

**Centers for Medicare & Medicaid Services
National Physician Payment Transparency Program (OPEN PAYMENTS):
What You Need To Know
Moderator: Aryeh Langer
May 22, 2013
2:30 p.m. ET**

Contents

Announcements and Introduction	2
Presentation.....	2
Background	3
ACA 6002 Overview	5
Program Operation.....	12
Specific Guidance	19
Resources	22
Keypad Polling.....	23
Question-and-Answer Session	23
Additional Information	30

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Operator: At this time, I would like to welcome everyone to today's 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: Hi, good afternoon, everybody. This is Aryeh Langer from the Provider Communications Group here at CMS, and I will serve as your moderator today. I would like to welcome you to the first National Provider Call on the National Physician Payment Transparency Program, or Open Payments. Today's National Provider Call is brought to you by the Medicare Learning Network, your source for official information for health care professionals.

During today's call, CMS subject-matter experts will provide information on the Open Payments program. This National Provider Call will include information on Section 6002 of the Affordable Care Act, or ACA, which requires manufacturers of pharmaceuticals or medical devices to publicly report payment made to physicians and teaching hospitals, creating greater transparency around the financial relationships that occur among them. A question-and-answer session will follow the presentation.

Before we get started, I have a couple of announcements. Links to the slide presentations for today's call were e-mailed to all registrants this afternoon. These materials can also be downloaded from the CMS MLN National Provider Call's Web page at 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 5-22-13 date, today's date, from the call list.

Secondly, this call is being recorded and transcribed. An audio recording and written transcript will be posted soon to the National Provider Calls and Events section of the MLN National Provider Call's Web page that I just mentioned.

At this time, I'd like to turn the call over to Dr. Shantanu Agrawal.

Presentation

Shantanu Agrawal: Thanks very much for that introduction. So, this is Shantanu Agrawal. I'm the Medical Director for CPI and the director of the group that's implementing this program. This is about ACA 6002, what was commonly known as the Physician Payment Sunshine Act, but now it's known as the Open Payments Program.

We are going to go through a presentation. You are going to hear a little bit later from Anita Griner, who is the deputy director of the group that's implementing this program. Hopefully, you have the slides, and then we'll kind of walk through the slides over the

course of the presentation. And after the slides are completed, I – we'll open up the phone lines for some Q&A.

I should note also that as we go through the various topics that we intended to cover today that we did receive a number of questions in advance of this call, and we have tried wherever possible to pepper in answers to those questions over the – just during the natural flow of the presentation. If you sent in a question and feel that it was not answered or adequately answered, you're welcome to ask again during the Q&A period or use our Help Desk, which we will provide the information for towards the end of the presentation.

So, thank you again everyone for attending. It is a long slide deck. We're hoping to really impart a lot of information to you. Hopefully, it won't be too tiring, and you have some coffee in front of you.

Background

All right, so I'm on page 6. Just to provide some background on open payments—this is a program about transparency and getting information about the volume and nature of financial relationships between the industry and physicians. So, the first few slides really just provide some general background on what the current state of collaboration is between industry and physicians.

You'll see on slide 6 that according to at least one survey that was published in the *New England Journal of Medicine* that a large portion of physicians, 94 percent, did report some type of relationship with the industry. Of course, that varies from basic meals to honoraria and research grants. Eighty-three percent of those physicians reported receiving food and beverages in the workplace as the primary type of relationship with the industry. And we have found in other materials that several billion dollars were spent by the pharmaceutical industry in both sales and promotional activities, a portion of which would be this kind of collaboration that we are describing.

It is very important—I will note it both here and frequently throughout the presentation—that there is no position really being taken on these collaborations by CMS. The purpose of our program really is about transparency. It is not to suggest that they are either beneficial or harmful universally. There are of course – are a lot of benefits that come from these kinds of collaborations.

Slide 7 talks about research, in particular, because it is an area of particular focus in the rule and in the program, which we will get to. I won't belabor the slide, but essentially, you know, the importance here is that a great deal of spending—national spending on research and development—really does come from commercial sources from the industry. And, again, that does hint at, of course, at the very beneficial nature that these collaborations can have.

The next couple of slides are on continuing medical education. So, CME courses were a major area that this rule did cover, and we will get into some detail about how continuing

medical education is handled. And, again, the point that we would like to make here is just that, again, a large percentage of continuing medical education has moved from historical sources of funding and support, which have been physicians, provider organizations, hospitals, to commercial funding, including many of the manufacturers and GPOs that will have to report data under our program to – you know, the portion of that CME funding can now be pretty significant – you know, 34 to 48 percent. Again, showing the really vital nature that some of these transfers of value can have in health care generally.

One of the reasons why there is probably a lot of public interest in these transfers of value or these relationships are the impacts that they can have downstream, again both positive and negative. This slide just tries to capture a couple of the impacts, going back to the original study that we cited of the percentage of physicians that actually had some kind of relationship with the industry. Of those physicians, 60 percent were also involved in medical education and about 40 percent were involved in creating clinical practice guidelines, which can show some of the impact of the collaboration and relationships that industry can have with physicians.

So, moving on to slide 10, in getting to a little bit more detailed discussion about CMS's program in particular, our purpose really is to promote data transparency. As I mentioned, cooperation between physicians and industry can promote discovery and development of new technologies that improve health. They can also create certain conflicts of interest that can potentially arise because of the financial ties between medicine and industry.

There is, of course, a delicate balance in the – in the impact that these transfers of value can have, but really, the purpose of ACA 6002, or Open Payments, is data transparency. It's not to take a position on whether the relationships are producing conflicts of interest or innovation. In fact, the answer is most likely, of course, both, and it's going to be a very heterogeneous and complicated picture. Our purpose is to provide the data that other people can view and analyze, as appropriate.

Moving on to slide 11, there are – for those who may not know, there are previous transparency programs that did do what 6002, or Open Payments, is now trying to do. Several States have created trans – their own transparency initiatives, some stemming for several years. And this slide just details several States and what their transparency programs kind of look like; it's just informational in terms of background.

Another major source of transparency to date have been – and now I am on slide 12 – Corporate Integrity Agreements. These are really agreements that OIG, HHS Office of Inspector General, has entered into with several companies, many of them pharmaceutical companies but also medical device companies, to require publishing very much Open Payments-type data on their Web sites or making it available to the public as part of the Corporate Integrity Agreement. And in addition to, of course, the companies that report under CIA, there are other – several other companies that have voluntarily opted to disclose their transfer of value information on Web sites and in other arenas.

ACA 6002 Overview

So, that is all in the way of background. Just to kind of get into the rule itself—I'm now on slide 14. And the overall objectives of the rule, as I have been hinting at, it does require a few things. It requires annual reporting of payments or other transfers of value. And we'll kind of get into what all these specific terms mean—they are terms that come from the rule themselves, but we'll try to translate them into things that are more comprehensible. Payments or other transfers of value between manufacturers—applicable manufacturers and physicians and teaching hospitals—and again, we'll try to unpack a bunch of those terms.

It also requires reporting of physician and close family ownership and investment interest in applicable group purchasing organizations, and applicable manufacturers. So, taken together, those first bullets basically say any financial relationship, you know, whether they're payments or other transfers of value between manufacturers and physicians or teaching hospitals, and ownership or investment interest between GPOs and manufacturers and physicians or their close family members.

For those physicians that have ownership interest, this rule also requires GPOs to report any payments or transfers of value they make to those physicians in particular. After this data is reported to CMS, again, on an annual basis, we will – we are required in the rule to display the data on a publicly available Web site.

So, slide 15 just gets into broad strokes about how this program will work. In essence, the industry will continue to conduct business as they do, they will make payments and transfers of value to physicians and teaching hospitals. They will then be required to collect information about those payments and provide that information – submit that information to CMS.

The primary center within CMS that is responsible for implementing this program is the Center for Program Integrity. And CPI will then work to aggregate the data in a way that will be described a little bit later and make it available on a public Web site.

So, on slide 16, we're going to just walk through some of the – more details about the program so that we can help to all make you aware about some of the specifics of the rule, not just the kind of high-level stuff that I just covered. So, slide 16, who is reported about? The answer is really these three categories of covered recipients. They are physicians, teaching hospitals, and then we will, for the purposes of this slide, talk about physician owners or investors only because they are very important, especially for the group purchasing organizations.

So, physicians are the entire set of physicians listed in the first bullet in black text there – so doctors of medicine, osteopathy, dentists, dental surgery, podiatry, optometry, and chiropractors. There's a few very specific issues that I would point out that I think are really important for this program and important for you all as stakeholders to understand. First, the rule really covers all physicians. It does take a Social Security Act definition of

physician, which really accounts for all the types of physician that I just discussed. But it does not really matter if the physician is enrolled in Medicare or Medicaid or not.

So, you don't have to have a prior relationship. You don't have to bill Medicare or Medicaid in any way to be involved and implicated in this program. What you really need is to be a physician as described in one of those bullets and to have active licensure. And if you meet that criteria and you received transfers of value from the industry, you will then be reported about in this program. Also, I think important to note is that the rule specifically excludes residents, or those individuals that are currently in undergraduate medical education. And it excludes those physicians that are employees of applicable manufacturers.

Teaching hospitals are defined as any institution that receives a payment under Medicare, either a direct Graduate Medical Education payment, or GME; or the inpatient hospital prospective payment system Indirect Medical Education payment, the IME; or the psychiatric hospital IME. And we will – as we will cover in a couple of slides, we will be – or we have provided a list of teaching hospitals. And basically, we are required to do that on an annual basis, so that applicable manufacturers know who to report data on as far as the teaching hospitals go, and we will make that available – information available for the most recent calendar year that we have information for internally.

Physician owners or investors, and by nature – by extension, their family members because family member – close family members are implicated in the rule. We will cover that in just a few slides. But these are what's listed in this third category – third column on the page are the various kinds of ownership or investment interest that are covered under the rule and that would qualify a physician or a family member as being an owner or investor and therefore, implicated and reported.

So, I think a major takeaway perhaps, especially for the providers on this phone call, is that physicians and teaching hospitals are what is reported about. They are not actually the ones doing the reporting, which we will get to in a couple of slides.

I should also say, and this is in answer to a couple of questions that we received; the program really does cover just physicians and teaching hospitals by statute. It does not apply, for example, to other mid-level providers such as nurse practitioners or physician's assistants. It also does not apply to health insurance plans. It is really focused on applicable manufacturers, applicable GPOs, physicians, and teaching hospitals. And we'll get into some definitions of applicable manufacturer and GPO.

So, slide 17 covers examples of transfers of value that are specifically delineated in the rule themselves. I think for those folks on the call that are really aware of the kinds of transfers of value that occur, many of these will look very common. So, for example, food and beverage transfers of value, gifts, honoraria; there are also of course consulting fees, compensation for services other than consulting, travel and lodging support, education, research, grants. There's a – the whole host of transfers of value that are

actually covered on this page need to be reported on about physicians and teaching hospitals.

Slide 18 – oh and let me, I’m sorry, on slide 17, I am going to go back and just make a couple of additional points. There was a specific question that was sent in advance about consulting. I think what we would say in response to that question is that it did seem to be highly scenario-dependent, and we would encourage you if there was a specific scenario that the questioner is concerned about, to actually use our Help Desk. It – there was not enough detail in the question for us to be able to address it now, and we will provide you the e-mail address for our Help Desk at the end of this presentation so that you can do that.

There was also some additional questions that we got on stock options and how to value stock options. Those are questions that we have received before to our Help Desk, and we have a Frequently Asked Question that is currently under development that is going through CMS clearance that we hope to release soon that will address that.

And let me address specifically group meals. This is a question that has come up actually several times. It is important to note that we really are only interested in the transfers of value that actually go to physicians. So, in the example of a group meal where several people partake of a meal, we really want to know the per capita cost of the meal and only have it be reported under the physician’s name that actually partook of the meal.

I hope that makes sense. But essentially, we don’t want to just divide up the cost of the meal over the one or two or handful of physicians that might be in the room. It’s meant to be divided up over all the people that ate the meal and then to have only the portion that is really consumed by the physician to be reported under this program. I hope that makes sense. If it doesn’t, please feel free to ask again at the end.

The teaching hospital is – I’m now on page 18. So, CMS is required to post a list of teaching hospitals so that manufacturers and GPOs have knowledge of what to report – who to report about. CMS has posted such a list for the purposes of the first data collection year, and it’s available at the Web site that’s provided for you on this page. It’s available in both Excel and PDF formats.

Just a quick couple of details about it, there were over a thousand teaching hospitals that met the definition laid out in the rule of receiving GME or IME payments that are provided in the list, and what we did provide is hospital name, address, and tax-payer identification number, or TIN. And those are the identifiers essentially that would – that manufacturers and GPOs would have to use in order to report the data back to us about the transfers – about the relevant transfers of value.

This will be—the teaching hospital list that we provided online—will be valid for the entire first program year – the first program cycle, which will be – and I’ll get into some of the details about the actual dates that are important. But the – essentially, the first program year will start in terms of data collection on August 1st and extend through the

end of 2013, and so this teaching hospital list will be good for that entire period. For 2014, we will post any changes or updates by October 1st for that – for 2014, and then of course, by October 1st of every consecutive year for future data collection years.

All right. So, now, moving on to page 19, who does the reporting? So, you have heard a lot about what – who is reported on. These are the entities that actually have to do the reporting under this rule. They are applicable manufacturers and applicable group purchasing organizations.

In bolded text at the top, in the top box, is the definition that's provided in the rule of these various entities. So, manufacturers are those entities that operate in the United States and that have – that either produce or prepare at least one covered drug, device, biologic, or medical supply. The coverage in this case I'll get to on the next slide in terms – or in the next couple slides in terms of a detailed definition, but essentially, it must be covered by Medicare, Medicaid, or CHIP, or this entity must operate under common ownership with another applicable manufacturer.

So, there are two ways of getting in. Broadly speaking, an entity could be an applicable manufacturer in its own right by meeting this definition, or as the first kind of sub-bullet indicates, the entity might be under common ownership, which is defined as a 5-percent ownership interest with an applicable manufacturer that would therefore also implicate it in the rule.

There is, I think, some important takeaways on this that manufacturers, I think, are already aware of, but once you are determined to be an applicable manufacturer, meaning you meet the criteria in bold and you produce at least one device, product, drug that is covered by Medicare, Medicaid, or CHIP, then you must report transfers of value to physicians or teaching hospitals on all of your products.

So, let me just repeat that to make sure people understand. Having one product that is covered by Medicare, Medicaid, or CHIP kind of gets you in the program, but then you are required to report data about all your products – about any transfers of value going to physicians or teaching hospitals for all your products.

The major exception to that—because every rule needs a good exception—is what we are terming the 10-percent exception, which is essentially that if the applicable manufacturer has less than 10 percent of their gross revenue coming from covered products, then they only need to report those transfers of value that are related to those covered products. That's the only way to kind of – or that's the major exception we're really getting out of reporting transfers of value on all products.

And I think importantly from the standpoint of manufacturers, we certainly heard throughout the rulemaking process that manufacturers are able to submit consolidated reports, meaning one report for several different applicable manufacturers or manufacturers that are implicated through common ownership. This is, I think, for ease of reporting by the manufacturers, but an important takeaway for physicians is that when

you go to review data – and we will talk, I keep promising, about these huge topics that we will cover, but we will also talk about data review and dispute.

When physicians go to review their data prior to public posting, it may be actually posted under the name of the submitter of the data; that may actually not be the manufacturer that provided the transfer of value. So this is an important caveat to note and will be something important for manufacturers and physicians to communicate about so that physicians understand the transfers of value that were reported in their name.

Moving on to the second column, group purchasing organizations. These are entities that operate in the United States and that purchase, arrange for, or negotiate the purchase of covered drugs, devices, biologicals, or medical supplies. And this definition does also include physician-owned distributorships, which purchase products for resale.

So, slide 20 is just kind of a very broad summary, hopefully an easier takeaway of a lot of language that I have been providing you up until now. This just covers when, you know, who is required to report and under what conditions. And I think what I would focus on is the applicable group purchasing organizations column for a second. They do have to report ownership or investment interest held by physicians and immediate family members. They also have to report payments or other transfers of value made to physician owners or investors. Importantly for them, they do not have to report payments or other transfers of value made to physicians and teaching hospitals who have no ownership stake whatsoever. Applicable manufacturers are required to do that, but that is an important area of difference between these two reporting entities.

All right. Actually, there was a question that I meant to cover on slide seven – on slide 19, let me back up for a second. We did receive a question about independent clinical laboratories and whether they were required to report. And again there was, it seems, some situational dependence here on exactly what the laboratory was doing. Well, we would say we actually do really defer to these definitions, and if the laboratory meets the definition of either being an applicable manufacturer, either independently or under common ownership, or a group purchasing organization, then it would be implicated. And if does not meet the definition, then it would not. If you would like to submit more kind of situational information in order to help us – help – in order for us to help you make that determination, you're welcome to do that at our Help Desk.

All right. So, moving on to slide 21, what is a covered product? So, these are the definitions of covered products that are from the rule itself. There are two broad categories – drugs and biologicals, and also devices and medical supplies.

I think for brevity I won't read through the entire thing, but essentially what matters for drugs and biologicals, while – and practically in both categories – is that Medicare, Medicaid, or CHIP make payments available for the product either separately or as part of a bundled payment, and that there be a prescription or a physician order in order for that drug or biological to be dispensed.

For devices and medical supplies, I think just an important detail that was in the rule is that part of the definition, in addition to the payment coverage by Medicare, Medicaid, or CHIP, is that it really do require – it does require pre-market approval or pre-market notification to the U.S. Food and Drug Administration. That should cover what is a covered product.

Now, what is reported? So, we'll get into some more operational details. Anita Griner will do that in the next section of this presentation, but essentially what the rule lays out in terms of what is reported to CMS about each transfer of value – it's the various information that is on this slide.

So, we need to know, for example, information about who the transfer of value was made to—the covered recipient, be it teaching hospital or physician. If it's a physician, we need to know their specialties, their National Provider Identifier, the NPI, and their – and state licensure information. All of that is to help identify the physician specifically, so we know exactly what physician that transfer of value's referring to.

For teaching hospitals, again, we require the name of the teaching hospital, the TIN, and the address, but all of that is available through the teaching hospital list that we provided. In addition to knowing who the payment was given to or the transfer of value was given to, we need to know the nature of the transfer of value itself—the amount, the date, the form of the transfer of value. This is specific sort of terminology from the rule, meaning, was it given in – as cash? Was it given as a cash equivalent or some other form of transfer of value? And then the nature of the transfer of value. And that is essentially the reason why the transfer of value was given.

So, it goes back to the various types of transfers of value that I covered in previous slides. You know, for example, a nature could be a consulting fee, the honorarium, a grant, a meal. If the transfer of value was made in connection to a specific drug, device, biological, or medical supply, then we would need to get information about that drug, device, biological, or medical supply.

Second major bullet on this page are payments related to research. We did, for many reasons, pull research out separately from other kinds of general transfers of value, and Anita will get into a little bit more of how and why that is. But essentially, payments related to research would also need to be reported, many of the same information that I already covered for the other kinds of transfers of value. But we would also need to know the name of the institution receiving the payments and the principal investigator, if that principal investigator is a physician.

For ownership and investment interests, there's a separate reporting style for that, and again, many of the same pieces of information that I've already covered. We need to know how to identify the physician that has the ownership or investment interest, the nature of that ownership or investment interest, whether it's held by an immediate family member, and then any payments or other transfers of value made to that physician owner or investor. And I should note here that the rule does really require reporting of the data if

there's an immediate family member that has the ownership or investment interest, but we do not on the public Web site – we will not release the name of that family member, really it will be a Web site focused on the physicians themselves.

Importantly, on slide 21 is what is not reported. So, this is a list of the major categories or types of transfers of value that are not reportable. A couple of things that I would highlight here: So transfers of values that are less than \$10 are not reportable. Again, every rule does need an exception. So, the only exception there is if in aggregate over the course of a year, a number of transfers of value worth less than \$10 aggregate, as long as they are the same nature and form and provided by the same manufacturer or GPO. If they aggregate to more than \$100, then it would need to be reported either as one single transfer of value in excess of \$100 or the disaggregated amount of each transfer of value. But generally speaking, transfers of value less than \$10 do not need to be reported.

Product samples, including, for example, medication samples, do not need to be reported. I think related to that, discounts including rebates do not need to be reported. Educational materials that directly benefit patients, or other products that is really provided of direct value to patients are not reportable. And in-kind items – again, just this is one more thing to highlight on this page, in-kind items used for charity care are not reportable.

All right. So over the next few slides, we're just going to provide some examples of what some transfers of value are and how they could be reported. Again, this is not meant to be comprehensive. It's meant to really be illustrative, so that people have more of a real-world connection to what we've been talking about.

We give – you'll see in slides 24, 25, and 26 that we have kind of various cases of transfers of value – several examples, and what we've tried to do is underline what, you know, could be the reportable payment or transfer of value in these cases. Again, this is really illustrative to make it a little bit more real for folks on the call, but we refer to the rule as far as the very specific guidance.

So, take, for example, on slide 24, the first case, reporting of any transfers of value between applicable manufacturers and covered recipients. So, we have a physician named Dr. Smith who attends a lunch that I think for the purpose of this example really has to be hosted by the applicable manufacturer, with say her clinical team, perhaps even office staff, to discuss a new drug. She is impressed by the drug, spends several months traveling and speaking to promote it, with expenses and honoraria that are also covered by the manufacturer. So, in this case, the initial meal would be a transfer of value that could be reportable, as well as the sort of longer-term collaboration that she has with the manufacturer that would include all of the expense support, as well as any additional honoraria. There might, of course, be other kinds of transfers of value, but this is just one example.

Another example on page 25 – so this is specifically about manufacturers and teaching hospitals. So, you know, the example is esteemed teaching hospital, ABC University

Teaching Hospital, receives \$10,000 from a drug manufacturer for—as a grant or for the purposes of research—that would also become a reportable transfer of value.

The final example is really concerning—or the next two examples are really concerning—ownership and investment interests. The first is in GPOs, and so in this example, Dr. Smith's sister—perhaps even the same Dr. Smith from the first example—is a direct investor in a major medical device manufacturer. In other words, the sister – the sibling has direct ownership interest. That becomes – that ownership interest then becomes a reportable ownership interest in the confines of this program.

There is another example of Dr. Jones who is given a – who has ownership interest in a GPO that is then – subsequently receives an honorarium from the GPO to speak at a conference. And again because this involves a GPO and – it only really is reportable because Dr. Jones is already an owner, and therefore the honorarium to speak at a conference is also a reportable transfer of value.

All right. So that is a lot of background just in terms of the rule itself; hopefully as much as possible that has been clear. I'm now going to turn it over to Anita Griner, who is going to walk us through a lot of the operational steps of this program.

Program Operation

Anita Griner: Great. Thank you, Shantanu. Good afternoon, everybody. This is Anita Griner, I'm the deputy group director for the team here in the Center for Program Integrity implementing this regulation. And in the first half of the presentation, you've heard a lot about the background of the program and the specific nuances of the rule and rule language. In the latter half of our time together, we'll focus on operational outlines for the different business functions that we'll be rolling out, as well as timelines, and then we'll talk to you about some specific guidance and some resources that are available for you.

So, I'm on slide 28, and this graphic really depicts six major business functions that we'll be rolling out from the operations of this program. I will then deconstruct each of these in subsequent slides, but to give you a high-level picture with the number 1, the first thing that you will encounter either if you are a applicable manufacturer, group purchasing organization, physician, or teaching hospital, is a function for registration. We'll talk later about the voluntary nature of registration for physicians and teaching hospitals, but it is required for applicable manufacturers and group purchasing organizations that have information to submit to CMS.

After registration, there will be the data submission and attestation process. Following that, there will be a period of time we will make available to physicians and teaching hospitals who have registered with CMS to come in and review their information. And if they feel that their information is inaccurate or incomplete, they have the capability to dispute such data.

Disputes are then routed back to the applicable manufacturer who submitted the information, who we hope will then resubmit corrected information. Number 5 is really the entire nature of this program and in the fact that it is attempting to create transparency we will be publishing this data on a CMS Web site that will be available for the public.

Subsequent to that, there will be a period of auditing and penalties as well as appeal rights for anyone that has been audited or levied penalties against. So again, we'll talk about each of these in detail following.

OK. So moving on to slide 29, let's dive a little bit down on the data collection process. Let me first start by saying that the data collection that is going to occur will be collected by the applicable manufacturers and group purchasing organizations. Physicians and teaching hospitals do not need to collect or track any data, although we will talk about some recommendations that we have for them to track this as well for their own record-keeping purposes.

There will be three types of templates or lists of data that we will – we have made publicly available, and we talked about them earlier. The three types are the general payment data collection, so these are for data that are not research transfers of value. The second type is a research payment data collection template, and the third type is ownership and investment interest by physicians and family members.

And the data templates themselves, which are publicly available—the link is coming up—include information about the specific data elements that need to be collected, descriptions and definitions of the data elements, including what file formats are valid, descriptions of whether each element is required or optional, and other information to help aid in the data collection process. Again, data collection will occur by the applicable manufacturers and GPOs.

Slide 30 gives you the link for where you can go to locate the details behind these data templates, and let me clarify that when we use the word “template” what that means—these are not tools for the applicable manufacturer to physically enter data into, these are lists of data elements and descriptions of such data to help aid them in creating their data collection tool.

The non-research general template captures consulting agreements with physicians that are related to a clinical trial, but are not part of the clinical trial protocol or written agreement. That was a specific question that was submitted to us, so we wanted to clarify that consulting agreements that do not – are not backed by clinical trial protocol or written agreements should use the non-research or general template.

We did also get a question around the collection of NPIs for teaching hospitals, and that will not be required. We will be requiring that the TIN, which we have made publicly available on our teaching hospital list, be what is used in the data submission.

So, moving on to Slide 31, just to reiterate some of these points around the data templates. So, the applicable manufacturers and GPOs will use these three different templates in different ways.

So, the – the applicable manufacturers will use the general payment data collection to report payments and transfers of value to covered recipients. Again, these are physicians and teaching hospitals that are not research-based transfers of value. The same will be used by applicable GPOs to report general non-research payments to the physician owners or investors. Now, if it is a research-oriented transfer of value, both of these parties, the applicable manufacturers and group purchasing organizations, should use the second template, which is the research-based data collection template.

The third template specifically will capture data about the investment interest withheld by the physician or close family member. To reiterate a point that Shantanu made earlier, the names of the individual family members, non-physician, will not be posted on the Web site, although they will be collected. We will know that it went to a family member of the physician in the data template itself.

OK. So, that is what will be collected out in the industry by the applicable manufacturers and GPOs. So, registration is the next function that we'll talk about, so this starts on slide 32. The first slide on registration is focused on – around the red box, which includes the applicable manufacturers and applicable GPOs.

So, what will happen for them is that they will register with CMS. It is required that they do so if they have data to report. So, for example, the 2013 reporting cycle, which starts August 1st of this year and goes through December 31st, if you are an applicable manufacturer or GPO that has data to report from that period, you will be required to register with CMS. And the registration process for you will open in early 2014, and it will extend for the entire data submission period, which we're anticipating to be approximately 90 days. And then in subsequent years, we envision having the same registration and start and end dates as the first year.

Now, slide 33 is the same discussion, but with respect to the physicians and teaching hospitals. Now again, registration for physicians and teaching hospitals is voluntary, but we do encourage physicians and teaching hospitals to register with CMS because this affords them a very important opportunity to then review their data prior to public posting and dispute data that they feel is inaccurate. So, it's very important that physicians register, and you can register at the same – through the same mechanism, which will be on our Web site, as the applicable manufacturers and GPOs.

We did receive a question about physician group practice registration that we wanted to address. So, we can't – or we will not be allowing for bulk registrations, so a group practice cannot come in and register their entire practice. Each physician will come in and register for themselves. And we also had a question around data collection – or let me – let me come back to that in just a minute. So, that concludes the registration piece.

And now let's move on to submitting the data, so how the data will be submitted to CMS. So, this is on slide 34. So, for the applicable manufacturers and the applicable group purchasing organizations, they will submit the data about transfers of value or ownership interest to physicians and transfers of value to teaching hospitals to CMS.

The physician and teaching hospitals do not submit data to CMS. Again, I'll say that one more time. The physicians and teaching hospitals will not be required to submit data to CMS. This is the role of the applicable manufacturers and GPOs. So data submission will happen immediately after your registration, and it will extend for a period of 90 days, and we are anticipating this cycle to be from January 1st through March 31st of each year. Now, the physicians and teaching hospitals can come in any time after the registration process happens, and then the tables will turn to the applicable manufacturer or GPO to submit the data. There is no applicability for data submission for physicians or teaching hospitals.

I will make one note about something that we call consolidated reporting. And so, the applicable manufacturers, they are under common ownership. They can actually submit one report to CMS on behalf of all the entities that are subject to reporting that are under common ownership. So, this will hopefully make reporting more streamlined for large manufacturers and GPOs that have multiple subsidiaries, for example.

So, moving on to slide 35, which is data attestation. So, for each submission that the applicable manufacturer or GPO submit to CMS, they must attest that the data is timely, accurate, and complete.

The attestation requirement applies to all first-time submissions of data and any resubmissions of corrected data. Now, the attesters must be the appropriate designated officer within the applicable manufacturer or GPO, such as the chief financial officer or the chief information officer or chief compliance officer. Somebody at that appropriate level will need to do the attestation on behalf of the applicable manufacturer or GPO.

And back to consolidated reporting, another note is that if you are submit – if you are an applicable manufacturer or GPO submitting a consolidated report, you will attest to all of the contents of that consolidated report on behalf of all the entities that are included in your consolidated report. All of the other entities included do not need to come in individually and attest to the data that the consolidated reporter submitted about them.

And CMS will consider the most recent attested data from the applicable manufacturer or GPO as the final submission. So, if an entity comes in and submits data but neglects to attest to such data, CMS will not consider that data finalized. We'll provide additional information about the attestation process later on in this calendar year.

OK. So, now let's move in to the next function, which is the review, dispute, and correction. And this is, of course, predicated on registration. So, everyone that has registered with CMS—this includes the voluntary registration for physicians and teaching hospitals—will be able to come in and review applicable data.

So, the applicable manufacturers and GPOs will be able to review the data that they submitted or that was submitted on their behalf by a consolidated reporter, and very importantly, the teaching hospitals and group – and physicians will be able to come in after registration and view the data that was submitted about them from all of the participating or applicable manufacturers and GPOs.

This is a very important process. We want to underscore our recommendation that all the physicians and teaching hospitals take the opportunity to go through this voluntary registration so that you can come in and see your information prior to public posting. You can dispute such data that you feel is inaccurate or incomplete. We will then route such disputes back to the submitter of the information that we hope will then resubmit and reattest to the information so that our data is going to be as accurate as possible.

We did have some questions around the pre-submission review process. There was mentioned in public comment about the possibility of CMS mandating such a pre-submission review, but CMS has not mandated that in the regulation. But we do encourage the physicians and teaching hospitals to request a pre-submission process from the applicable manufacturers and GPOs that you interact with so that you can even get an earlier view of the information prior to their submission to CMS. And so, we encourage for you to request that or if you are an applicable manufacturer or GPO, we encourage you to provide such a function for your physicians and teaching hospitals.

Slide 37 is the second part of this review, dispute, and correction process. So, let me mention a few kind of duration points of note. Slide 36, you'll see that this is days 1 through 45. So, after the data submission window closes, so for example on March 31st of 2014, the data submission period will close, and then we will be opening up a 45-day review and dispute process. Corrections can also be made during that time. That time is specific for the physicians and teaching hospitals to review and dispute and any corrections that can be made as well.

There is a subsequent 15-day period that is discussed on Slide 37, which is just for the correction process. So, this allows for any disputes, for example, that were issued in the latter part of the 45-day cycle, so day 41 or 42; this allows for the applicable manufacturers or GPOs to have an additional 15 days just to address those late-breaking disputes.

And slide 38 discusses the data publication function. So, as was discussed, the regulation requires that we make the data available on a public Web site. I want to bring back the dispute discussion for just a moment to make the point that disputed data will still be made public. It will, however, be marked as disputed.

Any corrections that are made to the data by the applicable manufacturer and reattested to will then override that original dispute and will not be marked as disputed on the public Web site. That's an important note.

The data that we will post on the Web site must per the statute and regulation be searchable, aggregatable, and downloadable. So for example, we will make available certain files that you can download from the Web site. You can also view reports that are searchable and aggregatable by physician and by several other characteristics.

The data will be posted for the first reporting cycle, which is 5 months of data for 2013, will be posted on a public Web site by September 30th of 2014. And for subsequent implementation years, so for the full calendar year of 2014 for example, the data will be posted on June 30th. For the first year, September 30th will be the date of public posting, but in subsequent years, it will move and be earlier, on June 30th of each subsequent year.

So, the last function in our operational flow is the audits and penalties and also the appeal process. And so, applicable manufacturers and GPOs are required to keep all their records relating to payments or other transfers of value and also for ownership interest for at least 5 years from the dates the payment or transfer of value are posted. So that is a record retention note for applicable manufacturers and GPOs.

CMS also will be able to levy, in certain situations, civil monetary penalties, or CMPs, against the reporters for not reporting information in a timely, accurate, or complete manner. And then there's another category which we'll talk about that has a higher penalty, which is knowing failure to report information in a timely, accurate, or complete manner.

Now, before we get into the amount of penalty, let me make the very important note that the providers and teaching hospitals will not be audited or penalized relating to this program. The audits and penalties and future appeal rights are subject to the applicable manufacturers and GPOs only. Providers will not be levied penalties against.

So, there are two broad situations. The CMP, civil monetary penalties, are different in each of these circumstances. So, in this chart on slide 39, you'll see that there is a civil monetary penalty of at least \$1,000, but no more than \$10,000, with an annual maximum of \$150,000 for failure to report each payment or other transfer of value or ownership or investment interest in a timely, accurate, and complete manner. However, knowing failure to report each payment or other transfer of value or ownership or investment interest has a higher penalty of at least \$10,000, but no more than \$100,000, with an annual maximum of \$1,000,000.

And bringing back up the consolidated report for just a moment. The penalties are levied against the data submitter, so this would be the entity that submitted the consolidated report. The levy – the penalty is levied against them, and the penalty applies for each entity that is in that consolidated report. So, if there are 10 entities inside of the consolidated report, and five of them are subject to a civil monetary penalty in one of those two categories, that compounds the amount. And the penalty is levied against the data submitter of the consolidated report.

OK. So now, let's move into a bit of a timeline for how all this is going to roll out. So, on slide 40 you'll see some dates of note that correspond to these functions that we've just discussed.

So, 2013 is going to be a condensed data collection period. It's going to start on August 1st and run through the end of December, so it will be 5 months of data reporting for 2013. Subsequent years will be full 12-month periods, but the first year is a condensed 5-month period. The data collection will begin on August 1st.

Then the registration process will open up for applicable manufacturers, GPOs, physicians, and teaching hospitals in very early 2014, and then the statutory deadline for applicable manufacturers and GPOs to submit the data to CMS is March 31st of 2014. So that is the deadline for data submission. Then there will be that 45-day and the 15-day correction period that will follow the data submission.

We are anticipating for those periods to be approximately the second quarter in 2014, and then the public – posting of the data on the public Web site will occur by September 30th of 2014. So, that is the rollout of the 2013 5-month condensed reporting cycle.

Those timelines are also denoted on slide 41 in a graphical fashion so that you can see how they're – how they roll out, starting with the data collection by the industry, moving into the data submission, and obviously registration predicated the data submission. CMS will then take all those submissions and aggregate and get that data ready for review and dispute. There's the 15-day appendage for the dispute resolution and then public posting of the data by September 30th of 2014.

Now, the 2014 program cycle—I'm on slide 42—as I mentioned will be a full 12-month period, but the dates changed slightly so I'll point out some of the differences and the timeline depicted here will be the timeline for all subsequent reporting years for 2014 on. So, in a normal year, there will be a year of data collection, so in 2014 that would be January 1st through December 31st.

Then in 2015, a registration and data submission period will occur, CMS aggregation of the data and the same 45-day and 15-day dispute, review, and correction period will follow the deadline of data submissions, but the public posting date is much earlier in 2014 and the following years, so that date is June 30th of 2015. So, it will be June 30th for every year except for the first year.

So, hopefully that helps give you a bit of the operational picture of the different functions and how you can get involved and should be involved in each, and our next section is on some specific guidance on areas such as research delays in publication, indirect and third-party payments, and some other areas we've received some questions on.

So, I'll turn it back over to Dr. Agrawal to walk you through that.

Specific Guidance

Shantanu Agrawal: Thanks, Anita. So, you've heard about the high level of the program and a lot of the key operational milestones. There were just four areas that we were covering here, and I'm going to try to cover them quickly so that we have some time for Q&A.

These were areas that were of particular import to the rule that we also did receive a lot of questions about, so we just wanted to cover them. There's a lot of other topics that we cover in the rule, but this was the initial four that we thought we'd cover.

So, research is the first couple of slides, starting on page 44 of the deck. There – the rule really tries to take a balanced approach towards research in order to balance the interest that we have in data transparency about the transfers of value and also not stymieing any innovation that these collaborations can really produce.

So, the rule offers very specific definitions, and based on the specific definition of research, it is possible for a manufacturer or GPO to indicate as they are reporting a research-related transfer of value that that research transfer of value needs to be delayed in terms of public reporting or publication on the Web site.

So, they will be giving us, of course – manufacturers or GPOs will be giving us the – a lot of information about the research-related transfer of value, the amount of the research payment included in the research protocol, at – who the principal investigators were for example—all of that is contained in the data template that Anita described, but they will then have the option of – if they meet certain criteria that is spelled out in the rule to delay the public release of that information in order not to stymie innovation. And that delay will be good for up to 4 years or until the drug, device, or biological under investigation achieves FDA approval, whichever comes first. So, that is delay of publication with respect to research.

There's a, I think, an incredibly important area for physicians to be aware of, which is indirect payments. So, many of the examples that we had discussed earlier and that I think physicians will inherently be familiar with are direct payments, those that are – that go directly from a manufacturer or GPO to a physician or teaching hospital.

However, indirect payments are also possible. So, the question on page 46 was if the applicable manufacturer directs or instructs that the payment or transfer of value is made to a covered recipient, is this reportable? And the answer is yes.

So, on slide 47, you can see that if a manufacturer or GPO actually makes the payment or transfer of value to an intermediary, let's say a specialty society or some other intermediary, who then provides that payment or transfer of value to a covered recipient, meaning a physician or teaching hospital, then it suddenly becomes a reportable transfer of value as an indirect payment.

Slide 48 shows you what is reported. So for the kind of standard indirect payment approach, what would be reported is the covered recipient that ultimately got the transfer of value that originated with the applicable manufacturer or GPO. That includes, of course, both teaching hospitals and physicians.

There's a little bit of a summary on page 49. So again, an indirect payment is one that goes from a manufacturer to a physician or teaching hospital through an intermediary, again like a specialty society or perhaps even a research organization.

The payment is considered indirect and reportable—importantly, and reportable—if an AM or GPO requires, instructs, directs, or causes the intermediary to provide the payment or other transfer of value to a physician or teaching hospital. That definition is very important because it turns the relevant indirect payments into reportable indirect payments.

In those reportable circumstances then, the manufacturers would be required to identify each physician who received the payment or transfer of value and report that appropriately as they would any other direct payment or transfer of value.

So, that was really quick on indirect payments, but let me cover now continuing medical education. This was obviously a really important aspect of the rule. Again, to try to strike a balance between transparency and stymieing I think a really important collaborative activity between the industry and physicians and teaching hospitals.

So, certain kinds of continuing medical education are actually not reportable under this rule. They are actually part of the exception. In – I think, let me start with the bottom half of this page. There are three important criteria that must be met to even consider – for consideration of not reporting CME activity.

The first is that the program meets the accreditation or certification requirements of specific organizations that are discussed in the rule. The second criteria that must be met is that the manufacturer does not select the recipient speaker and does not provide the third-party vendor with the distinct identifiable set of individuals to be considered as speakers for the CME activity. And third, the manufacturer does not pay the covered speaker directly.

So, in the event that these three criteria are met, the actual cost of, you know, the payment or other transfer of value that's provided to the faculty or speaker for the CME is not a reportable transfer of value. As far as attendees go, those that are watching the CME program, any payments made to them to subsidize the cost of attendance is also not reported, and again those three very important criteria must be met in order for these transfers of value to not be reportable.

Slide 51 covers when CME actually is reportable. So, for an attendee, that would be any payment or transfer of value that is not actually subsumed under the CME itself, that is kind of an adjacent activity—that would be reportable. For the faculty or speaker, that's

any payment or transfer of value that is covered in the rule. And again the most salient thing in terms of CME are those three criteria, so if any one of those three criteria are violated, then it becomes a reportable transfer of value as it relates to CME. As long as those three criteria are kept, then the specific transfers of value that we've discussed in slide 50 would not be reportable.

There was a question about, I guess in the CME context, a price-fixed speaker program dinner and what happens if a person who registered for the dinner did not therefore show up. So I think the answer that we have contemplated here is very straightforward. We are really only interested in actual transfers of value that occur between manufacturers, GPOs, and physicians and teaching hospitals. So, if you didn't show up, no actual transfer of value occurred and therefore nothing would be reportable.

All right. Third-party payments—last major topic. There are quite a few slides on this. This can be a confusing area, so let me just take some time to cover it.

Third-party payments as distinct from indirect payments are situations in which the covered recipient, let's use the example of a physician, actually designates or requests that somebody else get the payment. In other words, that the payment or the transfer of value go to a third party. So, the physician could have worked with a manufacturer, have received an honorarium as a result of that collaboration and then the physician him or herself designates that payment to go elsewhere—that would be a payment made to a third party.

So, essentially the question on page 53 is, if that were to occur, really what is reportable to CMS? And what's important on page 54 is that if the covered recipient makes the designate – you know, requires or requests that the manufacturer or GPO actually make the payment to a third party, then both the covered recipient would be reported to CMS, as well as the organizational name of the third party that actually received the transfer of value, or if there's an individual that received that transfer of value, what we would get from the manufacturer in their data report is the term "individual." We would not get the specific name of the individual, but just that it went to a third-party individual.

Let's take as another case the situation in which the covered recipient, again the physician let's assume, waives the payment or transfer of value. In other words, they had some kind of collaboration with the manufacturer or GPO, but they actually decide to waive that payment, and the manufacturer then provides the payment to another covered recipient, let's say another physician. What would that – be reported then in that case?

In that case, what would be reported is really that other covered recipient. And it would almost fall into the rules for an indirect payment in a sense. The first covered recipient who waived or declined the payment would not be publicly reported at all.

Finally, the third situation is when the covered recipient, again a physician, waives the payment, and the manufacturer basically holds on to the payment or the transfer of value. No payment or transfer of value is provided to anyone.

In that case, essentially nothing is reported to CMS. Neither the name of the covered recipient nor any kind of generic information about the transfer of value would have to be reported because ultimately it did not leave the confines of the manufacturer or GPO.

All right. With that, just the last couple of slides, I'm going to turn back over to Anita to give you some ideas of some resources that we have at your disposal.

Resources

Anita Griner: Great. Thanks. And for the latter – the last part of this presentation really is about some guidance that we have, as well as some tools and training and resources that we have made available.

So, slide 60 is really our guidance to the physician or teaching hospital about what your role is in this program. So again, the physicians and teaching hospitals are not required to register with or send any information to CMS for the Open Payments program, but we do encourage you all to do so, and there's a checklist here of some things that we'd like for you to consider.

The first is – you're accomplishing through this mechanism today, which is become familiar with the information about the program and also what will be reported about you. The way that you can become familiar with the program, we'll talk about resources and Web sites and factsheets and other tools that we have for you to become familiar, but becoming familiar with the data that will be reported about you is a job that you'll have as soon as the data collection window opens on August 1st.

We encourage you to keep records of all these payments and transfers of value that you may receive from an applicable manufacturer, and ownership interest and payments from group purchasing organizations that you may be an owner in. We encourage you to keep accurate records so that you can then compare those records against what the applicable manufacturers or GPOs submit.

We'd like for you to register with CMS. Again, this is voluntary. And we also have a listserv and a Web site, so we encourage you to subscribe to the listserv and then look at the information submitted about you after your registration process concludes and make sure that the information is correct. And if it's not, you will be able to dispute the data.

Slide 61 just makes physicians aware of the fact that we have created a continuing medical education through Medscape, and you can qualify for one credit and additional information can be found at the link below.

Slide 62, we do have a Web site, which we've referenced numerous times. The URL is here. It's go.cms.gov/openpayments. And we also have a Help Desk where we encourage you to submit any questions that you may have about the program, and that address is openpayments@cms.hhs.gov.

The Web site has a lot of valuable resources about the program, including factsheets, the data templates that we discussed, the list of teaching hospitals, and other Frequently Asked Questions and definitions, so I encourage you to visit that site at your leisure.

So, with that, I think we'll turn it back over to our moderator for some questions and answers.

Keypad Polling

Aryeh Langer: Thank you very much. At this time, we'll pause for a few moments to complete keypad polling so that CMS has an accurate count of the number of participants on the line with us today.

Please note there will be a few seconds of silence while we tabulate the rules – the results, excuse me. We're ready to start polling.

Operator: CMS greatly appreciates that many of you minimize the Government's teleconference expense by listening to these calls in your office using only one 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 between 2 and 8. 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 continue to hold while we complete the polling. Please continue to hold.

Thank you for your participation. This concludes the polling session. We will move now – we will now move into the Q&A session for this call.

Question-and-Answer Session

Operator: To ask a question, press star followed by the number 1 on your telephone keypad. To remove yourself from queue, please press the pound key.

Remember to pick up your handset before asking your question to assure clarity. Please note, your line will remain open during the time you're asking your question, so anything you say or any background noise will be heard in the conference. Please hold while we compile the roster.

Your first question comes from the line of Denise Andresen.

Denise Andresen: Hi. If a manufacturer pays a consultant firm to provide services directly to a physician group so the payment itself isn't passed on to the group, but the value of the services is, is that an indirect payment?

Aryeh Langer: Will you please repeat the question?

Denise Andresen: Oh, I'm sorry. If a manufacturer pays a consulting firm to provide services to a physician group and so the consulting firm does not pass on the payment to the physician group, but does provide services to the physician group free of charge, is that an indirect payment?

Shantanu Agrawal: Yes, I think. Thanks for your question. I, in talking internally – sorry, this is Shantanu Agrawal for the purposes of the transcription.

In talking internally, it really does depend on if the consulting service itself meets the definition of a transfer of value, where the sort of fair market value of that consulting service would then have to be reported since it did ultimately go to covered recipients. That would make it essentially – you know, what you're describing giving just the details that you gave, it does sound like it could meet the criteria of an indirect payment.

So, I just encourage you to look at that part of the rule and also just the definition of transfer of value. Since it went to a group, there is also a relevant part of the rule where – which discusses how the payment should be divided up among the physician members of that group, so I'd just refer you there as well.

Denise Andresen: Thank you.

Shantanu Agrawal: Thank you.

Operator: Your next question comes from the line of Kara Drolet.

Aryeh Langer: Go ahead.

Kara Drolet: Hi, I think that's probably me. My question is about registration on behalf of a teaching hospital. Is there any – will there be any limit to the number of people who can register to receive, or to be able to do their pre-review on behalf of the teaching hospital?

Shantanu Agrawal: Currently, what we envision for the program is a primary – again just to highlight what Anita had said earlier, this is a voluntary activity. We do envision a primary registrant for the teaching hospital if they would like to voluntarily do so, and then we would make a backup also available so that if, you know, there would be no, be – there would not be any continuity issues in case the primary point of contact, you know, disassociated themselves from the program or from the teaching hospital. So, currently, we envision two possible registrants for every teaching hospital. And this was Shantanu Agrawal for the purposes of the transcription.

Operator: Your next question comes from the line of Danielle Sloan.

Danielle Sloan: Hi. My question is regarding the covered devices that are covered by the program. The definition for covered devices includes, as you said, devices that require pre-market approval, pre-market notification, and are covered by Medicare or Medicaid or any other – or CHIP, either separately or under a bundled payment. What about devices that are not themselves covered by the program, but the tests that they perform, including like an X-ray machine or an MRI machine—are they considered devices or medical supplies that are captured by the rule?

Shantanu Agrawal: Hi, this is Shantanu Agrawal. Thanks for your question. This was a question that we also did receive to our Help Desk, whether from you or another source, but it was certainly a question that came up commonly. So, we are currently formulating some guidance on that, which is going through CMS clearance, and please look for it in the next few days. We hope to release it pretty soon.

Danielle Sloan: OK. Thank you.

Shantanu Agrawal: Thanks for your question.

Operator: Your next question comes from the line of Louise Alessi.

Lois Almasi: Ah, very close. It's Lois Almasi. Greetings.

There are a couple of spots in the rule that state exclusions that are available at large-scale conferences and events, but there doesn't seem to be a definition of what large scale is, so I'm wondering if you have any guidance on that.

Aryeh Langer: Just give us 1 minute to discuss please.

Lois Almasi: Sure.

Shantanu Agrawal: All right. I'm looking – this is Shantanu Agrawal again – just looking around at the team. So we also did receive this very specific – this exact same question to our Help Desk; it's also going through clearance. We do have a specific answer, but we want to clear it internally before it's released. So, do look at the Web site at the FAQ section, and both this question and the other question that I referenced will be addressed as soon as we can.

Lois Almasi: OK. Thank you.

Shantanu Agrawal: Thank you.

Operator: Your next question comes from the line of Roger Smith.

Roger Smith: Hey, good afternoon. I'm just curious if you have something as generic as an unrestricted educational grant being given by an applicable manufacturer to a college of medicine, is that a – is that a reportable event?

Aryeh Langer: Just give us 1 second please.

Shantanu Agrawal: Hi, Shantanu Agrawal. The rule does discuss totally unrestricted grants made to, I think, as in your question, to a medical society or some other intermediary.

As the rule kind of—I'm sort of paraphrasing the rule—if it's completely unrestricted and there really is no direction on the part of the manufacturer or GPO how the money be spent, then most likely, again dependent on some other variables, it becomes – it does not become a reportable transfer of value.

But, I think – I'd encourage you to just look at that section of the rule to make sure that you, you know, you understand the complete definition of unrestricted, and for any particular situation that the grant support provided by the industry actually does meet the requirement of being unrestricted in its entirety before you deem it to be non-reportable.

Aryeh Langer: We'll take the next question please.

Operator: Your next question comes from the line of Alice Dong.

Alice Dong: Yes. Hello. I had heard a number of sources saying that for accredited CME events, that reporting on attendee meals would still be required. Is that true?

Shantanu Agrawal: So, we have received, and I apologized to have to sound a little bit like a broken record here. This was also a Help Desk inquiry that came in. We are working through that actually right now and don't have a specific answer quite yet, but we will provide some additional guidance on this question.

So, this question did come in about attendee meals and then other transfers of value that were related to CME, so we're going to try to tackle it in one piece of guidance that is pending pretty soon.

Alice Dong: OK. Thank you.

Shantanu Agrawal: Thanks.

Operator: Your next question comes from the line of Karen Kellogg.

Karen Kellogg: Hello. My question is in regards to research payments. So if a manufacturer provides research payments to a research group, is that amount reported only under the principal investigator's name, or can that amount be divided among all the physician participants in that clinical research?

Shantanu Agrawal: So, what the rule currently requires as far as research payments is reporting the recipient of the research payment, whether it's teaching hospital, physician,

or frankly non-covered recipient if that's the situation, than reporting of the primary investigator – I'm sorry, the principal investigator or investigators, again assuming that that is a physician.

As far as the division of the – I think it really does depend on the specific research protocol, how you choose to divide it and what – you know, and if truly there are numerous principal investigators, some of whom may be physician and non-physician so some of this is going to be highly situational and really dependent on the specific nature of the project and the way it's set up. But I refer you to just kind of the general section of the rule that talks about how to report these transfers of value, and then if you wanted to send us a more specific inquiry about a particular protocol, we'd be happy to look at that.

But I think it does, based on the question that you're asking, sound like it really depends on the, you know, whether the – how many people are actually recipients of the money – of the payment or the transfer of value directly, and how many of them actually carry the title of principal investigator. Those are the two most substantive aspects of reporting research payments.

Karen Kellogg: OK. Thank you.

Shantanu Agrawal: Thank you.

Operator: Again, if you would like to ask a question, simply press star 1 on your telephone keypad.

Your next question comes from the line of Tony Bentivegna.

Tony Bentivegna: Yes. I had a question regarding the value of reprints.

We want to track reprints that we distribute to our physicians during the sales or detailed call, but a lot of times those reprints are available to the physician free of charge either through their institution or through the AMA or whatever organization they may belong to, so we're trying to determine the value of the reprint.

I know it's a discernible economic value on the open market, but the value to the physician will be zero because he can actually obtain it for free. I just want to see what your input would be on that.

Shantanu Agrawal: Hi, yes. This is Shantanu again. This directly reflects a Help Desk inquiry that we got, I don't know, perhaps you sent it in or somebody else did, but this is an often-asked question.

We are working internally with our colleagues to develop a specific answer to that question. So again, like the others, I apologize. I have to ask you to stay tuned just so that I don't say anything on the call that doesn't hold to be true in guidance later on, but we are hoping ...

Tony Bentivegna: No, I understand.

Shantanu Agrawal: ... to get that out very quickly.

Tony Bentivegna: Thank you.

Aryeh Langer: Thank you.

Operator: Your next question comes from the line of Rosanne Model.

Rosanne Model: Hello. Thank you. If a covered recipient appoints an event organizer to receive payments for booth space at an industry event at that covered recipient's place of business, such as a teaching hospital, and we do not direct that the event organizer transfer over our payment to the teaching hospital, would you then say that the cost for the booth or for whatever else is not reportable?

Aryeh Langer: Can you give us 1 minute please?

Rosanne Model: Sure. Thank you.

Aryeh Langer: Can you repeat the question?

Rosanne Model: Sure. Often, we will be asked by a teaching hospital to pay their appointed event organizer for the booth space or for whatever other sponsorship-type activity we're participating in at the teaching hospital's event. We do not – so we pay the appointed event organizer rather than an organization, such as the Mayo Clinic, OK?

We don't tell the event organizer what to do with the money. We don't know if they pay it over to the Mayo Clinic or what portion they keep themselves. In that case, do – is this a reportable or trackable and reportable pay – transfer of value?

Shantanu Agrawal: And when you say we, are you – are you talking about ...

Rosanne Model: Oh, I'm sorry. I work for a – I'm an applicable manufacturer.

Shantanu Agrawal: Got it. OK. Hold for 1 minute.

Rosanne Model: Mm-hmm.

Shantanu Agrawal: OK. Thank you for your question. This is Shantanu Agrawal again. You know, based on the details that you've provided, this really does sound like an indirect payment and probably would be reportable then under that definition.

If there is other salient factors, you know, aside from what you've described that you think might change that determination, then, you know, feel free to use our Help Desk,

but based on what you described I do think this seems like an indirect payment to the teaching hospital.

Rosanne Model: OK. Thank you.

Shantanu Agrawal: Thank you.

Operator: Your next question comes from the line of Matt Adlai-Gail.

Matt Adlai-Gail: Hi. Thanks for taking my question. The question is, if we need to update a record that was – that was already sent in to Open Payment, like say it was – it was disputed and then a charge was changed or removed or something like that, how do we go about sending updates of expense records that were previously sent in to Open Payments?

Shantanu Agrawal: Yes, great question. Thanks for that. Shantanu Agrawal again.

So, I assume you're speaking from the vantage point of an AM or GPO, and we are looking into establishing the specific system capabilities that would do that. We're trying to make it as user friendly as possible so that, you know, we are looking to a few options of doing another large data dump if necessary, if there are a lot of corrections to make. Or if there's relatively few, we are looking into whether we could have a more kind of direct interface with our system that would allow you to make those changes directly.

So do look for some additional guidance on that as we continue to build our system, and we will also have additional technical outreach calls for AMs and GPOs for questions like that where we can also discuss other aspects of the system and the implementation.

Matt Adlai-Gail: Thank you.

Operator: Your next question comes from the line of Deborah Lyle.

Deborah Lyle: Yes. Good afternoon. I had a quick question.

You had said that nurse practitioners were exempt; they didn't fall under the physician category. And I just wanted to double check that that also extends to dentistry, so we have dental hygienists or dental assistants or other people within the dental office, is that correct or incorrect on my part to assume that?

Shantanu Agrawal: Hi, this is Shantanu. That is correct. So, dental hygienists and dental assistants would not be covered by this rule.

Deborah Lyle: OK. Thank you.

Shantanu Agrawal: No problem.

Operator: Your next question comes from the line of Gary Shangold.

Gary Shangold: Yes. Hi. Thank you. I'd like to follow up with a question in the research context.

If a pharmaceutical company is conducting a large, multicenter clinical trial, and they engage a contract research organization to set up, execute, and manage that study on their behalf, they have a budget, which entails multiple payments to the CRO over a period of time. Some of that money ends up being paid out to the principal investigators at each site. Other parts of that payment may go to laboratories that do diagnostic studies, and still other parts of the monies paid are retained as management fees by the CRO.

What's more, the payments to the investigators may occur in a multiyear trial in a year that's subsequent to the year in which the payment is made by the pharmaceutical company. Does this now entail a – another layer of reporting in fact, not to you, but from the CROs to the pharmaceutical company sponsors in order to get precisely when each payment to each principal investigator is made?

Aryeh Langer: Can you hold one – for one moment please?

Shantanu Agrawal: Hi, this is Shantanu. Thank you for your question.

The rule does specifically talk about contract research organizations playing the role that you're describing. As you laid out the scenario, the portion of the transfer of value, the research support that actually goes – ends up going to a covered recipient would be reportable under this program.

Again, as you described, you know, the amount that goes to the principal investigators would be reportable, and that would include, of course, both physicians and teaching hospitals. So, yes, it does entail the kind of tracking and reporting of data as you described, but again, I would emphasize just the portion that actually went to covered recipients. Does that address your question?

Gary Shangold: OK. Thank you.

Shantanu Agrawal: Thank you.

Gary Shangold: Yes, I think it does.

Additional Information

Aryeh Langer: Thank you. Unfortunately, that's all the time we have for questions today. If we did not get to your question, you can e-mail it to openpayments@cms.hhs.gov, excuse me, openpayments@cms.hhs.gov. This e-mail address is also mentioned on slide 62.

On slide number 64 of the presentation, you'll find information and a URL to evaluate your experience with today's call. Evaluations are anonymous and strictly confidential.

I should also point out that all registrants for today's call will receive a reminder e-mail from the CMS National Provider Calls Resource Box within 2 business days regarding the opportunity to evaluate this call. You may disregard this e-mail if you have already completed the evaluation.

Please note, evaluations will be available for completion for 5 business days from the date of today's call. We appreciate your feedback. In addition, as mentioned earlier, an audio recording and written transcript of today's call will be posted soon to the CMS MLN National Provider Calls Web page.

Again, my name is Aryeh Langer. It's been a pleasure serving as your moderator today. I want to thank our CMS subject-matter experts here and those who participated and called in with their questions. Have a great day, everyone.

Shantanu Agrawal: Thank you.

Operator: This concludes today's conference.

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