. A laboratory as defined in CMS as Clinical Laboratory Improvement Amendments of 1988 of CLIA. Using its National Provider Identifier or NPI is considered an applicable laboratory if the majority or more than 50% of its total Medicare revenues are received from payments under the CLFS and the Physician Fee Schedule.

Continuing with the definition of applicable laboratories on slide 6. We defined applicable laboratories in terms of the NPI rather than the tax payer's Tax Identification Number or the TIN. Therefore, the Majority of Medicare revenue threshold for example more than 50% of Medicare revenue are received from Physician Fee Schedule on CLFS. On low expenditure threshold, during the data collection period are determined by and applied to the NPI level rather than the TIN level entity.

CMS excludes the definition of applicable laboratory, NPI level entities that receive less than $12,500 dollars from CLFS during the data collection period. An entity that does not meet the definition of applicable laboratory is not permitted to report applicable information that is private payor rates and volume data to CMS.

Additionally, generally an applicable laboratory will also have to receive at least $12,500 in Medicare revenue received from CLFS services during the data collection period to be an applicable laboratory. The $12,500 will not apply to certain laboratories in respect to the ADLTs they offer and furnish.

Moving on to slide 7 to discuss revisions to the definition of applicable laboratory. The Physician Fee Schedule, PFS final rule entitled Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program, and Other Revisions to Part B for CY 2019 published on November 23rd, 2018 made two revisions to the regulatory definition of applicable laboratories. Both revisions were effective January 1, 2019. The first revision indicates the Medicare Advantage plan payments are excluded from total Medicare revenues which is the denominator of the majority of the Medicare revenue threshold.

The second revision indicates that hospital outreach laboratories that bill for their non-patient laboratory services using the hospital's NPI must use Medicare revenues from the Form CMS-1450 14x Type of Bill. To determine whether they meet the majority of Medicare's revenue threshold and low expenditure threshold.

Under the revised final policy for the new Medicare CLFS, an applicable laboratory is a laboratory as defined under CLIA regulatory definition laboratories 42 CFR Section 493.2 that billed Medicare Part B under its own National Provider NPI or the hospital outreach laboratories bills Medicare Part B on the form CMS 1450 under bill type of 14.

In addition, the laboratory must meet a majority of Medicare revenue threshold that is in a data collection period it received more than 50% of its Medicare revenues of one or a combination of the CLFS for the Physician Fee

Schedule. That also must meet a low expenditure threshold that it receives at least $12,500 of its Medicare revenue from the CLFS.

For purposes determining an applicable laboratory status under the CLFS, a hospital outreach laboratory means a hospital-based laboratory that furnished this laboratory tests to patients other than admitted inpatients or registered outpatients of the hospital. The hospital allows laboratory bills for Medicare Part B services furnished to a non-hospital patient using the form CMS 1450 14x Type of Bill. It's important to know that the form 1450 14x is a type of bill as defined by the National Uniform Billing Committee. It's used in hospital claims submissions associated with hospital laboratory services provided to non-hospital patient.

Hospital outreach laboratories that deal Medicare Part B for non-patient laboratory services using the hospital NPI instead of their own NPI separate from the hospital are required to determine applicable laboratory status from its Medicare revenue attributed to the forms CMS 1450 14x TOB. Hospital outreach laboratories that bill Medicare Part B using their own NPI separate from the hospital's NPI but uses its own NPI to determine applicable laboratory status.

All hospital outreach laboratories that meet the definition of an applicable laboratory will be required to report applicable information to CMS during the next data reporting period which is January 1, 2020 through March 31st, 2020. Additionally, sub-regulatory guidance we made available to CLFS website under the PAMA regulatory tab.

Moving on to slide 8, applicable information. Under the CLFS reporting entities must report applicable information for each CDLT furnished by its component applicable laboratory. This slide provides details of what is considered applicable information. In general, there are three major pieces of information, the reporting entities are required to report or required to submit to CMS as applicable information.

This information includes specific HCPCS code associated with the test. The private payor rate for each test for which the final payment has been made during the data collection period and the associated volume for each test corresponding to each private payor rate. PAMA determines the term private payor as a health insurance and the group health plan as defined in the Public Health Service Act in Medicare Advantage Plans under Part C and Medicaid Managed Care Organization as defined in 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 the different private payor for the same test. Reporting entity will report each such payment rates and the volume for the tests at each such rates. 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 have received during the six months data collection period, the final rate pay would be considered applicable information.

Laboratories should look to their claims data for guidance on which final payment received during the data collection period. Also, in the final rule to clarify, that applicable information includes private payor rates for out of network of laboratory as long as the final payment for the laboratory tests was made by the private payor during the data collection period. We also know that non-contracted amounts paid to laboratories would include

any patient cost sharing amount if applicable. Final payments from the secondary insurance payor will also be applicable information if the final payment was made during the data collection period.

On slide 9, we continue our conversation on applicable information. We will also clarify in the final rule what applicable information does not include. Applicable information does not include unresolved appeals. For example, where the laboratory tests claim is still under review by the private payor or 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 used to determine private payor rate.

Applicable information does not include payments that do not reflect specific HCPCS code level amounts. Therefore, the final rule requires applicable information includes specific HCPCS code associated with each CDLT to prevent private payor rates corresponding to HCPCS level 2, not otherwise classified, not code or an unlisted CPT code from being reported.

Accordingly, if a laboratory cannot correlate a private payor payment amount to a specific HCPCS code that amount is not a private payor rate for purposes of applicable information. The final rule is specified that for each CDLT the associated by volume of test performed corresponding to each private payor rate is a component of the definition of applicable information. For the associated volume of tests performed corresponding to each private payor rate cannot be discerned by a laboratory from the private payor remaining. Those payments in that list would not be considered applicable information and should not be reported in CMS.

Therefore, were a private payors' group test level payment into a claim level payment instead by individuals' HCPCS codes, those rates would not be applicable information. Applicable information does not include the next payment. For example, if no payment amount was made for the test, if the test is performed during the data collection period or the final payment is not made until after the data collection period. The payment amount would not be a private payor rate for purposes applicable information and this therefore, would not be reported to CMS.

Moving on to reporting applicable information on slide 10. CMS is retaining the TIN level entity as the reporting entity, which is defined separately from the applicable laboratory. As such, the TIN level entity is responsible for reporting applicable information for all of its components laboratories that meet the definition of applicable laboratories. Voluntary reporting for applicable information is not permitted, that is applicable information may not be reported for entities 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 laboratory that is an applicable laboratory that is reporting entities cannot selectively report applicable information for their component applicable laboratory. For example, it cannot report some applicable information, but not other applicable information. This ends my portion of the presentation and I'll turn to presentation over to Sarah.

CLFS Private Payor Data Collection and Reporting Policies (Part 2)

Sarah Harding: Thank you Rasheeda. And I hope your voice survived that, thank you. I am going to walk through a few of the other policies related to data collection and data reporting. I did want to just pause and just reflect on Rasheeda's information, we recognize that it's quite technical as there's a lot to shift through especially if you

are new to this round. Rasheeda did mention, but I want to reiterate that we have extensive guidance that's been published already online.

Particularly, the questions that we received during the first round of data collection and data reporting many of those questions that specifically ask is, my entity and applicable lab were turned into either frequently asked questions or just other information in order to help other laboratories determine whether or not they are applicable. So, despite the information being rather technical, I do encourage you to take a look at that information that will help I believe answer that question.

But for now, moving on to slide 12, you'll see the once again the definition of a private payor as defined by PAMA, Rasheeda really went through this earlier in her slide, so I won't read it here, but the information is there for you to read.

Now on slide 13, we outlined what should be reported to CMS as far as the private payor rate goes.
A private payor rate includes all the payment rates for a test, even if more than one payment rate for the same private payor, for the same test exists or more than one payment rate from different payors for the same test. I just want to clarify this here the laboratories are expected and required to report each individual private payor rate and the corresponding volume for each test.

Private payor rates also include the final amount paid by a private payor for a CDLT after all private payor price concessions are applied. Only private payor payment rates for CDLTs paid for under the CLFS and any patient cost sharing amounts if applicable. Private payor rates do not include price concessions applied by laboratories. For example, a patient deductible is waived or co-insurance, finally private payor rates do not include information about denied payments.

Now regarding frequency of data collection and reporting, again this is somewhat made evident by the timing of this call, but reporting entities are required to report applicable information every three years for CDLTs and every year for ADLTs except for a new ADLT, which I'll talk about it in just a minute. So again, we're now entering the second phase the second cycle of the three years for CDLTs.

On slide 15, this is really the reason we're gathered here today. We've just entered a new data collection period from January 1 to June 30th, 2019. There's no action to be taken right now as far as reporting data to CMS goes. Again, our goal for this call is to remind laboratories that they should be determining their applicability under the PAMA and if they are applicable collecting the relevant applicable information. This applicable information will be reported beginning January 1 through March 31st of next year 2020.

And then those payment rates will be implemented as of January 1, 2021. Looking even farther into the future, subsequent data collection and reporting periods will correspond to the applicable update year. So, for example, for calendar year 2024 the data collection period will begin January 1st, 2022 and end June 30th, 2022. The reporting period will begin January 1st, 2023 and end in March. So, you can count on us being back together for another phone call just like this.

Now on slide 16, this talks about ADLTs, these are Advanced Diagnostic Laboratory Tests. I'm not going to spend a lot of time on the next few slides simply because we believe the majority of participants on this call will

be more concerned with the “regular clinical diagnostics laboratory tests.” But we mentioned the term ADLT several times during this presentation, so we at least want to describe a little bit of what they are.

Laboratories that have ADLTs have gone through an application process with CMS. So, for any laboratory new to this process, please don't worry that you might have an ADLT without knowing it. ADLTs are a subset of test on CLFS. There are two main parts to defining ADLTs. The first part is that they must be covered under Medicare Part B. They must be offered and furnished by a single laboratory and must be used only by the original developing laboratory. There are some specifics to this first part of the definition that again I'm not going to cover today because of the time and also because the resources available online clearly specify the details with regards to this.

On slide 17, this outlines the second major part of the definition of an ADLT. It must meet one of this list, this A, B, C list of criteria. The first is that the test of analysis of multiple biomarkers of DNA, RNA or proteins combined with the unique algorithm, to yield the single patient specific results or letter B the test is cleared and approved by the FDA—sorry, cleared or approved by the FDA, and finally the test can meet other similar criteria established by the secretaries. But to date no additional criteria have been established.

As I mentioned, if you're interested in learning more about ADLTs or the application process, please see the PAMA regulations webpage at CMS.gov. There is a link to this page at the end of the slide, I believe on slide 26 and there's more detailed information available there.

On slide 18, going back to our CDLTs, once CMS has collected all the applicable information from applicable laboratories next year, CMS will calculate a weighted median private payor rate for each test on the clinical laboratory fee schedule. This median then becomes the new CLFS payment rate. If CMS receives no applicable information for a given CDLT or ADLT, CMS uses it traditional payment processes of cross walking or gap filling to price the test.

This day we did see this happened with several HCPCS codes during the first round of data collection and reporting. These codes for which data were not reported, where brought to the laboratory public meeting and then we're either cross walked for gap filled.

Now slide 19 and a few on will mention other smaller, but still important PAMA provisions briefly on slide 19. There are coding provisions under PAMA typically the American Medical Association or AMA creates codes for tests on the CLFS. This is certainly still happening, but PAMA does create the opportunity if a new code is needed, CMS can establish a G-code.

Slide 20, I spoke earlier that the weighted median calculated from the private payor rate becomes the new CLFS payment rates. If the weighted median is lower than the prior year's payment rate; however, PAMA set a limit on how much it could be reduced. So, for example, during our first round, the reduction was limited to 10% less than the prior year's rate. For the upcoming cycle this reduction limit changes to 15%. So, this is the maximum reduction of 15% will be applied to each prior year's payment rate from the years 2021 through 2023.

On slide 21, regarding confidentiality, CMS and its contractors may not disclose any reported information in a form that would either identify a specific private payor or laboratory of the prices charged or payments made to laboratory. There is an exception however that allows the Comptroller General, the Director of CBO, HHS Office

of Inspector General or the MedPAC or other law enforcement entities such as the Department of Justice to review the information.

On slide 22, in the last PAMA cycle, CMS did publish in early release of CLFS payment rates for public review. We are planning a similar preview following next year's data reporting period. So, in or around early September of 2020, CMS will look to publish the weighted private payor rate, before they are finalized along with the summary of that data. Then in November of 2020, the final rate will be published and set for implementation in January 2021.

Slide 23 mentions our data collection system that we use to collect the data from applicable laboratories. This formally is known as the Fee for Service Data Collection System and within that is the Clinical Laboratory Fee schedules, data collection system. The system can either take the data entry manually, so HCPCS code by HCPCS code or using a file upload. Information on where and how to access the system is online on the PAMA resource page. Again, a link for this is on slide 26. But we will likely hold another call presenting details on how to use the system as we get close to the data reporting period.

Slide 24 simply outlines some early registration that you may want to consider. This registration is how laboratories can gain usernames and passwords to access the online data collection system. We will look to open the registration as early as October of 2019. So please keep an eye out for that opportunity so that you will be ready to go when the data reporting period begins.

So, before I stop, there are three kind of major points that I'd like to recap from the talk today. The first is that we are now in a data collection period lasting from January 1 through January 30th of 2019. If you are an applicable laboratory, you should be collecting applicable information from this time period. You can refer to the 2019 CLFS payment file for a list of HCPCS codes for which you should be collecting data.

If we make any updates to that list, we will make sure that is widely known, but certainly the best reference right now is that 2019 CLFS payment file. Second data reporting to CMS will begin next January 2020. An online data collection system will be available to you for data submissions, look to register or at least update your registration sometime in October. Finally, please take advantage of the PAMA regulations page on CMS.gov.

Once again a link to this page is on slide 26th of this presentation. Here you will find extensive sub-regulatory guidance particularly relevant if you have questions about whether your laboratory is considered applicable. I would encourage you to look through the resources online and if you still have questions on whether your laboratories applicable, feel free to reach out to us directly. The inquiries email address is also on slide 26. So, thank you for your time today. I will now pass the microphone back to Diane.

Question & Answer

Diane Maupai: Thank you Sarah. We'll now take your questions. As a reminder, this event is being recorded and transcribed. In an effort to get to as many questions as possible, each caller is limited to one question. To allow more participants the opportunity to ask questions, please send questions specific to your organization to the mailbox on slide 26. So, our staff can do more research. Preference will be given to general questions applicable to a larger audience and we will be mindful of the time spent on each question. All right Dorothy. We're ready for our first caller.

Operator: To ask a question, press star followed by the number one on your touchtone phone. To remove yourself from the queue, press the pound key. Remember to pick up your handset before asking your question to assure clarity. Once your line is open, state your name and organization. Please note your line will remain open during the time you were asking your question, so anything you say, or any background noise will be heard in the conference. If you have more than one question, press star one to get back into the queue and we will address additional questions as time permits. Please hold while we compile the Q&A roster.

Please hold while we compile the Q&A roster. Your first question comes from a line of Jill Robinson.

Jill, your line is open.

There is no response from that line. Your next question comes from a line of Lina Silka.

Lina Silka: Hi. My question has to do with laboratories that meet the definition of an applicable laboratory by Other Type of Bill 14x. And the question is for the reported data is that only for non-patients or is it for all laboratory tests that are listed on the clinical lab fee schedule regardless of their patient type.

Craig Debinski: Yeah this is Craig Debinski of CMS. The private payor rate is separate from the applicable lab determination. So, it's each HCPCS code subject to the data collection and reporting requirements and each private payor rate and the volume of data for each such rate. (unintelligible) that is what is important for each applicable lab.

Diane Maupai: Thank you Craig.

Operator: Your next question comes from the line of Rosie Fussell.

Rosie Fussell: Good afternoon. My name is Rosie Fussell and I work for the laboratory at Avent Health in Orlando. I have the same question as the previous caller except I'm not sure I understood the answer. So are we required to report both tests that are billed on a 14x, tests that are built on a 13x, and hospital outpatient volumes in addition to those volumes that are on a 14x.

Craig Debinski: All applicable information attributed to the applicable laboratory must be reported. Regardless..

Rosie Fussell: I guess I'm confused about the applicable information.

Craig Debinski: Applicable information is a HCPCS code subject to the data collection and data reporting requirements; the private payor rate, each private payor rate and the associated volume with each private payor rate. Now all applicable information for all private payors must be reported regardless of the bill type required or not required by the private payor. Does that answer your question?

Rosie Fussell: Yes, it does. Thank you.

Craig Debinski: Good, thanks.

Operator: Your next question comes from a line of Berry Allison.

Berry Allison: Yes, Good Afternoon. It's Berry Allison, Wood Center for Primary Care in Augusta, Georgia. I was looking for the link for the 2019 CLFS codes that you had mentioned earlier. I googled the just 2019 CLFS codes and couldn't find anything. You have an absolute link for that?

Sarah Harding: Sure. This is Sarah. It's a long link. If you look on the, if you get to the PAMA regulations webpage which is linked on the slides and look on the left-hand side of the page, I believe toward the top of the menu is a link that says CLFS files. If you click in that link, I think we're pulling it up right now, if you click on that you'll see the last several years of links for the different files. Yes. Okay, so if you look at, yes, it's under the menu that says clinical laboratory fee schedules the first link says clinical laboratory fee schedule files. And if you click on that, the first download is the calendar year 2019 Q1 release clinical laboratories fee schedule.

As we're publishing further sub regulatory guidance, we will post a sort of simpler file that is just the codes that you'll need, but it will be a redundant file to what's there. So, you can use that. The only additions that will be made to that file is any new what's called a PLA code, which is their proprietary laboratory analyses. The only reason that these will be updated between now and June is that we anticipate there will be new PLA's between now and then. But again, if your lab doesn't use these particular codes, it won't affect you. So the majority of the codes that need to be reported for will be on that file.

Berry Allison: Okay, thank you.

Sarah Harding: Sure.

Operator: Your next question comes from a line of Elena Haber.

Elena Haber: Yes. I'd like to know do you have consults and second is walk us through this because I find that every time, I try to figure this out on our own and go to all these sites, it's just more and more confusing for someone who's just a small office that has a small lab and it doesn't make sense. Do you suggest there is someone that really knows how to walk us through this to tell us yes you are to report or you're not to report?

Sarah Harding: Hello, this is Sarah. That's a great question and what we do come back is probably something you're not going to like hearing from us is that it really is something that we can't determine for you whether you're applicable or not. It's something that PAMA very specifically outline needs to be and tested statement from a laboratory. Now that's not to say there aren't consultants available I'm sure who are excited to take a look and help determine that. I would say if you have specific questions about you know that you have information about your revenue, about ins and outs like that, we're certainly willing to help as we can and then walking through you know kind of what to report and how to report that's definitely something we can help with.

So I would say if you have discrete questions about kind of analyzing your applicability, you can certainly ask us, and from there, you know, I know that there are been the larger laboratory organizations like the American Clinical Laboratory Association has certainly been involved with other organizations kind of at that level, I'm sure would be willing to help.
Elena Haber: So, the way to get in touch with you would be though Clfsinquires@cms.hhs...

Sarah Harding: Yes, that's correct.

Elena Haber: Okay so I'll try it that way. Okay

Diane Maupai: Thank you.

Operator: Your next question comes from a line of Sue Royal.

Sue Royal: Yes, this is Sue Royal. I'm from Royale Internal Medicine. My question is regarding the 14x TOB, and I know they've already been a couple of questions about that already, but I'm not sure I got my answer from that. In the description for today's call, it says that the people who should report are laboratories that are using a 14x TOB are required to report. Our office never reports anything on a 14x TOB, does that mean that I am not an applicable laboratory.

Craig Debinski: Okay. Hi this is Craig Debinski. I'm going to try to explain this quickly. Here's how an outreach laboratory determines applicable laboratory status. If the outreach laboratory bills Medicare Part B using the hospitals NPI, the hospital outreach laboratory uses the revenues, the Medicare revenues on the 14x Type of Bill to determine applicable laboratories stats.

That means they go through and determine whether they meet the majority of Medicare revenue threshold and a lower expenditure threshold based on the revenues attribute to the 14x Type of Bill. As Rasheeda pointed out in her presentation if the hospital outreach laboratory has a unique NPI separate from the hospital and uses that unique NPI to bill Medicare Part B for non-hospital patients. The hospital outreach laboratory then uses its unique NPI to determine whether they meet the majority Medicare revenue threshold and the lower expenditure threshold. Does that answer your question?

Sue Royal: Yes, I believe it does. Because we are not a hospital outreach laboratory. We have an internal lab for our patients only. So, I really appreciate your help clarifying that for me. Thank you.

Craig Debinski: You're welcome.

Operator: Your next question comes from the line of the Mark Robert.

Mark Robert: Hello, this is Mark Robert with South Coast Health. Again, my question is in regards to the majority of Medicare test for this. Once again getting back to the CMS-1450 and the 14x TOB as I'm figuring out what to put in my numerator and my denominator. May I assume that both numerator and denominator will be limited to only those items that were billed under that TOB?

Craig Debinski: Yes, that's correct.

Mark Robert: Both the numerator and the denominator, excellent. Then I have a comment the CMS webpage, the PAMA regulations webpage has got an FAQ, but it says it was updated last in March of 2017. So, I assume it would not include any discussions on the revisions that we're discussing right now.
Sarah Harding: That's correct and thank you actually for pointing that out. The sub regulatory guidance that will summarize the 2018 rule changes. We anticipate that being published really as soon as possible, but realistically

in the next few weeks or so. We look to this discussion today as a way to start off the conversation around it, but yes specifics sub reg guidance on the 14x details will be forth coming on to the website.

Mark Robert: Excellent. Thank you.

Sarah Harding: Absolutely.

Operator: Your next question comes from a line of Jill Robinson.

Jill Robinson: Question, we are a hospital that does not have a unique NPI for our outreach lab. We do bill under the 141 type of bill. However, we're still confused about how to calculate the 50% greater than 50% in the threshold because we're still uncertain what are we comparing the Medicare revenue to, is that are we comparing it to hospital wide, are we comparing it to all the lab services that our laboratory bills under the same NPI.

If we're only looking at 141 type of bills, I think it's all of those under the clinical laboratories fees schedule. Any help you can give on that or if you could post something because it's so confusing? Thank you.

Craig Debinski: Yeah this is Craig. Basically, what the 14x type of bill does is it isolates your outreach laboratory business from your total hospital business. So therefore, what you're going to do in the majority of Medicare revenues threshold, in the numerator you're going to put all the CLFS and PFS revenues attributed to 14x Type of Bill and as the denominator you can include total 14x revenues. Now they maybe close or even one of the same, so that in that case you're going to meet the majority Medicare revenues threshold.

You then go to the lower expenditure threshold, you look at the same 14x Type of Bill, you look at your revenues on there. If you have more than $12,500 in CLFS revenues during the data collection period and in this specific case is January 1st, 2019 through June 30th, 2019, then your outreach laboratory would also meet the lower expenditure threshold, and you would be an applicable laboratory, and therefore would report applicable information during the data reporting period.

Jill Robinson: Okay thank you and I will say that we're still confused but thank you for your efforts on this and anything you can publish that's real clear cut on your website would be greatly appreciated, thank you.

Craig Debinski: Sure.

Sarah Harding: Well and I would reiterate what we said before you know please submit a specific question you know along these lines. Like I said, we can't go so far as to say yes or no you are applicable or not, but we can certainly continue to walk through you know the definition of processes and give guidance on helping you make that decision.

Operator: Your next question comes from the line of Merlin Sherick.

Berlin Sherick: This is Berlin Sherick. Could Craig repeat the numerator on that equation again? He fortunately answered that question; I just didn't catch hold what was in the numerator.

Craig Debinski: Yeah, the numerator is physician fee scheduled revenue and clinical laboratories fee schedule revenue. That's derived from the 14x Type of Bill. And then the denominator is total Medicare revenues derived from the 14x Type of Bill.

Berlin Sherick: So, the denominator would be all payors.

Craig Debinski: No, no. This is your own laboratory. How much revenue was attributed to the 14x Type of Bill for your own laboratory.

Unknown Woman: That's the numerator?

Craig Debinski: That's the denominator. The numerator is physician fee schedule plus clinical laboratory fees schedule revenues derived from the 14x Type of Bill for your specific hospital outreach laboratory compared to total Medicare revenues derived from the 14x Type of Bill. If the numerator PFS plus CLFS is greater than 50% of the denominator then your specific hospital outreach laboratory meets the majority of Medicare revenue threshold.

Berlin Sherick: Okay. Thank you.

Operator: Your next question comes from a line of Jeannette Gray.

Jeannette Gray: Hi. I am an applicable lab. So, I do not have a question about that, but I do have a question about the private payor and what that definition includes. In doing it the previous period, it was my understanding that traditional Medicare, traditional Medicaid, Tricare, workers comp, and railroad Medicare or Indian health were the plans that technically were excluded from the calculation. I just wanted to verify that, that is correct because they do not meet the definition for private payor.

Craig Debinski: Well, yeah this is Craig. As Rasheeda and Sarah pointed out the definition of a private payor that includes a health insurer and a group health plan under 2791 PHS Act, a Medicare Advantage plan under Part C, a Medicaid Managed Care Organization as defined in section 1903M of a Social Security Act and we would advise anyone to consult with our legal counsel to determine whether a specific product payor meets one of those criteria as outlined in our presentation.

Sarah Harding: Or in this case doesn't meet those criteria.

Craig Debinski: Right.

Operator: Your next question comes from a line of Rita Gassert.

Diane Maupai: Rita…

Operator: Rita, your line is open.
There is no response from that line. Your next question comes from a line of Tom Peters.

Tom Peters: Good afternoon. We are also a hospital with a single NPI, and the laboratory does not have its own separate designation. So while we've heard several times this numerator and denominator information, we're still a bit confused if there happened to be and we don't know if this happens right now at our facility or not, non-laboratory Medicare payment that were on the 1450 14x Type of Bill, those dollars go into the denominator I mean or again the way we've heard the previous explanations we can't come up with the scenario where you wouldn't meet the threshold because you were basically saying use the same data in the numerator and denominator if you're limited to just lab services.

Craig Debinski: Yeah that's correct. You would probably, most likely meet the majority of Medicare revenues threshold. You're 100% correct.

Tom Peters: So, it really becomes the definition of if you're using CMS-1450 14x your applicable.

Craig Debinski: Well no, we've all said here…

Tom Peters: If it's…

Craig Debinski: Well like we said here, there's another criteria, threshold you have to meet at the low expenditure threshold so your lab would also have to receive at least $12,500 in Medicare revenue under the CLFS, the clinical laboratory fee schedule during the data collection period, the six months data collection period January 1st, 2019 through June 30th 2019, and all this is going to be explained in the sub-regulatory guidance that has been discussed here and in fact you can go online now and look at the existing sub-regulatory guidance and pretty much all the stuff is in there, but it will be tailored and revised to accommodate the new the changes that were made in the calendar year 2019 Physician Fee Schedule final rule.

Tom Peters: So again, on the $12,500 would be out of the 1450 14x dollars.

Craig Debinski: Yes. Because what we're trying to do here is we're trying to isolate the outreach labs.

Sarah Harding: You're correct.

Tom Peters: Thank you.

Operator: Your next question comes from a line of Jackie Long.

Jackie Long: Hi, my question was just answered. Thank you.

Sarah Harding: You're very, very welcome. Those are our favorite.

Operator: Your next question comes from a line of Barbara Zimmer.

Barbara Zimmer: Hi, thanks for taking my call. We are a hospital within outreach lab, and I understand how we determine if we qualify as a reporter. My question is what group of tests are we reporting on? I thought you said earlier that we are reporting on all tests done by that lab, but I understood that we are reporting on the private

payor payments from again that non-patient revenues. So, are we reporting on non-patient revenues or reporting on all tests, so that would include non-patient and hospital outpatient?

Diane Maupai: This is Diane. We're just going to confer for one minute, we'll be right back.

Sarah Harding: So, this is a great question and I agree this is why these calls are so good, is that it helps us to develop you know the clarification that we need to make. So, I would ask that we table this specific question right now and please look for the answer in sub reg guidance is coming, but I appreciate you reiterating the question because we just started to debate in our end, so clearly, we need to you know think it through and then communicate it out. So, thank you.

Barbara Zimmer: Okay, thank you.

Operator: Your next question comes from a line of Joanna Reyes.

Joanna Reyes: Hi, yes. This is Joanna Reyes and I work for American Bio Clinical Lab in California. I just wanted to have it clarified. So, this is, the applicable laboratories are only for hospitals, I'm sorry, hospital outreach laboratories? Because it was stated that you guys are trying to isolate the information for the outreach lab, is that correct or?

Sarah Harding: That just had to do with those laboratories that are billing on a 14x form. I'm not entirely sure of your question, but the broader PAMA relevance is to all laboratories.

Joanna Reyes: Okay it is to all Laboratories. Okay, thank you.

Diane Maupai: Okay. Dorothy, we have time for one more question.

Operator: Your last question comes from the line of Lena Silka.

Lena Silka: My question was answered by Craig earlier. Thank you very much.

Diane Maupai: Great, thank you.

Lena Silka: Thank you.

Operator: Your next question comes from a line of Mark Roberts.

Mark Roberts: Hi, this Mark Roberts. You answered the question. Thank you.

Sarah Harding: Great.

Operator: There's no further questions at this time.

Additional Information

Diane Maupai: All right. So, I guess we answered all the questions, great job and if you have additional questions you can email them to the address listed on slide 26. There you'll also find frequently asked questions and a lot of other good information. We hope you'll take a few minutes to evaluate your experience, see slide 27 for more information. An audio recording and transcript will be available in about two weeks at go.cms.gov/npc. It will also be announced in the MLN Connects newsletter.

Again, my name is Diane Maupai. I'd like to thank our presenters and also thank you for participating in today's Medicare Learning Network call on the requirement for Clinical Diagnostic Laboratories to Collect and Report Private Payor Rates. Have a great day everyone.

Operator: Thank you for participating in today's conference call. You may now disconnect. Presenters please hold.