



**MLN Connects®**

**National Provider Call Transcript**



**Centers for Medicare & Medicaid Services  
Clinical Diagnostic Laboratory Test Payment System: Data Reporting Call  
MLN Connects National Provider Call  
Moderator: Diane Maupai  
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2:30 pm ET**

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This transcript was current at the time it was published or uploaded onto the web. Medicare policy changes frequently so links to the source documents have been provided within the document for your reference.

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**Operator:** At this time, I would like to welcome everyone to today's MLN Connects® National Provider Call.

All lines will remain in listen-only mode until the question-and-answer session. This call is being recorded and transcribed. If anyone has any objection, you may disconnect at this time.

I will now turn the call over to Diane Maupai. Thank you. You may begin.

## Announcements and Introduction

Diane Maupai: Well, thank you, Holley. This is Diane Maupai from the Provider Communications Group here at CMS in Baltimore. And I'll be your moderator today.

I'd like to welcome you to this MLN Connects National Provider Call about data reporting for the Clinical Diagnostic Laboratory Test Payment system. MLN Connects Calls are part of the Medicare Learning Network®.

During this call, CMS experts will detail how to report private payer rates required for the new clinical diagnostic laboratory test payment system. A question-and-answer session will follow the presentation.

Before we get started, I have a couple of announcements. You should have received a link to the slide presentation for today's call in previous registration emails. If you have not already done so, please view and download the presentation from the following URL, <http://www.cms.gov/npc>. Again, that URL is <http://www.cms.gov/npc>.

At the left side of the webpage, select National Provider Calls & Events. And select the November 2<sup>nd</sup> call from the list.

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

We thank everyone who took the opportunity to submit questions when they registered for this call. We will answer these questions during or after the presentation.

We have two speakers today, Sarah Harding from the Division of Ambulatory Services in CMS and Ray Lee from DCCA who are listed on the front of your slide deck. I'll now turn the call over to our first presenter, Sarah Harding.

## Presentation

Sarah Harding: Thank you very much. Good afternoon. Thank you so much for joining us today. As Diane mentioned, my name is Sarah Harding. I work within the Division of Ambulatory Services at the Centers for Medicare & Medicaid Services.

With the implementation of the Protecting Access to Medicare Act, or PAMA, we needed to create a secure system to collect the large volumes of applicable information from laboratories across the country. This call today is an introduction to what we have begun to call the CLFS data collection system.

I'd like to spend just a few minutes looking at slide 3, which is the overall agenda of the talk. For this presentation, we're going to start with just a brief overview of PAMA backgrounds and then a walkthrough of the data reporting schedule that is in place.

Again, this call today is meant to be an introduction to the system we've built. We're not going to spend too much time on policy-oriented questions such as what determines whether a laboratory is applicable.

Through the talk today, we will frequently refer to the CLFS PAMA webpage. This is linked from the resources slide at the end of the presentation on slide 23. We're using this page as a repository of helpful information for both the system and for help interpreting the PAMA statutes. For example, to help with more policy-oriented questions, there is a list of frequently asked questions that have been developed to help laboratories answer questions such as whether they must report data or what data they need to report. There are also publications for sub-regulatory guidance that are listed on that webpage as well.

But this talk -- this call today again is not going to be centered on those types of questions but rather the data collection system to be used when reporting data. Please just keep this in mind during the question-and-answer session at the end of the call as well.

So the next part of the presentation will be all about registering for the data collection system. And to be honest, the registration process is going to be the most time consuming for users of this system. Because this is a CMS system that contains confidential laboratory data as well as personally identifiable information, or PII, we have several security measures and requirements that we must adhere to. These requirements are also in place to insure that the data laboratories submit are kept secure and confidential.

The first step to gaining access to our system or any CMS system in fact is to register through the Enterprise Identity Management System, or EIDM. This registration step is actually completely independent of our CLFS data collection system. Once you've gained access to EIDM, you'll then be able to request access to our specific data collection system for CLFS through the request catalogue.

Now, I want to mention one critical piece that relates to the name of our system. Our CLFS data collection system is in fact one part of a larger system that collects multiple types of payment data for CMS. Therefore, another term we'll be introducing during this presentation is the Fee-for-Service Data Collection System or FFSDCS.

The CLFS data collection system is one component of that. And I say this because part of the registration process will include requesting access first to FFSDCS and then to CLFS.

This is critical. There are many many different systems across CMS. And it would be easy to request access to the wrong one, which would be a little like going down a rabbit hole just to be honest.

Our user guides and instruction manuals are clear in this respect. But we feel the more we can mention the relationship of FFSDCS and the CLFS data collection system, the clearer the registration process will be.

Now, our CLFS system will be open to laboratories on November 14<sup>th</sup> of this year. We will be walking through the system itself today. But please keep in mind that if you try to gain access to our system today, you won't be able to access the system immediately. However, you can get your EIDM registration all set up. You can request access for the CLFS system. And on November 14<sup>th</sup>, you'll receive notification that you have access.

We'll be talking in more detail of what that entails. And at the end of the presentation, there is a link to EIDM resources that can help you walk through the process.

Now, looking back at the agenda, we'll next talk about the two distinct roles available in the CLFS data collection system. PAMA requires that all data submitted from laboratories must be certified by a second individual from that lab. Therefore, each reporting laboratory must have two distinct individuals registered in our system. The first is the data submitter who will be entering in all of the data for the lab. The second is the data certifier who will certify the data are correct. We will go into more detail on each role in the presentation.

Finally, we'll help you -- we will show you how to report your data. We've worked hard in making it as simple a process as possible. And we'll show you the highlights here today.

As I've already mentioned, we have several types of resources in place to help laboratories through the registration and use of our CLFS system. These are listed at the end of the presentation on slide 23 and also on the CLFS PAMA webpage. Excuse me. We also have a CLFS system-specific helpdesk in place to help you navigate through the system and answer any system-related questions that may arise.

### **Brief Overview**

Now, if we could move on to slide 4. This gives a brief background of PAMA. CMS published its final rule implementing section 216 of PAMA on June 17<sup>th</sup>, 2016. PAMA requires applicable laboratories to report private payer rates for laboratory tests on the clinical laboratory fee schedule.

These rates are then used to calculate the Medicare payment rates. These rates will be implemented starting January 1<sup>st</sup>, 2018.

On slide 5, we will begin collecting applicable information on January 1<sup>st</sup>, 2017. The data reporting period will be open for 3 months, closing on March 31<sup>st</sup>, 2017.

As I mentioned in the introduction, the system will be open starting November 14<sup>th</sup> so that laboratories can get their registration and approvals all set up prior to January 1<sup>st</sup> if

they would like. However, data submissions should not be made until January 1<sup>st</sup>, 2017. We do encourage laboratories to register early, however.

Now, I'd like to introduce Ray Lee who's our project manager for the development of this system. He will walk through more of the details on how to register and how to submit data.

## Registration

Ray Lee: Thank you, Sarah. So we'll be slide -- starting on slide 6, final registration. The first bullet is titled CMS Enterprise Portal. This is the actual hyperlink that takes you to the Enterprise Portal, where you will be registering for the system. The link is simply available through any web browser at [portal.cms.gov](http://portal.cms.gov).

Once you enter into -- that web address into your browser, you'll go through a series of steps that we'll go through. One important side note is that when -- once you are registering for the system, the submitter role, the -- will need their information current within the CMS PECOS system.

The CMS PECOS system is the provider enrollment system. And your name must match, at least to a degree, we'll take some variances, but they need to match the PECOS system of record to complete your registration.

Another important note is that once you get to the portal, cms.gov, you'll need to register for a CMS EIDM username and password. The CMS username and password is different from the CMS Enterprise User Administration, EUA, account. So this is commonly, if you worked with CMS before -- is a four character account name.

This username and password may work for the portal. But this will not give you access to the CLFS data collection system. So if you do not have an EIDM account, make sure to create a new user registration for this type of account. An easy way to differentiate the two is that an EIDM username must be six characters or more unlike the EUA, which is four.

Once you have finished creating the EIDM username and password, you will be selecting a role for either the CLFS submitter or certifier. Once you request this, due to security matters -- measures, you will be asked to go through a remote identity proofing process.

The remote identity proofing process will ask you for information pertaining to yourself, such as your date of birth, your social security number, your address, your email, and your phone number.

Once you have completed this information, this will run a soft credit check based on your social security number and will ask you some verifying information about your individual, such as information about where you have last lived, information about your mortgage, etc. So in summary on registration, the two roles that you will be requesting -- is either for the submitter role or the certifier role.

If you advance to slide 7. After you have finished the registration process for your EIDM username and password, you will be asked to actually request the role for the system. The place to do this is from the request catalogue as shown in slide 7. Currently highlighted is the box called FFSDCS, which stands for Fee for Service Data Collection System.

If you look inside the box, there will be some helpdesk information if you require it. But most importantly, you will be clicking the request access button that is in that box. So it's important to note to select this box because, as Sarah mentioned, there are many systems that you may request access roles from but only this one will get you into our system.

If you advance to slide 8. After you click the Request Access button, there will be a dropdown that's pointed by an arrow right now toward the FFSDCS data collection system. If you click on the dropdown menu, there will be several roles that are listed in the box. The two that are relevant for data collection or reporting purposes for PAMA is the CLFS certifier role and the CLFS submitter role as identified by the arrow in slide 8.

Advancing to slide 9, titled Registration—Role Approval. After you have requested the specific role, after November 14<sup>th</sup>, please wait up to 72 hours where you will receive an email confirmation from the CMS portal and EIDM system that you have been granted access to either the CLFS submitter or CLFS certifier role. If you have any issues in terms of registration, please contact our application helpdesk via the information provided in the bullets below.

Some common examples that you may be calling for are things -- are if your portal and EIDM account become locked based on not remembering your password or putting the wrong password in too many times. If you need a password reset, you can request that through our helpdesk, any basic registration questions, or any other problems related to system availability, or any other technical questions to get you into the website. If you ask a policy-related question to this helpdesk, you will likely be escalated to the policy group over at CMS, where they will return your answer directly.

Advancing to slide 10. After you have waited your up to 72 hours for your role access, you will come back into the portal, that cms.gov website, where you'll enter in your credentials. And if you have been successfully approved, you will see the following navigation menu in yellow that is depicted on slide 10.

If you hover over the Fee-for-Service Data Collection System, please click on the CLFS menu option circled in slide 10.

The one other thing to note is that there, after your remote identity proofing process during your registration and your role request, you will be asked to register a multifactor authentication token device. This is probably one of the more complex parts of registration. It is not depicted in this slide deck. But in our reference material I believe on page, on slide 23, there is a CLFS user guide that walks you through the exact steps that we're going through today, probably a little bit more in detail, step by step on how to register and how to register the token device.

Moving on to slide 11. Once you have successfully clicked on the CLFS link, you will be taken. And we will be talking about the CLFS submitter role to start. The picture depicted on slide 11 shows the first screen after you have selected Laboratory Information from the left-hand navigation. Here, you will be going through a secondary registration process to supply your laboratory name, your reporting tax identification number, as well as any NPIs that are associated to this reporting tax identification number, as well as any CMS certification numbers, CCNs, into the boxes in this screenshot.

These fields are validated by different rules. So make sure that your NPIs and CCNs as well as TINs are formatted in an appropriate fashion.

Once you have hit the save button, the next step is to generate a one-time password. This one time password -- the objective for this is to establish the relationship between the CMS -- the CLFS submitter role individual to the CLFS certifier role. The submitter should click on this Generate One Time Password button, which will give you a string of characters that should be either copied and pasted via email or spoken directly to the certifier so that they may continue and complete their registration process.

Moving on to slide 12. Slide 12 talks about the PECOS identity verification that will happen in the background. Once you hit Save as a submitter, the information and your name will be submitted to the PECOS repository and, based on that validation, will report success on that registration process.

The one time password that we talked about on the last slide is depicted below with an arrow pointing to the letters in green. This string of characters is valid for 1 week upon generation and must be shared with a certifier so they may complete their registration.

If 1 week lapses, you must log back in to the same registration page, and you can simply hit the Generate One Time Password again to generate a new one time password to share.

### **Data Submission/Reporting**

Moving on to slide 13. After you have completed your registration process, you are now ready for data submission or data reporting. There are two easy options that you can choose from in the left-hand navigation menu.

The first one is via file upload. And the second option is manual entry of that applicable information.

Moving on to slide 14 to see some of the options and some of the details associated. On slide 14, the first bullet is Option 1, the data upload. So this is --there is a template available at the PAMA webpage in the URL listed on this bullet where you'll be directed and can download a CSV file. A CSV file is a comma-separated file where we have the appropriate data fields marked as a header, which should not be changed. But additional rows can be added via comma-separated rows right below.

This is the best option if you have a large number of -- amount of data that you need to submit into the system. If you have a small amount of data or fewer records, the option -- the better option would be manual entry. For manual entry, we have a series of web screens where you are able to add data similar to the upload fields to go through and go -- also go through the data validation steps. So we'll be going through a little bit more detail on each of these options.

Slide 15 shows a depiction of the data templates that you'll be using to submit the data. For this example, we have opened up the CSV data templates using Microsoft® Excel®.

Opening up the Microsoft -- in Microsoft Excel, I see five -- I see actually four column headings. The first is for the HCPCS code. The second is for the payment rates. The third is for volume. And the last is for the National Provider Identifier.

Going a little bit more into detail on the specific columns, column A for the HCPCS code, the HCPCS code is a list of CLFS HCPCS codes, which is available online at the CMS CLFS PAMA regulations webpage. If you would like a reference on which codes out of all of the CMS HCPCS codes that CLFS deals with, please visit the PAMA regulations page.

If an applicable laboratory has more than one payment rate for the same private payer for the same tests or more than one payment rate for different payers for the same tests, the reporting entity will report each such payment rate and volume for the test at each such rate. The system will accept duplicate HCPCS codes within your submission.

Column B, which is for the payment rate -- this number is a number value that must include two decimal places. For more information on the definition of payment rate, please refer to our frequently asked questions list on the CMS CLFS PAMA regulations webpage.

Column C is for the volume of each test at a particular payment rate. This number should always be a whole number or rounded to a whole number to be populated into your submission.

Column D is for the National Provider Identifier, or NPI, which is associated with the specific volume and payment rate for each row. Each column must be formatted

correctly. And this is explained at the top of each column and in all of our user guides referenced on slide 23.

None of the columns should be -- have decimal values except the payment rate, which must have two decimal places. The system will ask you to correct any formatting errors before it will accept your data.

Slide number 16 is a depiction of that same data template. But we have opened it up in a text editor such as Notepad. Here, I'm able to see some of -- a little bit in a more simplified format the exact headings that are required as well as a sample list of data that conforms to the rules that we have specified.

Some of the recommendations based on if you are working directly with Microsoft Excel is that you must convert all of your fields to text by selecting the Format Cells and going to the "text" option. If you don't, you may not be reporting all of your data in the required format as Excel will sometimes round and display formatting that is not accurate with what is actually in your file.

To preview this, you may as a secondary option open up your CSV file within a text editor such as Notepad. If you are generating this data template from a larger system or database, please verify your submission via text editor to complete the process.

We'll now move on to slide number 17, which walks us through the upload process of that file. So if we take a look at the screenshot that is on the right side, and we take a look at the -- where that first table is and the red arrow, there is a box right below it that says Browse. And it says Upload Data.

You'll click the Upload Data button to search for your file that conforms to the data template requirements and hit the Upload Data button. The system will then accept your file, pass it through the validation of rules, and will give you the results of your submission below. If any of your rows do not pass the validation rules, you will receive a result, which is circled in the table below, of why it did not pass validation. Your rows will not be saved unless all of your rows have passed validation. Once they have passed validation, the system will automatically save your submission into the database.

Moving on to slide number 18. Slide 18 depicts the manual entry option for data submission. So if you have a fewer amount of records or if you would simply like to view the information that you have already submitted for the CLFS data reporting period, simply go to the Manual Entry Applicable Information in the left hand navigation, as shown on the screenshots.

Here, you'll be presented with the four fields with up to five records that can be entered in on the screen. If you need to enter in more than five records, simply hit Add More, which will give you five more records at a time until you have the sufficient number of records for you to manually enter the data.

Moving on to slide 19. Slide 19 is for any data corrections for once you have uploaded any information via the upload screen or the manual entry screen. If you select the Edit and View Data button from the left-hand navigation on the side, you'll be presented with all of the data that you have successfully entered up to now.

From here, you'll be able to manipulate any of the data if there are corrections needed or remove any rows using the Remove icon that is on the last column of this table. You may also search or sort based on either the HCPCS code or the NPI. Also, there is a search feature for any HCPCS codes in the upper right-hand portion of the screen if you need to narrow it down to a certain HCPCS code. Contextual help is available at the upper right-hand of any screen if you need help on any actual page of the application itself.

All right. Next, we'll focus on the CLFS data certification role. The data certification role also goes through the EIDM registration process. And they will have registered or requested the role as CLFS certifier.

Once they are successful, they'll go through a similar registration process as a CLFS submitter. The differences here are depicted in the screenshot on the bottom of slide 20. The certifier must successfully enter in the name of the lab as well as the reporting tax identification number and, where the arrow points, the one time password that was supplied by your CLFS submitter for your organization.

Moving on to slide 21. After registration is complete of the certifier role, you will go to the left-hand navigation of the screen and select the certification menu option. This

option will give you all of the saved records that the CLFS submitter has put into the system to this point in time.

The certifier now has the ability to review any of this data. And if any corrections are needed, they will need to work with a submitter so that the submitter will have to correct the data. The certifier simply has the option to register and to review the data but not to modify any data.

Once the review is complete, the certifier will press the Certify All button, as depicted with the arrow on the screenshot on slide 21. After the Certify All button is pressed, a disclaimer with the attestation statement will be presented to the user. And they will submit the data to CMS.

Slide 22 talks about the various constraints presented for the CLFS data certifier. The first one is that they -- the certifier cannot make any edits to the data. If changes are necessary, they must contact the data submitter to make changes for the organization. Then once the data submitter makes any edits, the certifier must then re-review and certify that data. Once the data are certified, that data is now not accessible to the laboratory until the next reporting period.

I'm going to turn over the presentation back over to Diane to go through the rest of the presentation.

## Keypad Polling

Diane Maupai: Thank you, Ray. You will see on slide 23 links to many at -- much of the reference material, and again the email address and the phone number of the helpdesk. So at this time, we're going to pause for a few minutes to complete keypad polling so that CMS has an accurate count of the number of participation -- participants on the line with us today. Please note there may be a few moments of silence while we tabulate the results. Holley, we're ready to start polling.

**Operator:** CMS appreciates that you minimize the Government's teleconference expense by listening to these calls together using one phone line. At this time, please use your telephone keypad and enter the number of participants that are currently listening in.

If you are the only person in the room, enter one. 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 nine.

Again, if you are the only person in the room, enter one. 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 nine. Please hold while we complete the polling. Please hold while we complete the polling. Again, please continue to hold while we complete the polling.

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

## Question-and-Answer Session

Diane Maupai: Thank you, Holley. Our experts will now take your questions.

But before we begin, I like to make two points. First, I'd like to remind you that this call is about the data collection system. Questions of a policy nature, you can find information on the PAMA webpage. There you'll find links to FAQs and other guidance. And that link is found on slide 23.

The second thing is to remind you that this call is being recorded and transcribed. Before asking your question, please state your name and the name of your organization. In an effort to get to as many questions as possible, we ask that you limit your question to just one.

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

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

**Operator:** To ask a question, press star followed by the number one on your touch-tone phone. To remove yourself from the queue, please press the pound key. Again, that's star, one to ask a question. Remember to pick up your handset before asking your question to assure clarity.

Please note your line will remain open during this time you're asking your question, so anything you say or any background noise will be heard in the conference. Please hold while we compile the Q&A roster.

And our first question will come from the line of Mike Hatt.

Mike Hatt: Hello. Yes. Can you hear me?

Diane Maupai: Yes.

Mike Hatt: Okay. I had actually two questions. I apologize. One is to register, that is only for those labs that will be submitting data. Correct? Not all labs need to register.

Sarah Harding: That is correct, yes.

Mike Hatt: Okay. Thank you. Then my second question, on slides 16 and 17, it seems that one of the criteria is on the five numeric characters for the volumes, but yet the examples show more than five characters. And on slide 17, it looks like it could be an error if it's more than five characters. Some of these labs are going to have more than five characters. How do you deal with that?

Sarah Harding: This is Sarah. And I think you have just revealed one of the characteristics of having a brand new data collection system.

I think you're absolutely right. And I can only thank you for pointing it out to us. We will make sure -- I have -- my understanding is the system is actually indeed set up to accept volumes larger than five characters. And that the delineation, the instructions may not have been edited to reflect that. So we will certainly make sure that that is the case. So thank you.

Diane Maupai: Thank you.

Mike Hat: Thank you, Sarah.

**Operator:** And our next question will come from the line of Suzanne Brusseau.

Suzanne Brusseau: Hello. I see on one of the slides that the certifier must be the president or CFO of the lab. It cannot be like our administrator of the office on which we have the lab?

Sarah Harding: This is Sarah again. And thank you for -- thank you for pointing that out. The rule -- the final rule that was published in June did say that the certifier can be somebody who is appointed by the -- by the lab who is in a place to make that attestation.

Suzanne Brusseau: Okay, good.

Sarah Harding: So, yes, that is fine. The only real requirement -- well, I mean there are several real requirements. But the important requirement is that the certifier and submitter do have to be two distinct people. So you cannot submit it and then certify it yourself. That does have to be an appointed person.

Diane Maupai: Thank you, Sarah.

**Operator:** And our next question will come from the line of Elizabeth Bunda. Elizabeth, your line is open.

Elizabeth Bunda: On slide 6, there's remote identity proofing -- I believe the first part was a credit check. And what else did they say was part of that?

Ray Lee: This is Ray Lee. The credit check is a soft credit check. And it will simply ask you four to five questions based on your credit reports. There are no more -- there are no more questions other than the -- your identifying information such as your social security number, address, email, phone number, and your name. I think ...

Elizabeth Bunda: Okay.

Ray Lee: ...that's the extent of the IEDP.

Elizabeth Bunda: Did I misunderstand something about the mortgage?

Sarah Harding: This is Sarah. So a type of question that is asked by any organization that's doing a soft credit check—it's not just us. But, so Ray was giving an example of a question. It might say -- it might list five banks as a multiple choice question and say, "Which of these banks did you recently take a mortgage with?" And you have to choose the correct option of those five.

Similarly, a question might be they'd list four streets. And they'd say, "Which of these streets have you at one time lived in your life?" And so it's mainly -- and so all it is is -- it's a check against the information that your credit -- it -- quite frankly, it's what is on your credit report. So it's checking information against what they're getting from Experian.

Elizabeth Bunda: ...only paid through the clinic, not to me personally.

Sarah Harding: I'm sorry. Say that one more time.

Elizabeth Bunda: I guess my -- I'm not clear on why they need to check my credit for information on monies that are paid to the clinic, not to me personally.

Sarah Harding: So the identity proofing has to do with assuring that you are who you say you are, the individual who you say you are. So it is a process that is required by CMS in having a system like this. And again, it's -- it's something that is used to confirm the identity of the person wishing to gain access to a Government system.

Diane Maupai: Thank you, Sarah.

Elizabeth Bunda: Ok, thank you.

**Operator:** And our next question will come from the line of Jane Evans.

Jane Evans: Our question was the same. It was about the credit check and the need for that when there's plenty of other ways to identify that we are who we say are without doing a credit check. And that was our question, was we still don't really understand the need for that.

Ray Lee: This is Ray Lee. So just to add more on that. Even if the submission is on behalf of an organization, based on the security guidelines that are presented by FISMA and the CMS ARS standards, any system that is classified as moderate—which this system is because it contains the PII, for personally identifiable information, as well as the trade confidential information—we are mandated to go through a remote identity proofing process, which for CMS involves the soft credit check. There, we do not have any other options other than this.

Diane Maupai: Thank you, Ray.

**Operator:** And our next question will come from the line of Richard Fairley.

Richard Fairley: Hi. Thanks for this call. I just need some clarification on the collection of the data. It seems either I'm misinterpreting this or it's as overwhelming as I think.

We're a physician office laboratory. We probably do -- we're pretty robust. We do 150 different laboratory tests. We probably have at least 50 or more insurance payers.

Each individual insurance payer may have 10 or 15 different payment amounts for -- a potassium may be \$3 in their fee schedule. But depending on what other tests they had that day, it might be \$2.27 one day -- one time. And then they come back again with some other test. And it's 200 -- \$2.87 the next time. I don't see how we could possibly check all the reimbursements for all the payers for all the tests. It just seems overwhelming to me.

Diane Maupai: Please give us 1 minute to confer.

Richard Fairley: Okay.

Diane Maupai: Okay. We're back on the line.

Sarah Harding: This is Sarah. And I do very much appreciate the question. And the -- you know, the first question to ask is to determine whether you do have an applicable laboratory. And then the second is to consider, yes, all of the information that would be considered to be applicable information.

We do expect some labs to be reporting quite a high volume of information. But I would strongly encourage you to look at the -- both the frequently asked questions as well as the sub-regulatory guidance to insure that you do have a clear understanding of what is entailed.

Diane Maupai: Thank you, Sarah.

Richard Fairley: Okay. And one quick follow up to that is the -- from my understanding is that generally physicians are registered in PECOS but other people aren't. So my finance director isn't and my lab director, nurse manager isn't, lab manager isn't. How do these people become submitters if they're -- can they register in PECOS when they're not physicians and nurse practitioners and such?

Ray Lee: So this is Ray Lee. In terms of the PECOS information, there -- the primary on each provider is the authorized official. But there are several other name fields that can be populated for the designated officials on the various positions. So we will be matching on any of those name fields that are in PECOS that are -- that are applicable.

Richard Fairley: Okay.

Diane Maupai: Thank you, Ray.

**Operator:** And our next question comes from the line of Mary Jane.

Mary Jane: This Mary Jane with Family Care Partners. Just a question on -- we're a primary care office. So we can submit under the group NPI rather than the individual NPIs is my question?

Sarah Harding: So this is Sarah. I would encourage you to look at the frequently asked questions on the PAMA webpage. It specifically talks about this question of which NPI within an organization.

Mary Jane: Okay. And then you indicated, you know, offices or entities would have multiple lines for the same CPT code. So would we list those all together for the multiple payers or is there -- do we do a different page for each payer?

Sarah Harding: Are you talking about the -- filling out the data template?

Mary Jane: Yes, probably on a manual submission.

Sarah Harding: Okay. So, no, you would not have to submit anything, a different page per payer. I apologize if I'm not answering your question correctly. The applicable information that needs to be reported is the private payer rates for each HCPCS code and the associated volume. So...

Mary Jane: Correct.

Sarah Harding: ...if that means -- if those are the same across many payers, then you can report that on one line. If there are different payment amounts for different payers, those can be reported on different lines as well.

Once again, the frequently asked questions as well as the final rule that was published does speak to, you know, the substantive content of the data and how it should be reported. There are rules against aggregating data that a laboratory would need to look to. And, as I said, those are mentioned in those regulatory guidelines.

Mary Jane: Thank you.

Diane Maupai: Thank you, Sarah.

**Operator:** And our next question will come from the line of Leslie Coach.

Leslie Coach: My question's been asked and answered. Thank you.

**Operator:** Our next question will come from the line of Joyce Nurenberg.

Joyce Nurenberg: Thank you. So I was imagining we will -- so we work as an agent for another tax ID. So I was imagining because we're pulling in financial information, that I would have to ask the entity to give me permission to be able to be a submitter. Would they assign that role?

Sarah Harding: This is Sarah. Can you clarify a little bit of the situation you're asking about?

Joyce Nurenberg: Sure. Sure. So in the business office, we're having to pull all this financial data on the lab code. So what I was thinking was that we would ask the tax ID who's affected by this, by the criteria. That – I was thinking that rather than turn this over to someone else, that they could give us permission to be submitter and certifier. And, of course, now, I'm hearing that both the submitter and the certifier have to have one of the either authorized or delegated official roles on that PECOS Medicare enrollment, which ...

Sarah Harding: Right.

Joyce Nurenberg: ...I think you only get three. So that is going to be -- I don't know that's an -- not...

Sarah Harding: The submitter does have to -- the submitter will be matched against PECOS. The certifier will not be. So as long as the submitter can be validated in PECOS, then you can move forward.

Joyce Nurenberg: So it sounds like you have to be an employee of the tax ID. Is that a condition or not?

Sarah Harding: No, it's not a condition.

Ray Lee: It's not a condition. But they do need to be in the system. And their name needs to be registered as part of that provider.

Sarah Harding: Right.

Ray Lee: So it does not necessarily have to be an employee of that reporting TIN. They can still be designated as one of the officials.

Diane Maupai: Thank you, Ray.

Joyce Nurenberg: Thank you.

**Operator:** And our next question will come from the line of Julie Allen.

Julie Allen: The question was asked and answered. Thank you.

**Operator:** Our next question will come from the line of Laura Chaney.

Laura Chaney: Hi. Thanks for this call. One quick question I had was about this token authentication that you mentioned back in the registration process. Is this some sort of device that you have for a two-factor authentication? You sort of skipped over that. And I was asking for a little clarification on that.

Ray Lee: Sure. This is Ray Lee. To clarify on the multifactor token, we do have a lot of detail within the CLFS user guide as well as the EIDM user guide, which is in the reference material. But to clarify, at a high level, they are not hardware-based tokens. They're soft tokens.

So some of the options include a smartphone app that you can download or an -- a little app that you can download onto your PC. It can also be your phone number where you can provide a number that the portal can SMS you a code. Or it can also be an email address where if you select that email option and press -- at time of authentication, you press the Send Me My Code Now. It will send you a code where you will have 30 minutes to enter that specific code that the token generates into your authentication page.

Diane Maupai: Thank you, Ray.

Laura Chaney: Okay.

Diane Maupai: We have time for one final question.

**Operator:** Our final question will come from the line of Rick Pening.

Rick Pening: You know basically you've answered all my questions. But somebody previously brought up the NPI issue. And I think people need to understand that the NPI

is one of the four criteria upfront. If the lab doesn't have its own NPI, then they're not an applicable lab. Correct?

Sarah Harding: This is Sarah. And, yes, you are correct.

Rick Pening: Right. Because that for me eliminates all of my labs except one.

Sarah Harding: Yay.

Rick Pening: No. I know. I mean that it took us a while to get to that point. But, that's an important piece.

Sarah Harding: Yes. Thank you for pointing that out. I appreciate that very much.

## **Additional Information**

Diane Maupai: Okay. Well, unfortunately, that's the -- we go out on a high note. Unfortunately, that's all the time we have for questions today.

If we didn't get to your question, you can refer it to the resources on slide 23 or contact the helpdesk. And the hours of operation are listed on slide nine.

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

On slide 26 of the presentation, you'll find information and a URL to evaluate your experience with today's call. Evaluations are anonymous, confidential, and voluntary. We hope you will take a few minutes to evaluate your MLN Connects Call experience. Have a good day.

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

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