Drug Manufacturers: New System to Report ASP Data for Part B Drugs 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. This is Diane Maupai, from the Provider Communications Group in CMS at Baltimore, and I'm your moderator today. Welcome to this Medicare Learning Network call for drug manufacturers about the new system to report average sales price data for Part B drugs. There'll be a presentation followed by questions and answers.

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

At this time, I'd like to turn the call over to Sarah Harding from CMS's Division of Ambulatory Services.

Presentation

Sarah Harding: Thank you, Diane. Good afternoon, everyone. As Diane said, my name is Sarah Harding. I work within the Division of Ambulatory Services at the Centers for Medicare & Medicaid Services. Our team is responsible for collecting average sales price data for Part B drugs. For quite a while, we've been working on a new data collection system that would make the quarterly submissions both more efficient and more secure to use.

Up until now, quarterly submissions have been either via email or by putting the data physically into the mail. We wanted to improve the efficiency both on your end, from the drug manufacturers' perspective for submitting the data, and also to make the data transfer process more secure. And finally, to have the data validation and calculation steps more at our fingertips here at CMS.

We are excited to finally be opening this new system and talking about it today. I'm going to spend some time talking about the system in a general way and highlighting a few items that will hopefully make it easier for you to transition to this new system.

For the next quarter at least, we will be asking you to submit data both through the new system as well as using the manual submission process that you've been using up until now. This will allow us to perform a final validation of the system in processing all of the data that we will be accepting.

So if we could move on to slide 2, this is simply a list, an explanation of acronyms that I'll be using throughout the presentation. The presentation will be available online after the call today, and that information will be sent out to you after the call if it hasn't already been sent.

The one acronym that I really wanted to call your attention to is right in the middle—of FFSDCS. It's not the most glamorous acronym. It doesn't spell any special word. But it stands for Fee-for-Service Data Collection

System. Now, I'll be talking about this later in the presentation, but this is a really important distinction and acronym to look for when you're registering for the system.

FFSDCS is an umbrella system that we use in our division to collect different types of Part B data, one of which is average sales price data. It's more efficient for us to use one large database to collect several types of information rather than creating a whole bunch of smaller, separate systems. The downside of course is that it leads to some confusion in the visibility of the system. But the ASP portion is one module underneath the umbrella that is FFSDCS.

This is important because when you register for the system you're going to want to look for something that says ASP. But it's – at least in the initial parts of registering for the system, you're going to first need to see FFSDCS. And once you're in that, then you'll have the option to select for the ASP subsystem underneath it.

On slide 3, there's a brief agenda for today's call. I'm going to talk about four major themes. First is the overall ASP reporting schedule that we've laid out for launching this new system. As I mentioned, there will be a period of time during which we ask you to submit data using both the new system and the manual submission process you've used up until now. We did not want to simply stop accepting manual submissions until all manufacturers had a chance to become familiar with the system and update any of their own systems that may need to sync up with the new data template. Eventually, however, we will complete this transition period and will only accept submissions through this new system.

Secondly, I will talk about the registration process for using the system. The good news here is that if you already submit data to a different system at CMS, perhaps to Medicaid, the chances are you have already completed this registration process. You may already have an EIDM username and password. Please do note, however, even if you do have the EIDM password and username, you'll still have to do the second half of the registration process, which is to link to our specific ASP system. That process, though, is quite simple.

Third, we're going to go over the two possible roles that you may select when linking to our specific data collection system. A challenge we came across when we built this system is that you, as different manufacturers, submit data in different ways. Some of you use just one person to submit all of your data and certify it; others have multiple people selecting different sections of the data.

There will be a few changes to note about the roles that each user can play, and it's important when setting up your registration for the system that you request the correct role. Otherwise, you may not be granted the correct type of access and it is – it's not impossible, but it's a little difficult to change the role once you've already had a different one approved.

In this step, I'll also show you the new data templates to be used in the new system. These have also been changed and updated from what you've typically been using in those Addendum A and Addendum B worksheets. I'll go over this again when we get to it. But the most important point I can make about these templates is that you can't change any of the formatting that's in the background of the template files. This is similar to the Addendum A macro file that you've been using, but these new data templates are formatted specifically to be accepted by the data collection system.

There are notes available for each column showing exactly how the data should be written, such as the number of decimal points and other details. But it's important to note that the system will not accept your data if these columns are not formatted correctly. And so, you want to be careful when you copy and paste data in from any other source that there's no background formatting that gets pasted as well. This may pose some challenges initially in setting up the templates, but it will make the data submission much more seamless.

Finally, I'm going to go over the contact details for our help desk. As with any new data collection system, we anticipate some bumps in getting this off the ground. Please be assured this system has been independently tested and validated. It's also been beta tested by small-group manufacturers. We believe that we've worked out any kinks, any show-stopping errors. But with any new system, once all of the users are in the system, we always come across pieces that do need improvement.

We launched a different data collection system last year, and users were able to utilize our help desk staff to either help with issues they found or simply to help walk them through the setup. I ask for your patience while we transition all of the USP – the ASP users into this new system. But I can assure you that our help desk will assist with any problems that may arise.

ASP Reporting Schedule

So looking at slide 4, this is our most immediate ASP data reporting schedule. As I mentioned earlier, this is the first time the system will be open to all ASP manufacturers. It will be open as of April 1st and will remain open and collecting data until the deadline for the 2018 Q1 data, or April 30th, 2018. We recommend that, even if you don't intend to submit data until the end of the month, until the end of April, use the time early in the month to get your registration set up.

Also, we recommend that you take a look at the data templates to see how they differ from those you're using now. Again, we'll walk through this later in the call. But I'll point out now that a significant difference is that there are now two distinct data templates. Whereas, up until now, you've used a single Addendum A to report all of your data, we now have two templates: one for product information and the other for financial information associated with each project – product. The reason for this is that the system will keep your product information available. And once it's in the system, you won't have to enter it again. In other words, unless you have a new product to report on in a given quarter, all you will have to submit is the financial information about each of your products. Again, we'll talk about this in a few minutes.

But as I mentioned earlier, we're asking that you submit your data through both the new system and through your manual submission method. For this quarter, we plan to still use the manual submission to calculate the ASP pricing amounts for each product. We will run simultaneous calculations using the new system, but we just want to make sure – absolutely sure that the system gets it right before we transition completely. Have the submissions – having the submissions entered in both methods allows us to fully validate our own system against the method we've been using. As we move forward in the transition to the new system, we will continue to open the system a full month before each quarterly deadline. Eventually, we will be accepting data using only the new ASP system.

EIDM Registration

So looking at slide 5, the first step in gaining access to the FFSDCS and then the ASP system is to create a username and password through our CMS Enterprise Identity Management System, which is also known as EIDM.

EIDM is a shared service across CMS. So, as I mentioned, if you already have an EIDM username, you don't need to get a separate one for this system. If you do not – if you do need a new username, you'll need to walk through the steps outlined by EIDM. This includes choosing a username of six characters or more and going through a remote identity proofing process. You'll be asked several questions that the RIDP process uses to prove that you are really you. There may be some soft credit questions or other demographic questions posed, and it is a required process for obtaining an EIDM username.

Once you do that, you'll need to register a separate device or a separate pathway for multifactor authentication. This a secondary process that you need to use every time you sign in to any CMS system that uses your EIDM username or password. For example, you can register your cell phone and your cell phone number as your MFA, your multifactor authentication. Each time you enter your EIDM name and password, a randomly generated number will be texted to your phone. That code will be good for about 10 minutes and can be used to complete each sign-in.

You can also use email or the other options that are listed on the slide. Once you set up your MFA selection, so once you pick either text message or email, you don't have to do it again. It will just automatically send the random number to that resource.

So once you submit all of the information to generate your EIDM username and password, wait a few minutes before you try to log in with it, and then go for it.

So once you're through, as we'll move to slide number 6, once you're through the EIDM username process, now comes the time where you need to request access to our specific system. So as I mentioned early on in that acronym page, the system that – the system name to look for at this time is the Fee-for-Service Data Collection System, or FFSDCS. You'll see a screen that's similar to the one shown here, and I know it's small, but you can see each block represents a different system, a different possible CMS system that you could sign up for. If you really wanted to, you could request access to each and every system. Hopefully, if people are doing their jobs, you won't be granted that access. But if you request access to FFSDCS, I will let you in, I promise.

So look for the block that's labeled Fee-for-Service Data Collection System. If it's big enough on your screen, you can just make out the reference to the ASP Help Desk within that box, and you'll know you're in the right place. But, again, if you go looking for a system called ASP, you won't find it. So just, you know, keep that in mind as you're going. Start with FFSDCS and click Request Access.

ASP System Roles

Looking at number 7, that's slide number 7, the final step is to request the specific role that you need in the ASP system. So here's where the acronym of ASP comes back into play. You can see on the slide all the

possible roles that you could request. But the two that are relevant to all the manufacturers on this call are either ASP Certifier or ASP End User.

I mentioned also that it's important to determine what your role will be before you request access. It's difficult to change your role once it's been approved by us. So there are two – stepping back a second, there are two broad processes of submitting data which really haven't changed with our transition to this system. So one is you have to submit the data, and the other is you have to certify that it's correct.

So this has taken place up until now with the use of Addendum A to submit the data and Addendum B to sign a certification. So broadly speaking, this has not changed. But the role you select depends on how much access and exactly what kind of access you need within the system.

If you plan to only submit data and have nothing to do with the certification of that data, if you're only submitting it, select the ASP End User role. Each manufacturer – you may have multiple users that can submit data on behalf of a manufacturer, and that's fine. You can have multiple ASP End User roles associated with your manufacturer.

One issue, though, that we are watching to see how it unfolds is you need to be aware of any overlapping submissions for the same NDC. So if you – if one submitter enters data about a specific NDC and another submitter submits different data about that same NDC, the system is set up to recognize that second submission as a correction of the first. So, it will only take the second submission of that data. So right now, that's the way the system is set up. We are again just kind of watching how this unfolds. But one recommendation we have is that if you do have multiple submitters, you could potentially compile all of your data into a single template to submit it or else just go ahead and contact our help desk and we'll help guide you through the process.

If it does prove to be a problem for submissions, in other words multiple manufacturers come to us saying that this is a common occurrence, we'll certainly make changes to allow for these multiple entries. The problem is that then we'll lose the ability to flag corrections or duplicate entries. But again, as I mentioned, that's all part of learning kind of the necessary tweaks and ins and outs out of a new system as it actually gets put into use.

But anyway, back to talking about the role discussion, once data are submitted, they have to be certified through the system. Now, the certifier either has to be a CEO or CFO of your company or else somebody designated by those individuals who can certify the data. If you do plan to certify the data, you'll need to select the ASP Certifier role from the drop-down menu you see on the screen. Now, an ASP certifier can also submit the ASP data. So, in other words, one person can take care of an entire submission if they have been so designated by their organization. And in that case, if you're looking to both submit and certify the data, you should select the ASP Certifier role.

Okay, so slide 8. Once you've gotten through all of this, your EIDM username, your FFSDCS request, and ASP role request, the whole request comes to us for approval. For the most part, we are able to approve your request right away. But we do ask that you give us 72 hours before thinking that we've either forgotten about you or that the request did not go through.

Okay, so slide 9 gives you a look at the first template that you'll be using. Once you're in the system, you will be able to look around. You'll notice that there are two ways to enter data. You can do so either through manual entry keying in information about each product individually and then saving each product that you enter information about. Or you can compile your whole submission on the data templates available and then simply upload the information pretty much in one click that would then head over to the certification.

The system will check the data for formatting errors, and you'll be able to make any fixes on the screen. The two data templates are available on the CMS Average Sales Price webpage. We'll see that URL on a slide later in the presentation. But I'm not going to read it out, because it's really long. But if you've used either Addendum A or B to submit data, the new templates here are on the same webpage.

The template here is for product information. Now, I mentioned earlier that we've gone ahead and have actually uploaded product information that manufacturers have submitted to us in prior quarters. So this is a pretty important point here that I wanted to make sure got highlighted. If the product data are already in the system, which they should be, you can't actually try to upload it again. The system will say this NDC is already in the system.

So once you have access to the system, you've gone through all the steps that we've been talking about, you can go through, and you can see the product information that are already there, and you can check that it's correct. So really, once you get moving with the system and once you sort of figure out how to – how it best works for you, you really only are going need to use this product template when you're uploading data for a new product.

Looking at slide 10, this is the template for the financial data of each product. This is the template that you'll – you will have to fill out in its entirety every quarter as these data do change. But I zoomed in on this sheet just so you could see an example of the formatting requirements for this page.

This is another really important point that I just wanted to make clear in this call. The formatting requirements for each column are detailed in the headers. As you can see under column H, there are five formatting requirements for the average sales price entry. So it's a required field. The data must be any positive or negative number, including a zero. It has a certain number of decimal points and whatnot.

It's important, again, I know I mentioned this, but it really is important that if you copy and paste data onto this template that you don't inadvertently paste the background formatting into the column, because the system will flag that as an error.

But once you've submitted the financial data and check the product is – product information is correct, the system will generate a one-time password that needs to be given to your certifier. Give this one-time password over, and the certifier will need to go through the same EIDM process for that initial access to the system, and then they'll be able to see the data that have been submitted and certify them online.

Now, there's one last important point that I do want to make. Once the data are certified, neither the submitter – I should say once the financial data are certified, neither the submitter nor the certifier will be able to view the data. We've done this as a security precaution to protect against unauthorized viewing of the financial data. And so therefore, it's a good idea to try to maintain any records of your submission on your end of things.

Help Desk

So as you – on slide 11, this is the contact information for our help desk. As you get familiar with the system, you'll also note the process for restatements.

The best advice I can give you is to download the user guide and use it to step through your use of the system. The user guide is incredibly comprehensive with detailed screenshots of each step you'll need to take. The user guide is available on the CMS ASP webpage. If for any reason the user guide does not suffice, please take advantage of the help desk, and the contact information is detailed on this slide. The staff support is excellent at troubleshooting and any potential issue that you may come across. And again, look to the email or the telephone number to access.

Helpful Resources and Information

So in conclusion, on slide 12, the ASP data collection system is open as of April 1st. We will be accepting submissions through the system, but we do ask that you still submit your data manually so that we can validate the calculations.

Please visit the website listed here. So here is where that URL for the CMS ASP website is laid out. You can see why I didn't want to read it. Visit the website listed here to download all the resources—the user guide, the new data templates. They're found – they can be found at the very bottom of the screen under the Downloads section.

Once again, keep an eye on the formatting of the data templates. The system will flag errors if the formatting is not correct. And also, look for that product data to already be entered in the system.

So thank you very, very much. We are happy to take any questions. But I do know that, typical of systems like this, sometimes you just kind of have to dig in and use it and questions will arise. So, don't be shy to contact us at another time. But we're more than happy to answer any questions now. Thank you.

Question & Answer Session

Diane Maupai: Thank you, Sarah. As a reminder, this event is being recorded and transcribed. All right, Dorothy, we're now ready for our first caller.

Operator: To ask a question, press star followed by the number 1 on your touchtone phone. To remove yourself from the queue, press the pound key. 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're 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 1 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 Dana Belig.

Dana Belig: Hi. Can you hear me?

Diane Maupai: Yes, we can.

Dana Belig: Hi. So I'm on the landing page once you log in to portal.cms.gov, and I see two, essentially, buttons: one for MAC BIS and one for Request/Add Apps. How do I get into the page you showed in your presentation where you can find the FFS login? Or to add that application?

Sarah Harding: That's a great question, and I wish – let me see if I can get it in front of me too. I believe, if you click on the Request/Add Apps, that will bring up the button of all possible applications and then that will show the different blocks you can see.

Dana Belig: So it's showing – it look – it appears that we did that and it appears to be more of personal information to change my password, modify my job code, modify my profile, etc. It doesn't take us to the page that you show in your presentation.

Sarah Harding: Okay. So this is another good example of things that sometimes our shared services friends change things without us knowing right away. So we'll take a look at this. I'm trying to pull up a couple things and doublecheck that nothing has changed, and we'll get a – can we get a message out through the users?

Diane Maupai: Yes, I'll send it out to the association today.

Sarah Harding: Okay. So thank you for bringing this up and we'll look right into it and send a message out to everyone on the call.

Diane Maupai: Okay. Thank you.

Operator: Your next question comes from the line of Joanna Soban.

Joanna Soban: Hi. Hello?

Diane Maupai: Hello. We hear you.

Joanna Soban: Hi. Yes, hi. Sorry. So I had the same question. I was just on the EOA portal and didn't see the FFS box, but the caller just asked the same question that I had. So I don't have a question.

Sarah Harding: All right. Well, thank you. Yes, I saw it. I did not pull it up this morning to confirm that it was the same thing. But things do sometimes change. So we will confirm. I can say this to everybody on the call that, by tomorrow morning, if there are any changes to this step, we will update the user manual that is online and the user manual as of tomorrow morning will reflect the updated steps if something has changed.

Diane Maupai: Okay. Thank you.

Operator: Your next question comes from the line of Lisa Impens.

Lisa Impens: Hi. Can you hear me?

Diane Maupai: We hear you. Yes, we hear you.

Lisa Impens: Hi. I have a question. So for NDCs that have been divested from one company to another, in the system will it allow for the company that's divesting those NDCs give the certifying and upload authorities for those specific NDCs to the new company?

Sarah Harding: So if that – if that's the case, so right now, yes. You'll be able to submit data. The new company will be able to submit data. If the changeover, though, happens in the middle of a quarter, you can still submit the partial data for the part of the quarter after it changed hands. One thing to potentially do is just to let us know that that's happening just so that we can kind of understand the data as we see it. But yes, the system will allow for that.

Diane Maupai: Thank you.

Lisa Impens: Thank you.

Operator: Your next question comes from the line of Mary Gamble.

Mary Gamble: Hello. My question has to do with – I know that you started the call saying this is ASP reporting for Part B drugs. I was wondering if it also would cover Part D?

Sarah Harding: Part D?

Mary Gamble: Yes.

Sarah Harding: Yes. It does not. We – at least not at this time. We – I think we've explored possibilities of that, and just having some slight differences in the data reporting requirements sort of keeps that from being a possibility right now. But it's a really good suggestion that we agree with.

Diane Maupai: Thank you.

Mary Gamble: Thanks.

Operator: Your next question comes from the line of Marijo Bustos.

Marijo Bustos: Good afternoon. I'm curious about how the process will work in the case of errors? Errors do occur. So if – for example, if product information's uploaded and in the next quarter there's a need to change something, maybe there's a misspelling in the name, something like that or some other error, how will that be handled?

Sarah Harding: So there is a section of the system that can handle restatements. And I didn't touch on that, just because I didn't want to get too in the weeds. Again, it's something that I think as you step through the user guide it will work. But the restatement process is in there.

And if I can just go back – again, I – we'll look into this issue with the request of the system. But I – and I'm not doubting that it didn't work on all of your machines at all. But I did pull up my own access and when I get my – I have my – when it says My Portal and then there's a big button that says Request/Add Apps, when I click on that, I do see several options of different systems at CMS. So that does seem to work. Again, I'm not doubting that you're not seeing it on your machine. And so perhaps if you it try again or maybe try it in a different browser, if it still doesn't work, I would suggest that you try out our help desk. You can be some of the first users of our ASP Help Desk, and they will determine whether it's an issue with our system or with the broader shared service.

Diane Maupai: Thank you.

Marijo Bustos: Thank you.

Operator: Your next question comes from the line of Kathleen Schaum.

Kathleen Schaum: Yes, good afternoon. I was wondering now that this is more automated, will all of the products that are reported now be printed in the Medicare Part B drug list?

Sarah Harding: That's a great question that we can take back to our team. My inclination is to say no. But again, I will completely admit that I'm not an ASP expert. I've just played it on TV today and just have been working on the system side of things. But I will certainly ask. I would say that as we get going with this system, one thing that the system will allow us to do is to create several more, you know, kinds of reports and data analytics of all the data. It's one major benefit of automating the system. And if that's something that you're interested in seeing that potentially contacting us, you know, at a later time as we get going with the system and, you know, really ramping it up and perhaps looking into that.

Operator: Your next question comes from the line of Pamela Garcia-Gomez.

Pamela Garcia-Gomez: Hello. I had a question about the roles. I understand that we can have multiple end users to submit. But as far as the certifier, is that to be just one person? Is there only one person who can have that role?

Sarah Harding: There can be multiple certifiers with that role, so this would help, you know, if the certifier goes on vacation or is not available on a particular day that the data have a deadline. So you can register more than one certifier. The, you know, the – just the – I guess the piece of it that I would just recommend is, you know, the more users you have associated with multiple roles in the system, you know, you just potentially run into – to difficulty of, you know, were the data submitted, were they certified, you know, just kind of questions of that.

So, you know, yes, you can have more than one certifier, so that they can pick it up if needed. But, you know, just – I would just say make sure that, you know, that coordination is there too.

Pamela Garcia-Gomez: Okay. And then, I guess the second part of that question is only one certification is necessary, right? So if we have a designee go in and certify, that's it. It can't be – if somebody else in that role tried to go in, it would already be certified and done.

Sarah Harding: Correct.

Pamela Garcia-Gomez: Okay. Thank you very much.

Sarah Harding: Welcome.

Operator: Welcome. Your next question comes from the line of Adrienne Shipps.

Adrienne, your line is open.

Adrienne Shipps: Hello, can you hear us?

Diane Maupai: We can hear you a little bit. I don't know if you can move closer to your phone.

Let's move on to the next caller, please.

Operator: Your next question comes from the line of Gilead Sciences.

Gilead Sciences: Yes, question about the data. Are there any known limitations on field lengths? We've run into issues with submitting in DDR on – some of the fields there can't handle large data sets.

Sarah Harding: So there very well may be. I would just need – I would need to look at the header fields for all of the pieces. You'll be able to know ahead of time. I'm being told that – let's see. Yes, I mean in terms of, you know, if you have – there's definitely a limit for the decimal places. But if, you know, the digits on the other side of the decimal are inherently big, I don't know it offhand, but if you download the two templates and scroll across the – that header field, you'll see all of the restraints that are built in. So nothing's hidden.

Gilead Sciences: Okay.

Sarah Harding: You'll know it before you try to fill it in.

Gilead Sciences: And if there is a limitation of that type, it would be in those comments?

Sarah Harding: It would be in those comments, yes. And if any of those pose a problem – this actually did happen for the system we launched a year ago. We didn't make a field big enough for the amount of money they needed to report, which is great for the company. But the – just let us know. It's something, you know, that's pretty easy to change. You know, we just put those on just to help, you know, crack down on any errors or erroneous data. But if, yes, something needs to be enlarged, you know, lengthwise, let us know.

Operator: Your next question comes from the line of Miree Lee.

Miree Lee: Hi. Thanks for the conference call. This is very helpful. Just a couple of things. On the EIDM user information, so most of us are used to the CMS DDR system as well as the EUA and also HPMS for Medicare Part D. And our user IDs are four characters or four characters/digits, whereas you noted in your presentation that it should be six.

And just so a – in addition to that is what Dana raised is that when you do log in to the system itself, it actually does end up taking you to EUA when you want to add an application. So I don't know if that is a shared service issue, but I'd like some clarification on the number of digits of the character code and then also the EUA platform.

Sarah Harding: Yes, so this – I am so glad you called and asked this question. So for better or worse, EUA and EIDM are totally separate systems. So, your EI – EUA ID will not work for this. You have to have an EIDM username. So I don't – I'm not – I'm sort of familiar with what DDR is using. But you can't – in other words, you can't use the EUA and EIDM name interchangeably. They are distinct. So, if you have – if you only use a four-digit EUA username, then that probably means you're going to have to register separately for EIDM, which is what this system is under.

And so perhaps that's the issue that the first couple callers were not seeing is, if they're logging in using their EUA name, it won't work. And I can say, personally, this is a problem for me for the first, like, 3 or 4 months that I was working on the system because of the CMS employee, I have a – an EUA ID and I would always use my EUA and get complete – and drive the contractors crazy because I couldn't get in to access the system. So, they are distinct. Again – and that is one reason that, you know, it's valuable to know that EIDM is six characters or more to know and EUA is only four. So, if you have only four, you need to go through the full registration for EIDM, get that full username, and then you will be able to see all the different systems that I spoke of. Thank you very much for this question.

Operator: Your next question comes from the line of Sam Woronoff.

Sam Woronoff: Yes, hello. Can you hear me?

Diane Maupai: Yes, we can hear you.

Sam Woronoff: Yes, in addition to – you mentioned something about past or given after you have made submission of prices and before – and then you had – we had needed to share that password with the certifier. Did I get – catch that correctly?

Sarah Harding: Yes, there is a one-time password that is to be communicated from – if you have two distinct users, you know, or that once the final data are submitted – you know, once you're ready for certification, there'll be, you know – on the screen you'll have a one-time password appear and it's a – it's long. So, you'd want to, you know, copy and paste it in an email or print it or something over to your certifier. And that's what they'll use to pull up all of the data that have been submitted.

Sam Woronoff: So that would be for every quarter we'll have a new password for each submission we – that's made, correct?

Sarah Harding: Correct. And I should note – I mean, you know, again, it's all going to depend on how you all submit the data. But, you know, if, for example, you have multiple people submitting data and they all, you know – person A, B, C all submit their portions of the data and you just want to certify it once, you know, you'll there will be – there'll be a one-time password generated each time for each submitter. Just use the last one. You know, but once all – in other words, once all the data are uploaded to the system and your submission is complete, use the final one-time password that is generated for that final submitter, give that to the certifier, and have them use that.

And that's why I said, you know, you all will get to know the system and what's best for your own setup. But it may make sense, you know, instead of having multiple submitters in and out of the system, it may make more sense to compile all of the data outside of the system and just have one person submit – upload that full template and then one person certify. But it's – I mean it's totally up to you how you all do it. But it just – it does add a little bit of confusion if you have, you know, three, four, five different people submitting data in the system itself. Does that all make sense?

Operator: Hold one moment.

Sam Woronoff: If I may, if we are – some of us are third-party processors and if we are responsible for multiple labelers reporting, how will that work as far as getting – separating – getting a separate reporting? Is it the same basically? Is there anything – any specifics that we need to be aware of?

Sarah Harding: For submitting for multiple labelers?

Sam Woronoff: Labelers, yes. So we have one end user for multiple certifiers, I should say.

Sarah Harding: Right. So, yes. So that's kind of what I was getting at that there's nothing you need – there's nothing system-specific that's going to keep that from happening. But it will, you know – you just need to – you'll just need to work to make sure, you know, you know when as – you know when the data are all entered and ready for certification, to know, you know, that nothing's being overwritten. It's just going to take a little added coordination. But from a system perspective, it allows for that.

Operator: Your next question comes from the line of Phil Coburn.

Philip Coburn: Hello. Good afternoon. During the current manual process, there's a requirement to submit our reasonable assumptions. Is the requirement still there once everything goes into this automated system?

Sandra Harding: Yes, that requirement is still there and there is a component in the system that allows for uploading the assumptions.

Operator: Your next question comes from the line of Agnes Goins.

Agnes Goins: Yes, hi. I wanted to get clarification on the roles that you have. You had mentioned—and tell me if this is correct—that, if you have the dual role as an end user and a certifier, you should register as a certifier?

Sarah Harding: Sure. Sorry. We had a mute mechanism. Okay, so yes. And I recognize where the labeling of those roles is a little bit confusing. So I apologize. But in terms of your interaction with the system, if your interaction is to both submit and certify the data, then you want to be – you want to register for the ASP Certifier role. If your interaction is to only upload the data or enter the data and you have nothing to do with the certification, then you should register as an end user.

Operator: Your next question comes from the line of Dhirendra Jena.

Dhirendra Jena: Hi. This is Dhirendra Jena. I have a question on your product template and financial template. When those templates will be available online?

Sarah Harding: They are available right now, or at least when I checked this morning they were. If you go to that webpage that's listed on the slide or just – you can just Google CMS and ASP. And if you go to – so it's the Medicare Part B Drug Average Sales Price and scroll down to the very bottom – well, not the very bottom, but toward the bottom under the section called Downloads, the last two links in that section you'll see Medicare ASP Product Data Template. And then it says for New System, just – I don't know, just try. And then the last is the ASP Financial Data Template, again, for New System.

You know, we couldn't – we didn't want to erase or delete the Addendum As and Bs because we're asking for data in both ways. So I recognize some potential confusion on the webpage that they're both there. The good news is they're at opposite ends of the list. So, you know, maybe that will help. I don't know. But they are all available for download now.

Dhirendra Jena: Related to that question, your product template is made for the new product. If anybody wanted to update any of the product information, that same template can be applied to override the product information?

Sarah Harding: Yes.

Dhirendra Jena: Or is there any …

Sarah Harding: Yes, so you could do it in two ways. You can either log in to the system and find the product data that are in there and make any updates there or you can use the template and update it, upload it, upload the template into the system, and it will override the existing product data in there now.

Operator: Your next question comes from the line of Joanna Soban.

Joanna Soban: Hi. Sorry. My question has been already answered.

Sarah Harding: Yay! Great.

Diane Maupai: Thank you very much. I believe Sarah has gotten to all the questions. So thank you all. You really raised some good ones. So let's see. So that's the end of our question portion today.

Additional Information

Just a reminder that you can find resources on slides 11 and 12 both with respect to the help desk and where to get more information. So thank you very much, Sarah, and thanks for all of you for attending our call today.

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