



Clinical Diagnostic Laboratory Test Payment System: Data Reporting Call

Moderated by Diane Maupai
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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.

Announcements & Introduction

Diane Maupai: Thank you Dorothy. Again, this is Diane Maupai. I'm from the Provider Communications Group of CMS, and I'm your moderator today. Welcome to this Medicare Learning Network call, Clinical Diagnostic Laboratory Test Payment System Data Reporting. During this call, learn how to report private payor data that CMS will use to set Medicare payment rates effective January 1, 2021. Before we get started, you received a link to the presentation in your confirmation email. The presentation is also available at the following URL. 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're a member of the press, you may listen in, but please refrain from asking questions during the question and answer session. If you have questions, 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 everyone. Thank you to all of you who are joining us today. I'll be honest right from the outset. If you've participated on one of these calls before, you may find this a little bit boring as much of the information being presented today has been talked about in the past. But we hope that you'll all find the information helpful and at the very least will know where to go if you still have questions after today.

Looking first at slide 3, they are going to be 2 main topics we cover today. The first will be the overall policies that define who should be reporting in our upcoming data reporting period for the Clinical Laboratory Fee Schedule and what they should be reporting, again beginning January 1st of next year. The second main topic will be an overview of how you can report the information using our online data collection system.

So, looking at slide 4, 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 required significant changes to the process for pricing Clinical Diagnostic Laboratory Tests, also called CDLTs under the fee schedule. CMS's initial proposal for implementing these provisions of PAMA were displayed first in the Federal Register beginning in September of 2015, published in October of also 2015.

But other subsequent rules, including one in June of 2016 for the final rule and others that just came out last year changing some policy of who this relates to, have continued to be published. So, most of all of the policy guidelines are online, but this is essentially the policy that came out of the original PAMA of 2014. So 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 under the Physician Fee Schedule.



A laboratory, which is defined in CMS's Clinical Laboratory Improvement Amendments or the CLIA regulations uses its NPI or its National Provider Identifier, and 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.

Looking now at slide 6, we identify an applicable laboratory in terms of the NPI rather than the taxpayer Tax Identification Number. So, the majority of Medicare revenues threshold and the Low Expenditure Threshold, meaning that at least \$12,500 in Medicare revenues are received from the CLFS, is used -- is evaluated during the data collection period.

These are determined by and applied to the NPI level rather than the TIN level entity. Now, if you've been following some of our recent MLN calls, you know that this data collection period occurred during the past year from January through June of 2019. We have a lot of publications and frequently asked questions online that can help if you have further questions on how to evaluate either your majority revenue or your low expenditure threshold in determining whether or not you are indeed an applicable laboratory.

Now, CMS does include, as I mentioned, any NPI level entities that receive less than \$12,500 from CLFS during that data collection period. An entity that does not meet the definition of applicable laboratory is not permitted to report applicable information to CMS.

Now moving on to slide 7, after the initial publication of the final rule that implemented PAMA, and after our first round of data reporting and subsequent calculations, and private payor information and private payor rules for the CLFS, there was a more recent revision to the definition of applicable laboratory.

Now, this came out -- this was published last year, and it made two major revisions to the regulatory definition of an applicable laboratory. Both of these revisions were effective January 1, 2019, which means this new definition does affect who will be reporting beginning January 1, 2020. So, the first revision indicates that Medicare Advantage Plan payments are excluded from the total Medicare revenues. This is in the denominator of the majority of Medicare revenues threshold.

The second revision, speaking more to what I started with in terms of who reports, this 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 Type of Bill to determine whether they meet the majority of Medicare revenues threshold and low expenditure threshold.

Under these revised policies an applicable laboratory, is the laboratory, again, beginning with the definition that we see under CLIA, that bills Medicare Part B under its own NPI or for hospital outreach laboratories that bill Medicare Part B on the form CMS 1450 under bill type 14X. In addition, the laboratory must meet a majority of Medicare revenues threshold in a data collection period meaning it must receive more than 50 percent of its Medicare revenues from either the CLFS or the PFS and must also meet a low expenditure threshold of at least \$12,500 during that data collection period.

Moving on to slide 8, we see a brief summary of what must be reported once you've determined whether or not you are an applicable laboratory. So, under the CLFS, reporting entities must report applicable information for each CDLT furnished by its component applicable laboratory. So, in other words, if you have a larger



laboratory that may have a single Tax Identification Number, you are responsible for reporting data for each of your component laboratories if they have different NPIs, if they all in turn meet the definition of an applicable laboratory. So, in general, there are three major pieces of information that reporting entities are required to submit to CMS as applicable information. This information includes first the specific HCPCS code associated with the test. Second, the private payor rate for each test for which the final payment has been made during the data collection period. And finally, the associated volume for each test corresponding to each private payor rate.

Now, PAMA further defines the term private payor as either a) a health 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. Now, like I said, I know this all gets very, very technical to be listening to on a call. All of this information can be found online. When you do look at our resources online, there is an extensive list of frequently asked questions that have been compiled over the last four years, and so chances are your question would be outlined in those, particularly with regards to who and what should be reported.

One point that I do want to make very clear is that the definition of applicable information is for each private payor rate for each code. So, in other words, labs should not report a total dollar amount for test over the data collection period. So, for example, if there were a test which had a rate of \$10 and that was the test that's being reported, the lab should report a rate of \$10 for however many tests were furnished, perhaps 500 tests during the data collection period. You would not report the total amount of money for that one test over the data collection period.

And moving on to slide 9, there are a few things that applicable information does not include. One of these is that it does not include unresolved appeals. For example, if a laboratory test claim is still under review by the private payor or is under appeal during a 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 a private payor rate on the CLFS. Applicable information also does not include payments that do not reflect specific HCPCS code level amounts.

Therefore, the final rule that was published initially for the first data reporting period, that final rule required that applicable information included the specific HCPCS code associated with each CDLT. Let's go to the example that I gave in the last slide. We want to prevent private payor rates corresponding to either a NOC 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 associated volume of tests performed corresponding to each private payor rate is a component of the definition of 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. Therefore, where private payor has grouped test-level payment into a claim level payment instead of by individual HCPC code, those rates would not be applicable information.

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Finally, applicable information 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 would not be reported to CMS. Now again, these are only a few examples of some of the nitty-gritty that I understand does happen to many labs that are considering what they need to report.

So, once again, I encourage you to look at the resources that we have online to look at other questions that have been asked by labs and in our previous reporting period, and if those still don't do the trick, you can feel free to contact us at an email resource that I will make sure you have by the end of this presentation.

So, looking at slide 10, as I said before, the applicable lab is defined at the NPI level, but it's the TIN-level entity that's responsible for reporting applicable information for all of its component laboratories that meet the definition of an applicable laboratory.

And as you'll see when we get into the data collection system details, it helps with the organizational data and in making a little bit easier, I think, to submit data to CMS. And I have mentioned before that voluntary reporting of applicable information is not permitted. You may not report data for an entity that does not meet the definition of an applicable laboratory. On the flip side, 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 laboratories. Looking at slide 11, we see the definitions of a private payor rate. Private payor rate includes all payment rates even if more than one payment rate for the same private payor exists for the same test, or more than one payment rate from different payors exist for the same 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 under the CLFS, and any patient cost sharing amount, if applicable.

Private payor rates do not include price concessions applied by a laboratory. For example, if there was either a waiving of the patient deductible or co-insurance, and as I mentioned previously, private payor rates do not include information about denied payments.

On slide 12, we see the current and upcoming data collection and reporting schedule. As I mentioned, we have passed the data collection period. So, this means that for anyone who considers themselves to be an applicable laboratory, hopefully you've had an opportunity to collect these data this past January through June of 2019.

If not, please be advised that that is the time period that CMS is looking for your data to come from. The data reporting period is going to begin January 1st, 2020, and last through March 31st, 2020. There will be, of course, subsequent data collection and reporting that will happen three years from now. So, we'll be back here then, but the rates that are reported on, starting this January, there will be the calculation period following that reporting period, and those rates will be implemented January 1st, 2021.



So, looking at slide 13, after the data reporting period is over, CMS will use the data provided to calculate a weighted median for each test. As I said, this calculation then becomes the new CLFS payment rate going into effect on January 1, 2021. If CMS received no applicable information for any given CLFS test, that code will be brought to the annual public meeting in July of 2020 so that it can either be cross-walked or gap-filled to establish new payment rates for the test.

On slide 14, payment rates for this next data reporting period are still subject to a limitation on payment reduction for existing laboratory tests. If you were part of the data reporting period during the first cycle, you remember that there was a 10 percent limit to how much a payment rate could be reduced. This upcoming payment cycle, this 3-year reduction rate is limited to 15 percent each year. So, the weighted median private payor rate calculated for 2021 will be compared to the weighted private payor rate from 2020 and so on. Looking at slide 15, CMS and its contractors may not disclose any reported applicable information in any form that would either identify a specific private payor or laboratory, or also any prices charged or payments made to a laboratory.

There is an exception in this as CMS determines necessary to either — to implement aspects of 1834A of the Act if the information is requested either by the CBO, the Office of Inspector General, MedPAC, or other law enforcement entities such as the Department of Justice, to review the information. I did want to just mention on this slide that this is an important aspect. We've been getting a couple of questions from laboratories wishing to see information that they uploaded into the system during the last data reporting period.

And again, following the stipulations that are on this slide and the need for confidentiality, we're not able to provide that information. So, the hope is that labs were able to save the data that they uploaded if they want to see what was submitted.

Online Data Collection System

Okay, so looking at slide 16, this brings us to the second section of this presentation, which is talking about our online data collection system that we have available to facilitate the collection of data again starting January 1st.

But before you can access this system, you need to register with what is called the CMS Enterprise Identity Management System, or EIDM, to get a username and password. Even if your lab did this in the first data reporting period three years ago, if you haven't been using the CMS system or your EIDM ID regularly since then, you will likely have to go through this process again, or at the very least get your user name and password unlocked. You can go to a web address portal which is portal.cms.gov to begin the registration process, and you can start this today even though the system itself is not open.

That's to say, our system, the CLFS system is not open, but you can still start your registration process with EIDM. There are several resources online to help you with this process. Once you successfully get this username, you'll have the chance to gain access to the Fee for Service Data Collection System. I know that's a really long name, but the system actually collects data other than just the lab data and so you'll have to sort of maneuver within that larger system to get to the CLFS data collection system, but as I said, there are a lot of resources online that will help point you through how to do this.



So, slide 17 shows a screen that outlines many of the different roles that we have available under the system. One of the features of the portal is that all of these roles are visible to the public even though they're not all accessible to the public. So, it looks like a long list but the only two you really have to worry about are the ones at the bottom. The CLFS Certifier and CLFS Submitter. We recommend that before your lab starts this process, figure out who these individuals will be. The Submitter will be responsible for organizing the data in the data template that's provided online and uploading the file to the system. The CLFS Certifier must be a separate individual and must be able to attest that the data are correct.

Both individuals must register separately for the system, and your submission will only be considered complete once the data are certified. So, on slide 18, after you choose a role, please give us up to 74 hours, sorry 72 hours, to approve your access, but these days there really is someone checking the requests every day. So, it should not be that long. If you have any trouble registering, you can contact our helpdesk. It's listed on the slide as clfshelpdesk@dcca.com and then of course there's a phone number provided. The hours for the helpdesk will be extended once the data reporting period begins in January, and they can handle anything you need about your system access.

If you have questions related to the policies of PAMA, for example, do I have to report or what should I report, the helpdesk will refer you back to our office and we can help you with those. So, as I mentioned, you can start this registration process now but access to the CLFS system itself will not begin until January 1, 2020. But just as a preview, when you do get access to the system, on slide 19, you'll have the opportunity to log in. Again, the Fee for Service Data Collection System is an umbrella system. It collects different types of data so make sure you choose the CLFS system when you log in.

Looking at slide 20, the CLFS Submitter will be responsible for filling in information about the laboratory. Now if you've already done this and your laboratory information is already in the system, and I believe you would be the same -- you have to be the same Submitter as the last data reporting period. This information should be populated already in the system. But again, since it's been three years, I would recommend checking that it is correct, checking that all the NPIs are correct and the other data associated with your lab don't need to be updated. This registration screen will be a little bit different when you do see it on January 1st.

We will have a few additional questions that help us to understand what types of labs are reporting data to us so that we can better analyze those when the reporting period is over. Now, looking at slide 21, there are a couple of steps that the system uses to verify the Submitter information, also the lab information, one of these is to check the lab data that we receive against what is in the CMS Provider Enrollment Chain and Ownership System or PECOS. We checked this against the reporting TIN. This just helps us again to characterize the types of labs that are reporting data, if all of your lab information is updated and up to date in PECOS, because this helps to move the process through quite quickly.

In addition, a step for verifying the Submitter, and also the Certifier, which I'll talk about again in a minute, will be to generate a one-time password that gets shared with the Certifier. This is basically like an online handshake that allows the system to be confident that the Submitter and Certifier are truly part of the same lab and really are working together. It's just the validation step and allows, again, to make sure that the people in the system that are seeing your data are the ones that are supposed to be seeing the data. Looking at slide 22, so once you add the Submitter or verified within the system, and you have your data ready to upload, you can



have, you have 2 choices: you can either upload your information from a file that I will show you in a couple slides, or you can enter each data point manually.

So, moving on to slide 23, so as I mentioned, the first action is to upload your data template that can be found online. This is really the best option for any laboratory that either has a moderate or large amount of data to upload or to report. It gives you a chance to work offline, get all of your data together, allows you to format it correctly, check for any errors there, and the template is available now. It's online on our PAMA resources page. Anybody can use it to get your submission ready to go. The other option, as I mentioned, is the manual entry. This could be useful for a laboratory that only has a few HCPCS codes to report for.

Slide 24 shows what a potential data submission could look like if you're using our first option of uploading data. You can see the HCPCS codes in the left-hand column, the associated payment, and volume information. Now, it's extremely important that you pay close attention to the formatting of the cells. The system has certain validation criteria that it will check when you go to submit. So, for example, payment information is only allowed to have up to two decimal places. If you report more than two, the system is going to reject the data and ask that you fix it.

Similarly, the volume of test must be a whole number, and in this case as well, the system will not accept your data if the data are not formatted correctly. This is one reason that we recommend using the data template that's provided online to prepare your data set, since you can check for these criteria before attempting your upload. All of these data fields and verification steps are all spelled out very clearly in the user guide and on the template itself. So, you'll know well ahead of time what needs to be -- how it needs to be collected.

On slide 25, this is an example of you doing a data upload via just the text editor. This might be used if your lab has its own system of collecting the data that, if you don't want to use excel, the system will also accept data from either text editor or notepad or anything like that as shown here.

So, on slide 26, as I mentioned, the system validates the data post upload. You can see some of the feedback that the system is giving this person. The system is checking the data for any formatting errors. So, as I mentioned, like a HCPCS code must have five alpha numeric digits, a payment rate must have two decimal places. The volume can have no decimal places. You have the opportunity to fix the errors on screen and reevaluate. So, you don't have to take your excel sheet back and do it all there.

You can do it on the screen, but again, just keep in mind that several labs have a lot of data to report and so it can be a long scroll down a screen to check and find the errors that exist. So again, the more you do sort of on the upfront before you try to submit the data, the easier it will be when you get to this point. Once data passed the validation, the data are automatically saved in the system.

So, just really quickly, slide 27 shows the field for a manual entry. Again, it is basically the same, except you're just keying in the data into the system itself and then saving when you're done. And similar to the upload method on page 28, if you enter your data manually, the system will check for any validation errors.

Okay, so slide 29 talks about the CLFS Certifier role. So, as I mentioned, the CLFS Certifier must be a separate individual from the CLFS Submitter. Once all the data are submitted and uploaded to the system and saved within the system, the Submitter, after generating that one-time passcode that I showed you on a



previous slide, would share that passcode with the Submitter. It's not an easy-to-remember code, as you can see at the bottom of that slide. So, you'd want to email it to them. You can copy and paste it. Email it to your Certifier. They will be asked to enter that code when they go to log in, and then they will have access to all of the data that the Submitter uploaded or entered.

So, on slide 30, the Certifier in this case is seeing all of the data that has been submitted and saved by the Submitter. All they have to do is click that button at the end that says that they certify all of the information.

Now slide 31, it's important to note that the Data Certifier cannot make any edits to the data. So, if they see something that's off, if they see something that they believe is incorrect, they need to communicate that back to their Data Submitter so that the Data Submitter can make any of those edits. Once the data are certified, a laboratory cannot access that data. This is, again, a detail we decided upon during the first data reporting period, to maximize the security of that data once they were in the system. So, once they are certified, the laboratory can no longer access that data.

Now, if something does happen, and we're still within the data reporting period and a laboratory realizes that some huge horrific mistake was made, my recommendation would just be to get in touch with the helpdesk and we would try to walk through a solution; but it is still, I do just want to make it very clear that once that data are certified, that there's no going in to check what was sent.

Okay, so for slide 32, as a summary, the first step for all of this is to create or update your EIDM username and password. There is a user guide up online that is a step-by-step walk through of the system itself, and there will be other additional tools available beginning January 1st.

I'd actually recommend that you use those tools as opposed to this presentation, because our, this presentation had a lot of summary steps in terms of walking through how to gain access to the system and what to do -- those online tools are much more detail oriented and much more step-by-step. So, we just didn't have the time to go over it in that much detail today.

So, slide 33, again, I mentioned several of our online resources. This slide has a link directly to our PAMA webpage. There are user guides that are available now both for the data collection system, also for getting an EIDM username. The helpdesk is open and available now for any issues that you may have. In addition, on that PAMA webpage, are resources that you can see briefly on slide 34, you can submit any questions to the email address that is on that slide. It is clfs_inquiries@cms.hhs.gov.

And then, as I mentioned before, there are several other resources, frequently asked questions, the rule language, summaries of the rules, that are available online at the webpage that's listed on this slide. So, I do thank you for your time today. We have some folks on hand if you have questions that you want to ask on the phone. We welcome those. But otherwise, we look forward to hearing from you throughout our data reporting period starting in January, and once again I thank you for your time.

Question & Answer Session

Diane Maupai: Thank you, Sarah. So, 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, please limit yourself to one



question to allow others to ask their questions. You can also email specific questions; on slide 35, you'll see the address to do that. And if you have questions specific to your organization, please do use that address so we can use more -- we can do some more research. So, preference is going to be given to general questions applicable to a larger audience; and with that, Dorothy, we're ready to take our first caller.

Operator: To ask a question, press star followed by one on your touch tone 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 are 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 the line of Angela McKinney.

Angela McKinney: Hi, I wanted to ask about the contract piece or the payor payment information. Is there a threshold? Because we have hundreds of contracts. Is there a threshold for reporting that payor data information?

Diane Maupai: So, do you mean the number of labs you have to report about?

Angela McKinney: The number of private payors we'd have to report about. I've got the number of labs, but I want to know how many private?

Sarah Harding: So, this is Sarah Harding. So, the threshold really has to do with -- well, first the threshold really has to do with if the laboratory is applicable. If it is, then the first sort of thread is really your HCPCS code. So, it's looking at each test that's on the CLFS and then, yes, reporting each private payor rate for each test. Now, if you have the same private payor rate across multiple payors, you can report that one private payor rate with a total volume, but if you have a different rate for every single private payor, then yes, you would need to report every single rate for each private payor.

Angela McKinney: Oh.

Diane Maupai: Thank you, Sarah.

Operator: Your next question comes from the line of Karen Robinson.

Karen Robinson: Hi. For determining if the lab is -- if it's an applicable lab, did I understand that they have to meet both the low expenditure threshold and the majority of their Medicare revenues?

Sarah Harding: Yes ma'am. That's correct. Again, this is Sarah Harding, yes. So, your first criteria, if you will, would be to look at your majority revenues, and if it passes that, then you want to look at your total expenditures to determine if it's applicable, but yes, both criteria must be met.



Karen Robinson: Okay and does that -- if the provider determines that they have met both of those thresholds, I guess, is that reported somewhere or they just -- they determine that they don't have to report it and that's the end of it.

Sarah Harding: That's a great question and thank you for asking that. No. This entire system is really predicated on labs attesting that they are themselves applicable. So, if you send us your data, then that's the assumption that you consider yourself or that you met the requirements to be applicable, and the converse is true as well.

Diane Maupai: Okay. Thank you, Sarah.

Operator: Your next question comes from the line of Dawn Mazzola.

Dawn Mazzola: Hi. I think I missed it. Did you say that if we had already registered to do this 3 years ago that we need to unlock it or do I just start over and do a completely new registration, because I can't remember if I was the Certifier or the Submitter. Me and the other employee who did it 3 years ago do still work at this office, and we're probably going to do it again together, but I can't remember who is the Certifier, who is the Submitter, and I don't know if we just need to completely start from scratch or if I put my information in it's going to kind of ping back and say hey we already know who you are, you have to do ---

Sarah Harding: No. That's a great question, and I I'm going to be really honest and say that I don't know. There aren't a lot of systems at CMS that only engage with their users every 3 years. It's a long period of time to be silent. So what I would recommend you do before trying to access your information would be to contact the helpdesk, tell them who you are, the lab you're from, and they should be able to look up your information that you used during the last round and tell you whether you were a Submitter or a Certifier.

And then they'll also be able to tell you whether your account still exists and if it's just locked, or if you do need to do it all over again. Hopefully, it's the former, that you don't have to do it all over again. You just have to get it unlocked.

Dawn Mazzola: Okay.

Sarah Harding: But that said, there should also be -- the information for your lab should already be in the system as well but yes, I would -- I would start by getting in touch with the helpdesk.

Diane Maupai: Thank you, Sarah.

Dawn Mazzola: Thank you, and then just really quickly, I did click on the EIDM user guide like through this slide and it says that it's not available, like when I click on it, is this a bad link or is it not up yet?

Sarah Harding: No. The user guide is definitely online. It may just be the link from the slides. So, I apologize, and we'll make sure that the link that's on the PAMA resources page, so not on our slides, is the right one, and we'll definitely get the link on the slides corrected. So, thank you for letting us know that.

Dawn Mazzola: Okay great, thanks.



Diane Maupai: Thanks Sarah.

Operator: Your next question comes from the line of Anthony Brozzen-Noni.

Anthony Brozzen-Noni: Hi, I have a quick question about the applicable labs. So, if the lab charges that we billed under our hospital NPI -- that is not considered applicable labs. Is that correct?

Craig Debinski: I'll just take that. This is Craig Debinski. First of all, if your laboratory bills using the hospital's NPI, you basically have to figure out whether or not it's an applicable laboratory. The way you do that is you use the Medicare revenues attributed to 14X Type of Bill. So, if you go through the majority of Medicare revenues threshold and the low expenditure threshold, and if you meet those two thresholds, then your outreach laboratory is an applicable laboratory. So, I don't know if that answers your question or not.

Anthony Brozzen-Noni: Yes. Our outreach laboratory that bills under the 14X Type of Bill -- they bill under our own NPI. So, we were under the impression that that's what we're reporting on, not for any labs that are billed under the hospital NPI.

Craig Debinski: Correct and that's rare -- I mean it's rare -- I mean I don't want to call it that, but yes that's correct. If your hospital laboratory has its own NPI assigned to it that's separate and unique from the hospital's NPIs, and then all the applicable laboratory status would be determined based on the laboratory's own NPI and all the applicable information would be reported by the laboratory's own NPI.

Diane Maupai: Thank you Craig.

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

Rosie Fussell: Hi, I have a question about applicable information, and most of our contracts with private payors require us to submit a 1500 bill. So, are the payments that we receive on those types of bills reportable?

Craig Debinski: Yes hi, this is Craig Debinski. Can I ask you a question? Are you referring to a hospital outreach laboratory?

Rosie Fussell: Yes, I am. We're a hospital outreach laboratory. We use the hospital's NPI.

Craig Debinski: Okay, well, if you're a CLIA-certified hospital outreach laboratory that does bill Medicare Part B using the hospital's NPI. You must then determine, as I spoke earlier, whether it meets the majority Medicare revenues threshold and low expenditure threshold based on its Medicare revenues, attributed to the 14X Type of Bill. If you're a CLIA-certified hospital outreach laboratory that bills Medicare Part B because the hospital's NPI does meet the requirements of the applicable laboratory, only applicable information attributed to the non-hospital patients is to be reported. We would refer laboratories and the reporting entities to the National Uniform Billing Committee, that's NUBC official UBO4 data specifications manual for instructions on the Type of Bill used for hospital laboratory services provided to non-patients.

Diane Maupai: Thanks, Craig.



Rosie Fussell: But we bill on the 1500 because that's what our contracts say. So, my question is, is that data on the 1500 reportable?

Sarah Harding: So, thank you for this, and I think, you know, this is the first round that we're including this type of laboratory in the overall system. So, I think one of the best ways to do, would be if you would write your question into our inquiries mailbox that's listed on the slide because we'll really be --

Rosie Fussell: Yes, I did it.

Sarah Harding: Okay, so if you already have, then we'll make sure that we get back to you in a way that I think can better answer the question than just kind of on the fly. Yes so that would be my recommendation.

Rosie Fussell: Thank you.

Diane Maupai: Thank you, Sarah.

Operator: Your next question comes from the line of Kathy Boo. Kathy, your line is open. Your next question comes from the line of Amanda Foster.

Amanda Foster: Hi, this is Amanda. I have a question in regards to the majority of Medicare revenues threshold where you're actually doing the equation that you have listed. Are we only pulling the Medicare Part B encounters for this equation? That's my first part of it. And my second part to that is what if we received amounts outside of the CLFS fee schedule, like say they said we would get \$3, but one encounter we got \$4, one we got \$5. How do we make sure that we're using the right information on that formula?

Craig Debinski: All this information is explained in our summary guidance available in our website, but just briefly, the equation for the Medicare or the majority Medicare revenues threshold is in the numerator you have to have CLFS revenues plus Physician Fee Schedule revenues, and they have to be at least 50 percent or greater than 50 percent of total Medicare revenues. And total Medicare revenues is Medicare Part A, plus Medicare Part B, plus Medicare Part D, received during the data collection period, and when you do the equation, you have to have greater than 50 percent of your total Medicare revenues derived from the Clinical Laboratory Fee Schedule and the Physician Fee Schedule.

And if you are having trouble distinguishing what Clinical Laboratory Fee Schedule is, you basically can go to our website on the PAMA regulations page and look at the applicable information HCPCS codes, and that will let you know the types of codes that are on the clinical laboratory fee schedule.

Diane Maupai: Thank you, Craig.

Amanda Foster: So, in the denominator would be the Medicare Part A, Part B, and Part D, correct?

Craig Debinski: Correct.

Sarah Harding: Correct.



Amanda Foster: And in the numerator would be only the Part B or would it be all three?

Craig Debinski: Well, it would be Medicare Part B specifically to the Clinical Laboratory Fee Schedule services and specifically to the Physician Fee Schedule services. So, any of your doctor and practitioner services, and all those lab tests that are only applicable information HCPCS code table would be the numerator.

Diane Maupai: Okay, thank you so much, and we're going to move on to the next question.

Operator: Your next question comes from the line of Bambi.

Bambi: Hi, yes. Thank you for taking my question. That is my real name. Just throwing it out there. I just wanted to ask if you can clarify a little bit more on the applicable information slide where it indicates that remittances where the payor has grouped test-level payments into an encounter or claim-level payment, that it would not be included in the data submitted. Would that be if there are multiple HCPCS codes that are reimbursed on the same claim?

Sarah Harding: Okay. So yes thank you for this question, and I think there are several instances that would go to this point, but basically an example would be like any time there's a situation where you can't actually correlate the specific payor rate to an individual test, that data would not be reported. So, I think like if you had a situation where it was paying for 20 tests online and you had a total payment for that 20 tests, we wouldn't be able to take that data. It has to be the negotiated rate for the individual test.

Diane Maupai: Thank you, Sarah.

Operator: Your next question comes from the line of Susan Grondin.

Brian Costello: Hi, we have a question. I'm with Sue. This is Brian Costello. The question is in regards to the question right before the last about the 14X numerator and denominator to determine if you need to submit data. In the numerator, we definitely do not have 50 percent of our revenues -- is not Medicare lab revenues, but when you look at all of our rare hospitals, so 100 percent -- we're definitely a very low percentage below 50 percent of our revenue is lab revenue. Do we need to submit based on that? I don't know if it makes sense ---

Sarah Harding: I think if you enter your revenue data and information into that equation, if it is less than 50 percent, then no, your lab would not report.

Brian Costello: The denominator---

Craig Debinski: The CLFS -- yes okay the majority of Medicare revenues thresholds is the CLFS plus PFS must be greater than 50 percent of your total Medicare revenues. So, it's not just laboratory data.

Brian Costello: So, our numerator is not just lab.

Female from Susan Grondin's line: We want to make sure the denominator is not just lab because we're filing under the hospital NPI.



Sarah Harding: Right. The denominator is all Medicare revenues. Well, A, B, and D.

Brian Costello: Okay, so there is no way we --

Female from Susan Grondin's line: Not just 14X but all Medicare revenues?

Sarah Harding: I think this might be another situation where ---

Craig Debinski: Well actually, excuse me, most if not all hospital outreach laboratories will meet the majority Medicare revenues threshold because their only revenues are from the 14X Type of Bill under the Medicare program. Does that answer your question?

Sarah Harding: And if not, I would also encourage you to write your question in to us so that we can make sure we get you a careful answer.

Diane Maupai: Okay, thank you Sarah and Craig.

Operator: Your next question comes from the line of Nate McClintock.

Nate McClintock: Good afternoon. This is Nate McClintock from Prism Health. I just want to see if I can get a little bit of clarity around your definition for private payor. In particular, I'm interested in -- we've got Medicare Advantage, Medicaid MCO, pending Medicaid, Workers Comp, other Tricare, and these types of payors. Could you provide some clarity around that?

Craig Debinski: Yes, your Medicare Advantage plan under Part C would be defined under the Social Security Act under section 1859.B1. If you have any other questions, a Medicaid Managed Care Organization would be defined in section 1903M, a group health plan would be defined in section 279, Rule A1 of the PHS Act. Basically, this information is online.

Diane Maupai: Yes. And you know, feel free to write in if you would like that in writing. That would be easier for you. We have time for one more question.

Operator: Your final question comes from the line of Peggy Moran.

Peggy Moran: Hi, this is Peggy Moran. I have a question regarding the claim-level payment versus a test-level payment. We've determined that most of our hospital laboratories would qualify as an applicable lab but we're being told by our billing department that all of our payors pay at the claim level. So, there's no way to get down to the detail. So then does that exclude us from the need to report for PAMA.

Craig Debinski: Yes, hi. I just want to reiterate what we've said earlier, that if a laboratory cannot correlate a private payor payment amount and the associated volume paid at that rate to a specific HCPCS code, that that amount is not a private payor rate for purposes of applicable information. And estimated private payor rates and volumes are also not considered applicable information.

Peggy Moran: So, if all payors are paying at the claim level, we would not be obligated to report.



Craig Debinski: Yes. If it's true that you can't correlate the private payor payment amount associated volume to specific HCPCS code, then that wouldn't be applicable information and you wouldn't have that to report.

Peggy Moran: Okay, thank you.

Additional Information

Diane Maupai: Okay, thank you. Unfortunately, that's all the time we have for questions. If we didn't get to your question, see the two resource slides -- on my laptop it's slides 34 and 35. We hope you'll take a few minutes to evaluate your experience. See slide 36 for more information. An audio recording and transcript will be available in about two weeks at go.cms.gov/npc. Again, my name is Diane Maupai, and I would like to thank Sarah and also thank you for participating in today's Medicare Learning Network Call on The Clinical Diagnostic Laboratory Test Payment System Data Reporting. Have a great day, everyone.

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