



MLN ConnectsTM

National Provider Call - Transcript

Centers for Medicare & Medicaid Services
OPEN PAYMENTS—Policy Updates on Payments
and the Physician Resource Toolkit
MLN Connects National Provider Call
Moderator: Leah Nguyen
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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 would now turn the call to Ms. Leah Nguyen. Thank you. You may begin.

Announcements and Introduction

Leah Nguyen: This is Leah Nguyen from the Provider Communications Group here at CMS, and I am your moderator today. I would like to welcome you to this MLN Connects National Provider Call on Open Payments—Policy Updates on Payments and the Physician Resource Toolkit. MLN Connects Calls are part of the Medicare Learning Network.

During this call, CMS subject-matter experts will give an update on program policy with a focus on third-party payments and indirect payments, as well as the physician resource toolkit.

Open Payments, or the Physician Payment Sunshine Act, requires manufacturers of pharmaceuticals or medical devices to publicly report payments made to physicians and teaching hospitals, creating greater transparency around the financial relationships that occur among them. It is important to know that data collection began on August 1st, 2013. A question-and-answer session will follow the presentation.

Before we get started, I have a couple of announcements. You should have received a link to the slide presentation for today’s call in previous registration material. If you’ve not already done so, please download the presentation from the following URL: www.cms.gov/npc. Again, that URL is 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. An announcement will be placed in the MLN Connects Provider eNews when these are available.

And third, registrants were given the opportunity to submit questions in advance of today’s call. We thank those of you who took the time to do so. While they may not all be addressed today, they will be used for future presentations, frequently asked questions, or other educational materials.

At this time, I would like to turn the call over to Doug Brown from the Center for Program Integrity.

Presentation

Doug Brown: Hi. Good afternoon, everyone. My name is Doug Brown. I'm the division director for the Division of Health Informatics and Systems within the Center for Program Integrity in the Data Sharing and Partnership Group. We are the component of CMS actually implementing the Open Payments program, and I'll begin my presentation on slide 5 and quickly read a disclaimer that'll apply to the remainder of the presentation.

So this information provided through this National Provider Call is a summary of the final rule implementing the Open Payments program, also known as the Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, codified at CFR – 42 CFR Parts 402 and 403. This summary is not intended to override or take the place of the final rule, which is the official source for requirements and information on the program.

So, the agenda for today's discussion. We'll do a quick introduction to review what Open Payments is, the regulation and the statute bringing – or putting Open Payments into place, the data that the industry will be tracking about physicians and teaching hospitals beginning on August 1st through December 31st of this year. We'll quickly touch on registration, review and dispute, publication of the data, and additional tools and resources available to physicians.

Introduction

So quickly on the introduction. Relationships between the industry and physicians are common, as you know. The pharmaceutical and device industries fund nearly two-thirds of registered clinical trials in the U.S. industry sponsors over 80 percent of the most frequently cited papers.

Physicians believe they are not influenced by pharmaceutical advertising, but advertising and other drug promotion has been shown to influence prescribing behavior. Over 20 – only 20 to 40 percent of patients are aware of less visible gifts to physicians from industry, such as books and meals. And between 40 and 70 percent of patients believe that gifts from industry influence physicians' prescribing habits.

So we in the program, we believe that these collaborations between physicians and the medical industry can be beneficial. They are obviously beneficial by promoting discovery and development of new technologies that improve health and lower costs. However, these financial relationships may also influence professional judgment and create conflicts of interest that can potentially arise.

So, as you know, Section 6002 from the Patient Protection Affordable Care Act—6002 is actually the section of the Affordable Care Act that lays out the Open Payments program. We published our final rule implementing the Open Payments program on February 8th of this year.

Open Payments is a national transparency program requiring certain manufacturers and group purchasing organizations to disclose their financial relationships with physicians

and teaching hospitals. The objectives of the program are to make financial relationships transparent on a national scale and also to give consumers the information needed to ask questions and to make more informed decisions about their health care professionals.

Our role at CMS is to remain neutral and present the data on a public website and to do everything that we can to ensure that reporting and disclosures are complete, accurate, and clear.

Tracking Industry Data

So on slide 11, we will go through a timeline of activities that will be performed over the coming months. So starting in August of this year and continuing through December of this year, the industry will be in the process of collecting information on payments and other transfers of value, as well as ownership or investment interest held by physicians and their family members.

What physicians should be doing through this time is to also keep track of those payments and transfers of value made to them, and also be mindful about the investment interest held by both you and your family members. We'll walk through later portions of this timeline as we move forward through the presentation.

So, reporting requirements for the industry. Our Open Payments final rule requires that certain manufacturers report annually to CMS. They will report payments or other transfers of value made to physicians and teaching hospitals, as well as report ownership or investment interest held by physicians or their family members.

Our rule also requires that certain group purchasing organizations report annually to CMS—report ownership or investment interest held by physicians and their family members, and to report payments or other transfers of value made to those physicians who also hold ownership or investment interest.

The way that we are going about doing this data collection is that we have developed three file-specification forms, or what was otherwise known as the reporting templates, and these templates simply lay out the data elements, or the data fields, that we will be collecting and puts them into three different categories as to why we are collecting them.

So first we have the general payments, which collects reports of payments or other transfers of value made not in connection with a research agreement. Research payments—that template will collect reports of payments or other transfers of value made in connection with a research agreement. And then finally, our ownership or investment interest file specifications will lay out the data necessary to report on ownership or investment interest.

So we have two different types of covered recipients within the Open Payments program. The first are physicians. These are defined as doctors of medicine and osteopathy, dental surgery and dental medicine, podiatric medicine, optometry, and licensed chiropractors who are also legally authorized by the State to practice.

The other type of covered recipient are teaching hospitals, and these are hospitals that CMS has recorded as receiving payments under Medicare GME and IME. And we will be providing a list of the teaching hospitals on an annual basis at least 3 months prior to the beginning of each data collection period. We have provided a list supporting the 2013 program cycle back in May, and that is available for download at <http://go.cms.gov/openpayments>. Our next update to this list will be on or before October 1st.

So we'll get into additional definitions within the program. So the next is ownership or investment interest. *Ownership or investment interest* is defined as including stock or stock options other than those received as compensation until they are exercised, partnership shares, limited liability company memberships, loans, bonds, or other financial instruments that are secured with an entity's property or revenue, or a portion of that property or revenue. These may be direct or indirect, through debt, equity, or other means. There are some exceptions that apply to this definition, and this is found in Section 403.902 of the Open Payments final rule.

Physician owners or investors, we're providing a definition of what is included as part of the definition for *immediate family members*. These include spouse; natural or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-, mother-, daughter-, son-, brother-, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

So throughout this time, physicians should track all interactions that they have with the industry involving payments or other transfers of value in order to ensure accuracy. In order to preview data, we will ask that physicians and teaching hospitals register with the Open Payments program, and this will give us the point of contact necessary to provide those preview reports to you. And we are also providing tools and other resources to help you keep track of those payments or other transfers of value, which we will discuss later.

So, on slide 18 we're describing some specific physician identifiers that will be reported to CMS through the data templates that we described earlier. These identifiers will be the full legal name as it appears in NPPES, the primary type of the physician as well as the specialty, the business address, the NPI as it also appears in NPPES, State professional license numbers, as well as email address.

They will also be reporting information about the covered product for which they have provided the payment or other transfer of value in association with, and this will cover the name of the covered product, device, biological, or medical supply, and information about the payment to include the amount, the date, form, nature of the payment or transfer of value, the number of payments involved, and if those payments were designated to a third party, the name of the individual or entity the physician indicated to receive the payments.

How was the payment made? This is the form of payment. We have divided these into four categories of type – forms of payment, to include cash or cash equivalent, in-kind items or services, stock or stock options other than ownership interest, and dividend from profits or other return on investment.

The industry will also be categorizing the payments or the transfers of value into a nature of payment. These natures of payment sort of describe the – for what reason the payments were made. These include consulting fees, honoraria, gifts, entertainment, food and beverage, travel and lodging, education, research, charitable contribution, space rental or facility fees, royalty or license, current or perspective ownership or investment interest, a grant, compensation for services other than consulting, and direct compensation for serving as a faculty or a speaker for a medical education program, accredited or non-accredited.

So there are two primary types of payments. These are direct and indirect. So, direct payments are defined as those payments that are paid directly to physicians and teaching hospitals. And indirect would obviously go through some other intermediary. It also collects information on payments designated by physicians or teaching hospitals to be paid to another third – to another party. These are known as third-party payments.

So, direct payments—again, these are payments or other transfers of value provided by the applicable manufacturer or applicable GPO directly to a covered recipient or physicians holding ownership or investment interest.

We'll walk through some scenarios in order to sort of give these types of payment context. So, scenario one is that a university teaching hospital accepts a \$10,000 grant paid by check from ABC drug manufacturer on August 5th. What will be reported that – is that University Teaching Hospital had all of the information identifying that teaching hospital—such as the name, address, TIN—and these will all be published as part of our teaching hospital list that we do annually. And then, again, the form of the payment, which will be cash or cash equivalent; the date that that was made, which was August 5th; and the nature of payment, which would be grant.

So, the second scenario that we've put in here is that Root Canal Specialty, LLC, contracts with Dr. Jane White to speak at three dental school lectures on the 5th of August, the 5th of September, and the 5th of October in 2013, for \$5,000 per lecture. During the discussion, Dr. White will market Root Canal Specialty's prescription toothpaste, SparkleRx.

The industry will report Dr. Jane's identifying information, to include her name, business address, NPI, State license number, the primary type, and as well as her specialty. They will also include form of payment, which will be cash or cash equivalent; the date that the payment was made—in this case they could in fact report the 5th of August as the date that the payment made – was made—and the amount of payment, which in this case would be \$15,000 if they chose to report all three of these payments aggregated into one;

the nature of payment; as well as the fact that these payments were made in connection with SparkleRx.

Indirect payments are those payments that are made through an intermediary, like we mentioned earlier. These are payments or other transfers of value made by an applicable manufacturer or GPO to a physician or teaching hospital through this intermediary. So the manufacturer or GPO requires, instructs, directs, or otherwise causes the third party or that intermediary to provide the payment to a physician or teaching hospital.

So this – we should make sure that we keep this unique from third-party payments. So, hereto the applicable manufacturer or the applicable GPO is giving the money to another organization, and by giving it to that organization, they are either instructing, directing, or causing those funds to be funneled to a covered recipient.

So we have a few scenarios outlining this. Root Canal Specialty, LLC, provides \$10,000 to a dental specialty society on October 12th, requesting the award be split between two dentists chosen by the dental specialty.

So, they will – the applicable manufacturer or the applicable GPO will report each physician separately. So on each physician, they will report the name, address, NPI, as well as the specialty, which the five – who awarded the \$5,000, the form of payment, the date of payment, and the nature of those payments.

The second scenario that we have is that Asthma Relief, LLC, contracts with an advertising agency to create a newsletter valued at \$35, regarding cutting-edge treatments for asthma. The newsletter is targeted at top prescribers of Asthma Relief, LLC, drugs and is provided on December 7th, 2013.

It is a – we will expect that the applicable manufacturer or applicable group purchasing organization identify those top prescribers and provide the name, address, NPI, license number, specialty, and will attribute those \$35 for each of the newsletters provided. The – and they will also report the form of the payment, date, as well as nature of payment.

So third-party payments differ in that the payments or other transfers of value to a third party are done so at the request or as designated on behalf of the physician or teaching hospital. So these are payments that were intended to be received by the covered recipient, physician, or teaching hospital but that covered recipient requested or designated a third party to actually receive those payments.

And we have a scenario describing this situation, as well. So Asthma Relief, LLC, provides Dr. Henry Jones with a \$500 check for serving as a speaker at a round table discussion reviewing easybreathingRx and runfreeRx on August 5th, 2013. Dr. Jones requests that Asthma Relief, LLC, provide the compensation to a charity.

So the applicable manufacturer or applicable GPO will report on Dr. Jones his name, address, NPI, license number, as well as the \$500 payment. The form of payment will be

cash or cash equivalent, the date of payment will be August 5th, the nature of payment will be for whatever that the applicable manufacturer decides it to be. And then they will just identify that the payment was made to a charity and identify the name of that charity.

These – this payment will also be in association with the marketed name of the covered drugs, which is easybreathingRx and runfreeRx.

So, CME. Compensation for speaking at continued – continuing medical education is not required to be reported if all of the following conditions are met: The program, the CME program, meets the accreditation or certification requirements and standards of the ACCME, the AOA, AMA, AAFP, or ADA CERP. The manufacturer does not directly pay the physician speaker, as well as the manufacturer does not select the speaker, nor does it provide the third-party vendor with a distinct, identifiable set of individuals to be considered as speakers for the accredited or certified continuing medical education program.

So on slide 30 we have laid out sort of what is reported and when, based on whether or not the physician was an attendee or a speaker, and whether or not the CME event was accredited or certified, or non-accredited or non-certified.

So, as you see, meals, as well as travel, lodging, tuition fees, educational materials included in the tuition fees and those not included in the tuition fees—none of those things are reported if it is at an accredited or a certified event for physician faculty or speakers.

For physician attendees at accredited or certified events, meals will be included – or reported; travel and lodging will be reported. Tuition fees do not need to be reported, nor do educational materials included in those tuition fees. However, educational materials not included in the CME tuition fees will be reported, as well.

For non-accredited or non-certified events, all of these items will be part of the submission from the applicable manufacturer or group purchasing organization. So they will report on all meals, travel and lodging, tuition fees, educational materials both included and not included in the tuition fees.

There are some conditions that apply to whether or not, you know – the meals will be reported so you should confer with Section 403.904(h) of the Open Payments final rule to make sure that you understand those. So, and again, in order to meet the definition of accredited or certified, please refer to Section 403.904(g)(1) of the Open Payments final rule.

So there are some exclusions from reporting regarding educational materials, and these are items that directly benefit patients or are intended to be used by or with patients, including the value of a manufacturer's services to educate patients regarding a covered drug, device, biological, or medical supply, are not required to be reported. This is found in Section 403.904 of our final rule.

So, slide 32 lays out some examples of educational materials. So the manufacturer or GPO provides a textbook to a physician or teaching hospital. This would be reported since that textbook would not necessarily be used directly by the patients or intended to be used with the patient. So textbooks would be reportable.

When we're talking about a wall or anatomical model, these are situations where we would think that it would be intended for patient use or used with the patient, so payments or other transfers of value in the form of that wall or anatomical model would not be necessary for reporting under our program.

Registration

So, moving on to slide 34, registration. Registration is intended to open within the Open Payments program early in the first quarter of 2014. During this time, the industry will register and submit 2013 information to CMS, and this is the information that they have collected between August 1st and December 31st of 2013.

Physicians should also register with CMS in order to receive notifications and other information submitted by the industry, as well as any notifications coming out from our program that you need to be aware of.

Physicians and teaching hospitals are not required to register with the program. However, voluntary registration will allow physicians and teaching hospitals to review their data prior to public release. They will also be able to dispute any data thought to be incorrect for manufacturers and GPOs to review.

Physicians and teaching hospitals can also, upon registration, nominate an authorized representative. Information will be needed to register – the information needed to register is undergoing review and comment following the Paperwork Reduction Act process. You can have access to that comment period by visiting our website.

Physicians and teaching hospitals and authorized representatives will be able to review and dispute information provided by the industry. And again, registration will start early in 2014 and will remain open for physicians and teaching hospitals.

And again, I would just note that by registering in our program as soon as this – the registration module is available, will allow physicians and teaching hospitals to receive notification of information reported about them, to review that information, and then also later on to initiate disputes on any data before it is made public.

Review and Dispute

So, moving on to review and dispute, this will occur within the second quarter of 2014. Physicians and teaching hospitals will be receiving reports from the Open Payments program about the information that has been submitted in the first quarter of 2014. Physicians and teaching hospitals should review that information; compare it with any records that you have to ensure that the data is accurate.

During this time, you will be able to submit a dispute, and the industry will work with you in order to correct that disputed information. Physicians and teaching hospitals may initiate disputes to correct inaccurate information any time before the end of the calendar year in which the information was publicly available.

If the manufacturer or GPO can't resolve the dispute with the physician or teaching hospital and correct the data during the initial 45 days or the subsequent 15-day period following the review and dispute period, the manufacturer or GPO and the physician teaching hospital – physician or teaching hospital should continue to seek a resolution for that dispute.

Corrections from disputes initiated after the 45-day review and dispute period may not be reflected in the initial public data. Data from unresolved disputes will still be posted publicly, but will be marked as disputed. CMS will monitor the disputes and resolution process, and will update the public data at least once annually.

Publication

So, we are intending to post all of the data that we receive in the first quarter of 2014 in September of 2014. And this, again, will be all submitted data, based on the period of August 1st through December 31st of 2013.

These data will be available on a publicly accessible website. Again, any data that is disputed and yet not resolved will hold the marker as being disputed but will still be displayed. Data will be organized and available for search and download. The 2013 data will be posted in the fall, or September, of 2014.

Applicable manufacturers and applicable GPOs may request delay in publication of data when it is associated with research. Type of payments for which research – or that a delay in publication may be requested is reserved for research on or development of new products or new product applications, as well as clinical investigations regarding a new product, written research, or development agreement, or where a development agreement is required.

Publication will be delayed based on two factors until one of two things occur: Number one, the date of the FDA approval kicks in whereby they have received licensure or clearance of the product, or 4 calendar years after the date of the payment or other transfer of value is made.

So now I'd like to turn it back over to Leah for a few announcements before continuing on.

Keypad Polling

Leah Nguyen: Thank you, Doug. At this time, we will pause for a moment to complete keypad polling so CMS has an accurate count of the number of participants on the line

with us today. Please note, there will be silence on the line while we tabulate the results. Victoria, we're ready to start polling.

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

If you are the only person in the room, enter 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 – enter the corresponding number. If there are nine or more of you listening in, enter 9. Please hold while we complete the polling.

Thank you. I would now like to turn the call back over to Ms. Leah Nguyen.

Special Announcement

Leah Nguyen: Thank you. Before we continue the presentation, we would like to make a special announcement. CMS will soon provide an opportunity for Medicare-enrolled providers and suppliers to give us your feedback about your experience with your Medicare Administrative Contractor, or MAC, the contractor that processes your Medicare claims.

This new assessment tool is called the Medicare Administrative Contractor Satisfaction Indicator, or MSI. Your feedback will help CMS monitor MAC performance trends, improve oversight, and increase efficiency of the Medicare program.

Each year, CMS will randomly select its MSI administration sample from a list of providers who register to become participants. If you would like to register to become an MSI participant, or for more information, please visit the website listed on slide 57.

And now I will turn the call back over to Toula Bellios to continue our presentation.

Presentation Continued

Toula Bellios: Thanks, Leah. This is – again, this is Toula Bellios. I'm the division director for the Division of Policy and External Partnership. Our division is – it's tasked with basically doing a lot of the outreach with our key stakeholders, physicians, and industry.

Our goal is really to create awareness about the program and its intricacies and to also provide physician – the physician community and industry with useful and helpful tools about the – explaining the program as well as providing resources to help support the implementation of it.

So in terms of awareness, what we've been doing and working on continuously is – this is our second National Provider Call, and we anticipate having more calls over the course of the next coming months to, again, create more awareness about the program and as

information becomes available regarding the operation of the program, use this as a means to help get the message out of what needs to happen and when it needs to happen for everyone to adhere to the program guidelines.

We're working closely with national professional associations as well as keeping them abreast of what's going on with program development, as well as leveraging national publications, the Medicare Learning Network, and existing CMS contractors like the MACs and other – and the CMS regional offices to help get the message out.

So we're leveraging as many tools as we possibly can to create awareness about Open Payments and key deadlines and actions that are required out there both by physicians and industry.

Physician Tools and Resources

We're also creating a lot of useful information and resources for everyone out there that's impacted by the program. We have a dedicated web page for physicians, specifically physicians and teaching hospitals, as well as industry users.

We also have factsheets that explain the rule. It takes a 200-some-page rule and we've condensed it down to something more manageable. We also have created two continuing medical education modules for physicians to get CME credits that focus on Open Payments, and we're going to discuss those shortly.

And recently, as of today, we have created new brochures, one for physicians about Open Payments, which is a really easy-to-understand, four-page document that really explains what Open Payments is and how it impacts you and the resources available to you. So, that's available on our web page, as well, and we have – more information will again follow.

We also realize that due to all the press that's going on about Open Payments and what's going on, that physicians are liable to have patients come up to them and ask them what Open Payments is, and we've created a brochure for physicians just to answer those kinds of questions that patients – or you can refer your patients to this brochure to help explain about what the program is.

We've also developed two key resources for physicians out there. Our help desk is open – it's an email box at the moment. So you're more than welcome to – if you have any questions about the program or specific scenarios, we encourage you to email the questions into our help desk.

The most exciting part of all that we've created, this great resource, is a mobile application for physicians to use, as well as a mobile application for industry. CMS is not traditionally in the market of creating mobile apps, but for this program we have done so. It's a free mobile app that's available in iOS and Android platforms.

So if everyone could just take a moment to pull out your smartphones right now and actually go to your app store and do a search for Open Payments and download this app right now, we can quickly walk through it, and I can give you a quick little tutorial of it right now. So if we don't mind taking a pause for a minute while you guys do that, that would be great.

So as you're downloading, I'll just go through what the whole purpose of the mobile app is. The purpose of the mobile app is really to create a tool for physicians to use to track their transfers of value in real time throughout the course of the year. So it's really a tool for you to use as a point of reference. So, back – you know, in the coming months next spring, when you voluntarily go in and register for our system and review the information that has been provided to CMS by industry, you are going to be looking at payments and transfers of value that occurred in the past, you know, 6 months beforehand or 7 months beforehand.

And if you're not tracking that information, you're going to be questioning a lot of that information, and that's where we hope that the mobile app will really become very useful to you. You'll be able to reference the information in the mobile app and say, "Yes, this did occur. This payment or transfer of value did occur at this date and this is correct."

So we're hoping that, with this tool that we'll be able to minimize the number of disputes that occur, as well as identify the correct provider information and help physicians really track their payments and transfers of value.

So, once you've downloaded the app, the app asks you to create a password and a security question that you determine – whatever you determine it to be. A lot of thought went into regarding the security of the app. In terms of creating a password, there are very – there are multiple security features identified, and there is an FAQ available on our website specific to the mobile app that you can download and review, and it'll give you the intricacies of how the mobile app works.

If you go to the next slide, on slide 48. This is really the crux of the mobile app. The mobile app, the real benefit here is the ability for physician apps to send their profile information to the industry app, and this can be done using a QR code.

So, if you are looking at your mobile app right now, on your home screen there's a – first line button is personal profile information. So if you go in there and you populate it with your name, your address, email address, business number, business phone number, your NPI, your specialty, and your licensure numbers, you can create a QR code and that QR code can be scanned by the industry code.

All of the information that's mentioned here on this profile – Personal Profile tab is referenced on slide 18 of this presentation. This is the information that industry will be sending to CMS about us and how we will be identifying you in the data.

On the flip side of it, you'll be able to also manage your interactions with vendors and add profile information. So you will be able to – go to the next button on your home screen on your mobile app, go to Manage Vendors—you'll be able to create a vendor and vendor profile information. So when you do have that interaction with that industry representative, you can capture their information—again, using a QR code—to capture who you met with that day.

In addition, using a separate QR code, you'll be able – the industry app will also be able to send information to your phone using the Add Payments features or the ability to scan a code—or read a QR code, I should say—and that feature is available on your first – on your home page.

And what this does is it – you'll be able, as a physician, capture the information that's discussed on slides 19, 20, and 21 about the event that occurred: What was that nature of value; nature of payment; how much was that for; when it occurred; what was the topic or the specific drug, device, biological that was discussed at that event?

So that's what's really being transferred from the industry app to your app, and that's really where the value is in the app, of being able to capture this information and then refer to it 6 months later and say, as you're reviewing your data, that way you can confirm that, yes, this did occur, I do have a record of that occurring.

Again, on slide 49, we quickly just go over – and if you did not have a chance to do so already, we do encourage you to go look for the mobile app on your smartphones. You can see there are two mobile apps out there, one for physician and one for industry. Download the physician app and try to get acclimated to it and begin to use it.

Slide 50. Through – on our web page, you're able to access MedScape. We have two continuing medical education activities going on right now that are available for you to use. The first is one, called “Are You Ready for the National Physician Payment Transparency Program?” and this is a one-credit course and it allows – it gives you a high-level overview of the overall program.

The second one is targeted more to data collection and what information would be – will be captured during this – beginning on August 1st and what will be communicated to CMS.

The next slide is the educational brochures that are now available. As I mentioned, the one brochure – they are both available on our home page. The first one is specific to physicians themselves about the program, a very high-level, simple brochure that explains the program, the resources available, and what physicians need to know now. And the second one is for your physician – for your patients, and how if they have questions a – someplace for you to point them to.

There are other materials also available for you to learn about Open Payments. We have had multiple articles on the Medicare Learning Network. There's one that has already

been developed. There's multiple ones in the hopper right now, they're being developed and will be published over the course of the next few months. There is a *New England Journal of Medicine* that has already been published, and you can also access these through our web page.

Lastly, on page 53 is just a high-level summary of how you can access what and where. So, again our help desk is openpayments, one word plural, @cms.hhs.gov. Please use this. We are taking a lot of the questions that have been submitted and turning them into FAQs that are published for all to – so that we're sharing all that information with everyone. So please take a look at that.

Again, on our web page, there is general information; factsheets; policies; FAQs; mobile FAQs; links to our resources such as the MedScape, CMEs, the brochures, the teaching hospital list that Doug mentioned earlier; as well some other great tools available for you to access.

And our web page is listed there. Again, that's go.cms.gov/openpayments, one word plural. Thank you, Leah. That's all.

Question-and-Answer Session

Leah Nguyen: Thank you, Toula. Our subject-matter experts will now take your questions.

I'd like to remind everyone that this call is being recorded and transcribed, so before asking a question, please state your name and the name of your organization. In an effort to get to as many of your questions as possible, we ask that you limit your question to just one. If you would like to ask a followup question or have more than one question, you may press star 1 to get back into the queue, and we'll address additional questions as time permits. All right, Victoria, we're ready to take our first question.

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 you say or any background noise will be heard into the conference. Please hold while we compile the Q&A roster.

Your first question comes from Brad Nokes.

Brad Nokes: Hi, this is Brad Nokes. I work for Intermountain Healthcare. We own 22 hospitals, 5 of which are teaching hospitals. We use a single tax ID number for the majority of our operations, including all of our hospital operations.

We have heard that manufacturers, to be conservative in responding to this, will be reporting majority of payments to a tax ID. What do you recommend for us in our position?

Leah Nguyen: Could you hold on for a moment?

Doug Brown: Hi, Brad. This is Doug Brown. Why don't we submit that question through the help desk, and we will actually provide an FAQ on that particular issue.

Brad Nokes: OK. Appreciate that.

Leah Nguyen: Thank you.

Operator: The next question is from April Duley.

April Duley: Hi. I work for a manufacturer, and our question is, if we provide promo items to a physician such as mouse pads, for example, would this be reportable?

Doug Brown: Yes. That would be a reportable payment or other transfer of value.

April Duley: OK.

Leah Nguyen: Thank you.

Operator: Your next question is from Bobbi Southwood.

Bobbi Southwood: Yes. My question is, if you could give an example, possibly when drug reps provide lunches in the physician's office, and how that will be reportable, or if there's any exceptions to that?

Doug Brown: I'm sorry. Could you repeat your question one more time?

Bobbi Southwood: Yes. My question is, is we – at times we have educational lunches that are provided by manufactural companies, drug manufacturers, and where the physicians are present along with the employees. Are those going to be considered as reportable items? Or is there a certain dollar limit attached to those?

Doug Brown: Well, there is the dollar limit of \$10 or, you know, we can talk very briefly about small payments.

Bobbi Southwood: Yes.

Doug Brown: So, but I think your question sort of covers a few different areas. Number one, providing a lunch to a physician's office which will include the physician as well as any other employees that might also work in that office, those would be reportable only to the physician. So you would need to discern the value of the lunch provided to the physician and report that value in association with that physician.

However, if the lunch does not exceed the \$10 threshold, you would need to make sure that you kept track of that, and, if over the course of the reporting period that, you know, the aggregate of all payments or other transfers of value did not exceed \$100 for that particular physician, you would not need to report anything about that physician.

Leah Nguyen: Thank you.

Operator: Your next question is from Lea Harrison.

Lea Harrison: Hi. I work for a nonprofit foundation, and we do both CME and non-CME education for physicians. Now, we also – some of our programs are sponsored by manufacturers. How would that impact reporting?

Doug Brown: So, your organization provides CME, and sometimes those CME are sponsored by . . .

Lea Harrison: We sponsor the program so we receive funding, you know, from various manufacturers to support the program.

Doug Brown: I would first go back to whether it is – you're sponsoring it, and it is accredited or non-accredited?

Lea Harrison: We actually offer both forms.

Doug Brown: OK. Well, I would say that if it's accredited, then it would – the rules on accreditation – so the speaker fees and those sorts of things would not be reported. However, if it's not, you know, if it doesn't meet all of the criteria for being accredited, then yes, you would report that event both for speakers and attendees.

Lea Harrison: Because it's in part funded by a manufacturer.

Doug Brown: Yes. If the manufacturer is providing the funding to host the event and the – and that event provides a payment or other transfer of value – so, I think you're caught up in the other transfer of value issue, so yes, that would be reported.

Lea Harrison: OK, thank you.

Leah Nguyen: Thank you.

Operator: Your next question is from Andrew Rosenberg.

Andrew Rosenberg: Thank you. This is Andrew Rosenberg with the CME Coalition. There's significant confusion among CME commercial supporters regarding the treatment of attendee meals and beverages and refreshments. With regard to accredited CME events that meet the three criteria outlined for your Sunshine Exemption, how should event organizers and supports know how many people must participate in a

buffet-style meal to qualify as a group setting, as stated in the Q&A that you posted, for the purpose of avoiding the tracking or reporting requirement?

Different companies are setting different and conflicting numerical definitions. And also, by way of clarification, if a Sunshine-exempt CME event provides refreshment or food to physician participants in a non-buffet manner, or if it cannot provide it in a group setting so to speak, is it accurate that commercial supporters must only report these indirect payments once they become aware of the physician participant enjoying the meal? Or must the CME event organizers affirmatively monitor and provide identifying information about participating physicians to an event's commercial supporters? Thank you.

Doug Brown: Yes, excellent question, and these are actually things that we are internally working on as providing guidance. Your question covers several issues: number one, the distinction between large and small. We are working on guidance to help applicable manufacturers and GPOs and CME organizations specifically to make that determination. As well as your other – the other component of your question, of knowing or being able to sort of recognize when someone partakes of the other refreshments provided. So, we are currently – that is on our radar to prepare and provide guidance on this. And we will try and have that out as soon as possible.

Andrew Rosenberg: I appreciate that. Thank you.

Leah Nguyen: Thank you.

Operator: Your next question is from Lori Kaufman.

Lori Kaufman: Yes, I work for a manufacturer, and we provide education transfers of value to physician who – physicians who are part of a teaching hospital and also employees that are non-physicians at a teaching hospital.

My question is regarding the reportability. I know that the transfer of value for the physician has to be reported as an education transfer of value. But do we report it under the name of the physician, or does that go as a transfer of value to the teaching hospital?

And then the same question would apply for the non-physician employee—would that be a reportable transaction, but in the name of the teaching hospital only?

Doug Brown: OK. I do believe we have an FAQ that addresses that on our website. However, I would question to whom was the sort of payment made? If the payment was made to the teaching hospital in order to sponsor that event, then you would report on the teaching hospital.

However, if it was made out individually to both the covered recipient physicians and the non-covered recipient employees that received the training, then you would only report on the covered recipient physician.

Lori Kaufman: OK, thank you.

Leah Nguyen: Thank you.

Operator: Your next question is from Jim Christina.

Jim Christina: Yes. I have a question in regards to your accreditation certification requirements. In the final rule you identify all the physicians that are listed under Medicare, including MDs, DOs, DPMs, dentists, optometrists, and chiropractors. Yet – and in your proposed rule, there was no mention of an exclusion or any type of accreditation requirements, yet you came up with a fairly random list of accrediting bodies, and you did not include some of the recognized accrediting bodies by the Department of – U.S. Department of Education for other professions.

Can you explain how you did that, and also the fact that you have two listed on there, AMA and AAFP, that are not accrediting bodies?

Doug Brown: Sure. And I appreciate the question. We've been struggling with this, as well. We are – you know, we're – the way that the – I – our group cannot really speak to the way that the comment period and the final rule was developed. However, we do see that there are some opportunities in additional future rulemaking that we can ameliorate this problem.

However, given the way that the final rule is written currently, we are sort of stuck with where we are now.

Jim Christina: Can you expand on that further? Because it says, "Meets the accreditation or certification requirements," which some of these other organizations do have identical requirements, so technically they are meeting the accreditation or certification requirements.

Also, future rulemaking's going to be several years. We already have industry sponsors that have indicated they will not accept grant requests from any groups that are not accredited by those accredited bodies that you've already listed, essentially putting us at an unbelievable disadvantage to get grants for accredited continuing medical education.

Doug Brown: Well, first off, I would say that, you know, we're – we have – as we have been going through and trying to implement this rule, we have found a few places that we would like to sort of shortly address with rulemaking. So I would not sort of say that rulemaking is, out of hand, several years down the road.

So, I would like to – maybe we can just take this part of the conversation offline, and maybe set up an additional speaking engagement that we could sit down with you guys specifically.

Jim Christina: That would be great. Thank you.

Doug Brown: You're welcome.

Operator: Your next question is from Daniel Carlat.

Daniel Carlat: Hi. I'm Daniel Carlat from the Pew Charitable Trusts. I have a question about promotional payments. I noticed that you put an FAQ on the Open Payments website saying that a promotional – payment for a promotional speaking or for a speaker's bureau can be categorized in either of two ways—either as a service other than consulting or as an honorarium. And the decision about which category it should be in should be made depending on the quote “specific facts.”

And I'm wondering what kind of guidance you provide to companies to decide what facts are relevant to which category promotional speaking should be in, and also in the final website, how are consumers going to be able to decipher whether payments listed under these two categories are for promotional speaking or for something else? So, I guess I have two questions in that one question.

Leah Nguyen: Hold on for one moment.

Doug Brown: I think I can take a shot at at least addressing part of your question. As far as the way that you've made the determination as to whether or not the nature of payment is put into service or honorarium, we've asked that applicable manufacturers and applicable GPOs that are submitting their data, or – they have the option to also submit an assumptions document.

So if we are seeing that the industry is generally holding a standard course with regard to how they are classifying those payments, then we may determine to sort of provide some additional guidance in the future beyond year one to help further clarify and help guide applicable manufacturers in making a consistent determination as to where those categories – or where those payments are classified.

I think that the other part of the question maybe we do need to follow up and have a quick touch base with you guys, as well, on the remainder.

Daniel Carlat: Thank you.

Leah Nguyen: Thank you.

Operator: Your next question is from Brad Levin.

Brad Levin: Hi. My organization recently provided training at a teaching hospital. I think part of this question was asked before, but the training was delivered individually to a variety of radiologists.

So, while they work at the teaching institution, the training was delivered to this group of individuals. Does it have to be reported to the individual physicians or to the institution?

Leah Nguyen: Hold on for one moment.

Doug Brown: Could you repeat the question, please?

Brad Levin: Sure. We recently provided training to a group of radiologists on a software application that the institution owns. The training was delivered to the individuals, so it's our assumption that the transfer of value of the training needs to be documented and reported based upon the individuals that participated in the training. But does that also have to be aggregated as a transfer of value to the institution?

Leah Nguyen: Hold on one moment, please.

Brad Levin: Because of the – it's a teaching institution.

Doug Brown: Yes, I think I have a few followup questions for you. So, in this scenario was there actually a transfer of value made to the teaching hospital for which the training was provided? Was there some sort of payment for rent and that sort of . . . ?

Brad Levin: No. There was no payments. It was the training on the product.

Doug Brown: Right. So I think that in this case, you would report on the individuals that received that training, and the training would be the payment or the transfer of value.

So, if the entity itself is not sort of also capping on some sort of payment or fee that – charging for space and that sort of thing, then I would say that you're only reporting on the individuals.

Brad Levin: OK, thank you.

Leah Nguyen: Thank you.

Operator: Your next question is from David Vulcano.

David Vulcano: Yes, hi. Before the question, I just wanted to comment that – we seem to have been all over the CMS and Open Payments website, and we cannot find Publication 11710, which is the handout for instructions – or handout for patients. So we hope that that might be put in a more prominent space.

But the question—if an applicable manufacturer is offering research protocol training to a physician and part of that training is universal standards, such as FDA regulations or what we might call good clinical practices, that has commercial value outside of that research protocol training, is that included as a research payment, or does that need to be carved out as in-kind education?

Toula Bellios: So I'll take – this is Toula. I'll take the easy question, and Doug will take the hard question.

In terms of the publication, it'll be available by the end of the day today. There seems to be a delay in the release cycles of the refreshing of the web page, so if you don't mind checking back by the end of the day or first thing tomorrow morning, they should be available and up.

Doug Brown: So, as to your other point, I think unless those payments or transfers of value are part of the research agreement, then they would be reported on the general payments template or file specification.

David Vulcano: OK. So even if it had commercial value outside of the research, it would still be included in the research if it was part of the research contract, so to speak. Is that correct?

Doug Brown: Well, yes. Again, I would say if it's part of the research agreement, then you're reporting, oh, any associated payments or transfers of value using the research template. If it does go outside of that, then using the general payments template yet referring and identifying the research agreement for which it is connected to is appropriate.

David Vulcano: OK, understood. And then, on item number 36 of that research payment template, you know, this is an item that, you know, doesn't have – or seem to be able to hang its hat on anything in the Affordable Care Act Section 6002. Is – is this item something that is going to stick for this year? Because it's a tremendously burdensome item to do that we've not been able to find anything in Section 6002 to hang its hat on.

Doug Brown: Could you specify what that data item is?

David Vulcano: That item is further subdividing the payments into categories. They give six: professional salary support; number 2, medical research writing; number 3, patient care; number 4, non-patient care; number 5, overhead; and number 6, other.

Doug Brown: So, that's not a required field to be reported. So it's not necessary for you to report on that information.

David Vulcano: Yes.

Doug Brown: But if we – I'll put you on hold for – or mute for just a second while we describe the – we'll sort of make sure that we can describe the context in which that would be reported.

David Vulcano: Thank you.

Male: It's not required by the manufacturers, OK? One does not require (inaudible) to report it. And (inaudible) a lot of work to do. Of course, we could just say, "We'll charge you for it because it's not required," but I would still ...

Doug Brown: So actually, while we have that question come into the help desk, and we will sort of work on an FAQ around that, as well.

David Vulcano: That would be great. It's already been submitted to the help desk. So, I . . .

Doug Brown: OK.

David Vulcano: . . . hope that I can resubmit it.

Doug Brown: OK, great.

Leah Nguyen: Thank you.

Doug Brown: Thanks.

Operator: Your next question is from Mark Sherman.

Mark Sherman: Hello, can you hear me?

Leah Nguyen: Yes, we can.

Mark Sherman: Thank you. A medical products distributor representative who's not a manufacturer's representative sometimes brings in a meal and some descriptive product literature to my office to discuss several products from a couple of different manufacturers. And the literature is not for patient information. So will this distributor's representative report to CMS the value of the meal given to me and the value of the product literature given to me?

Doug Brown: Yes, if they – if they meet the definition of an applicable manufacturer, and it sounds like they do, whereby they are engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply. And as well as, you know, this also is sort of expanded to include distributors.

So, the entity that you're dealing with would have the option to report up to five of the covered drugs, devices, biologicals, or medical supplies most associated with the payment or other transfer of value. But you're right, they would report really separately, the literature that they have provided as well as the lunch, if they meet the definition of an applicable manufacturer.

Mark Sherman: OK. Well, I don't know. It would be a distributor representing several different companies that sells a variety of products.

Doug Brown: Right.

Mark Sherman: And obviously, I guess these manufacturers give the literature to the distributor, but I think the distributor buys the products and resells them.

Doug Brown: Right. We have in the definition that if they are holding title to the covered drug, device, biological, or medical supply, then they are in fact at that point an applicable manufacturer.

Mark Sherman: OK. And then, what – how would – do I need to ask the rep “So what’s the value of this product information sheet?” Because it sounds like if it’s – there’s some – even though it’s sort of educational, it’s got some value that has to be disclosed.

Doug Brown: Yes. For your own records, you should ask what the value of that literature is, as well as what the – the value of the lunch that they are providing.

Mark Sherman: Right. Thank you.

Leah Nguyen: Thank you.

Operator: Your next question is from Audrey Kotzur.

Audrey Kotzur: Yes. I work for a device manufacturer, and we were wondering about, when it comes to the 90-day loaner units, our units are able to be remotely turned off. And so first I was wondering, if they are remotely turned off on day 91, would we need to report that? And also, if we did need to report any devices out past 90 days, do we report on the sale price or the cost of goods price?

Doug Brown: Yes, I would defer that one to the help desk, as well.

Audrey Kotzur: I turned that in 2 weeks ago.

Doug Brown: OK.

Leah Nguyen: We'll be getting back to you soon. Thank you.

Audrey Kotzur: Sounds good. Thanks so much.

Operator: Your next question is from Marianne Hockema.

Marianne Hockema: Yes. Clarification on the discussion that you had about the training—if a hospital buys a piece of equipment which requires orientation by a manufacturer’s representative to use it properly, did I understand your prior answer to say

the value of that training is a reportable transfer of value to the physicians who are going to use that equipment?

Doug Brown: So . . .

Marianne Hockema: I'd assume it's included in the purchase price.

Doug Brown: Yes. If it's included in the purchase price, then no, that would not be reported.

Marianne Hockema: Thank you.

Operator: Your next question is from Alice Dong.

Alice Dong: Hi. With respect to payments that – and transfers of value that are associated with a product, it's a requirement that we report the NDC code. However, with many products, there are various NDC codes based on, for example, dosage or strength. Which NDC code should be reported?

Leah Nguyen: Hold on a moment.

Doug Brown: Yes, you'll report one NDC that matches the product. It doesn't matter exactly which NDC that is, provided – as long as it is in line with the product.

Alice Dong: Great, thank you.

Operator: Your next question is from Carlotta McKee.

Carlotta McKee: Hi. We're a nonprofit professional society, and we're comprised of stakeholders involved in CNS drug development. We specifically focus on clinical trial methodology, and one of our activities is to facilitate consensus group meetings. These meetings are directly supported through industry. However, they're not for the purpose of educating patients and they are not product centric. They're topic driven. And they're driving consensus regarding drug and device trial methodology.

Now, there may be an occasional prescribing physician that attends as an expert, but – and I'm wondering, since it's not topical, is this a reportable activity? And if so, do we then have to ask for the disclosure of ownership and investments for all drugs developed in this space? For instance, if the topic is improving cognition in schizophrenia, any investment in any companies involved in developing drugs in cognition and/or schizophrenia by all of the family members would have to be disclosed.

Doug Brown: So, first off, I would ensure that you're meeting the definition of an applicable manufacturer. And I would say that if you're making a payment or other transfer of value, even if that payment or other transfer of value is not in direct association with any specific drug—you know, you can kind of go back to the

distributor's example to have some additional context on this—but, even when they're not on a particular drug, anytime that that payment or other transfer of value is made is a reportable event.

Carlotta McKee: So, even though – so because it's supported by industry and even though we're a third party as a nonprofit professional society, you're saying if we have a physician attending as an expert, then it is a reportable. And they are – and they are – they have to report all of their – they have to disclose all of their investment.

Doug Brown: Yes.

Carlotta McKee: OK, thank you.

Doug Brown: You're welcome.

Operator: Your next question is from Laurie Churchill.

Laurie Churchill: Hi. I work for a manufacturer, and I understood it to be the case that there would be guidance on therapeutic areas forthcoming. Is that still in the pipeline?

Doug Brown: Yes, that it is still in the pipeline. We are shooting towards getting that out hopefully by the end of this month.

Laurie Churchill: Great, thank you.

Doug Brown: You're welcome.

Operator: Your next question is from Nicholas Copernicus.

Nicholas Copernicus: Yes, hi. This is Dr. Copernicus. Can you hear me?

Leah Nguyen: Yes, we can.

Nicholas Copernicus: Yes. I'm a pediatrics doctor and I know for most part that, you know, generally medicine says, like, 18 or older to be given out to. So, if sales representative comes into my office and gives me, you know, a pen or a paper product, is that going to have to be reportable even though I'm a pediatrician?

Leah Nguyen: Hold on one moment.

Doug Brown: We – typically, things like pens and paper are excluded from having to be reported. We're tracking down the exact reference within the final rule that we can point you to. But it doesn't sound like those would necessarily be reported. But, you know, the applicable manufacturer that you're meeting with will actually have to make sure that they are meeting this section of the final rule. So, this is, again, going back to the \$10

value, and the rule specifically identifies things like pens and notepads that are typically less than \$10 would not be reported.

Nicholas Copernicus: OK, thank you.

Doug Brown: You're welcome.

Operator: Your next question is from Sang Lee.

Sang Lee: Hi. I work for a manufacturer, and I had a question around family ownership and the reportability of that. So if there was a – I understand about stock options if that will be attributed to compensation so that would not be reportable. But with employee stock purchase plans, which are optional plans for employees to purchase stock, would that be reportable? And also, if they purchased stock on the open market, is that a reportable event? Would the employees have to disclose to us to then disclose to CMS?

Leah Nguyen: Could you hold on a moment?

Doug Brown: Could you just, again, walk through that question one more time please?

Sang Lee: Sure. I'm guessing that stock options and stock grants given as normal compensation or bonuses would not be reportable because that would be part of compensation. Please correct me if that assumption's wrong. Also if the employer offers stock purchase programs where the stocks would be granted to employees at a discounted price—you know, this would be an optional activity similar to 401(k)s or other programs like that—would those stock purchases be reportable to CMS if they are a family member of a physician? Also, if the employee purchased the stock on the open market, who is also a relative of the physician, would those open purchases be reportable to CMS?

Doug Brown: I think we're actually going to request that you send that question through our help desk. There were several components to that. Some might, you know – in some instances stock, you know – stock options are not reportable until those options are exercised, as well as you seem to have gotten into some employee–employer relationships that we would also need to take into consideration, as well.

Sang Lee: OK, thank you.

Leah Nguyen: Thank you.

Operator: Your next question is from Angela Harutunian.

Angela Harutunian: Hi, good morning. I have a question. We're a private practice here in Pasadena, and we do have pharmaceutical reps bringing in lunches, and we do have a total of sometimes eight people. So what is the minimum amount that I have to report in?

Doug Brown: Well, you're a private practice, you – you know, you're not reporting anything.

Angela Harutunian: Oh.

Doug Brown: Physicians and teaching hospitals do not report anything under this program.

Angela Harutunian: Oh, OK.

Doug Brown: Yes. The reporting requirement purely lies on applicable manufacturers of drugs, device, biologicals, or medical supplies and applicable group purchasing organizations, so . . .

Angela Harutunian: Oh, God, thank God. OK, great. OK, thank you so much. I was like, "Oh, no." OK, thank you so much.

Doug Brown: You're welcome.

Angela Harutunian: Bye.

Operator: Your next question is from Pam McIntosh.

Pam McIntosh: Yes. I had a followup question on the research payment template, item 36. We loan equipment to physicians that are researchers if they don't have a specific piece of equipment in their office. And I was wondering, how do we categorize loan of equipment if it's not part of their stipend for their services and research?

Doug Brown: So, it's not part of the research agreement, and it is a loan of a piece of equipment that is at least in some part associated with the research being conducted, is that correct?

Pam McIntosh: Well, the research agreement states that if they don't have a specific piece of equipment, the sponsor will supply it at no charge to the researcher, and then they use it during the course of the study. And they can either return it to us or decide to purchase it, whatever. Its situation isn't known at the time of the agreement. It's just that it will be out for more than 90 days. So I would have to report the value – the fair market value of having that equipment since it's provided at no cost to the researcher.

And my question is, how do I categorize that?

Doug Brown: So, a few things. If it's part of the research agreement then it is, number one, reported under the research template. And also, you would just factor in the value of the equipment that you provided as, you know – as part of the payment or other transfer of value.

Pam McIntosh: OK. And on line 36, where it says expenditure category, I know they said that it's not a requirement to break that down. But if I did break it down, would that go under, say, overhead rather than professional salary support?

Doug Brown: It sounds like it certainly would.

Pam McIntosh: OK.

Leah Nguyen: Thank you. Victoria, it looks like we have time for one final question.

Operator: Your last question is from Kim James.

Kim James: Hi. I am actually from a manufacturer, and I had some questions about free product. We give it to the hospitals and some of them are non-teaching hospitals. Does that have to have a physician associated with it?

Leah Nguyen: Hold on a moment.

Doug Brown: Yes, this is kind of a tough question to ask – or answer, based on the information that we have. So, you're making – you're giving these products to a hospital. I take it that it's not a, quote unquote “teaching hospital” or a hospital that's listed on our teaching hospital list.

Kim James: Correct. We have that list and we know that. We'll report on all those, but we do give them to the normal hospitals, the non-teaching hospitals.

Doug Brown: Yes, I think that we need to make a – need to make the distinction between an event like this, that you're purely giving it to the hospital, or is it really something that is affecting an indirect payment, that you're providing these to the hospitals with the intent – or causing them to be transferred to a physician-covered recipient.

Kim James: We would not have that information, it would go directly – we work with the hospital administrator, so we don't know the actual physician that would be using the product.

Doug Brown: So, based on just this limited information, it does not sound like that would be a reportable event.

Kim James: OK, thank you.

Additional Information

Leah Nguyen: Thank you.

Unfortunately, that is all the time we have for questions today. If we did not get to your question, please send it to the email address listed on slide 55. On slide 58 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 that you will take a few moments to evaluate your MLN Connects Call experience.

Again, my name is Leah Nguyen, and I would like to thank the presenters and participants of today's MLN Connects Call. Have a great day, everyone.

Operator: This concludes today's call.

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