Centers for Medicare & Medicaid Services
Open Payments 2016: Prepare To Review Reported Data Call
MLN Connects National Provider Call
Moderator: Hazeline Roulac
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2:30 pm ET

Contents

Operator: At this time, I would like to welcome everyone to today's MLN Connects®
National Provider Call. All lines will remain in a listen-only mode 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 Hazeline Roulac. Thank you. You may begin.

Announcements and Introduction

Hazeline Roulac: Thank you, Holley. And welcome, everyone, to today's call – to today's
Open Payments Program Call providing an overview on preparing to review reported
data, open payments or the national transparency program, and to financial relationship
between industry and physicians.

Today's call will discuss how to access the Open Payments system to review the
accuracy of the data submitted about you before it is published on the CMS website.
A question-and-answer session will follow the presentation.

And before we get started with this MLN Connects National Provider Call, just a few
quick announcements. You should have received a link today for the slide presentation
in an email. If you have not already done so, you may view or download the
presentation from the following address, www.cms.gov/npc. Again, that URL is
www.cms.gov, as in victor, forward slash npc. At the left side of the webpage, click
on National Provider Calls and Events. Then on the following page, select the date of
today's call from the list, and the presentation can be found under the Call Materials.

The second announcement is: This call is being recorded and transcribed. An audio
recording and written transcript will be posted to the MLN Connects Call website.
Registration – registrants will receive an email when these materials are available.

And finally, this MLN Connects Call is being evaluated by CMS for CME and CEU
continuing education credit. For additional information, please refer to slide 38 of
today's presentation for a link to the CE Activity Information & Instructions document.

At this time, I would like to turn the call over to our first presenter, Robin Usi, Director
of the Division of Data and Informatics. Robin?

Presentation

Robin Usi: Thank you, Hazeline, and thank you for the introduction. Again, this is
Robin Usi. I'm the Director of the Division of Data and Informatics. And also with me
today is Erin Skinner, who is the Acting Deputy Director for the Division of Data and
Informatics. We will both be presenting today, so I'm going to go ahead and get started.

Open Payments Program and Timeline

Robin Usi: I'm currently on slide 5. It begins – I'll begin with a brief overview of the Open Payments Program and Timeline.

Moving on to slide 6, I'd like to start by talking about what is reported. Open Payments reports direct or indirect payments or other transfers of value made to physicians and teaching hospitals, collectively known as covered recipients, as well as physician owners or investors.

An indirect payment is a payment or other transfer of value made by an entity to a physician or teaching hospital, through a third party, where the entity requires, instructs, directs, or otherwise causes the third party to provide the payment or other transfer of value, in whole or in part, to a physician or teaching hospital.

Open Payments also reports on certain ownership or investment interests held by physician owners or investors, or their immediate family members.

Slide 7, who's responsible for reporting? Well, the responsibility for reporting for Open Payments lies with applicable manufacturers and applicable group purchasing organizations, also known as GPOs.

Applicable manufacturers are entities which operate in the United States and engage in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply. This includes distributors or wholesalers that hold title to a covered drug, device, biological, or medical supply.

Now, applicable GPOs—again, group purchasing organizations—are entities which also operate in the United States and purchases – and arrange for or negotiate the purchase of a covered device – drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself.

Now, a covered drug, device, biological, or medical supply is reimbursed by Medicare, Medicaid, or CHIP, and for covered drugs and biologicals, requires a prescription or doctor's authorization to administer; for devices and medical supplies, requires premarket approval by, or premarket notification to, the FDA.

Slide 8, who is reported on? So, Open Payments reports information on payments or other transfers of value and ownership or investment interest held by covered recipients. Covered recipients includes physicians, teaching hospitals, and physicians who are owners or investors of an applicable manufacturer or applicable GPO. This includes physicians' immediate family members who have ownership or investment interest in an applicable manufacturer or applicable GPO. More information is provided on the slide further defining covered recipients.

On slide 9, I'm going to talk a little bit about the types of payments. Open Payments categorizes records into three payment types. The first category is general payments, which are payments or other transfers of value not made in connection with a research agreement or research protocol. The second category is research payments. These are payments or other transfers of value made in connection with a research agreement or research protocol. And lastly, ownership or investment interest, which is information about physicians or their immediate family members who have an ownership or investment interest in applicable manufacturer or applicable GPO.

Now, slide 10, I just would like to review with you the 2015 and 2016 program year timelines. So, the Open Payments Program is really broken into four steps or stages.

And normally from January through December 31st of each year, applicable manufacturers and applicable GPOs collect data on the payments that they're making.

During the – February to March 31st of each year, those manufacturers and GPOs submit their payment data to CMS.

The third step or stage in the process is where we are right now, where teaching physicians and teaching hospitals have the ability to review and dispute the data, which will be published regarding the transactions made to them. This occurs from April 1st through May 15th for this year. That period is always 45 days. The following 15 days, from May 15th until June 1, is a period that allows for applicable manufacturers and GPOs to finish the dispute resolution process.

Step 4 is public display of the data, and we do that on June 30th of each year. We are required by statute to publish the data by June 30th.

Moving on to slide 11, I just wanted to give you an overview of the published data. These numbers reflect the 2013 and 2014 program years totaled. So as you can see, almost $10 billion have been reported by industry regarding payments and transfers of value to covered recipient physicians and teaching hospitals. That represents over 15 million records published to date.

At this point in the presentation, I'm going to turn it over to Erin, and she will review the registration process with you.

Open Payments Registration Process Overview

Erin Skinner: OK. Thank you, Robin. I'm going to start on slide 12. Now that Robin has given a – some background on the general Open Payments program year process flow, I'm going to provide an overview of the review, dispute, and correction process for any data that is submitted about covered recipients in the program.

So if you turn to slide 13, you can see that there is a two-step registration process that is required in order to go in and start review and dispute for data that's submitted about you. The first – the entire process takes about 30 minutes, and you need to successfully complete both steps in order to be able to start review and dispute. If you begin the process for registration, you have to complete it fully or else, when you return to the process, you'll have to start over again. So we encourage you, when you do begin the registration process, that you allow ample time so that you'll be able to complete it in one sitting.

The first step will be through the Enterprise Identity Management portal. You can see the website there on slide 13. After you go through the portal website, https://portal.cms.gov, you're going to select the correct user type—and it's important that you select the role of either applicable manufacturer, GPO, physician, or teaching hospital—and then you want to request access to the Open Payments system for yourself. After that, you're going to register in the Open Payments system. You'll either register as a teaching hospital or as yourself if you're a physician in the Open Payments system. And again, successful registration is necessary in both the EIDM and the Open Payments system in order to perform the review-and-dispute process.

Moving on to slide 14, I'm going to talk a little bit about the review-and-dispute process. In order to review and dispute any data that's reported in the Open Payments system, like I said, you have to go ahead and perform the two-step registration process.

You do have the opportunity, if you're a physician, to nominate one authorized representative to perform system functions after you've already registered for yourself. So, you can nominate someone to go in and review and dispute data on your behalf after you perform the initial registration steps.

Teaching hospitals can designate 10 authorized users, authorized representatives, and officials to act on their own behalf in the system after the registration is performed.

This is all important to know because, starting on April 1st, 2016, covered recipients, physicians, teaching hospitals, and principal investigators were able to start reviewing, affirming, and disputing records submitted about them by reporting entities regarding payments and other transfers of value or physician ownership and investment interest.

This review-and-dispute period lasts for 45 days. And the process allows for you to request corrections to records prior to date of publication, which will be on June 30th, 2016, as Robin just explained. During this review-and-dispute and correction period, reporting entities will be able to acknowledge and work with you to resolve the disputes that you register in the system. The opportunity to review and dispute data is going to expire the year that the data is first published.

I'm now going to move on to slide 15. I think I just sort of went over slide 14. I'm sorry if that wasn't clear. So, slide 15, all physician profiles that are created after you've registered are vetted against CMS-approved sources to confirm that you are a covered recipient physician. If you are a physician trying to register in the system, but you don't meet the definition of a physician for the purposes of Open Payments, you will not be able to register in the system. You won't have any data reported against you, and you won't have any need to come in and try to review and dispute any records.

So, if you can't create a profile and register, then you don't have to worry about having any data reported against you. We're vetted using information that's supplied during the Open Payments system registration. We use your first and last name, NPI, state license information, and primary type, which is your taxonomy.

You will receive an email to confirm successful vetting. And if you're unsuccessfully vetted and you want to double-check on your status, you can contact the Open Payments Help Desk. That contact information is provided later on in our presentation.

In order to – and I'm moving on to slide 16. In order to make sure that you are successfully vetted, some additional tips:

- You can use the NPPES system that is publicly available to make sure that your registration matches exactly. If you've changed your name prior to December 31st, 2015, you should use the earlier version of your name that was in NPPES, because our system takes a little bit of time to catch up.

- You want to enter your NPI, if it's available, exactly as it's listed in NPPES for the current calendar year and also use all of your active state license numbers to ensure successful vetting.

Basically, the rule is to provide as much information as possible. Some other rules—
if you're going to go in and do some review and dispute, we want to make sure:

- that you are double-checking that you're spelling your name correctly,
- that none of the numbers are transposed, and
- we do require exact matches when you're entering information into the system.

The next thing that I want to make you aware of is that, if you have previously registered in the system and you've been active in the system in the last 60 days, then you don't have to take any additional action in order to access the system and start reviewing and disputing the data. You'll just be able to go in, enter in your User ID and password, and you should be able to start the review-and-dispute process without any issues.

If you have not been active in the system in the last 60 days or more, then your user name and password will be inactive. So, you will have to answer the security questions that you previously established for yourself. You'll have to reset your password and then be able to proceed with review and dispute of the payment or ownership records that were attributed to you.

If your account has been inactive for over 180 days, then as a security measure, it has been inactivated or deactivated. You'll need to contact the Open Payments Help Desk. Again, that contact information is located at the end of this slide presentation. And you can work with the representative to – reactivating your account in order to go in and review any data that is attributed to you before the publication on June 30th.

That should put us through slide 16. I'm now going to hand it over to Robin on slide 17 to talk a little bit more about the review, dispute, and correction process overview.

Review, Dispute, and Correction Process Overview

Robin Usi: Thanks, Erin. So, now that Erin has explained how to register in both EIDM and the Open Payments system, I'm going to spend just a few minutes talking about the review, dispute, and correction processes.

So, as indicated here, physicians, teaching hospitals, and principal investigators can review, then either affirm and/or dispute records submitted about them by the reporting entities, meaning, the applicable manufacturers and GPOs.

You may take any of the following actions on each individual data record: You can affirm a record, initiate a dispute, or withdraw a dispute. And I will go into more detail about these actions in just a few minutes.

So, moving on to slide 19, the dispute resolution process, I think it's important to understand that the dispute resolution process takes place outside of the Open Payments system, that CMS does not mediate disputes. What that means for you, actually, is that you will work with the applicable manufacturer or GPO to resolve that dispute.

And what we've implemented that is new this year is: Reporting entities were required to enter contact information into the Open Payments system in order to facilitate this review-and-dispute process. So, you can now find their contact information on the Record Detail page. You would just select the Record ID hyperlink, and you will find the contact information.

We hope that that will prove to be useful in the dispute resolution process this year and help to expedite the process for you. So, again, you'll work directly with those entities to resolve any issues you may have.

So moving on to slide 20, the review, dispute, and correction period, as I mentioned earlier, does last for 45 days. This is the time that you can review and dispute the payment records which have been submitted by reporting entities. Corrections can also be made by reporting entities at this time, but they do have an additional 15 days immediately following the 45-day period to finish the corrections on these disputes.

So, physicians, teaching hospitals, and principal investigators do have until the end of the 2016 calendar year to initiate disputes of data published in 2016. However, you really would like to – or you should initiate disputes by May 15th in order for that to be reflected in the June 30th publication.

So moving on to slide 21, records with a new dispute initiated after the 45-day review-and-dispute period will be published as originally submitted. And so therefore, you can still initiate a dispute on that record up until the end of the calendar year; however, it will have already been published as initially submitted.

Additional details regarding disputes initiated after the 45-day review-and-dispute period are available in the "Open Payments System Quick Reference Guide." There is a section regarding "Review and Dispute Timing and Data Publication." You can go out to the Open Payments website as shown on slide 21.

So on slide 22, I'd just like to review some of the record statuses during the review-and-dispute process.

The term "initiated" indicates that a physician, teaching hospital, or principal investigator has initiated a dispute of the data.

The term "acknowledged" indicates that the physician, teaching hospital, or principal investigator has initiated dispute of the data and the dispute has been acknowledged by the reporting entity. This status does not indicate agreement or acceptance of the dispute by the reporting entity; it is only meant to serve as a notification to you that the dispute has been received by the reporting entity.

Now, records that indicate "resolved no change" indicate that the reporting entity and physician, teaching hospital, or principal investigator have resolved the dispute in accordance with the final rule and no changes were made to the disputed record.

"Resolved" indicates the record was updated by the reporting entity as a result of the dispute with you.

And lastly, "withdrawn"—the dispute was withdrawn by the physician, teaching hospital, or principal investigator.

So, those are the different statuses that a record can be in once you've disputed – once you've initiated the dispute. So, that concludes slide 22. So, I'm going to turn it back to Erin to talk about the review and dispute actions.

Review and Dispute Actions

Erin Skinner: Thank you, Robin. The next section of our discussion today is going to focus on what actions covered recipients—which, again, are physicians, teaching hospitals, and principal investigators—can take in the Open Payments system during the review, dispute, and correction period.

So we can turn now to slide 24, and you'll see here that there are four different actions that physicians, teaching hospitals, and principal investigators can take in the Open Payments system with respect to review and dispute. Remember that all of these actions are voluntary, none of them are required. Similarly, review and dispute is a voluntary action. Records are still going to be published regardless of whether review and dispute is performed on records that are attributed to physicians or teaching hospitals, and they will be published regardless of how many actions are taken with respect to records.

The four actions are:

- To review records, which would be to just review the data submitted about – or submitted by reporting entities, which are again the applicable manufacturers, the GPOs.

- You can affirm the records which would be to confirm the accuracy of the data, which just allows people to have confidence that the data is valid.

- Physicians and teaching hospitals, as we've discussed in depth—Robin just discussed, can initiate disputes when there are inaccurate data records.

  We encourage you, before initiating disputes, if you don't understand the payment record, to take advantage of the new function that we've just put into place in our system and use the contact information that AMs and GPOs have been providing in the Open Payments system to reach out and ask questions about the payment record. A lot of times we're finding that disputes are initiated because you don't understand the reason for the payment. It's not actually a dispute, but it's more a matter of a question, so please use that contact information. Again, you can initiate a dispute, but if it's just a question, then go ahead and do that reachout. AMs and GPOs are certainly amenable and welcoming to that outreach. But you can initiate a dispute for inaccurate data records.

- And then, finally, if you register a dispute and later find that you didn't mean to or you discussed it and you no longer dispute the payment, then you can withdraw a previously initiated, or acknowledge a previous, dispute.

So, physicians, teaching hospitals, and principal investigators can review all the data records associated with them to ensure that the information is submitted by the recording entities as accurate. We encourage you to do this. Again, it's voluntary, but we do ask you to take the time and go in and look at the data that's submitted about you.

I'm now going to turn to slide 25 and talk a little more in depth about reviewing records. Again, in order to begin the review-and-dispute process, you have to review your records. This is where you're going to look at the records that are submitted about you by reporting entities.

In order to review the records, once you are in the Open Payments Program, you're going to go to the Review and Dispute tab in the system and select the physician, principal investigator, or teaching hospital that you're affiliated with to view the records associated with you. An example of the page is shown on this slide. From this page, you can review, affirm records, initiate disputes, or withdraw any dispute that you have previously initiated.

I'm now going to go to slide 26. Here, we're going to discuss affirming records. Again, affirming a record means that you, the physician, teaching hospital, or principal investigator, have reviewed a record that's submitted about you by a reporting entity and found that the record is correct. When a payment or other transfer of value, or a physician ownership or investment interest, is affirmed by a physician, teaching hospital, or principal investigator, then you've confirmed that the information is accurate.

Like the rest of the review-and-dispute actions, affirmation of records is not required; however, it's encouraged to ensure that the reporting entity and the physician, teaching hospital, or principal investigator are in agreement with respect to the details of each payment record. Records not affirmed by the physician, teaching hospital, or principal investigator will be published as reported by the reporting entity, regardless of whether or not any action is taken with respect to the record.

Physician-authorized representatives can only affirm records if they hold the Dispute Records access level, which is necessary for a representative to be able to affirm and dispute records. So, this is important if you'd like to designate somebody to act in your stead for the review-and-dispute function of reviewing records. This access level can be granted to an authorized representative by the physician at the time of the nomination. If you need any help with this, you can speak to the Help Desk. Again, direct contact information is provided at the end of this slide deck. Authorized officials and authorized

representatives or teaching hospitals will have the same access levels, and both types of these users can affirm records.

I'm now going to switch to slide 27 and discuss initiating disputes. After records have been affirmed, physicians, teaching hospitals, and principal investigators can initiate disputes on records that have been attributed to them when they believe that they're inaccurate.

Once a dispute is initiated, the reporting entity is going to receive email notification that a dispute has been initiated. I think this is an important point because we have a 45-day review-and-dispute window. So, while covered recipients are provided 45 days to review and dispute data, the sooner that you go in and look at the data that's attributed to you, the sooner you give industry or reporting entities time to respond to any dispute that you choose to register, which gives them more time to go ahead and resolve the dispute in advance of data publication. While they are provided an additional 15 days at the end of the review-and-dispute period, the sooner you can review the data and dispute anything that you might find inaccurate, the sooner that they are able to respond to the email that they received and start to work with you to resolve the dispute.

So, if you're disputing multiple records at one time, it's suggested that the dispute be – I'm sorry, I've lost my train of thought.

So, the reason for the dispute provided by the physician, teaching hospital, or a principal investigator is also going to be sent within the notification email. So, if you're disputing multiple records at one time, it's suggested that the dispute be for the same reporting entities, because the reason for the dispute is going to be sent to all of the reporting entities that are referenced in the dispute. So, if you're going to be initiating a dispute – multiple disputes for multiple records, we suggest that you keep them all within the same entity that submitted the payment so that your reason for the dispute isn't sent to multiple paying entities at the same time if the reason is not the same across all paying entities.

The reporting entity might acknowledge the dispute in the Open Payments system, but they're not required to do so as part of the process. Acknowledgment from the reporting entity does not constitute a commitment that they're going to resolve the dispute. A reporting entity's acknowledgment of the dispute will only serve as a notification to you, the covered recipient, that the reporting entity has received the dispute. The physician, teaching hospital, or principal investigator will receive an email notification that the dispute has been acknowledged.

You can always review the dispute status in real time on the Review and Dispute page in the Open Payments system.

Principal investigators – oh, pardon me.

Now, going to switch to slide 28 and talk about withdrawing disputes. Finally, you know that you have the option to withdraw a dispute from a record if you no longer wish to proceed with the dispute.

Disputes can be withdrawn even after a dispute has been initiated or acknowledged by the reporting entity. Once a dispute is withdrawn, the reporting entity will receive an email notification that the dispute has been withdrawn and no additional action is needed.

Physician-authorized representatives must hold the Dispute Records access level to withdraw disputes. Physicians, principal investigators, and teaching hospital authorized officials and authorized representatives for teaching hospitals and physicians do not need additional access to withdraw disputes.

For detailed instructions on completing Open Payments system access, actions relating to the review and dispute process, you can refer to our "Quick Reference Guide for Physician and Teaching Hospital Review and Dispute Actions," which is located in the Resources section of the Open Payments website, www.cms.gov/openpayments.

Now, I am going to turn it back to Robin on slide 29.

Resolving Disputes

Robin Usi: OK. Thank you, Erin. At this point, we will provide an overview of the dispute resolution process. Some of the points I may touch on, you may have already heard, but we want to just talk one more time about how to resolve disputes.

So, let's move on to slide 30. So, disputes may be resolved by reporting entities in one of two ways.

The first way is to update or correct information for disputed records. Updated records are automatically placed in a review-and-dispute status of Resolved.

The second way a dispute can be resolved is for no changes to be made to the disputed record. This can be done when a reporting entity and the physician, teaching hospital, or a principal investigator have resolved the dispute in accordance with the final rule, and no changes were needed or made to the disputed record. Following this process will place the disputed record in a review-and-dispute status of Resolved No Change.

Physicians, teaching hospitals, and principal investigators will receive an email notification when a disputed record has been resolved by either of these two methods.

You can view the details of the resolution and any corrections that have been made by logging into the Open Payments system and viewing the record. If a teaching – if a physician, teaching hospital, or principal investigator believes a record's dispute has not been sufficiently resolved despite the record having a status of Resolved, you can initiate another dispute for the same record. I think that is why communication is key in this process. And again, we just want to mention – or I'd just like to mention again the contact information that is available to facilitate this process.

So moving on to slide 31, I'd like to reiterate that CMS will not mediate disputes. And I have some other – there are some other points to keep in mind regarding the dispute resolution.

Entities should work directly with you outside of the Open Payments system to reach resolution.

If a dispute is resolved by reassigning the record to another physician, teaching hospital, or principal investigator, the record will be reassigned to the correct physician, teaching hospital, or principal investigator, and will no longer appear in your view.

Once a disputed recorded has been corrected, resubmitted, and reattested by the entity, the review-and-dispute status will automatically change to Resolved in the Open Payments system. Once the status has been updated in the Open Payments system, the physician, teaching hospital, or principal investigator will receive an email notification that the dispute has been resolved. And, I'm sorry, I actually just kept talking, and that was slides – that represented slides 31 and 32.

So now, I am on slide 33, and I would like to mention that corrections made to data by reporting entities after the 45-day review-and-dispute period and the subsequent 15-day correction period will not be reflected in the June 30th, 2016, public posting.

Those data updates will be seen in the next data publication refresh, which will occur at the end of the calendar year or early the following year. Reporting entities may correct data and resolve disputes at any time, and the corrections will be updated in the next data publication refresh.

CMS will provide a data publication refresh with updated data from the current and previous program year at least once annually, in addition to the initial data publication that followed the data submission.

In the cases where a dispute cannot be resolved, the latest attested-to data submitted by the reporting entity will be published and identified as under dispute.

So, moving on to slide 34, the next steps, here's what you should do now. You can register in EIDM, as well as the Open Payments system, if you've not already done so.

Registration in both EIDM and Open Payments is required in order to perform any of the review-and-dispute activities that we've discussed today.

Once you've registered in both EIDM and the Open Payments system, you may review and affirm records associated with you. You may also initiate any disputes against information you feel is incorrect, withdraw disputes on any records associated with you, and participate in any dispute resolution activities with the reporting entity.

So lastly on slide 35, CMS has made a number of resources available to you to help you understand and to use the Open Payments system. These resources are available on the resources page of the CMS Open Payments website, which is shown here, www.cms.gov/openpayments. Key resources on the site are the Open Payments User Guide; there are other tutorials and a number of quick reference guides to provide simple step-by-step instructions for various aspects of the Open Payments system. If you haven't already, you can register for the CMS listserv to receive email updates about Open Payments. You can complete listserv registration on the Open Payments website.

If you have additional questions, you can also contact the Open Payments Help Desk by email at openpayments@cms.hhs.gov or by phone, which is shown here on slide 35, 1-855-326-8366. Hours of operation for the Help Desk can be found on the Open Payments website. However, I will tell you their hours of operation are 8:30 to 6:30 Monday through Friday. They are not open on Federal holidays.

This concludes the Open Payments physician and teaching hospital review, dispute, and correction presentation. Thank you very much for attending today. I'm going to turn it back to Hazeline for next steps.

Keypad Polling

Hazeline Roulac: Thank you, Robin. So at this time, we're going to pause in our call for a few minutes to complete keypad polling. Holley, we're ready to start the 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 1. If there are between two and eight of you listening in, enter the corresponding number. If there are nine or more of you in the room, enter 9. Again, if you are the only person in the room, enter 1. If there are between two and eight of you listening in, enter the corresponding number. If there are nine or more of you in the room, enter 9. Please hold while we complete the polling.

And continue to hold while we complete the polling.

Thank you for your participation. I'll turn the call back over to Hazeline Roulac.

Question-and-Answer Session

Hazeline Roulac: Thank you, Holley. So, at this time, we're going to start our question-and-answer session. And before we take questions from our participants today, during the registration process, you were able to submit questions. We're not able to reply to all of the questions, but our subject matter experts plan to address some of your questions. So, I'll now turn the call back over to Robin and Erin. Thank you.

Robin Usi: Thank you, Hazeline. So, we're just going to read off some of the questions that were received while you registered for this presentation today.

The first question is, does every physician in the practice register with Open Payments, and will one physician suffice for the entire practice?

The answer is every physician in the practice must register. Payments are reported to physicians individually and, therefore, in order to review and dispute your records, you need to register for yourself. I mean, once you join the registration process, you may assign an authorized representative. However, if you do work in a practice, every physician in that practice does need to register in Open Payments.

Erin Skinner: OK. The next question we received was, how can a physician sign up to ask CMS to email the physician the 2015 listing of alleged payments made to the physician, as soon as it becomes available?

Currently this feature is not available. That's why we are messaging and encouraging everybody to go in and register and check to see what payments have been attributed to them for the program year.

As a gentle reminder, we also want to let you know that industry is continuing to report payments for previous program years. So while you might think that there are not payments attributed to you for program year 2015, there may be new payments that have been reported for you in this latest submission period for program year 2013 or program year 2014, which have not been previously published. That means that these records are also available for you to review and dispute, and they will only be available for you to review and dispute for the first year that they are published. So, again, we encourage you to go in and review and dispute during – at least once a year before the data is published. OK.

Robin Usi: Thanks, Erin. There were several questions about the process to give compliant staff access to multiple physicians' information within an organization. That was also worded as, are there any shortcuts to aggregate physician data?

So, to try to answer that, well, I think we actually did answer that. And the answer is, really, we cannot give multiple physicians' payment information to one particular entity. So, each physician must register individually. However, again, a physician can assign an authorize user or an authorized representative that then allows that person or entity to review and dispute records on their behalf. However, the physician needs to take that action in order for that to occur.

Erin Skinner: OK. We received a question asking for additional understanding on reporting requirements or exemptions for transfers of value pertaining to investigational device exemptions. If you'd like to get a little more guidance on this, then I'm going to direct you back to our regulations. They can be found in the Title 42, Part 403, Subpart I, and you can look specifically at Section 403.902 for definitions. You can look at the definition of an indirect payment, and also look for the definition of a medical device or a covered product. And you can also look in Section 403.904(h), which covers exemptions or exceptions to reporting.

If you have additional questions, you can look at the guidance on our Law and Policy page on our website, and you can also call our Help Desk if you have specific questions about how to report something.

Robin Usi: Thank you. Another question, is there a way to streamline the access steps for physicians? Some will just stop before they get to their report.

We do understand. I mean, it is a two-step registration process requiring registration in both the CMS identity management portal as well as the Open Payments system. The entire process should only take you about 30 minutes to complete. That is the process that must be adhered to at this time. If you have all the appropriate information with you when you sit down to do your registration, it shouldn't be that cumbersome.

Erin Skinner: OK. We have another question that says, "During the 45-day review-and-dispute period, will reporting entities still have the ability to mark a disputed item as Resolved without working with the covered recipient to truly resolve the matter?"

This is certainly something that could happen. However, you still have the ability to go back and initiate a new dispute on that same payment record or ownership-and-investment-interest record if you believe that the dispute has not been resolved. So, again, you can go back in and initiate another dispute if the resolution does not, in fact, satisfy your concerns. Once again, this could be another opportunity to use that new feature that we put into place in the system and take advantage of the contact

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information that reporting entities are being asked to submit into the Open Payments system.

I think at this time we can open up for additional questions.

Hazeline Roulac: OK. Thank you. I just want to remind you that we did get other questions. However, many of them were outside the subject matter of the topic of this call today, and so we were not able to address them.

So, we have a few minutes left in the call, so our subject matter experts will take your questions. But before we begin, I would like to remind everyone that this call is being recorded and transcribed, so when you ask your question, please state your name and the name of your organization once your line is open. And in an effort to get to as many questions as we can in the last few minutes, we ask that you limit your question to just one.

Holley, you can open the line for questions.

Operator: To ask a question, press star followed by the number 1 on your touchtone phone. To remove yourself from the queue, please press the pound key. Remember to pick up your handset before asking your question to assure clarity. 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. Please hold while we compile the Q&A roster.

And our first question comes from Rebecca Scott.

Rebecca Scott: Hi, thank you so much. My question relates to principal investigators. I've heard reports that they've had trouble registering in the system because they don't have an NPI and they also don't have a license number to provide, and so they don't pass the vetting process. What advice can you provide?

Hazeline Roulac: Thank you for your question.

Robin Usi: Yes, thank you, Rebecca, for your question. This is Robin. At this point, my best advice is for that person to contact the Help Desk to facilitate the registration process. So, again, if you can look back into the slide deck for either the email address or the phone number, they'll be happy to assist you.

Rebecca Scott: OK. So, we have, you know, hundreds of PhDs who are principal investigators who can't register. Is there a way that they can provide a guidance – that they can receive a guidance document from CMS, so they don't each individually have to take that step? Because, I'm sure that this is the case at all academic teaching facilities across the country as well.

Robin Usi: All right. Rebecca, this is Robin again. You know, if you like, we can take your response back. If you'd like to email us directly—if you'd like to email me or Erin directly—we'll be happy to try to figure out a resolution for the issue that you're bringing to bear.

Rebecca Scott: Thank you.

Hazeline Roulac: Thank you. Next question.

Operator: As a reminder, to ask a question, please press star followed by the number 1 on your telephone keypad. If your question has already been answered or to remove yourself from the queue, please press the pound key. Again, that's star 1 to come into the question queue.

Again, to ask a question, press star 1.

OK. We do have a question from the line of Jean Ortega.

Jean Ortega: Hello. I would want to ask, when is the last day for the – when is the 45th day?

Robin Usi: Hi, Jean. This is Robin. The 45th day in this review-and-dispute period is May 15th.

Jean Ortega: OK. Thank you so much.

Robin Usi: You're welcome.

Operator: Your next question will come from the line of Rebecca Scott.

Rebecca Scott: Hi. Sorry to be a pest. I wanted to just make a comment about the inability of compliance officers to review data for their faculty prior to the end of the review-and-dispute period. You know, sometimes what we do is, we have offer letters that are pending based on the results of the Open Payments review. I was wondering if there're any plans in the works to allow sort of an institutional review or rule in the future.

Erin Skinner: Hi, Rebecca, this is Erin. We really appreciate that feedback, and we're always looking for – appreciative of stakeholders to give that sort of feedback so that we can work to improve the system and work to improve our processes to make it less burdensome for our users. So, we're happy to take that back and consider it for future improvements. That's really all that we can say at this time, though.

Rebecca Scott: OK. Thank you.

Erin Skinner: Thank you.

Hazeline Roulac: Next question.

Operator: And at this time, we have no further questions.

Additional Information

Hazeline Roulac: OK. Thank you, Holley. So, that's all the time we have for questions today. If we did not get to your question, please refer to slide number 35 for the Help Desk email address and phone number.

As a reminder, an audio recording and written transcript of today's call will be posted to the MLN Connects Call website. We will release an announcement in the MLN Connects Provider eNews when they become available.

On slide 37 of the presentation, you will find information and a URL to evaluate your experience with today's call. Evaluations are anonymous, confidential, and voluntary. We hope you will take a few moments to evaluate your MLN Connects Call experience.

My name is Hazeline Roulac, and I would like to thank our presenters for this afternoon, Robin Usi and Erin Skinner. And also, thank you all on the line for participating in today's call.

Have a great day, everyone. Thank you.

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

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