



**MLN Connects®**

**National Provider Call Transcript**



**Centers for Medicare & Medicaid Services  
Open Payments (Sunshine Act) 2015 —  
Prepare to Review Reported Data  
MLN Connects National Provider Call  
Moderator: Aryeh Langer  
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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 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 Aryeh Langer. Thank you. You may begin.

## Announcements and Introduction

Aryeh Langer: Thank you Salema. As you just heard, my name is Aryeh Langer from the Provider Communications Group here at CMS, and I'm your moderator today. I would like to welcome you to this MLN Connects National Provider Call on National Physician Payment Transparency Program, also known as Open Payments or the Sunshine Act.

MLN Connects Calls are part of the Medicare Learning Network®. During this call, CMS subject matter experts will provide a brief overview of the Open Payments National Transparency Program and highlights — highlight the parts of the program timeline when it is most critical for physicians and teaching hospitals to be aware and get involved. The call aligns with the beginning of the program phase, when physicians and teaching hospitals are able to enter the Open Payments system and review the accuracy of data submitted about them prior to the publication of this data on the CMS website.

Today's target audience is physicians, teaching hospitals, and physician office staff who need to view and possibly dispute data submitted about them by reporting entities, such as applicable manufacturers or applicable group purchasing organizations.

There are two main learning objectives on today's call. Participants should be able to identify the parts of the review, dispute, and correction process and should be able to recognize how to take appropriate actions in the Open Payments system. That information you can see on slide 4 of today's presentation.

You should've received a link to today's slide presentation in an email earlier today. If you have not already done so, you may view or download the presentation from the following URL, [www.cms.gov/npc](http://www.cms.gov/npc), again that URL is [www.cms.gov/npc](http://www.cms.gov/npc). At the left side of the web page, select National Provider Calls and Events, then select the date of today's call from the list.

Second, this call is being recorded and transcribed. An audio recording and written transcript will be posted to the MLN Connects Call website. Registrants will receive an email when these materials become available.

I'd also like to acknowledge the receipt of questions that were submitted prior to today's call. Some of those questions were used in the preparation of today's materials.

Finally, this MLN Connects Call is being evaluated by CMS for CME and CEU continuing education credit. For additional information, please refer to slide 35 of today's presentation for a link to the CE activity information and instructions document.

At this time, I'd like to turn the call over for the formal presentation part to Merri-Ellen James, Deputy Director of the Data Sharing and Partnership Group here at CMS.

## **Presentation**

Merri-Ellen James: Thank you Aryeh. We're going to start this presentation today on slide 5. We're going to begin with a brief overview of the Open Payments program and timeline.

The Open Payments — Open Payments is the implementation of the Physician Payments Sunshine Act, Section 6002 of the Affordable Care Act. Open Payments gives the public more information about the financial relationships between physicians and teaching hospitals and drug device manufacturers.

## **The Open Payments Program**

Moving to slide 6. First, What is Reported? Open Payments reports direct and indirect payments or other transfers of value made to physicians and teaching hospitals. Physicians and teaching hospitals are 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 hospital — 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 is Responsible for Reporting Open Payments? The responsibility for reporting Open Payments lies with the applicable manufacturers and applicable group purchasing organizations, or applicable GPOs.

Applicable manufacturers, also known as AMs, are entities which operate in the United States and engage in the production, preparation, propagation, compounding, or conversion of a covered right — covered drug, device, biological, or medical supply. This includes distributors or wholesalers that hold title to a covered drug, device, biological, or medical supply. Later in the presentation, we will also review the definition of covered drugs.

Applicable group purchasing organizations, or GPOs, are entities which also operate in the United States and purchase — and purchases — and purchase — arrange for or negotiate the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but no only for the use of the sole — for the sole use of the entity itself.

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

Slide 8, Who is Reported On? Open Payments reports information on payments, other transfers of value, and ownership or investment interest held by covered recipients. Covered recipients include physicians, teaching hospitals, and physicians who are owners or investors of an applicable manufacturer or GPO. This includes physicians' immediate family members who have ownership or investment interest in an applicable manufacturer or applicable GPO. Please note that covered recipients are not — are not necessarily Medicare providers. Covered recipients are any of the recipients who received Open Payments.

Slide 9, Types of Payments. There are three general types of — three types of payments:

- The first is the general payment. General payments are payments or transfers of value not made in connection with a research agreement or research protocol.

This document has been edited for spelling and punctuation errors.

- The second category is research payments, which are payments or transfers of value made in connection with a research agreement or research protocol.
- The third category is ownership or investment information, which is information about physicians or their immediate family members who have an ownership or investment interest in an applicable manufacturer or GPO.

Slide 10. The Open Payments Process Flow. Slide 10 illustrates the high-level process flow that was used in 2013. Specific timeline for program 2014 will be discussed in the next slide.

In general, the process begins with data collection, where the applicable manufacturers and applicable GPOs collect payment data for program year. Program years run from January 1<sup>st</sup> to December 31<sup>st</sup>. Following the data collection period is the data submission period. This is when the applicable manufacturer or applicable GPO submits their data for the program year to the Open Payments system.

Upon completion of the submission window, the review and dispute period begins — and correction period begins. This is when physicians, teaching hospitals review and, if necessary, dispute the submitted data. Applicable manufacturers and applicable GPOs can then correct the data to resolve any disputes. Upon completion of the correction and review and dispute period, the data is published.

Slide 11. Slide 11 depicts the timelines that were implemented for contract year 2000 and predicted — or proposed timelines for contract year — calendar year, rather, 2014.

The — of note specifically in this graphic is the data for program year 2013 was published on September 30<sup>th</sup>, 2014. And, again, it was published with refreshed data on December of 2014, which is not depicted on the graphic.

A specific note for calendar year 2014 is that the review and dispute period began on April the 6<sup>th</sup> and will extend 45 days. So physicians who are monitoring the call, now is the time to get in and look at your data.

Slide 12 is a high-level overview of the data that was published on — in this slide indicates that the information was as of September 30<sup>th</sup>. This is actually published data as of December 2014. A total of 4.45 million records were submitted at a value — at \$3.7 billion. Of these —of this data, 2.27 — I mean 2.7 million records were de-identified

— I'm sorry, identified data at a value of 1.4 billion, 1.8 million records were submitted, de-identified at \$2.3 billion.

Next I'm going to hand over the presentation to Toula.

Toula Bellios: Thank you Merri-Ellen.

### **Overview of the Open Payments Registration Process**

Now that we've got the background on the general program year process flow, we'll provide an overview of the Open Payments registration process.

Slide 14. Open Payments registration is a two-step process. First, you have to register with the CMS's Enterprise Identity Management system, EIDM. After you register in EIDM, you must request access to the Open Payments system. Please note that only individuals register in EIDM. Teaching hospitals themselves did not register in EIDM. They are only registered in the Open Payments system. Physicians will register as individuals in both EIDM and the Open Payments system.

Once you have successfully registered yourself in EIDM, you can register yourself and your teaching hospital, if applicable, with the Open Payments system. If your teaching hospital has already been registered in the Open Payments system, you can simply register yourself and request to be affiliated with the teaching hospital. Successful registration of yourself in both EIDM and the Open Payments system is required in order for you to perform any system-related functions.

Slide 15. To review — The Registration Process Overview. To review and dispute any data reported in the Open Payments system prior to its publication, users must follow the two-step registration process to register for the Open Payments system.

Physician and teaching hospitals who register during the program year 2013 do not need to register again. A physician may nominate one authorized representative to perform system functions on their behalf. An authorized representative could be an office staff manager or an independent consultant. Teaching hospitals can designate up to 10 authorized representatives and authorized officials to act on its behalf in the Open Payments system.

All physician profiles are vetted against CMS-approved sources to confirm that the registrant is a covered recipient physician. Physicians are vetted using information supplied during Open Payments system registration, including first and last name, National Provider Identifier, your NPI, state license information, primary type if no NPI is provided. Physicians who — physicians will receive an email confirming vetting success or failure. If vetting is unsuccessful, physicians should contact the Open Payments help desk. The help desk number is provided at the end of the presentation.

While some users may experience difficulty with registration process, the vast majority of physicians in teaching hospitals have been able to complete the two-step registration process between 15 to 30 minutes.

Here are some tips to ensure that vetting process is successful:

- Make sure the name used for registration matches exactly with the name in the National Plan and Provider Enumeration System, or NPPES. If you've changed your name in NPPES after December 31<sup>st</sup>, 2014, use the earlier version of your name that was in NPPES.
- Enter NPI if available. Enter exactly as listed in NPPES for the current calendar year. Do not enter NPI if it is obtained after January 1<sup>st</sup>, 2015.
- Enter all active state licenses.
- Provide as much information as possible. More information can speed vetting and ensure all records associated with the physician will be accurately matched with them.

Now that we've had the background on general program year process flow, we'll provide an overview of the review, dispute, and correction process.

### **Overview of the Review, Dispute, and Correction Process**

Slide 18. Starting April 6, 2015, physicians, teaching hospitals, and principal investigators may review and then affirm and/or dispute records submitted about them by reporting entities regarding payments, or rather, transfers of value or physician ownership or investment interest.

This process allows them to request corrections to records prior to data publication in June 2015. During the review, dispute, and correction period, the reporting entities

acknowledged and work to resolve those disputes. In the Open Payments system, physicians, teaching hospitals, principal investigators may affirm records, initiate disputes on records, or withdraw disputes. These actions will be explained later in this presentation.

The reporting entity works directly with whoever initiated the dispute to resolve it. The reporting entity will work directly with the physician or the physician's authorized representative, authorized official, or authorized representative for the teaching hospital or the principal investigator to reach a resolution for the disputed record.

Dispute resolution takes place outside of the Open Payments system, and CMS does not mediate disputes. However, CMS will monitor disputes and resolution to inform the program auditing process. Statistics gathered by CMS include how many disputes are initiated, as well as the volume of unresolved disputes. Once the resolution is reached, the status of the resolution must be captured in the Open Payments system.

Slide 19. Now that the submission period for 2014 program year has ended, the review and dispute period will run for 45 days, which started on April 6<sup>th</sup>, to allow physicians, teaching hospitals, and principal investigators to perform their review and dispute actions. During this time period, reporting entities may make corrections. They have an additional 15 days after the 45-day period to resolve any outstanding disputes and continue to make corrections.

Though the review and dispute period for June 2015 data publication is only 45 days for physicians, teaching hospitals, and principal investigators, they do have until the end of 2015 calendar year to initiate disputes of submitted data in 2015. This includes records submitted for program 2014 as well as late submissions for program year 2013.

At the end of the calendar year, records from the previous program year will be available for viewing only. Records with a new dispute initiated after the 45-day review and dispute period will be published as original attested-to data in the initial data publication. CMS will soon publish a quick reference guide to the resources page of the Open Payments website that lays out additional details regarding how the timing of dispute initiation impacts data publication.



Slide 20. These are the review, dispute, and correction statuses that will be shown for records in the Open Payments system. Records in Initiated status indicate that a physician, teaching hospital, or principal investigator has initiated a dispute of the data.

Records in Acknowledged status indicate that a physician, teaching hospital, or principal investigator has initiated a 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 and is only meant to serve as a notification to physicians, teaching hospitals, or principal investigators that the dispute has been received by the reporting entity.

Records in Resolved No Change status indicate that the reporting entity and the physician, teaching hospital, or a principal investigator has resolved the dispute in accordance with the Final Rule. Since status should only be used — this status should only be used when the dispute resolution does not require a change to the data by the reporting entity.

Records in Resolved status indicate that a record was updated by the reporting entity as a result of the dispute by physician, teaching hospital, or principal investigator.

And finally, records in Withdrawn status indicate that a dispute initiated by a physician, teaching hospital, or principal investigator has been withdrawn or no longer — I'm sorry, and no longer requires resolution by the reporting entity. It is important to understand what each status means so that the appropriate action can be taken for each record.

Merri-Ellen James: Thank you Toula.

## Keypad Polling

Aryeh Langer: OK, at this time, we'll pause just for a moment to complete keypad polling. Salema, we're ready to start the polling, please.

**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.

Once 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 between — if there are nine or more of you in the room, enter 9. Please hold while we complete the polling. Please continue to hold while we complete the polling. Please hold while we complete the polling.

Thank you for your participation. I would now like to turn the call back over to Aryeh Langer.

## **Presentation Continued**

Aryeh Langer: And I'll turn the call back over to Merri-Ellen.

Merri-Ellen James: Hi, thank you. We're going to be beginning with slide 21. We're resuming with slide 21 rather, Review and Dispute Action overview.

## **Overview of Review and Dispute Actions**

There are four — physicians, teaching hospitals, and principal investigators can take four actions in the Open Payments systems related to review and dispute. Please remember that all of these actions are voluntary and none of them are required. Records will still be published, regardless of how many actions — of these actions are taken. Physicians, teaching hospitals, and principal investigators can review all data records associated with them to ensure that the information submitted by the reporting entity is accurate. They may also affirm data records, initiate disputes for incorrect data records, and withdraw disputes. We'll discuss those actions on the following slides.

Slide 23, Reviewing Records. Physicians, teaching hospitals, and principal investigators start by reviewing records submitted about them by reporting entities. To review these records, go to the Review and Dispute tab, the Open Payments system, and select the physician, principal investigator, or teaching hospital you are affiliated with to view the records associated with them. An example of the page is shown on the slide. From this page, you may review, affirm, initiate disputes, and withdraw disputes.

Slide 24, Affirming Records. After records have been reviewed, physicians, teaching hospitals, and principal investigators may affirm records submitted about them by

reporting entities — affirm records submitted about them by reporting entities are correct. When a payment or transfer of value or physician ownership or investment interest is affirmed by a physician, teaching hospital, or principal investigator, they are confirming that the information is accurate and correct. Like the rest of the review and dispute actions, affirmation of records is not required. However, it is encouraged to ensure that the reporting entity and the physician, teaching hospital, or principal investigator are in agreement with the respect of the details for each payment.

Records not affirmed by the physician, teaching hospital, or principal investigator will be published as reported by the reporting entity, regardless of whether a record is affirmed. Physician-authorized representatives may only affirm records of they are — if they hold the dispute records level — access level which is necessary for a representative to be able to affirm and dispute records. This access level is granted by the physician at the time of nomination. Authorized officials and authorized representatives for teaching hospitals have the same access levels, and those types of users may affirm records. Principal investigators may also affirm records they are associated with. Note that records that are affirmed may still be disputed at any time if any information in the record is later found to be inaccurate.

Slide 25, Initiating Disputes. Physicians, teaching hospitals, and principal investigators may initiate disputes on records they are associated with which they believe could contain incorrect information. Once a dispute is initiated, the reporting entity will receive an email notification that a dispute has been initiated. The reason for the dispute provided by the physician, teaching hospital, or principal investigator will also be sent with the notification email. For this reason, if you're disputing multiple records at one time, it is suggested that disputes be made to the same reporting entity. If multiple disputes are initiated at the same time across multiple reporting entities, the reason for the dispute will be sent to all reporting entities referenced in the dispute.

The reporting entity may acknowledge the dispute in the Open Payments system but is not required to do so. The acknowledgement from the reporting entity does not constitute a commitment to resolving the dispute. The reporting entity's acknowledgement of the dispute only serves as notification to the physician, teaching hospital, or principal investigator 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. The dispute status can be viewed in real time on the Review and Dispute page in the Open Payments system.

Slide 26, Withdrawing Disputes. Physicians, teaching hospitals, and principal investigators can withdraw a dispute from a record if they no longer wish to proceed with the dispute. Disputes may be withdrawn even after a dispute has been initiated or acknowledged by the reporting entity. Once the physician, teaching hospital, or principal investigator withdraws a dispute, the reporting entity will receive an email notification that a dispute has been withdrawn. No additional action is needed by the reporting entity once the dispute is withdrawn.

Physician authorized representatives must hold the dispute records access level to withdraw a dispute. Physicians, principal investigators, as well as teaching hospital authorized officials and authorized representatives for teaching hospitals and physicians do not need additional access to withdraw a dispute. For detailed instructions on completing Open Payments — completing Open Payments system actions relating to the review and dispute process, refer to the Open Payments System Quick Reference Guide: Physician and Teaching Hospital Review and Dispute Actions on the resources page of the Open Payments website at the — at the address listed in the slide, <http://www.cms.gov/openpayments>.

Toula, would you like to continue?

### **Overview of the Dispute Resolution Process**

Toula Bellios: Thanks, thanks Merri-Ellen. Now we will — now we will now provide an overview of the dispute resolution process.

Disputes may be resolved by a reporting entity in one of two ways.

- The first way is to update or correct information for disputed records. Updated records are automatically placed in the review and dispute status of Resolved.
- The second way a dispute can be resolved is for no changes to be made to a disputed record. This can be done when a reporting entity and the physician, teaching hospital, or 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 be — will place the disputed record in a review and dispute status of Resolved No Change.

The physician, teaching hospital, or principal investigator will receive an email notification when a disputed record has been resolved by either of these two methods. Physicians, hospitals, or principal investigators can view the details of the resolution and any corrections that may have been made by logging into the Open Payments system and viewing the record. So physician, teaching hospital, or principal investigator believe the record dispute has not been sufficiently resolved despite the record having a status of Resolved, they can initiate another dispute for the same record.

Slide 29. Here are some other points to keep in mind regarding the dispute resolution process.

As previously mentioned, CMS will not mediate disputes between physicians, teaching hospitals, principal investigators, and reporting entities. Reporting entities should work directly with the physician, teaching hospital, or principal investigator outside of the Open Payments system to reach a resolution on disputed records.

If a dispute is resolved by reassigning the record to another physician, teaching hospital, or a 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 the disputed record has been corrected, resubmitted, and re-attested, 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.

Slide 30. Corrections made to data by reporting entities after the 45-day review and dispute period and after the subsequent 15-day correction period will not be reflected in the June 2015 initial publication of the data. Those data updates will be seen in the next data publication refresh. Reporting entities may correct data and resolve data disputes at any time. 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 publications

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

### **Next Steps**

Slide 31. Here's what you should do now. You can register in EIDM as well as the Open Payments system if you have not already done so. Register in both EIDM and the Open Payments system is required in order to perform any review and dispute action. Once you have 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 for any records associated with you, and participate in any dispute resolution activities with the reporting entity.

### **Resources**

Slide 32. Finally, CMS has made a number of resources available to help you understand and use the Open Payments system. These resources are available on the resources page of the CMS Open Payments website at [www.cms.gov/openpayments](http://www.cms.gov/openpayments). Key resources on the site are the Open Payments User Guide, other tutorials, and a number of quick reference guides that 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 the — about Open Payments. You can complete listserv registration on the Open Payments website.

If you have any additional questions, you can contact the Open Payments help desk by email at [OpenPayments@CMS.HHS.gov](mailto:OpenPayments@CMS.HHS.gov) and by phone at 1-855-326-8366. Hours of operation are noted on the website.

Thank you for your attention today, and now we're ready to answer any of your questions.

### **Question-and-Answer Session**

Aryeh Langer: Thank you Toula. Our subject matter experts will now take your questions. But before we begin, I would like to remind everyone that this call is being recorded and transcribed. Please state your name and the name of your organization

once your line is open. In an effort to get to as many participants as possible, we ask that you limit your questions to just one.

All right, Salema, we're ready to take our first question, please.

**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 are asking your question so anything that you say or any background noise will be heard in the conference. Please hold while we compile the Q&A roster.

Your first question comes from the line of Denise Zingman.

Denise Zingman: Hello. I am wondering if on the database for the next year, if hospitals or departments will be listed to make it easier for us to find out who actually got the funds?

Aryeh Langer: Could you give us one moment, please?

Merri-Ellen James: Well, actually could you — are you referring to the data that's actually published? I'm just trying to ...

Denise Zingman: Yes, on the Open Payments Act on the spreadsheet online.

Doug Brown: No, unfortunately, the way that we're collecting data about teaching hospitals is consistent with the teaching hospital list.

Denise Zingman: OK.

Doug Brown: We have not made that sensitive enough to capture the individual departments within the teaching hospital.

Denise Zingman: OK, that's what we needed to know. Thank you.

**Operator:** Your next question comes from the line of Julie Wilson. Julie, your line is open.

Julie Wilson: Yes. What happens if — yes, I'm sorry, what happens if our physicians decide not to participate? Is there a penalty — a financial penalty at all?

Merri-Ellen James: No, this is Merri-Ellen James. So physicians — physicians ...

Toula Bellios: Participation.

Merri-Ellen James: ... participation is voluntary. However, if an AM or GPO reports a payment for that physician, the payment will get published, regardless of whether the physician registers in the system to review that data or not.

Julie Wilson: OK, thank you.

Toula Bellios: And there's no penalty associated with the physician.

Julie Wilson: OK, thank you.

**Operator:** Your next question comes from Ron Peterson.

Ron Peterson: Yes, I think I heard you earlier but just wanted to clarify. A physician who may be employed at a health care system, they can — once they register, assign an affiliate, which could be another hospital. I just wanted to confirm that.

Merri-Ellen James: So, there are specific instructions. Each individual physician should go in and register individually. A teaching hospital also has the ability to go in and review the records associated with that particular teaching hospital. But EIDM is an individual-based system, so an individual from the hospital would need to register and then in EIDM — and then once they are in EIDM — I'm sorry, in Open Payments — they can affiliate themselves with a teaching hospital.

Ron Peterson: And if they affiliate themselves, then that would give the hospital the ability to review the data for that particular physician?

Merri-Ellen James: No, it would allow them to review the data for that particular hospital. However, an individual physician could nominate an authorized representative at a teaching hospital to go in and review the physician's data.



Ron Peterson: OK, so once the physician has registered themselves, then they could, in turn, put the hospital as the nominee, and the nominee would then have access?

Merri-Ellen James: Correct.

Ron Peterson: OK.

**Operator:** Your next question comes from the line of Joseph Campbell.

Joseph Campbell: Yes, I have a question regarding payments for research. Is it true that if the hospital receives research funds, that the same dollar amount is also attributed to the physician who is the primary investigator?

Toula Bellios: Hi, this is Toula. That is correct.

Joseph Campbell: OK. So it's kind of duplicate reporting on behalf of the teaching hospital and the physician?

Toula Bellios: I'm struggling with the word duplicative. We are associating that payment with a principal investigator and with the teaching hospital, so ...

Joseph Campbell: OK, thank you.

**Operator:** Your next question comes from the line of Michelle Green.

Michelle Green: I work for a physician who speaks for many different pharmaceutical companies, and some of them he speaks multiple times throughout the year. Is there one identifying factor that can help me link the honorarium or the fee to a particular program?

Merri-Ellen James: Hi, that's a good question. I would sus — that's something that you — that the AMs or GPOs may be able to put in the note section for contextual information. When they submit the record, they may reference the event. But they also note that the event of when that honorarium took place. So it depends on what information is submitted by the AM and GPO.

Michelle Green: One single identifying piece of information they always issue is the program ID. Every program is associated with a different ID number. Is there a way to

add a field so that they have to put that information in there? It's one way of me going in and confirming — or affirming for the doctor, you know, that yes indeed, he spoke on the program.

Merri-Ellen James: That's actually a great suggestion. That's not built into the system at the moment but we are — we will take that back for — and include it as a possible enhancement for out years. I guess my only recommendation is to go in and review the data that's been submitted and they may have indicated that information in the notes section, in the contextual section.

Michelle Green: I didn't realize there was a note section. I did go in and review the data and matched it based solely on dates and dollar amounts.

Merri-Ellen James: Um-hum.

Michelle Green: OK, thank you.

Merri-Ellen James: Um-hum.

**Operator:** Your next question comes from the line of Susan Leggett-Johnson.

Susan Leggett-Johnson: Yes, my question is, when we — when we're dealing with physicians who attend medical society organization meetings and the meals are sponsored by drug companies or others that they may not be aware of — and they sign into the MED CAI meeting, is that something that will be reported, or would that not be considered under the circumstance?

Merri-Ellen James: Could you repeat the question again, please?

Susan Leggett-Johnson: So we had physicians in our organization listed on Open Payment last year, and when we looked into it, some of those physician listings were associated with medical society meetings that they attended, signed in to the meeting because the physician is a member of that particular medical society, and didn't realize that the meal that was being provided at the medical society was sponsored and paid for by a pharmaceutical manufacturer. And I guess they took the list of attendees and reported that would be my guess. And we have a number of cases like that. Should that be something that the physicians should be reported on?

Doug Brown: Hi, this is Doug Brown. I would say that, first, it does sound like it's an unfortunate circumstance that the physicians weren't informed that the meals were sponsored by applicable manufacturers and purchasing organizations. There are within the Final Rule circumstances and specific rules around reporting meals. If the applicable manufacturer or GPO thinks that it was an indirect transfer of value or a direct transfer of value from them to a covered recipient physician, it is a reportable event.

And I would hope that as these events occur, that both attendees of those events are made aware and that the industry is making sure that they are communicating enough with the physician community to let them know that these are going to be reported.

Susan Leggett-Johnson: OK.

**Operator:** Your next question comes from the line of Rebecca Browning.

Rebecca Browning: Yes, I am Rebecca Browning with Freeman Health System. And I was wondering if it is possible for a person to be designated as an authorized representative for both a teaching hospital and a individual — and individual physicians?

Merri-Ellen James: Absolutely.

Rebecca Browning: The reason I ask is because right now I am in there for the whole hospital, but I was wanting to be able to view physician information as well, so be assigned by those individuals. But when I go in for request a role, only additional teaching hospitals are presented.

Doug Brown: Yes, the way that you would go about that is actually to communicate with the physician that you're wanting to be an authorized representative for and have them nominate you to be that role, and then you'll receive the access based on their request for you to take on that position.

Rebecca Browning: So it is possible to do both at the same time?

Doug Brown: Yes, it is.

Rebecca Browning: OK, thank you.

**Operator:** Your next question comes from the line of Shoshana Milstein. Shoshana, your line is open.

Shoshana Milstein: Yes, can you hear me?

Aryeh Langer: Yes, go ahead.

Shoshana Milstein: OK, I come from an academic medical center. This is more of a comment rather than a question and a reiteration of some of the previous comments, just for CMS to recognize the issues related from the hospital provider side in trying to review the payments and determine the accuracy of the payments. So we're a large academic medical center, we have 5,000 plus employees, and the data — I've encountered this issue last year, and I've already logged on to the site this year and encountered the same issues. The data that's included in the actual record when you do the View Record is so general and so overall and broad, that it's so difficult to drill down and try to figure out where the payment went to, you know, what it was really for, and, you know, to determine whether it's accurate or not.

So just, I guess, maybe — again, more of a suggestion. You know, it had been mentioned before in terms of — that there's contextual information, an element for that. In my situation, every single one of the payments that had been reported, there was not a single one that had contextual information listed in it. So I don't know if that's something that could be more of a mandated field when getting that information from manufacturers. And if there could be, you know, a thought process put in for the future years in terms of additional elements that could be more helpful for us in the provider side to determine the accuracy of these payments.

Doug Brown: Hi, this is Doug Brown again. Thank you very much for the comment. Periodically we go through a process under the Paperwork Reduction Act where we are describing the data elements in which we will collect from the applicable manufacturer industry and GPOs. One thing that I would hope that we can do is, as we go through the next cycle of data collection and getting approval through that process, that any of the data elements that really would make review and dispute more efficient for you guys, that we would be able to incorporate those in future PRA requests for approval.

Shoshana Milstein: OK, that would be excellent. Thank you.

**Operator:** Your next question comes from John Hazuri.

John Hazuri: Hi, yes, I was wondering if at any point there is going to be a possibility to create an export field or export option. For the teaching hospitals, at least, it's rather difficult when we have hundreds or thousands of records to try and get a grip on all of the data for ongoing research.

Doug Brown: Hi, this is Doug Brown. Yes, it's a great suggestion and one that we've certainly heard before, especially in this current review and dispute period. It is something that's on our radar, and we are heavily contemplating it for future system enhancement.

John Hazuri: All right, thank you very much.

**Operator:** Your next question comes from Wanda Torres.

Wanda Torres: Hi, I'm calling from a physician practice. And my question is, if a dispute gets corrected from 2014, gets corrected in July of 2015, when does the public website get updated? And — I'm sorry, and how does the public know there's a correction?

Doug Brown: So generally, we plan to do at least one data refresh and we announce those — the timing of those refresh or the new data or whatever data has changed since the first initial June 30<sup>th</sup> publication. We're working out that schedule now either to be later on in this year or very early next year in order to close out all of 2014 activity. Though that schedule is still under development, it, you know, the rule does say that we will put up a refresh of that data at least once.

Wanda Torres: So once perhaps during the same year, but we're not sure. The schedule's not out yet?

Doug Brown: No, the schedule is still under development right now.

Wanda Torres: OK. And does the public become aware that there was a correction?

Doug Brown: Yes, we do ...

Wanda Torres: I was wondering how that would work.

Doug Brown: We do broad announcements announcing that the data has been refreshed. We also try and highlight those areas of change with a supplemental file indicating the changes that have been made to the previous publication.

Wanda Torres: OK, thanks.

**Operator:** Once again, to ask a question, please press star then the number 1.

Your next question comes from Nancy Lynch.

Nancy Lynch: Hi, I'm calling from a hospital system, and I'm actually just trying to get information regarding who typically — what department typically would be authorized to, you know, investigate — affirm the records? You know, I understand with the physicians they can designate somebody. And I'm just wondering if that somebody in the medical staff office or — I guess, it varies depending on the system, but I just kind of wanted to get an idea who is being assigned.

Doug Brown: Yes, we at CMS do not dictate what departments or which individuals within the hospital system can access. We validate that the individuals requesting to take that role are associated with the organization. But as far as whether or not, you know, that's consistently applied, that it's the same group or the same organization from hospital to hospital, we would not know.

Nancy Lynch: Yes, I understand that. I just thought maybe, you know, I can get an example of what — I just want to know which department typically would do that, like the medical staff. Or you can't answer that, I guess.

Doug Brown: No, I can't answer that with ...

Nancy Lynch: OK.

Doug Brown: ... with specificity, but I would imagine that it's probably a compliance group within the hospital.

Nancy Lynch: OK, all right. Well, thank you.

**Operator:** Your next question comes from Jan Mall.

Jan Mall: Hi. I'm from a large teaching hospital and I just want to reiterate comments that have already been made. Not only would it save us time, it would save the people reporting time if we had a very descriptive field for what, like, the item is. It just says "gift." Well, a gift to a large teaching hospital doesn't tell us where that went, what department it went to. So if we had a specific, detailed name of what that item is and what department, that would really help and, again, save the manufacturers time because I'm contacting them now asking them, you know, what is this that you reported? And they know that when they're putting — when they're doing the data entry. If they could just give us a few more keystrokes, if that was required, it would save everyone a lot of time. Thank you.

Also, I'm from compliance. For the previous caller who asked who is doing this, I'm from our corporate compliance department at a teaching hospital, and I'm the one responsible for reviewing the data. Thank you.

Aryeh Langer: Thank you.

**Operator:** Your next question comes from the line of Carol Coates.

Carol Coates: Hi, this is Carol Coates from Extended Care Physicians. I just wanted to verify that physicians can dispute the data any time during the year for that data that is out there publicly. And I also just had a comment. I had several of my physicians try to register to view and dispute their data last year and they gave up. They said it was incredibly difficult and they didn't have the time to complete the process. And so they just said, "I'm sorry, I give up."

Rachel Winer: Thanks for your question. This is Rachel Winer. For the first part of your question, yes, you are correct that you have the — until the end of the calendar year to dispute data submitted for the previous year. So you have until the end of 2015 to dispute 2014 data.

Regarding your second statement about difficulty with registration, we have heard in the past that some physicians have encountered difficulties with the vetting process that was described earlier in our presentation. And we've taken some steps to sort of streamline — simplify that process a bit. And, for the most part, we are happy to report that, based on our feedback that we have received this year, that two-step registration

process has been — most physicians, teaching hospitals have been able to complete that two-step registration process in 15 to 30 minutes.

Like I said, you know, I'm sure there are some outliers in there and some have — still have some difficulty, and we regret that difficulty. But, again, the vast majority that we've seen and heard from are able to accomplish it this year in that 15 to 30 minutes. So we hope that they are able to check — to go in again and register and participate in the review and dispute process after registering.

Carol Coates: Thank you. I'll let them know that you've been working on that. And so if they see something that was reported in 2013 and they want to dispute that, is that window closed?

Doug Brown: If 2013 data has been published in its identified form and no changes have been made to that record since its publication last September then, yes, that — the window for disputing those data is closed.

One sort of additional note to the registration problems that you had just mentioned, don't hesitate to engage the help desk. We also have quick reference guides available, so access those. And if you're still having trouble, you know, don't hesitate to engage the help desk, and they'll be happy to walk you through it.

Carol Coates: Thank you very much.

**Operator:** Your next question comes from the line of Catherine Ostapina.

Catherine Ostapina: Hello, thank you. I want to echo everyone else's comments, too, about the lack of specificity of information in the system to be able to do any research.

The other thing I would like to ask or suggest in terms of enhancements or future possibility is if there's any way to indicate a contact person or at least a phone number of who reported the payment or the item of value. We spent an incredible amount of time not only once we determined who was the right person to talk to. So a lot of manufacturers have on their website specific information about a phone number to contact, and that was a little bit easier. But in instances where the manufacturer has no information available on their website, it's just really — you know, I was doing searches of trying to find compliance individuals at organizations to try to figure out who



reported this information and who could actually help provide additional detail. So that was one thing.

The second thing is, I am from a large academic medical center teaching hospital, and what we found is that when — particularly in the — on research payments or even some dollars that they — and so manufacturers, it was quite interesting, have reported the same type of dollar payment. So, for example, a device or instrument loan, we had one manufacturer report that as a gift, one manufacturer report that as space and rental — facility rental, one manufacturer report that as consulting.

So it's very difficult in terms of really trying to identify what these payments are when, you know, there's — it's unclear to the manufacturers. But they have indicated, particularly in our situation where we have a teaching hospital and then the university, a lot of grants and monies were allocated to the university, specifically the university's tax ID number, which is different than the hospital's as payments being reported to the teaching hospital. So I spent a fair amount of time arguing those points with manufacturers. And a couple told me that CMS instructed them that even if it was the university in terms of research things, that they had — that they were supposed to be reporting that under the teaching hospital when the monies truly didn't get directed to them. Is that true? Or is there something I'm not understanding in terms of the rule or the regulation?

Doug Brown: So you brought up a couple of really good points. First, with regard to the way that certain AMs or GPOs interpret the meaning of certain natures of payment, be it gifts or grants or whatever. We try and provide, you know, for all of those natures of payment, some guidance in the form of either self-regulatory guidance to help them make the determination or make a consistent determination. We offer a set of frequently asked questions to help guide that process. Ultimately, however, the determination as to which nature of payment category to classify any particular payment is made by the reporting entity. And hopefully, through the review and dispute process we can begin to, as a community dealing with the Open Payments program, start migrating toward consistent understandings and definitions across the entire industry.

Onto your second point — just 1 second. Yes, on the second point with respect to whether or not, I guess, CMS has directed the industry to classify any payments made to

a university as a — as payments made to a teaching hospital, it is — I am not aware of any guidance that has done that. We'll take another look through the outreach material that we've made available just to make sure, but it's not something that is being brought to mind.

Catherine Ostapina: All right. Thank you for your comment. I mean, it's obvious that the name of our — of the university is in the name of our teaching hospital so that — as soon as somebody sees that name, they automatically direct it to that. We actually had a situation where a employee of a manufacturer attended our university and made a alumni gift, the company matched that gift, they reported that \$50 gift to the teaching hospital, and it took me hours to try to unwind that.

**Operator:** Your next question comes from the line of Russell Bogartz.

Russell Bogartz: Hello. I'm speaking from a medical device company, and I'm hearing these questions and requests about the need for specificity and contextual information be filled out. From our side, there are hundreds of thousands of transactions in some cases. And so if we do create — or if CMS does change the system so that this field is mandated by — on our side, then I would ask that CMS be very careful about how they go about doing that because it might be — we might get a lot out of standardizing specific — or categorizing transactions rather than having to fill — just fill something out wouldn't help anybody. So it might be a — we may get some value out of, you know, having a form where a medical device company then — and some folks from the health care provider side, you know, get a chance to sort of have a forum about it so that there's standards — standards about how we fill it in so it's easy for everybody.

Doug Brown: Yes, and this is Doug Brown again. I would say, thanks for your comments. Any process that CMS would use to alter any data collection associated with this program would be very public. We would operate under either the Paperwork Reduction Act and seeking public engagement and comment on any changes that we made to the data submission requirements. So I agree, it should not be taken lightly at all and — nor would we. We would follow the very public engagement way that we do things.

Russell Bogartz: OK. I just — the idea of making — for example, you know, the contextual information field a mandatory field to fill in, well then what will end up happening — I

mean, I can't speak that our company would do this, but I can imagine a lot of other companies might be tempted to just put something in there that, again, doesn't mean anything to the health care provider side. So to create a standard is crucial, you know.

Doug Brown: Right. Totally, yes, I know.

Russell Bogartz: OK, thank you.

Aryeh Langer: Thank you very much.

**Operator:** Your next question comes from Tracy Koval.

Tracy Koval: Hi, thank you for taking my call. My question comes — I guess I just want to know if CMS is actually tracking how many people go out on the public website and look at that information. I hear a lot about how much time this takes, all the providers and the teaching hospitals and the manufacturers, and I'm just wondering if maybe it's too soon to know that — exactly how many people are actually going out there and looking at it. Because when I talk about it outside of the medical field, nobody even knows what I'm talking about. They look like — at me like I'm an alien. So I just have that question. Thanks.

Doug Brown: Hi, this is Doug Brown. You know, this program is a very brand new program in the grander scheme of things. So there is a lot of effort underway at CMS to make sure that consumers are aware that these data exist. We do track, you know, hits that we get and, you know, people accessing the public data that's out there. So, yes, we of course take a very strong look at that and try and use that data to help our strategies for additional outreach to make sure that other people are aware of the program.

Tracy Koval: Thank you.

**Operator:** Your next question comes from the line of Cindy Lewis.

Cindy Lewis: Hey, thanks for taking my call — or my question. I work for a large medical group and we have engaged a third-party company to schedule all of our educational events for manufacturing companies to come into our clinics. And at CMS — its recommendation, part of that, is to document who we've met with, who had an event,

and to follow up — each rep is required to follow up with the amount of value that has been transferred to each provider. That's worked pretty well in most situations, especially given the large number of providers we have.

We have gotten some kickback, however, from some manufacturing companies who do not want to report that information to us. They have mentioned that there are some legal issues with that. And I just wanted to know from CMS's perspective, is there any reason why a drug manufacturing company could not report to us how much money or how much value was spent for each provider? And how would we be able to dispute those types of payments or value otherwise?

Doug Brown: Well, I'm not sure I entirely follow the question, but I think, in short, this would not be the appropriate forum to provide any legal interpretation of what might be going on in your specific situation. So I would suggest that those questions truly are on your mind, that you engage with the applicable manufacturer themselves.

Cindy Lewis: From a CMS perspective, is there any rules that drug companies — from the Open Payments Rules, are there any rules that say the drug company can't provide that information to us?

Doug Brown: Again, I'm not — so maybe could you go back and describe again the exact information that you're requesting from the drug company that they are suggesting that they cannot provide?

Cindy Lewis: If they come in for an educational event into our clinics and provide a meal, we ask them to provide us the dollar amount of that meal.

Doug Brown: OK, if — and you're a major teaching hospital or...

Cindy Lewis: I'm not — no, we're not a teaching hospital. It's a — it's a multispecialty medical group.

Doug Brown: I really think that this question belongs to the applicable manufacturer that's attempting to report it. Because they could be sensing that you're asking for information around how much will be reported per covered recipient and which covered recipients will be reported. And I believe that they may be responding that way because they feel that that's between them and the covered recipients themselves and

should not be disclosing that information outside of the public disclosure process. So, again, I am not in a position to know the full breadth of details or why the A — or the GPO is responding in the way that they are. My best advice is simply to engage them to have that conversation.

Cindy Lewis: Thank you.

**Operator:** And the next question comes from the line of Olga Edquist.

Olga Edquist: Yes, hi. Can you hear me?

Aryeh Langer: Hello, go ahead.

Olga Edquist: Yes, my question is related to your scheduled maintenance, because it appears that the system was down earlier this week, or was it last week, 6<sup>th</sup> through 8<sup>th</sup>, and information that had been changed during that time like, for example, I was entering — submitting my disputes. The information was gone and then the email went out saying that there was a scheduled maintenance, the system was down, and then now information is wiped out. And I confirmed, yes, information that I had submitted had been wiped out. So I had to start over again. I don't believe CMS sent out a single email notification or if there was any postings of scheduled maintenance. When does it happen? How do you announce that? That's my question.

And then also, a comment in regard to disputes. Since CMS does not work as a moderator in those situations, having contact information for vendors would have been extremely helpful. Just like the other caller said — enormous amount of time is spent just trying to find out who to talk to while you are working on a dispute with the vendor. And last year, working on disputes I did not get a single response back through the CMS website, through the dispute, and there was no information about the vendor or the contact person. So it was, you know, mindless Googling trying to find out who to contact in those. So that was very frustrating. Thank you.

Doug Brown: So first, on the maintenance schedule. We generally try and do all maintenance after hours, generally between the — midnight and approximately 2 a.m. It was an unfortunate system interruption last week, so we've asked that any individual that had taken activities last week or the early — Monday, Tuesday, and Wednesday of

last week — that you verify that the information within the system was still current and still accurate as to what you felt you had done in those first three days.

And as for your second comment, it is a great comment that we're considering heavily. Having contact information both for the physician community to outreach to the applicable manufacturers themselves, I think, would be helpful, and it's something that we're contemplating as we reconsider or think about the appropriate design of the review and dispute functionality within the system.

Aryeh Langer: Thank you very much.

**Operator:** Your next question comes from the line of Joseph Campbell.

Joseph Campbell: Yes, I have a question regarding the — actually a technical question about using the system itself. When I open it up and I see 37 pages of data with multiple columns, is there some way to print out or download into an Excel database the entire file rather than trying to copy page by page?

Doug Brown: Hi, thanks for the question. Yes, unfortunately — currently the system is not equipped with a download function. It is something that we've received several requests on, and it's certainly on our radar for future enhancements.

Joseph Campbell: OK. Just to comment on the disputes issue. For the 2013 data, it seems like every one I disputed, I had a call or an email from — immediately the following day — from any vendor that I disputed. So I didn't have that problem of having to search anybody out, they found me.

Aryeh Langer: Thank you.

**Operator:** And you have a followup question from the line of Susan Leggett-Johnson.

Susan Leggett-Johnson: Yes. I heard someone say something about educational program and trying to get the company to provide an amount for lunch. I want to clarify that CME activities, right, true CME activities where CME credit is provided, would not be covered under the Open Payment.

And then the second part of that question is, if one of our physicians attends a program that, say, I will pay for on behalf of the organization to learn how to use one of Medtronic's new, you know, equipment or, you know, prosthetic, whatever. If they cover the lunch or reimburse Medtronic for that lunch, they should not be reported, and I guess that's a question?

Doug Brown: Hi, this is Doug Brown again. I think – so there are certain exclusions in the Final Rule regarding CME. CME that is accredited by certain organizations that — in which the CME provider does not — or in which the applicable manufacturer does not pay the speaker directly or select a speaker in which the CME organization might eventually pay.

So there are some exclusions associated with speaking at CME events. I would not categorically say that all CME activities are excluded from the Open Payments program. We are also making — we have also finalized in the Physician Fee Schedule published in October of last year that the current CME exclusion has been removed and we're simply aligning all CME activities with the rest of the activities of Open Payments, whereby if it is a direct or indirect payment, as per those definitions, then it is a reportable event. If it is not a direct or indirect payment, then it is not a reportable event.

So I wasn't quite clear on your example or the discussion that you had around the Medtronic ...

Susan Leggett-Johnson: The Medtronic was a little bit different. We have physicians who still would like to attend training sessions to user certain equipment, learn how to use it better, etc. with companies like Medtronic and may travel to that site. And as you know, oftentimes Medtronic would pay for the travel and the boarding, but we pay for the travel, the boarding, the meals, all of that. But during the session, lunch might be provided, and as long as they reimburse Medtronic for the cost of that meal then that physician should not be reported for that activity.

Doug Brown: Again, so it sounds as though you're right. It's not an appropriate venue to sort of make the carte blanche statement that all things reimbursed are therefore excluded from reporting. Fundamentally, it does sound as though it's appropriate interpretation to make, although a lot of that interpretation will be placed on Medtronic, using your example, as to whether or not they feel like the reimbursement

covered the entire cost or what. So, again, I think having physicians heavily engaged in the review and dispute process and having the discussions with the organizations upfront certainly clarifies all of those missing — or all of those questions beforehand.

Susan Leggett-Johnson: Thank you.

**Operator:** And as a reminder, if you would like to ask a question press star 1. And again, that is star 1 to ask a question.

And there are currently no questions in queue.

Aryeh Langer: OK, great. Well if anybody has any ...

**Operator:** I'm sorry...

Aryeh Langer: ... questions after the call, they can certainly feel free to email the Open Payments help desk that's listed on slide 32 or also the number that was given out, that's also on slide 32.

## **Additional Information**

Just 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 these are available.

On slide 34 of the presentation you will find information and a URL to evaluate —excuse me, 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 today.

Again, my name is Aryeh Langer here in the Provider Communications Group. I'd like to thank our presenters and also thank you for participating in today's MLN Connects Call. Have a great day everybody.

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



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