

Centers for Medicare & Medicaid Services
Special Open Door Forum:
Open Payments Notice to Inform Future Rulemaking
Tuesday, August 2, 2016
1:30-3:00 pm Eastern Time
Conference Call Only
Moderator: Jill Darling
August 2, 2016
1:30 p.m. ET

Operator: Good afternoon. My name is (Stephanie), and I will be your conference operator today. At this time, I would like to welcome everyone to the Centers for Medicare and Medicaid Services Open Payments Notice to Inform Future Rulemaking Special Open Door Forum.

All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer session. If you would like to ask a question during this time, simply press star, then the number one on your telephone keypad. If you would like to withdraw your question, please press the pound key.

Thank you.

Ms. Jill Darling, you may begin your conference.

Jill Darling: Thank you, (Stephanie).

Good morning and good afternoon, everyone. Thanks for joining us today for the Special Open Door Forum, Open Payments Notice to Inform Future Rulemaking. We do appreciate your patience. I know that we had a few delay messages, as always we're waiting for folks to get in and so that they are able to hear the whole presentation for today. So, thank you again.

I do have one brief announcement. This Special Open Door Forum is not intended for the press, and the remarks are not considered on the record. If

you are a member of the press, you may listen in, but please refrain from asking any questions or comments during the Q&A portion of the call. If you do have inquiries, please contact us at press@cms.hhs.gov.

I will now hand the call over to Merri-Ellen James, the director of Data Sharing and Partnership Group.

Merri-Ellen James: Great. Thanks, Jill.

The Data Sharing and Partnership Group is the group within CMS that administers the Open Payments program. And first, I would like to thank all of you today for joining us in our efforts to gather stakeholder feedback and support future rulemaking.

I am sure most of you are familiar with the Open Payments program. It was created by the Affordable Care Act. It requires drug, device, biological and medical supply manufacturers to report on payments or transfers of value and ownership and investment interest held by physicians and their immediate family members.

Since the publication of the Open Payments final rule, various stakeholders have provided feedback to CMS about the aspects of the Open payments program. We have identified some of the areas – some of the areas in the rule that might benefit from revision or expansion. In order to consider the views of all stakeholders, we solicited comments, which is the Physician Fee Schedule, to inform future rulemaking in the proposed 2017 Physician Fee Schedule. We do not intend to finalize any requirements related to Open Payments directly as a result of the proposed rule. But, we do expect to conduct further rulemaking. We would like to use today's special open door forum to collect – to collect and engage with the program stakeholders and gather feedback on items contained in the proposed 2017 fee schedule. Again, thank you, all, for joining today.

I am going to hand it over to Erin Skinner. She will walk you through the items which we are seeking feedback. Each item is contained in the

presentation material. If you do not have a copy of the presentation, you can find the link on the Open Payments homepage. After Erin has provided context to each of the questions, we will open the line to hear your feedback. And, again, thank you, and I appreciate your time today and your patience.

Erin?

Erin Skinner: Thank you, Merri-Ellen.

And thank you, all, for joining us today.

I am going to start on slide three, for those of you who have the materials. This slide shows the nature of payments categories which we finalized in the Open Payments final rule. These are required for reporting under the Affordable Care Act. And these are all categories that payments or transfers of value can be attributed to. We do have a separate reporting template in the Open Payments system for research payments, which does not permit for the nature of the research payment to be further categorized.

So, turning to slide four, you will see that in the proposed 2017 Physician Fee Schedule, we have asked if the nature of payment categories are inclusive enough to facilitate full reporting. If not, we are curious to know if there are additional categories that will be helpful to include. We are also curious to know if it will be helpful for industry to be able to similarly categorize research payments or if it will be helpful for the covered recipient physicians and teaching hospitals to review research payments if they were similarly categorized.

Turning to slide five, I'd like to talk about how we are currently speaking to the reports on payments or transfers of value for prior years. We are curious to know how long it is reasonable to require reporting entities to continue to report on payments or transfers of value or ownership or investment interest. Basically, we want to know when a company can close the book on a past program year. We recognize that there are several factors at play here, including the five-year record retention requirement that we have in our

regulations and the delay in publication for payments related to research. With these considerations in mind, we are asking how long companies should be required to continue to monitor and report on past program years for the purposes of Open Payments.

Now, on slide six, we know that the Open Payments program is required to publish the prior program year's payments or transfers of value and ownership and investment interest on June 30 of each year. We also refresh all of our data around the beginning of each calendar year. We are curious to know how many years of data CMS should continue to publish and refresh. How many years are useful to our stakeholders and how many years will be useful as a static downloadable file available as an – as an archive? We recognize that the delay in publication exception may pose an exception to these publication rules as well.

Continuing to slide seven, we are also looking for feedback on whether all applicable manufacturers and applicable group purchasing organizations, or GPOs, should be required to register each year. Currently, we only require registration if a payment or transfer of value or ownership or investment interest will be reported. We would also like feedback on whether or not we should receive – whether or not entities should be reporting data on the reason why they are not reporting transactions. So, if we have annual registration for all applicable manufacturers and GPOs regardless of whether or not payments will be reported, we'd like to know if we should capture the reason that there will be no reporting.

On slide eight, we are getting some information on pre-vetting of payments. Of course, one of the goals of the Open Payments program is to increase transparency within the health care industry. To contribute to this goal, we are interested in receiving feedback on a proposal to require applicable manufacturers and GPOs to pre-vet payment information with covered recipients and physician owners prior to the submission of the payment record to CMS. We believe that this may help to contribute to the accuracy and the validity of the data and increase participation in the program. We are also

curious to know if entities are currently pre-vetting payments and, if so, how that process is carried out and to what extent it is already put into practice.

Slide nine in the material shows the current definition of a covered recipient teaching hospital and explains the way that CMS currently identifies the universe of entities that are considered covered recipient teaching hospitals for Open Payments purposes.

So, on slide 10, we are seeking feedback on the particular hurdles that the current definition of a teaching hospital poses. We are also asking for new proposed definitions or elements of a new definition. Any feedback that stakeholders can provide to facilitate the complete, accurate and timely reporting of payments or transfer of value to covered recipient teaching hospitals will be appreciated as we understand from reporting entities that the current definition of a covered recipient teaching hospital presents operational hurdles.

Moving on to slide 11, we have also heard that covered recipient teaching hospitals have difficulties verifying payments or transfers of value. We'd like to know if it would be helpful to add a new non-public data element to assist with the review period. Should the new field be mandatory, and what information should we be capturing to facilitate the payment review?

On to slide 12. We are curious if the current reporting cycle, which requires submitting data once annually for the previous program year by no later than the 90th day of the following calendar year, is ensuring successful and complete data submission. We would like to know if ongoing earlier or incremental data submissions would be more helpful.

On slide 13, you will see that we are also looking for feedback on how to change or add reporting requirements to ensure that entities can properly and easily represent mergers, acquisitions, corporate organizations and reorganizations or other structural corporate changes that occur throughout a program year.

Slide 14 illustrates how we currently define the dollar amount invested in our 2016 data submission mapping document for both ownership interest and investment interest. The dollar amount invested is one value which the statute requires reporting entities to report for each physician ownership or investment interest.

Similarly, slide 15 shows how CMS currently defines the value of interest in our 2016 data submission mapping document. This value of interest is another value that the statute requires reporting entities to report for each physician ownership or investment interest. With this basis of understanding, we recognize that stakeholders have difficulties reporting ownership and investment interest and have found it confusing or difficult. We would like to know, recognizing that the values have to be reported, if there are ways that we can make these definitions more operationally feasible. We would also like to know if there are any additional terms that could require additional clarification.

Physician-owned distributors are discussed on slide 17. Most of you are probably aware that physician-owned distributors, or PODs, are subject to Open Payments reporting requirements. We are seeking feedback on a couple of items regarding PODs. Is there a good definition for a POD for Open Payments reporting purposes? We are also curious to know what data elements a POD should have to report and which portion of that data that has been reported should be made public on the Open Payments Web site.

So, I just finished running through our specific list of items that were included in the proposed 2017 Physician Fee Schedule. As Merri-Ellen explained, the purpose of this open door forum is to receive feedback on future program initiatives and rulemaking and to particularly address those items identified in the fee schedule solicitation.

Slide 18 in your presentation material provides you some resources that are available to you that relate to the solicitation in the proposed fee schedule. There is also help desk contact information if you have general questions about the program or data submission.

Finally, on slide 19, we have some final reminders that the Open Payments program does conduct periodic Webinars and Q&A sessions which are announced through our Listserv. You can sign up through our Web site. The Open Payments Web site is also where you can find additional resources to learn about the Open Payments program.

We think we are ready to get started with gathering some live feedback from our callers. I'd just like to remind everyone once again that our purpose here today is to gather feedback on future program, rulemaking and system changes. If you have questions about the Open Payments program, you can address them to the contacts provided on slide 18. Thank you.

Jill Darling: Thank you, Erin and Merri-Ellen.

(Stephanie), we will open up the lines for comments, please.

Operator: Certainly.

As a reminder, ladies and gentlemen, if you would like to ask a question, please press star, then the number one on your telephone keypad. If you would like to withdraw your question, please press the pound key. Please limit your questions to one question and one follow up to allow other participants time for questions. If you require any further follow up, you may press star, one again to rejoin the queue.

Your first question comes from the line of (Jodan Molstein) with Intermountain Health.

Your line is open.

(Jodan Molstein): Hi. Thank you for taking my question. I work with a hospital system with five teaching hospitals, and we have run into the issue that you talked about with being hard to determine which teaching hospital is receiving which payment. I really like the idea of adding a new non-public data element to do

this. And my suggestion would be potentially a Medicare provider number because that is something that is split. And just to add to that, one of the complications that we have is all of our hospitals are under the same tax ID number. And when I disputed or asked questions to the manufacturers, they said that they were able to pull the data by tax ID number. And, so, they couldn't tell me specifically which of my five hospitals it was. And, I think, the Medicare provider number would alleviate that concern.

Erin Skinner: OK. Great. Thank you. That is very helpful feedback.

Operator: Your next question comes from the line of Coleman Martin with Saint Luke's Hospital.

Your line is open.

Coleman Martin: Hi. I like to think that I represent the largest group of physicians, which are those who don't take any payments at all from industry. The current system doesn't allow us to opt out from taking payments. So, therefore, we are required to log in on a yearly basis. Is there any movement to allow the log in and review process of our record to be easier than what it currently is, such as to notify us if we have been identified as having taken payment from industry?

Erin Skinner: So, that is helpful feedback. We are constantly striving to make sure that the registration and review and dispute process is streamlined and easy for the covered recipient physicians. You do have the option to appoint an authorized representative. If you'd like, you can go in and monitor your payments or transfers of value that have been attributed to you. So, that would be another option. But, currently, there is no availability to opt out except to decline any payments or transfers or value that could be made to you potentially.

Coleman Martin: If I might make a follow-up suggestion, currently, our CMS accounts will close after six months of inactivity. And since this is on a yearly cycle of revision, perpetually I am having to reactivate my account and requiring tech

support. So, if just that could be stretched out to 13 months, it would be helpful.

Erin Skinner: So, that is a security measure for your own protection. It is all CMS' security system. We are happy to have that feedback, and we will continue to consider this feedback as we continue to enhance the program. Thank you very much.

Operator: Your next question comes from the line of Catherine Hill with AANS.

Your line is open.

Catherine Hill: Hi. This is Cathy Hill with the neurosurgeons. Just to follow up on the last one, we too would find notifying some way to let our docs know, you know, that they have something in there – it's – and, then, this – the other follow up is, for us, the registration is the most onerous part. So, the – you know, we will provide comments on the other items requested. But, if there is a way to streamline – make registration easier and to make it so that if someone is interrupted in the process of registering, they can come back and they don't have to start all over again. Thank you very much.

Erin Skinner: Thank you very much.

Operator: Your next question comes from the line of (Monica Deep) with Siemens Medical Solutions.

Your line is open.

(Monica Deep): Thank you. I just have a quick question. I just want to confirm that if we have sent suggestions or recommendations to the questions of the slides to the Open Payments comments e-mail address provided in the slide that they will be reviewed and that you are not expecting other, you know, recommendations on this call.

Erin Skinner: Yes, that is correct. They will be considered with respect to the fee schedule solicitation. Yes.

(Monica Deep): Perfect. Thank you.

Operator: Your next question comes from the line of (Tom Kronan) with (Primecia).

Your line is open.

(Tom Kronan): Hi. This is (Tom Kronan) with (Primecia). And my question relates to difficulties in utilizing the definition of appropriate categories. A number of our physician clients have had ownership positions in companies acquired by large manufacturers. They receive large and visible payments from these acquisitions. While one might believe that that fits well into the category of ownership, it has been the position of the acquiring companies that the ownership category only applies to ownership of their organizations and, again, following through like in your slide of what the position was the prior year or the next year, not of acquiring a company. So, these companies wind up going in the general – the other general category and, in some cases, companies have even put it down as a gift. So, it shows up in Open Payments as like a \$3-million gift for an investment that a clinician had made in a company long before.

Erin Skinner: OK. So, you are – OK. Thank you. That is helpful.

(Tom Kronan): So, it is just a categorization issue that we – that hits a big payment area that doesn't seem to fit into any of the categories that you have.

Erin Skinner: Is there another classification or term that you would suggest to more properly capture that?

(Tom Kronan): It would – yes. It would seem that – I guess that we would suggest some type of just – to either broaden the current ownership category – I guess, the idea would be to broaden the ownership category to either include the ongoing investment in a firm, which is what it seems to contemplate, or the acquisition by a third party of a firm in which a physician has had an ownership interest in the past.

Erin Skinner: So, is this really an issue with the nature of payment categories or is it a misreported ownership or investment interest?

(Tom Kronan): It is the payment categories.

Erin Skinner: The nature of payment category. It almost sounds like they are misreporting the value of interest. I would be – I would have to look at it more closely. But, I think, this might speak to the problem with reporting the value of interest and the amount invested. The sort of sounds – I am looking around the room here and I think that is part of the confusion that we are hoping to resolve with getting this feedback.

(Tom Kronan): OK. Because (inaudible), sometimes, it is the company that wouldn't – like a pre – a company that doesn't have to report for Open Payments because it is not actually selling a product. And so, again, it gets sort of hidden in a backwater that then becomes a big visible that is difficult to categorize.

Erin Skinner: OK. (Tom), that is really helpful. Could you e-mail the resource mailbox that we have set up for this – for the comment with this information so we can look into it more closely?

(Tom Kronan): Of course. My second issue is on the large-scale access to – for clinical organizations and academic medical centers to roll all of its clinicians at once, which we have spoken with you folks about before. But, I won't take time with that. But, I think, based on the earlier comments, that would be something that would be very helpful. If a hospital that employs 300 doctors produce some kind of mass signup to become their authorized agent and then be able to provide their own doctors with information, I think that would be a terrific thing as well.

Erin Skinner: Great. Thank you for that feedback.

Operator: Your next question comes from the line of Randall Minter with Sunshine Act Software.

Your line is open.

Randall Minter: Hi. I have two comments. One is on pre-vetting. Will we allow our clients to send letters to the physicians with a report of all their transfers throughout the year and the physicians can then report directly to the manufacturer before the data is uploaded to CMS? And I do have a question about what is CMS' official opinion on transfers being reimbursed by the physicians? For example, could the physician at the end of the year write a check in the amount of all the transfers to the manufacturer and, then, the manufacturer not need to report those transfers to CMS?

Erin Skinner: Hi. Thank you for your feedback on the pre-vetting. And we are not in a position to give feedback or a position on your second question. Thank you.

Next question.

Operator: Your next question comes from the line of (Patrick Bourdain) with Medtronic.

Your line is open.

(Patrick Bourdain): Hi. I just want to piggyback on what (Tom) just said about acquisitions. And we are a larger organization. So, we make some quite a few acquisitions and we also struggle with that payment category. There is not really a good nature of payment right now to slot acquisition-related payments. So, then, we are forced to use royalty or (comfort) services (other than) consulting or some other nature of payment that doesn't really fit. And a lot of physicians might have a policy where they can't – with their – with their employer, they can't accept the royalty payment, for example. So, we struggle as the acquiring company with the same issue that (Tom) was suggesting on the other side.

Erin Skinner: OK. That is very helpful. Again, if you can – if you are able to provide more specific scenarios to the (inaudible), that would be helpful for us ...

(Patrick Bourdain): Yes.

Erin Skinner: ... additional rulemaking.

(Patrick Bourdain): Sure. Definitely.

Erin Skinner: Thank you so much.

Operator: Your next question comes from the line of Elizabeth Zellner with Medline Industries.

Your line is open.

Elizabeth Zellner: Hi. I just wanted to comment on the nature of payment category. So, there's a few FAQs out there. One is related to purchases and there is another related to bad debt. These would both be really, really good payment categories – nature of payment categories.

Erin Skinner: Great. Thank you. That is very helpful.

Operator: Your next question comes from the line of (Loreta Reden) with (Kaiser) (inaudible).

(Loreta Reden): Thank you. My question is there any plans that when a physician goes in to the Open Payments database, to search their name and it may match their name and/or specialty. But, there is no other way to verify that that is indeed the same person because there is no NPI or medical license number to validate against. Is there any plans to add those fields to know that it is exactly the person that is looking for their name?

Erin Skinner: So, the statute prohibits us from publishing the NPI in the publicly-facing data. If you would like to go in and verify that the payments are attributed to you, then you can go through the registration to review and dispute any – review and dispute any payment.

(Loreta Reden): OK. And there is no plan to list the medical license number other than to verify that that person is – you know, for a common name that may have 20 that show up matching.

Erin Skinner: We can certainly take that feedback back and consider it as we make changes to our rule and our system requirements.

(Loreta Reden): Great. Thank you.

Erin Skinner: Yes.

Operator: Your next question comes from the line of David Tomaselli with UPMC.

Your line is open.

David Tomaselli: Yes. Hi. This is David Tomaselli with UPMC. I had a question piggybacking on the earlier question with respect to teaching hospitals and falling under the same corporate umbrella. I believe that gentleman's question had to do with – I believe he said there were five teaching hospitals and they had all the same tax identification number. I actually want to confirm an interpretation of the final rule. So, it was my understanding that earlier this year, any payment to any facility falling under the corporate umbrella as your teaching hospital – so, for instance, we have 10 teaching hospitals but we have a number of non-teaching hospitals. And I understood the final rule to be interpreted as if a payment is made to one of our non-teaching hospitals under the corporate umbrella, that payment or value transfer can be attributable to one of our teaching hospitals simply by the fact that it falls under the same corporate umbrella.

So, we hadn't really run into any issues with that this year. But, I wanted to just reach out and see if I have that interpretation correctly whereby a payment made to a non-teaching hospital under the same corporate umbrella as an organization with teaching hospitals – could those payments potentially bleed and/or be attributed to our teaching hospitals?

Erin Skinner: Yes. Based on an indirect payment analysis, those payments could be attributed to the teaching hospital.

David Tomaselli: OK. So, would that have to go through – would that have to come from a non-teaching – so, you are saying ultimately because it goes to the – to the – to the – to the (pot) at large, those could be attributed to the teaching hospital on that basis?

Erin Skinner: Yes. I mean, we have to look at the situation more specifically. But, if it meets the definition of an indirect payment, then it could be attributed to the teaching hospital. Yes.

David Tomaselli: OK. Thank you very much.

Erin Skinner: Thank you.

Operator: Your next question comes from the line of Christian Krautkramer with GE Healthcare.

Your line is open.

Christian Krautkramer: Thank you very much. I have two comments and a question. The first two comments are on the nature of payment categorization. As we understand it from the guidance that has been provided on the Open Payments Web site, the (inaudible) category should reserved (not) (inaudible) but also at a de facto catch-all category (inaudible)) payments that cannot easily be put into any other payment category. We would like to see an additional payment category that serves as a either catch-all category for something other than gifts given that the (inaudible) (company as gifts) becomes (inaudible) under various (inaudible) and anti-corruption laws. Additionally, when we report out demonstration products or products or customer valuation that extend beyond 90 days, we are currently forced to put that into gift category and we would like to get a separate classification for demonstration and customer evaluation products.

The second comment is on the pre-vetting process. Currently, we as an organization do limited pre-vetting based upon the information that we have on hand or information that we purchase from a third party in order to be able to have accurate contact information for the covered recipient. This is a considerable cost to our company and, quite frankly, does not capture even the majority of payments that we are able to – that we are reporting in a given year. So, in terms of our feeling about this, that we don't think (it has) to be mandatory. We understand that from a relationship perspective and from a data accuracy perspective that will be helpful. But, for CMS to make it mandatory would result in a considerable burden on manufacturers unless CMS was also collecting highly accurate and current information about the (inaudible) providing (that to manufacturers).

And, then, my question has to do with the slide around nature of payment and around research (itself). One of you gave a comment about the fact that (inaudible) you can't change the classification of nature of payment for research. But, the slide had some comment about additional classifications for research payment. So, I was wondering if you could talk about that (inaudible). Thank you very much.

Erin Skinner: Sure. What – so, what we are wondering is whether – so, right now, we have – we capture non-research-related payments under one template and, then, industry can also submit payments that are research-related. But, we don't categorize them any further to say that they were research-related and then there is a subcategory that is like travel related to research or food and beverage related to research or a grant related to research. And what we are wondering is if it would be helpful for us to further categorize those research-related payment in the research payment template. That was – (that's my question).

Christian Krautkramer: Great. That is very clear. Thank you so much for that.

Erin Skinner: Sure. Thank you for your feedback.

Operator: Again, if you would like to ask a question, please press star followed by the number one on your telephone keypad.

Your next question comes from the line of (Eric Chen) with (NRFX) Therapeutics.

Your line is open.

(Eric Chen): Hi. Thank you, guys, for doing this. My questions relates to payments to entities – I think the guidance previously have been if you make a payment to an entity that is under the same corporate umbrella as the teaching hospital, then that payment goes as an indirect payment for all general payments, which is – which was great guidance and I think it has been really helpful this year. However, what we have seen with my company as well as a couple of other industry peers is that payment – research payments to companies that are non-teaching hospitals but under the same corporate umbrella as the teaching hospitals – research payments don't have an indirect payment indicator. So, I guess, my request or suggestion would be either have an indirect payment indicator or provide written guidance on, you know, whether or not that is considered – that payment to the entity under the same corporate umbrella as the teaching hospital is – should be reported to the teaching hospital (and not) (inaudible).

Erin Skinner: OK. Thank you. That is very helpful.

Operator: Your next question comes from the line of (Anne Fairchow) with (Facility).

Your line is open.

(Anne Fairchow): We have payments that go to a system where two of the hospitals are teaching hospitals and one is not. So, they are basically disputing everything saying everything should fall under the non-teaching hospital and not be reported. How should we address this?

Erin Skinner: Sorry. Could you repeat that one more time, please?

(Anne Fairchow): We have a system in California that is two teaching hospitals and one non-teaching hospital. They all share the same tax ID number. When we go to report, they say, "Oh, no. All the money went to the non-teaching hospital. So, you can't report any of it." How should we address that? Should we address that as one umbrella and, yes, we are reporting them all?

Erin Skinner: Yes, you should continue to treat it as one umbrella and continue to report them all. And they have the option to review and dispute the payments.

(Anne Fairchow): Thank you.

Erin Skinner: Yes. Thank you.

Operator: Your next question comes from the line of (inaudible) with Mayo Clinic.

Your line is open.

Female: Yes. We actually have both teaching and non-teaching hospitals and they have separate tax IDs. And we ran into the problem that the previous caller just describe where a lot of – we disputed payments and we got a lot of pushback this year. And there is a reference to under the same corporate umbrella. But, I searched and searched and I could not find how that term was to be defined (as such). How are the manufacturers in the – in the hospitals to know whether an entity is under the same corporate umbrella? If they have different tax IDs, are they not under the same corporate umbrella? I am looking for something written down to help out. Thank you.

Erin Skinner: And I think you are – so, your question sort of draws to – or takes us back to the reason that we have included this request for information in the proposed fee schedule. We are – it's obvious that everybody has a lot of questions surrounding teaching hospitals. So, we are really asking for industry to come forward with how we can better define this, how we can button up our guidance to make it more clear and to facilitate proper reporting. If you have a suggestion for how to make this to ensure that payments that attributed more

accurately, then we are open to suggestions. But, that is sort of what we are looking for from everybody right now. So, we are – we are happy (inaudible).

Female: (Inaudible) have a definition of corporate umbrella as to, you know, what are you meaning by that.

Erin Skinner: Thank you.

Operator: Your next question comes from the line of (Lisa Stevenson) with Johns Hopkins.

Your line is open.

(Lisa Stevenson): Hi. Just to piggyback on the last comment, I think there needs to be a considerable amount of education to the applicable manufacturers about the difference between entities that may share similar name (or, in fact) – or not under, as I interpret it, corporate umbrella that have separate tax ID numbers et cetera because I – what it appears on our end is that some of our teaching hospitals – or the manufacturer simply go in and attribute payments to some of our teaching hospitals just by name recognition and not doing any other due diligence to ensure that it is being accurately reported. In some cases, it is being reported to a teaching hospital and the payment did not go to any of the teaching hospitals in the health system but rather to a university under the same name. I just would, you know, recommend that some additional research guidance and education be done with the applicable manufacturers on this. And I think that will help eliminate a lot of the time and resources that is utilized to try to dispute these payments.

Also, I think, one of the ways possibly that would help would be the required pre-vetting payment information portion if that could be done ahead of time. In that way, if there's questions or some conversations that could be had before the 45-day time – review and dispute period, that would be helpful.

And then, finally, I would just suggest also that I don't think that the manufacturers having the ability to go in and resolving no change without

having at least some type of dialogue with the teaching hospital to see if they can reach some resolution regarding a payment. Thank you.

Erin Skinner: Thank you, (Lisa).

Operator: Your next question comes from the line of (Nicholas Nel) with (Sanofi).

Your line is open.

(Nicholas Nel): Hi. Thanks for opening it up for me. I think I'd probably do some reiterating a number of points that have already been brought up by a lot of other people. The concept of a corporate umbrella, you know, teaching hospitals being multiple – having multiple tax IDs and all of them being under one corporate umbrella – if you really want us to start reviewing corporate umbrellas, this would be something that you guys would have to provide more transparency into. At the moment, we report just the tax ID – just the payment to the tax IDs that are directly associated with teaching hospitals as per the guidance that you guys hand out on an annual basis and even beyond that would be very difficult to interpret without more – without clear guidance from you.

Regarding additional categories, this provides more burden on us, the applicable manufacturers. You know, we are happy to do what is best for the industry to certainly provide more transparency. But, I do question the – you know, how useful it would be to go down the path of opening up even more categories because I don't really know if necessarily it would create more transparency. I am concerned it would actually create more questions. There was one person that brought up the point of bad debt. That is something actually that would be of help to us. But, I can't think of many other categories that would be of help to us.

The last point I wanted to bring up was pre-vetting. This is something that our organization does quite a bit. We do it – basically, we allow the various business users to pre-vet if they want to. Our KOLs are usually well in the loop of the transfers of values that they have received. But, an organization of our size – we report quite a number of transactions of TOVs and to pre-vet

absolutely everything would be a very significant burden to us and we question really the value it would provide as other than really our high-level KOLs. The majority of our pre-vetting falls on individuals that don't really provide us much feedback and they – and it doesn't really provide much value.

Thank you.

Erin Skinner: Thank you.

Operator: Your next question comes from the line of Paul Steele with Sunovion Pharmaceuticals.

Your line is open.

Paul Steele: Hi. Thank you for taking my call. I wanted to reiterate the issue of pre-vetting. The gentleman just previous to me had mentioned that (inaudible) additional burden (and as a) manufacturer, we would see similar circumstances (inaudible) more difficult for us here as a manufacturer for reporting by (inaudible) time schedule (inaudible) already an opportunity provided by CMS (inaudible) pre-vet before public (inaudible).

We also – I'd like to mention (we would support) some changes to the data refresh. We feel that it would provide more accurate and timely information to the public using the data if they were – they (quarterly) refresh it so that (we receive the dispute on publication and not have to wait until) the following January to (inaudible).

And, lastly, I also would like to mention that we also (inaudible) cautious about opening up further natures of payment as (inaudible) lead to (change) (inaudible). As well, it may also cause (inaudible) data (inaudible) (years into the publication) (inaudible) inconsistencies (inaudible). Thank you.

Erin Skinner: Thank you.

Operator: Your next question comes from the line of (Tim Downing) with (Radia).

Your line is open.

(Tim Downing): Thank you. My concern has to do with something people mentioned about identifying physicians. What I would like to recommend is, if possible, that CMS make changes to the programming from year to year like how basic physician information is laid out and published, that some kind of notification go out to the physicians. This year, we had an issue where one of our physician's personal home address was listed as the address on the Open Payments site for 21 of our physicians. So, you know – and that was due to some kind of programming change. So, if there a change like that to be made at the CMS level, it would be nice to know in advance so that we could screen that and possibly prevent that from happening.

Erin Skinner: Thank you for that feedback. It is really helpful. And we will certainly take that into consideration and be sort of – provide appropriate messaging. You are able to verify the addresses that would be displayed through the review and dispute process.

Female: (No. That reminds you).

Erin Skinner: If you do go in and look at your (inaudible) registration so that you can make sure that you addresses are correct because those are the systems of record that we are pulling data from. Thank you.

(Tim Downing): Thank you.

Operator: Your next question comes from the line of (Roger Frank) with (Gastro).

Your line is open.

(Roger Frank): Hi. This is (Roger Frank) from Gastroenterology Associates. Is there any consideration in the future in the food and beverage category to raise the minimum level from \$10?

Erin Skinner: So, the increase on the food and beverage minimum is set by the statute and it is based on the consumer price index. So, it is increased based on statutory definition. So, we don't really have much control over that. We are just following what Congress puts into place. But, thank you for your question.

(Roger Frank): Is there any ...

Erin Skinner: I'm sorry. (Inaudible).

(Roger Frank): I know – and I know for my own physicians who are just ones of literally hundreds of thousands, when they go in the Web site, there are – under their name, there are tens, if not even hundreds, of those just because somebody has come and given our staff lunch. It just seems like kind of a big waste of time.

Erin Skinner: Sure. No. It is useful feedback. And we can certainly take that into consideration and see if there's other ways to work around that. But, like I said, we are sort of (holding) to the statutory requirement.

(Roger Frank): I understand.

Erin Skinner: (Inaudible). Thank you.

(Roger Frank): Thank you.

Operator: Again, if you would like to ask a question, please press star followed by the number one on your telephone keypad.

Your next question comes from the line of (Loreta Reden) with (Kaiser Permanente).

Your line is open.

(Loreta Reden): Thank you. I want to just piggyback on the gentleman that talked about the bad addresses. We have approximately 8,000 physicians in southern

California. And over 2,500 of them had one of our medical office buildings address and about another 1,000 had a different address that is not correct for that physician. And the (NPAS) address is correct. And, so, we are wondering if there was a glitch or something with addresses this year that that many physicians would have the wrong address listed and how soon that can be corrected. Or if there is someone I can work with offline on this, I would love a name and phone number.

Erin Skinner: So, the addresses are going to be updated with the next data refresh. We use the latest PECOS reassignment address. So, that is what is being published there.

(Loreta Reden): OK. Yes.

Erin Skinner: If you have additional questions or concerns, you can contact the (CMS help desk) and they are fully familiar and should be able to answer any additional questions that you have.

(Loreta Reden): Yes. I have two open tickets to them. But, I am not able to get a response. So, (I will be) (inaudible). Thank you.

Erin Skinner: OK. Thank you.

Operator: Your next question comes from the line of (David Crosswell) with (AFEL) Incorporated.

Your line is open.

(David Crosswell): Thank you. First, I just want to agree with (inaudible) (valuation of product) (inaudible) transfer of value would be very helpful. And, secondly, I would like to voice my support for incremental submissions throughout the year. Right now, you know, we submit before the deadline and we don't know what is (going to be our matching validation before we try to submit it) especially as it relates to physician license numbers and (inaudible). So, we

could, you know, do it monthly and sort of get our hands around it (and resolve these issues as we get it. That would be extremely helpful.

Erin Skinner: Thank you.

Operator: Your next question comes from the line of (Alex Sung) with (UCB).

Your line is open.

(Alex Sung): Thank you. I just had a question about taxonomy codes, actually. (What (inaudible) expand the currently taxonomy codes to include all those taxonomy codes that are currently in use in (MPAS).

Erin Skinner: We – so, we will accept taxonomy codes that are related to covered recipient physicians or teaching hospitals. Those are the only ones that we can accept payment for.

(Alex Sung): Correct. It is just that we have had a number of physicians that have, for example, the specialist taxonomy code, which is their taxonomy code listed in (MPAS). But, when we try to upload, it is not within the accepted set of taxonomy codes.

Erin Skinner: If you want to contact the help desk when you have that sort of issue, they are happy to help you walk through any – troubleshoot any sort of submission errors like that. Their contact information is on slide 18 of the presentation. But, you would be able to submit payments to any taxonomies related to covered recipient physicians.

(Alex Sung): Yes. Thank you.

Erin Skinner: You are welcome.

Operator: Your next question comes from the line of (Ally Walenta) with (AFEL).

Your line is open.

(Ally Walenta): Thank you. I had a question about disputes. When disputes are initiated in the database by the teaching hospitals and physicians, could it be mandatory to require them to add their contact telephone number and e-mail address? (This year, we received) a number of disputes which didn't have this information. It was difficult to track down the people that actually initiated them.

Erin Skinner: Sure. That is helpful feedback. Thank you.

(Ally Walenta): You are very welcome.

Operator: Your next question comes from the line of Wanda O'Toole) with Ferin Pharmaceuticals.

Your line is open. Wanda O'Toole with Ferin Pharmaceuticals, your line is open.

(Wanda O'Toole): Hello. I am following up on the question before about the specialist taxonomy code issue. We encountered that quite a bit this last year where the taxonomy code that is in NP – the NPPES system says specialist and yet it is a code that causes the records to fail. And it is not something the help desk can resolve. The resolution from the help desk is to delete the record. So, it would be helpful if CMS is going to rely upon the specialist code that is in the NPPES database (but then they could) allow that code to be accepted by the system.

Erin Skinner: OK. Thank you for the feedback. We will continue to look at the system and make sure that we are allowing the proper taxonomies for covered recipient physicians. Thank you.

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

Your next question comes from the line of Gautam Kumar with Emory University.

Your line is open.

Gautam Kumar: Hi. My name is Gautam Kumar. I am a physician at Emory University. I just had some feedback about the physician Open Payments. And one of the things I wanted to throw out there for CMS to consider is that they should probably consider excluding training and procedural workshops or at least think about reporting that in a different way for physicians especially in procedural specialties because, you know, I agree that these are industry-sponsored and there is a transfer of funds for these. But, does it actually benefit patient care, and it is not necessarily purely related to a conflict of interest.

Erin Skinner: OK. Thank you for that feedback.

Gautam Kumar: OK.

Operator: Your next question comes from the line of Tim McGuire with Eli Lilly.

Your line is open.

Tim McGuire: Hi. Thanks for taking my call. Just some further comments on the pre-vetting topic. I think, from our perspective, it really starts to – it defeats the purpose of having a central platform and, I think, as said earlier, it is a huge operational burden for the companies, not to mention it would have to occur at a crucial time when we are finalizing the data for submission. I know our experience has been inquiry disputes have been significantly lower this past reporting period. So, we actually, you know, don't see the value of that.

Also, a question for CMS looking at Senator Barrasso's Senate Bill 2978 – any consideration for looking at the possible exclusion of CME and items of medical utility – so, things like article reprints, textbooks et cetera?

Erin Skinner: Is that the 21st century (inaudible) that you are talking about?

Tim McGuire: I believe this is a new bill.

Erin Skinner: A new bill. Yes. We don't know any more about the status of it than you do at this point.

Tim McGuire: But, is there any plan to look at those types? There has been, I think, more than – there has been kind of several put forward that have focused on CME and then also, you know, patient educational-related materials that are – that are currently, you know, designed to be reported under the current requirements?

Erin Skinner: (Inaudible) we are certainly considering all feedback and not – I mean, nothing is off the table at this point. So, we can certainly take that into consideration as we move forward with future rule changes.

Operator: Your next question comes from the line of (Eric Grosse) with (NUI).

Your line is open.

(Eric Grosse): Hi. Thank you. Yes. To follow on (Tom)'s point, I am kind of curious do you – do you have the opportunity to give Congress this feedback when it does come to matters of statute? The reason being is considering the 45-day review and dispute period, considering the finite list of teaching hospitals, considering the PECOS and (NPAS) databases where all of this information could be available, where all of these pre-vetting could be done on a central platform, where all of the reviewing and potentially changing through a dispute the nature and category of the payments, the amount of the payments, the recipient information, is there a way that we can work with your program, your group, your – our Congress to improve communication, perhaps, to the recipients?

Erin Skinner: If you would like to send a proposal or a letter to the Open Payments comments box, then we can get in touch with you on how better we can work together.

(Eric Grosse): Great. Thank you.

Erin Skinner: But, I mean, beyond that, as – we are limited on being able to comment any further on that sort of matter. But, if you – if you have specific proposals or concerns, you can send us an e-mail and we'll see what we can do.

Operator: I am showing that there are no further questions at this time.

Merri-Ellen James: All right. Thank you. This is Merri-Ellen. I want to thank everyone for participating in today's open door forum. We do appreciate all of the feedback, and we will review responses both here and via the mailbox. Again, please feel free to provide as much information as you feel necessary to get your point across and clear and provide examples, if necessary.

Again, thank you, and we look forward to your feedback.

Operator: This concludes today's conference call. You may now disconnect.

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