

Centers for Medicare & Medicaid Services  
Special Open Door Forum: Discussion of the Medicare Intravenous Immune Globulin (IVIG)  
Demonstration

Moderator: Jill Darling  
November 22, 2013  
1:00 p.m. ET

Operator: Good afternoon. My name is (Sharon) and I will be your conference operator today. At this time, I would like to welcome everyone to the Medicare IVIG Demonstration Open Door Forum Conference Call. 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'd like to ask a question during this time, simply press star, then the number one on your telephone keypad. If you'd like to withdraw your question, press the pound key. Thank you.

Ms. Jill Darling, you may begin your conference.

Jill Darling: Thank you, (Sharon). My name is Jill Darling in the CMS Office of Communications and thank you for joining today's special open door forum. Before we begin, the forum today, I have one announcement.

The Medicare open enrollment period is October 15th through December 7th, when all people with Medicare can change their Medicare health plan and prescription drug coverage for 2014. Please advise your patients that information on 2014 plan is now available by calling 1-800-Medicare or visiting <http://www.medicare.gov/>.

After evaluating the available information and they are satisfied that their current plan will meet their needs for next year, they don't have to do anything. Your Medicare patients also need to be advised that they should not confuse the health insurance marketplace open enrollment period that run

through March 31, 2014 with the Medicare open enrollment period that ends December 7th.

If they miss the December 7th deadline, they will not be able to make a change until the next open enrollment period starting October 15, 2014. I will now hand over the call to (Jodi Black), project office for the CMS IVIG demonstration.

(Jodi Blatt): Thank you, Jill. Good afternoon, and to those of you on the West Coast, good morning. And thank you all for taking the time to join us today to talk about the Medicare intravenous immune globulin demonstration. My name is (Jodi Black) and as Jill said, I am the project officer for the Medicare IVIG demonstration.

For those of you on the call who do not have access to the slides, they can be downloaded from the demonstration website, which is <http://innovation.cms.gov/initiatives/IVIG/>. As we go through the slides, I will note the slide we are on.

So moving on to the second slide, our goal today is to provide some background information about the demonstration and get input from all of you representing interested stakeholders regarding how this demonstration should be implemented. We have done some preliminary design work, but want to get your input and thoughts before finalizing our plan. We would also like to answer any questions you might have about the demonstration to the extent we are able to do so at this time.

For those of you who may not be as familiar with the demonstration, I would like to start the conversation by providing some background about the demonstration. Let's move on to slide three.

The IVIG demonstration is authorized under Title I Section 101 of the Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012. Under the regular Medicare program, Medicare, under Part B pays for immunoglobulin for patients with primary immune deficiency disease when administered intravenously, but the traditional applications in the home.

But the traditional benefit does not cover any services necessary to administer the drug intravenously.

As a result, many beneficiaries, either self-administer the drugs subcutaneously, travel to their doctor or an outpatient hospital setting to receive the medication intravenously. Under the demonstration, medical – Medicare will pay for items and medically-necessary services needed for in-home administration of IVIG for persons with PIDD even if they are not home-bound and covered under home health episode of care.

The statute states that Medicare will pay a per-visit payment amount based on the National Per-Visit Low Utilization Payment Amount, or LUPA. However, I want to reiterate that although the payment rate will be based on the LUPA, the demonstration will cover these services for persons who are not part of a home health episode of care and we'll also recognize the average amount of time necessary to administer the drug and monitor the infusion.

Moving on to slide four, the demonstration will enroll up to 4,000 total Medicare beneficiaries nationwide over its three-year term. This is a statutory total limit and not applicable to the total enrolled at any one time.

In order to be eligible, the beneficiary must have Medicare Part B; must be covered under the traditional Medicare fee-for-service program, so that means not enrolled in a Medicare advantage plan; and be eligible to have the IVIG paid for, that is have the primary immune deficiency disorder or PIGG.

The demonstration will not pay for services when a person is in a home health episode of care as the nursing services to administer the drugs for those beneficiaries would be covered under the home health payment system. Again, under the demonstration, we are covering the administration of the drug for persons not in a home health episode of care, but it could be after the home health episode of care has ended.

Moving on to slide five, the statute also provides for an interim and final evaluation of the demonstration to examine the impact on beneficiary access to services, as well as the appropriateness of implementing a new methodology for payment for IVIG in all care settings. The evaluation will

also update a report previously produced by the Department of Health and Human Services in 2007, titled “Analysis of Supply, Distribution, Demand and Access Issues Associated of Immune Globulin Intravenous”.

Let’s move on to slide six. To start our discussion this afternoon, I have laid out some questions on which we would explicitly like to receive your input. Some of these questions relate to the identification and collection of beneficiaries to participate in the demonstration and others relate to providers and suppliers who will be providing the new service covered under the demonstration and how Medicare will be billed.

To start the discussion, we’d like to get your input on how these services will be provided. In discussions we have had to date, it’s our understanding that the providers and suppliers that bill for the drug will also be billing for the administration of the drug under the demonstration, either by using their own staff or through contracts with other entities.

This is important for us to confirm as it significantly impacts our claims processing system and the changes we will need to put in place to process demonstration claims. So, specifically, we would like thoughts as to whether it would make sense to acquire the new demonstration service to be billed on the same claim as the covered drug itself and, if so, would there be any negative ramifications of doing so.

Another question we have is whether CMS should seek to enroll specific providers or types of providers to allow – or to allow any entity that bills for the drug to bill for the administration of it with the understanding that they must operate within all state or other regulatory restriction.

With that introduction, I’d like to open up the telephone lines and ask for your thoughts on these issues related to the providers who will be providing the demonstration services. (Sharon), can you open the phone lines?

Operator: If you would like to ask a question, please press star, then the number one on your telephone keypad. We’ll pause for just a moment to compile the Q&A roster. And your first question comes from the line of a participant whose

information we could not gather. If you've queued up for a question, please state your first and last name and organization. Your line is open.

Dan Sweeney: This is Dan Sweeney from Baycare HomeCare. One of the things that I would want to clarify is that, on home health, usually they use the UV form to bill pharmacies probably use a HCFA 1500. So I would think we would need to clarify that to make sure that the pharmacy could actually bill for the home health on the HCFA 1500 form or vice versa.

And then, the second question I had for you – I think you said that the home health agency would be paid if they were not in the episode using a LUPA payment, which is – I'm thinking about \$113 per visit. And a lot of times these IVIG require a \$4 to \$6 infusion. That's my understanding.

(Jodi Blatt): Thank you very much for your question, Dan. I'll be happy to clarify. What we were anticipating is the pharmaceutical suppliers that supply the drug would – as it is my understanding they do with their commercially-insured patients – also bill this new – a new demonstration code for the administration of the drug and it would be on the HCFA – what is the HCFA 1500 that we like to call it, basically the card claim form they are using now.

We would anticipate that, if a beneficiary needed this drug and was in a home health episode of care, under those circumstances, the administration would be covered under the home health payment system and under the home health benefit. However – so that was that – in that case, it really wouldn't be a demonstration-covered service. It would be under the current home health benefit system.

Now, the statute says that the payment will be based on the LUPA, but it does not say that it will be the LUPA itself. And we are looking at – we probably intend that the payment rate – we have not determined the exact rate, but it will recognize that that administration of the drug is, on average, about four hours.

And I do want to clarify, again, this is – the demonstration service is not covered under the home health benefit. It is a new service. The idea is that we will now be paying for the administration of a drug that we now cover

under Part D, but we don't cover the administration. But it's not – it is not a new home health benefit.

Does that – does that answer your question?

Dan Sweeney: Somewhat. I mean, I'd still – I probably would need to clarify it with the billing people to make sure that we would be able to comply with that, but certainly, I would like too.

(Jodi Blatt): We are anticipating that when the pharmaceutical supplier bills the J Code for the drug that is currently covered under Medicare, they would bill another line item with a new code that we will get developed. That would be demo-covered services and that would comment on the HCFA 1500 form.

Daniel Sweeney: OK. And they could provide the nurse team whether they have the home health are part of their company or they subcontracted it?

(Jodi Blatt): Correct. My understanding from having talked with people over the past couple of months in the commercially-insured world, we're trying to adapt to the environment – the billing environment that folks operated now is that the providers of the drug (having through) their staff or depending on certain geographic areas, may subcontract.

But if they bill for the nursing services for the administration of the drug and if they subcontract, they would then be responsible for paying the subcontractor. And so, that – I would – if I am incorrect in that, I definitely would like to hear that today because I have heard current understanding of their situation.

Daniel Sweeney: I think that would be correct.

(Jodi Blatt): Next question, operator?

Operator: Your next question comes from the line of a participant whose information we could not gather. If you've queued up for a question, please state your first and last name and organization. Your line is open.

(Jodi Blatt): Go ahead.

Thomas Barker: Hi. This is Tom Barker with Foley Hoag. Hello?

(Jodi Blatt): Yes. We can hear you. Go ahead. There's a little noise in the background, but go ahead.

Thomas Barker: My question is how the patients are going to be selected. Has CMS given any thought to how the patients in the demo were going to be selected, whether they're going to come from the outpatient side, whether they're going to be patients that are currently getting treated in the home ---. That's the question that...

(Jodi Blatt): Our next section of the presentation will focus on beneficiary selection and enrollment. If you don't mind, I'd like to hold that question because ...

Thomas Barker: Sure.

(Jodi Blatt): So, right now, if you have any questions or comments regarding provider and supplier issues, I'd like to address those. If not, we can move on to beneficiary issues and catch up on any questions (doing this) there. Are there any...

Thomas Barker: Sorry, I think...

(Jodi Blatt): I'm sorry. Go ahead.

Thomas Barker: No. I was just saying I'm sorry for jumping in. That's all.

(Jodi Blatt): That's quite all right.

Operator: OK. Your next question comes from the line of a participant whose information we could not gather. If you've queued up for a question, please state your first and last name and organization. Your line is open.

(Jodi Blatt): Go ahead.

(Julie Kikstra): Hello?

(Jodi Blatt): Yes? Go ahead.

(Julie Kikstra): Hi. My name is (Julie Kikstra) and I'm calling from Fairview Home Infusion in Minneapolis Minnesota. The question that I had is, as an organization, we are not enrolled in Part A to provide nursing services. So as long as we are a Part B provider for Medicare, are we able to bill for the demonstration visit?

(Jodi Blatt): Correct. This service is being under Part B.

(Julie Kikstra): Thank you.

Operator: Your next question comes from the line of a participant whose information we could not gather. If you've queued up for a question, please state your first and last name and organization. Your line is open.

Larry LaMotte: This is Larry LaMotte with the Immune Deficiency Foundation.

(Jodi Blatt): Hi. Go ahead.

Larry LaMotte: I just want to know if there were any specialty pharmacies on the line that might be able to make sure that, you know, this is aligned with the current practices in the commercial (rule).

(Jodi Blatt): We definitely want to hear feedback if we are under some misunderstanding of how things are currently operating because our goal really is – again, this is a special demonstration covered service. It's not part of the home health payment system, so it isn't going to be covered under Part B and we do want to make billing easy for you.

Larry LaMotte: Yes. That's our understanding too and I just want to make – you know, if there's anybody who's in – working in that space – the things that this define.

(Jodi Blatt): We did invite specialty pharmacist to the open door, so if there's any on the line who would like to comment, please queue up for a call. Operator, are there any other calls? Or we – or, if not, we can go on to beneficiary-related issues and if there are any calls later, we'll – questions later regarding providers, we'll be answer them at that time. We're going to take one more call. Operator?

Operator: Yes. OK. We – the next question comes from the line of a participant whose information we could not gather. If you’ve queued up for a question, please state your first and last name. Your line is open.

Scott Sorenson: Hi. Good afternoon. This is Scott Sorenson with BioRx.

(Jodi Blatt): Scott?

Scott Sorenson: We are a specialty pharmaceutical services and, traditionally, how the commercial end works is that, just like the provision of any specialty service, we do have to follow all mandates. Some insurance companies require that we have URAC, we have (NC), any type of credentialing within that space and that we do currently hold. Medicare Part B, -- application and provider ID number to participate in that payer field. So to answer, I think, Larry’s question, yes, this is common practice.

(Jodi Blatt): Good. Well, thank you very much. I appreciate that. Why don’t we move on and if we don’t – and if have – if there’s any questions, we will definitely have time after the other section at the end to pick up on any other issues.

I do want to turn now to some of the beneficiary-related questions and we’re on slide seven. One of the things we do want is your input on the best way to reach out to beneficiaries who might be interested in most benefits by this demonstration.

Because there is a limit to the total enrollment, we would like your thoughts about how likely beneficiaries who are currently receiving the drug intravenously in the doctor’s office or in an outpatient department setting would like to switch and receive it in the home and whether there might be beneficiaries currently self-administering the drug subcutaneously on a weekly basis who might want to switch to a monthly IV formulation now that the services to administer it in the home available. And we definitely want your feedback on the best way to get information out to beneficiaries and their doctors about the demonstration.

To make sure beneficiaries have equal access, we’ve been thinking about having an open application process, whereby we collect applications for

perhaps a month and then select people from that. If we don't receive all 4,000 applications at the time, everybody who needs the requirement would be enrolled in the demonstration and then to the extent we have slots continuing to be open, it would – enrollment would be on a rolling basis.

Or we could do as a first-come, first-served basis so they just open the enrollment period and whoever gets their application in first. One of the concerns we have about doing that versus having an application period and then accepting people and making sure that those beneficiaries that might not be the most connected or tuned into various advocacy organizations have equal to – have a better access and opportunity to find out about the demonstration.

We'd also like your input on – if we do have an application period and receive more than 4,000 applications, is there a way we might prioritize or select beneficiaries or should we do it on a random basis?

So, with that – and again, this is a nationwide demonstration. We are not looking to restrict it at all based on beneficiary's place of residence. With that, I'd like to open up the lines again and answer any questions people may have about beneficiary enrollment or application processes or address anything regarding provider issues.

Operator: Once again...

(Jodi Blatt): (Sharon)?

Operator: Yes? Sorry. Once again, if you'd like to ask a question, please press star, then the number one on your telephone keypad. Your next question comes from the line of a participant whose information we could not gather. If you've queued up for a question, please state your first and last name and organization. Your line is open.

(Jodi Blatt): Go ahead.

Operator: Your line is open. Your next question comes from the line of a participant whose information we could not gather. If you've queued up for a question,

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OK. Your next question comes from the line of a participant whose information we could not gather. If you've queued up for a question, please state your first and last name and organization. Your line is open.

Denise Bagford: Hello? Can you hear me?

(Jodi Blatt): Yes, we can. Go ahead.

Denise Bagford: This is Denise Bagford with CVS Caremark, another specialty pharmacy on the line as well. So we are a provider of IVIG services. I would like to go back and kind of respond to your question about billing, whether we bill the drug and the nursing at the same time on the HCFA.

So, typically, in the world of third-party payers, we typically billed nursing after the visit has occurred, so then we know the length of a visit. But my understanding and I just want to verify, this is a flat fee that you'll be providing as far as the nursing service. Is that correct?

(Jodi Blatt): Yes. It will be a single code bundling the nursing services and medically-necessary supplies and it will be same for everybody. We are looking at the average length of time of the infusion as we develop the payment rate.

Denise Bagford: And so, you wouldn't be able to bill the drug and the nursing at the same time if you want that length of service at the visit. You wouldn't be able to bill until after the nursing visit occurred.

(Jodi Blatt): And would that cause major problems to you if we wanted to receive them all on the same claim?

Denise Bagford: No. You – then – we actually use – typically bill real time. As we ship the drug out, then the bill for the drug goes out. But what I think you're asking us to do is hold the bill and then drop it at the same time to verify the length of the nursing visit as well.

(Jodi Blatt): Correct.

Denise Bagford: OK.

(Jodi Blatt): That would be our – preference. That way, we can – basically, what we’d like our claims payment system to say is to process the claim for the drug as they currently do now. There’s no change in the payment for the drug.

And basically, the claims processing system would say, if, under the standard Medicare Part B, we’ll pay for the drug; if the beneficiary is enrolled in the demonstration, we’ll pay for the new demonstration code. So it – I will say it’s just a lot easier for us if we can get both at the same time.

Denise Bagford: Yes. I think we’d have to work through that on our side, but possibility that could be done. As far as moving patients from an outpatient to – or a physician’s office to home, I think that’s absolutely something that patients would like to see. Most – some of these patients aren’t well enough to get to the doctor’s office through outpatient setting.

So getting it into their home, number one, would – I think there’s lots of studies that show patients do better in a home setting, heal better in their home and, of course, are exposed to less risk of other infections if they’re in their home versus going to an outpatient or physician office.

(Jodi Blatt): Do you have a sense of – one of the things that we always have a challenge with is estimating – we know what we’re paying for in terms of the drug and where people are going, but many people – you know, it’s not inconvenient for them to go to the doctor particularly once a month and maybe they don’t mind.

If you had a sense – do you have any sense of how many people, based on who are already receiving the drug and if their doctors also – they’re an outpatient setting – might like to switch over?

Denise Bagford: I couldn’t give you a number. But I would guesstimate that the large percentage of them would then switch.

(Jodi Blatt): OK. Are we talking over 50 percent, 70 percent or 30 percent? Do you have any sense of how many?

Denise Bagford: I don't. But I would imagine it would be over 50 percent.

(Jodi Blatt): Thank you. That's helpful. I appreciate it.

Operator: Your next question comes from (Laurie England) from Barnes Healthcare. Your line is open.

(Laurie England): This is (Laurie). I'm with Barnes Healthcare. We are a regional specialty provider in Georgia, Florida, and Alabama. I can tell you, as far as applications and access into the program –, there are – I would agree with the lady that just spoke.

There's probably greater than 50 percent in the infusion (inaudible) that would love to come home and be in the market that we are in – their gas expenses that are great for patients like travel expenses, different things. Plus, a lot of the hospitals in these areas are not true outpatient infusion centers. A lot of the patients are going to hematology-oncology centers or sitting with patients that have other diseases and if you've already got a primary immune patient that's already immune compromised, you're actually just asking for more infection in the patient.

So I think an application process would be great versus a first-come, first served so you can truly get a picture of what's going on with the patient and who would be best suited to have it in the home.

(Jodi Blatt): OK. That's good. Now, if we – do you have any – given – we do want to make the application process as burdensome as – least burdensome as possible. And do you – if we were to get more than 4,000 – let's say, we have an open – an open application process per month and, let's say, we got more than 4,000.

Can you provide us any guidance or criteria that what we might use to select the 4,000 should be – should it be the first 4,000 that submitted? Should there be other factors, you know geography; you know, look at how far they have to travel or – to their current provider? Do you have any thoughts about that?

(Laurie England): I think, you know, in the space we're in and in the areas we're in, I think it would be helpful if we did look at, say, how far a patient had to travel in versus, you know, a patient that may be five minutes from the infusion center. That's not a big deal.

But if you've got some – I mean, we've got some patients that I know are traveling an hour to get their infusion. So that's really a burden on them that could be lifted. So I think that certain factors need to be looked at as far as how far they're having to travel, their disease state – you know, different things like that to decide who gets to come in.

(Jodi Blatt): You know, some of those patients are – if they're going to the doctor's office – there may be – they may have to be going to their doctor's office anyway or not, I mean, so they're traveling.

(Laurie England): Correct. And that's another (thing) because, like a lot of the doctors around here don't have their own infusion centers so they are going to hospital-based infusion centers, but in other areas, that's something to look at to especially if the doctor has their own center and they're going to their appointment anyway.

(Jodi Blatt): OK. That's good to know. Thank you.

(Laurie England): Yes.

(Jodi Blatt): Appreciate it.

Operator: Your next question comes from Andy Copeland from ARJ Infusion Service. Your line is open.

(Jam Sean): Hi. This is (Jam Sean) (inaudible) from ARJ. I think it is important that we look at, for comparison's sake for the – for the evaluation that we – that we gather, you know, from a cost perspective, the physician office infusion cost and outpatient clinic cost versus what it's going to cost from a home infusion setting. So I think the one thing that's going to be part of the criteria is they

need to be in an outpatient setting, you know, in a clinic or physician office, first of all.

I think the other thing is we need to look at how long the patient has been on active therapy, if they maybe had a gap; you know, maybe the patient has to be on service and actively on therapy for, you know, six – the past six months or some period of time so that you have active patients, you know, because that way you'll be able to get better data and so forth as well. I think those are important factors. And I think everything that the woman before made that were very (incorporated) as well.

One question I did have regarding kind of who the provider should be involved in this is there a contemplated – is there an -- contemplated for this or is it – I mean, can you speak to that a little bit, (Jodi)?

(Jodi Blatt): Yes. We are our current thoughts are that any supplier that supplies that IVIG drug now that Medicare pays for would be eligible to participate and bill under the demonstration as long as they're operating within their own state guidelines and regulations. We were – we were not anticipating putting out an RFP for suppliers and providers.

Again, we'll – we're trying to keep this simple and we are – our goal was that if, you know, current supplier provides the drug now, the IVIG to the beneficiary, they would bill then just this new code. It wouldn't be – we wouldn't have, you know, only one supplier in a region or anything like that. We weren't looking to have an RFP process for a supplier. The limit that the statute gives us is only on the number of beneficiaries and that's why we need the application process, but not on the number of suppliers.

(Jam Sean): OK. Thank you. That's good feedback.

Operator: OK. Your next question comes from Karen Butterson from Barnes Healthcare. Your line is open.

Karen Butterson: Yes. I just want to confer with the two previous individuals about what are the things that I'd like to see as part of the enrollment criteria is since we're looking at the outpatient and the in physician office administration, it would

make sense that we would probably prioritize by those that are being administered IV since we're looking at the nursing portion of it.

I will say right now based upon some of the things that we're seeing in the rule area, it just makes sense because that way they can have it administered in their home for that three- to four-period versus those that are in the Sub-Q arena. Why? Because, right now, they're doing OK. It's the ones that are having to travel. I really think that the administration of the IV portion should probably be one of the priorities, along with the time, the travel and the administration and the outpatient.

(Jodi Blatt): So if I (understand) correctly and we do need to prioritize, you would want us to prioritize those who are currently receiving the drug IV in the doctor's office or an outpatient setting over those who may be able to self-administer subcutaneously at the home, but for some reason, they want to switch to the IV?

Karen Butterson: That is correct. So they can have it in their home versus having to travel. Being in a rural area, like we are, we cover three states, access is an issue, travel time is an issue, cost is a very big issue to these patients.

(Jodi Blatt): I'd like to ask if there are any clinicians on the line to clear up one of the questions I have is my understanding is there may be different side effects with people (reactive) that we would subcutaneous versus IV administration and should – is that a factor of concern if – you know, there may be some people, because of travel, do administer subcutaneously but perhaps it is an ideal and IV might be better for them.

One of the questions that we'll get to that on the next slide, and actually, why don't we go to the next slide at this point and then we'll open up – take my questions – is when we – the application, whether we should require the patient's physician to sign the application as well not so much from a physician requirement but the – because we know they'll have to write the prescription, but because if a beneficiary is switching the locus of service and now going to be self-administering, we think that should start with a

conversation between the beneficiary and their provider, it's more of an awareness issue.

We were thinking about having an application that might be available to be sent out or downloaded from a website, but in addition to the beneficiary's information, should we require the provider to sign the application to indicate awareness?

We also – we're interested in your feedback as to whether the beneficiary's application should specify a particular drug or supplier. Again, we weren't looking to restrict suppliers. We know beneficiaries often travel during the year perhaps to visit family members if they're snowbirds in the south and so they might change their suppliers in that situation.

So I want to add to the mix of questions some additional questions we have on slide regarding the application process and I invite any clinicians that may be on the – on the line to get their input about that. (Sharon), if you could continue to give us any questions.

Operator: And, once again, if you'd like to ask a question, please press star one on your telephone keypad. And you have a question from (Larry Lemoff) from (Knee Deficiency). Your line is open.

(Larry Lemoff): Hi. I just wanted to go back a little bit on the – on the previous slide seven ...

(Jodi Blatt): Yes.

(Larry Lemoff): There are approximately 1,331 Medicare patients on subcutaneous according to Medpac report last year and that – so I don't know how many people were actually going to switch from SCIG to IVIG. I think that the previous caller is saying about that there'll be more interest coming from those folks in other settings. I think that would be more probably at that point.

And I think that the one question about how can you all reach out – how to reach out to beneficiaries, I really think that, through your own network of beneficiaries who are, you know, in other settings, at least in the hospital outpatient or the outpatient, then, you can probably identify and notify some

of those folks there'll be opportunity to – of the demonstration. I think through the specialty pharmacies and patient organizations, physicians and distributors and manufacturers of immune globulin, I think that that is almost I think are probably more than willing to identify anybody and get the word out as far as that is concerned.

I mean, for example, we, at the IDF, we have a database of patients of more than – you know, a database of more than 14,000 patients that, of which, we have identified that about 20 percent are Medicare-only or Medicare was a secondary insurance. So we certainly would be – you know, since we've been involved from – this whole issue from day one six-seven years, we are certainly going to be able to promote that.

And I think that, you know, you know, working together with CMS, we can probably work out some of that. And again, we also think that there should be a rolling enrollment – you know, obviously, an initial enrollment and rolling enrollment. And, you know, if people dis-enroll that – or leave for some reason, then, others can enroll.

So we think that, you know, working together with the various stakeholders, I think we should be able to get the word out and it'll – I think it'll take some time to actually reach the 4,000. It's going to be really hard and difficult to distinguish one primary immune deficiency patient versus another. I think that's going to be very difficult.

But anyway, on those questions, that's kind of – I've been trying to get in the – I never know whether you're in the queue or not, so it's hard – it's hard to know.

(Jodi Blatt): I appreciate your thoughts and feedback. I do want to – I know – I heard your questions that, you know, you would like people to be replaced. Unfortunately, our statutory limit is 4,000 beneficiaries, not 4,000 at any one time.

So if we do get to the 4,000 enrollment and, let's say, somebody passes away or dropped out of the demonstration, we can't back sell that slot. Now, that said, one of the good parts about that is if a beneficiary enrolls and, let's say,

they then subsequently joined a Medicare Advantage plan, we were not necessarily going to dis-enroll them for the period of time under which they are covered by the Medicare Advantage plan. That plan would be responsible for their care.

But if they then subsequently dropped the Medicare Advantage plan and come back to fee for service, their slot would be there for them. So that's one good aspect of that.

Similarly, as Mrs. (Jones) enrolls in the demonstration and is covered – receives her demonstration-covered services – and then has a home health episode of care, let's say, they break a hip or whatever and are covered for a couple of months on a home health episode of care, during the home health episode of care, their services will be covered under the home health payment system. But when that episode is over, they can come back and get their services covered under the demonstration for the duration of the demonstration.

(Larry Lemoff): OK. I guess we never read the 4,000 as being – you know, that once you're in and if you get out for some reason, then, there's only 3,999 and ever again. I just – I thought I – we were at this (phase) with...

(Jodi Blatt): Yes. We've had other demonstrations where we've had limits and that's the way it's been interpreted. So I think that's something that we just need to accept at this point. Operator, are there other questions queued up?

Operator: Your next question comes from (Tom Barker). Your line is open.

(Jodi Blatt): Thanks, (Tom). Hopefully, we can address – answer your questions now if we haven't.

(Tom Barker): Well, I appreciate the discussion that we've just been having. I think pretty much you've answered my questions. I would just say that it's important to get a broad mix of patients for the 4,000, so both from the hospital outpatient setting as well as the physician office as well as those patients who want to administer at home the IV.

But it's important to get a mix and, you know, I think it would probably not be a good idea to just get the 4,000 patients just from one setting, so a mix is good. I think that what you heard from the last couple of comments just reinforced that point. So I guess that's all I'm saying.

(Jodi Blatt): I appreciate that. I would agree a mix is good and as part of our outreach program will be to identify getting services in different settings and reaching out to them. And I very much appreciate all of your efforts and support and willing to help us get the word out to patients who are in different settings so that we can make sure they're aware of it.

That is one benefit of an application period. It gives time to get the word out. And, you know, first-come, first-served often, you know, (gets) people are most connected but not necessarily the best mix. So, thank you.

(Tom Barker): Thanks.

Operator: Your next question comes from Logan Davis from Vital Care, Inc. Your line is open.

Logan Davis: Hi. Thank you. I've been in the queue for some time. I'm going to back up and go through some of the questions you all posed and just affirm some of – some of the things you said so far.

We agree that it makes no sense for the drug and the administration to be billed by the same provider – the pharmaceutical provider – on one claim form. So, in the context of administration, things like that makes the most sense. So we agree with your plan from that perspective if that's the case.

(Jodi Blatt): That's – (inaudible) so I appreciate hearing that because if we were going down the wrong path, we definitely would like to know.

Logan Davis: Absolutely. There is also some talk about eligible organizations (trying) to participate as suppliers and we also agree that, you know, suppliers that are currently providing IVIG should be able to participate in the demonstration without having to have additional, you know, accreditations or jump through additional hoops.

So they're accredited to make your supplier and enroll as a supplier for those categories, they should be able to provide...

(Jodi Blatt): That's -- as long as they're operating under existing state regulations regarding delivering services and meet all of those requirements. That would be our goal.

Logan Davis: Yes. We agree on that as well. Then, you had had some questions about beneficiary-related issues and outreach and which beneficiaries would be most likely to use the demonstration project to enroll.

We also bill like you would see a large percentage of these beneficiaries migrating from outpatient infusion centers similar to how their commenters have suggested. Particularly in rural areas, you know, we see that there is a big need patients having to travel multiple hours to their infusion centers.

Then, there's often times issues that, as one of the commenters stated, with, you know, being in a room with, you know, patients that are sick with other diseases and being immune-compromised can be a problem. Our organization is a home infusion and specialty pharmacy organization that has many providers in rural areas, so we're definitely impacted by that as well.

And, the last page here, (business) – we do agree that it'd be good for a physician to be involved in the application process, to your point, you know, so they're aware that the patient is involved. I don't think the application should require a particular drug or supplier. You know, to us, it makes more sense for the beneficiaries to be enrolled at an administration project and then the prescriber and the pharmacy that the patients are working with can care for that patient appropriately. So while it may as if – you know, prompt the user to include that in the application, I don't think drug or supplier should be required on the application for enrollment.

(Jodi Blatt): Thank you. I appreciate your feedback. We are anticipating an application that we hope to keep it relatively simple. But there will be an independent evaluation of the demonstration.

And we may – we are thinking now about – if there is information that is most efficiency collected, you know, on the application form itself and we haven't really dealt with that in detail, but there may be a couple of questions related to that that we will want to ask on the application, so I appreciate that.

Logan Davis: Sure thing.

Operator: Your next question comes from (Julie Kikstra) from Fairview Home. Your line is open.

(Julie Kikstra): Hi. One – I had a couple of questions and comments on several of the slides.

(Jodi Blatt): Sure.

(Julie Kikstra): One concerning – as far as the billing you were looking to gather what the length of time to skilled nursing. How are you going to – are you going to require a time in and time out on the claim? Are you going to require units of service where units, you know, equals 15 minutes, half hour, hour?

Because when we bill commercial insurances, there is a code that states that the nursing visit was up to two hours. Then, there is a different code that is used for any hour half the initial two hours to give the commercial insurance companies an idea of how long a visit was for an infusion.

(Jodi Blatt): We were anticipating a single-code, single-unit per infusion at the home and we are looking – and talking to folks to look at the average length of time knowing some infusions may be a little shorter, some a little longer. But in the interest of keeping it fairly simple, we were looking for a single code that would include payments over an average duration.

(Julie Kikstra): OK. The other question that I had is have you thought about your time of the year for your enrollment period? Obviously, so that is not during the same time during, like, Part D enrollment and things of that nature that these people would be dealing with other enrollment issues at the time?

(Jodi Blatt): Well, that's a good point. We are hoping to implement the demonstration in 2014. We don't have a specific date. There are a lot of things that, unfortunately, we don't control.

For example – I mean, we do have an application that is covered under the Paperwork Reduction Act that involves publications in the Federal Register and approvals by OMB and while there's an average time period, we can't always control it. So our hope is that we will be implementing and being able to start paying claims sometime in 2014, but isn't likely to be the latter half. And I can't commit at this point to a particular date because we do have several approval (positives) to go through as we bring this demonstration up and running.

But I appreciate that thought about not doing it at the time other open enrollments going on. That's a good thought. We do want to make this minimally confusing for folks. So, thank you.

(Julie Kikstra): And then, just one final comment. I echo the sentiments and the comments by a lot of the previous callers concerning where you are likely to get the majority of the beneficiaries having interest. And the previous gentlemen, I do think it's a good idea to have physician involvement so that they are aware of where their patients are going to be receiving care. But I do not think that a specific drug or supplier should be indicated on the application either.

These patients may not be aware of the drugs that are available and that should be a discussion with their physician. And they also may not be aware of the variety of suppliers they may have an option to use. So that just might be an additional research that may not be warranted if their physician is going to be discussing and helping them make that transition.

(Jodi Blatt): Thank you. That's helpful.

Operator: Your next question comes from Scott Sorenson. Your line is open.

Scott Sorenson: Hi, again. (Sorry), good afternoon. One of the issues too that we're looking at is obviously those individuals where it would benefit the most. Has CMS put any thoughts into maybe opening up this to dual eligibles first because of

the access to both levels of our government payment, and also, individuals that have been identified with the involvement of their physician as we make (call as) – frequent flyers or utilization of services outside of the physician office, in particular urgent care or emergency rooms?

I'm sure that's part of your demonstration is to control that cost. I don't – I just don't know how you put that in as a variable.

(Jodi Blatt): Right. Let me handle first in terms of dual eligibles. Dual eligibles, meaning Medicare beneficiaries who also have Medicaid are equally eligible for this demonstration as any other Medicare beneficiary. In fact, when someone is a dual eligible, Medicare pays primary, so Medicare pays first for that.

So we're not looking to restrict based on that factor. Were you suggesting that if we got more than 4,000 people that should be a factor to be considered either pro or con because they may be eligible through Medicaid for the same services that the demonstration covers to exclude them? But, at this point, we were not – we were not taking to treat dual eligibles any different than any other Medicare beneficiary.

Scott Sorenson: Yes. I would think that, again, that would be a good (stamp hole) for you. I think as far as the – where they go through. I think because there may be individuals who are working for, it's much more difficult as far as convenience getting paid time off, you know, having to access or get infusion after hours or before hours. I think that is something that that particular population probably faces more than those that would be just primarily Medicare without any type of Medicare Advantage plan.

(Jodi Blatt): Again, this demonstration will be open to anybody who has Medicare Part B and is covered under the traditional fee-for-service plan. If they are working and they have coverage under their employer and Medicare is secondary, then, that is not a population we'd be looking to go because they're primary-insured. Their employer-based insurance would be covering them and most likely those services are already covered.

Scott Sorenson: Right. But that would only be if people are working more than 30 hours a week.

- (Jodi Blatt): Yes. Again, if Medicare is primary, they would be – and they’re covered under the traditional fee-for-service benefit, we would anticipate them being eligible for this demonstration.
- Scott Sorenson: OK. And, two, with the involvement with the physicians, I guess some of that feedback and I agree wholeheartedly as far as the decision of a product or a provider should be a discussion between them and their physician and then also the physician with the pharmacist where we are – we would have that expertise, but also, within that framework also maybe having discussions with the physician and discussing with some of the patients where they may have compliance issues.
- (Jodi Blatt): OK. Thank you. That’s good to know. Appreciate it.
- Operator: Your next question comes from Denise Bagford from CVS Caremark. Your line is open.
- Denise Bagford: Hi, again. It’s Denise. I wanted to add a subset of population I don’t think we’ve talked about. There are patients who don’t qualify today for home care, they’re opting out if not receiving the drug because they don’t have a covered service or they’re self-paying for their nursing services. So I think that’s another subset of population that we need – you need to look at and make sure they are in this category as well for this demonstration.
- (Jodi Blatt): I want to confirm that this – again, none of these patients that we are – anticipate covering under the demonstration are homebound and that is why they aren’t covered under the home health. So that – and that’s why they’re going either to a doctor’s office, an outpatient department or paying for the services in the home. So they would all be covered.
- Denise Bagford: Right. There is still a subset of patients that are not doing any of it because they can’t afford it, right?
- (Jodi Blatt): You know, if they’re Medicare beneficiaries, they would be eligible for the demonstration. My guess is that those if people would like it at home but can’t afford to pay for the services now to administer at home are probably

going to their doctor's office or an outpatient department and it may be inconvenient and – or not ideal – given their clinical situation and those are the people we would hope that the demonstration (that they were) better served.

Denise Bagford: Right. Then, you did ask a question if there are any clinicians on the line, so I am a nurse. I think you were asking about side effects and I wasn't clear on your question if side effects the difference between IV administration versus Sub-Q.

(Jodi Blatt): Well, someone had mentioned that if we needed to prioritize, we should prioritize those people who are currently – at least what I thought I heard, was getting – those folks who are traveling to the outpatient department or their doctor's office and getting it IV, not those who may already be at home and then self-administering subcutaneously.

So, my question was that, you know, in these situations where people are doing it at home for many of the reasons you stated because they wanted to do it at home, so they're doing it subcutaneously but hesitant to make the Sub-Q versus IV decision on prioritization because there could be side effects or other clinical reasons that it is preferable for a person to get an IV at home, but they're not doing it now. They're doing Sub-Q now because it isn't covered.

Denise Bagford: I don't believe – yes. I can't really speak to that, but I believe that I've seen that population of patients that are doing it Sub-Q that really should be doing it IV. So really there is an equivalent subset of patients that actually absorb the Sub-Q the same and the side effects are minimized from a Sub-Q perspective, so I think we're OK there.

(Jodi Blatt): Thank you. That's helpful. Appreciate it.

Operator: Your next question comes from (Keith Crawford) from (Forum) Specialty. Your line is open.

(Keith Crawford): Yes. Hi. One of the questions – or one of the comments I wanted to make related to identifying patients or subjects for this is I think we got to be careful

that we don't use selection bias where we say this particular patient may benefit more so they should be in it and that could be – I think an earlier caller talked about, like, distance from where they're receiving their infusion or somebody else who may have, let's say, subcutaneous.

I think we need to be careful if it's enrollment. I think everybody should have the opportunity to be enrolled in it regardless of what we believe is their challenge maybe.

(Jodi Blatt): I appreciate that. We really – and we're hoping that we can serve everybody within the 4,000 limit. The question we – and then, the question we have is if we hit the 4,000 limit and that's when – we (wanted) enrolled in the period, so it isn't just first-come, first-served; who's the best connected.

But, let's say, we have a one-month enrollment period and we get 6,000 applications. I'll be honest, having looked at some of the numbers, I don't expect we will, but I can't guarantee that. Is there a way to be fair to beneficiaries and enroll those people who might benefit the most? And so, we're looking for some guidance on prioritizing, if we get 6,000 applications. Particularly ...

(Keith Crawford): Yes. No, and I – yes.

(Jodi Blatt): Geographic ....

(Keith Crawford): Yes. No, and I understand that. I just think, you know, if we're looking at a demonstration project and if there are 4,000 potential beneficiaries you would think that 4,000 was chosen for a particular reason.

So, for an example, if you were by chance to put 4,000 patients into the demonstration project in January, you would have data on 4,800,000 patient months that you could use to determine if the demonstration project met whatever criteria we're trying to meet. So my point was is that somebody can be five miles away from their physician or the hospital and it's quite a burden for them to do that five miles or five minutes.

So my point is I'm just trying to say is we try to get – I mean, number one, you need to get subjects into this demonstration to either prove the point or not prove the point that home infusion therapy may be more cost effective than an institutional site of care or some of the other criteria that's been put forth in the demonstration.

So I'm just trying to say that, you know, we got to be careful that we don't have selection biased because we think it's either more beneficial for a patient or not beneficial for a patient. So that's my only comment. I'm not necessarily sure – like I said, if you get 6,000 subjects and, you know – I mean, that would be great.

Another thing I just wanted to make a comment on is some of the subcutaneous patients probably that are receiving – or Medicare patients that are receiving subcutaneous patients probably aren't ideally suited to do subcutaneous. They've chosen it because they can do it in the home and they don't have the out of pocket.

So I think we need to be cognizant of that. I think, you know, you need a certain level of dexterity to apply this, so there will be some subcutaneous patients that will switch just because the dexterity necessary for them to do it themselves in the home.

And just one more comment. As it relates to a physician – I think the physician is the one who makes the decision on the drug as well as who the service providers should be, so along with their – along with their patient and those needs. So I agree with everybody else who's made a comment related to that.

(Jodi Blatt): Great. Thank you very much.

Operator: Your next question comes from (Laurie Carr) from Walgreens Infusion. Your line is open.

(Laurie Carr): Hi, there. Thanks so much. I just wanted to raise a point around the – who should be allowed to allowed to provide the IVIG. I think that the thinking

sounds like we help pretty much anybody that's able to do it (or) the proper guidance.

I think we have a point of view that we need to think about the quality of care that relates to the nursing. You know, when you think about especially potentially averaging out a payment over four hours and coming up with sort of a lump sum payment, you have an opportunity depending on, you know, the level and quality of nursing to have people that, you know, may or may not be there the full time that's necessary to provide the quality of care.

Then, I also think, just obviously, you know, having a large home infusion company, we've got a lot of our own nursing. And, of course, if you contract out – so, you know, not to say that contracting out for nursing is ever a bad choice, but I think in terms of quality control and being able to evaluate that level of care given to the patients in home, that should be a consideration in terms of the – who is – who is providing the care essentially and, at minimum, if we can't do that, I would say there needs to be a large focus on the evaluation end of this around the quality of care delivered in the home from the provider that's delivering it at the end.

(Jodi Blatt): No, I agree that the quality of care is very important. We want to make sure that beneficiaries get the best quality of care. We would expect that if we are paying for these services that there would be someone present throughout the duration.

It may be that the duration is three hours on one person and five hours on another and we will come up with an average payment rate, but we would fully expect that the patient be present. Just like in the hospital, we paid – we may a DRG and some patients are there three days and some patients are there five days. But we – they get services, hopefully, on all of those days.

We – I would be interested – we – as I mentioned, we will be having an independent evaluation. There – one of the questions we have is whether the demonstration is likely to impact the supply of IVIG that's on slide nine.

If there are other factors that you would like us to consider as we plan for the evaluation, I do have my colleague, (Colleen, Carrie Martin) here who is

going to be the project officer for the evaluation. So if people have any questions or concerns about that specifically, we'd like to hear that, as well as any of the issues, again, about the implementation.

Operator, are there other calls on the line?

Operator: Your next question comes from Marcia Boyle from Immune Deficiency. Your line is open.

Marcia Boyle: Well, thank you very much. I want to go back to the discussion of subcutaneous. I completely agree with the gentleman who was saying that those patients should be included. It should be an open enrollment, non-biased.

We certainly, at the Immune Deficiency Foundation, have heard from patients who have been forced on to subcutaneous and really are not the best candidates for it, being not compliant or they don't have the dexterity as was explained, so I wanted to underscore that.

And again, with the drug, I agree completely that it should be, you know, between the physician and the patient, but no patient should be switched off of the products that they are doing well with. That should not happen. So, thank you very much.

(Jodi Blatt): I appreciate your thoughts. I mean, we were – our requirements of the patient being eligible to receive the drug intravenously. So the fact that – as some of you have already said, that they're doing it subcutaneously now is not an exclusionary factor.

And that we had also heard some of the same things you are telling us and so we appreciate confirmation of that and we understand that there may be some beneficiaries who would want to switch and that's a decision to be made between them and their doctor.

Marcia Boyle: Great. And, you know, in terms of your most recent question about likely the impact of supply of IVIG, we don't think that that's a concern at all if you saw the Medpac 2012 report. It indicated that drugs with a narrow indication and

precise diagnostic criteria would be less subject to a woodwork effect than drugs with broad use, et cetera. I'm sure you have seen that. So I just want to underscore that.

(Jodi Blatt): OK. Thank you. I appreciate that.

Marcia Boyle: Thank you.

(Jodi Blatt): Operator?

Operator: Your next question comes from (Carrie) Bertolazzi from Walgreens Infusion. Your line is open.

Kelly Bertolazzi: Hi. This is Kelly Bertolazzi from Walgreen. My comment has been addressed really related to the nursing that we wanted to make sure that there is no impetus to leave the patient (only) or to increase the rate of infusion based on the reimbursement. You know, as we know through many studies, the rate needs to be accomplished based on patient's clinical response and underlying co-morbidities.

One patient may take three hours. We have patients who take eight hours and we want to make sure that we can make – that the reimbursement is such that if a patient requires a long infusion that we are able to stay there, you know, without being financially unable to do that.

The second comment I had – or question – currently, we have five diagnosis codes that we using under Medicare B. (Inaudible) final four or five or six, 0.12 and 0.2 and, some of our patients, once they reach Medicare age, if they do not have one of the five diagnosis codes, for example, a common one is type of gammaglobulinemia, 279.0, those patients are not eligible to receive IG at home under Medicare B.

So I didn't know if that was part of the consideration for this project, if we are going to be opening up any of the codes because primary immune deficiency does encompass more than the five current Medicare B approved codes.

(Jodi Blatt): The current – the statute that covers this demonstration does not make any changes to our current coverage for the drug itself and I really can't comment on the specifics of what qualifies as PIDD. That is something that would be determined by our coverage folks under the regular Medicare Part B benefit.

What this demonstration does is if a beneficiary is eligible to receive the covered drug under Part B now, we will now pay for the administration of that drug. We are not changing anything about the coverage of the drug itself.

Kelly Bertolazzi: OK. Thank you. That helps.

Operator: Your next question comes from (Debra Apalooski) from Henry Ford Home. Your line is open.

(Debra Apalooski): Thank you. We do have a process in place at our home infusion company where we dispense the drug and we also bill for nursing and then reimburse the home care agency. We have a very diverse population where they can't get the treatment that they need and they can't go at an outpatient treatment center because they don't have the transportation, so, therefore, they're not able to get the medication because they don't have the cost to go to the doctor's office to even receive that.

We have kind of a different situation with our Sub-Q IG patients. I am a registered nurse and we have a – quite a large population at Sub-Q IGs and, apparently, we have a different type of patron in so much that I cannot think of one single one of our Sub-Q IG patients that would want to go back to IVIG.

So, you know, I don't think that we have the population that other people are experiencing where they've gone to Sub-Q IG because the IVIG was not covered or, you know, they had to do it in a home because the – if there is – and (either) independent after their education sessions are completed, 90 percent of our Sub-Q IG patients have no nursing involved except on a p.r.n. basis as needed and if they have a commercial B kit.

We also experience, and I concur with previous callers, in regard to the fact that equitable payments for nursing services provided to be a primary focus

because we also have patients that have IVIG infusions up to eight and 10 hours a day. The quality of that care is not properly reimbursed not only with the patient – with the care -- had to the patient, the home care agencies that are available need to have an equitable reimbursement in order for a nurse to stay in the home that long for the safety of the patient.

(Jodi Blatt): Thank you very much. And again, we are doing nothing to – there's nothing in our plan to try to move people who are currently receiving these services, whether the doctor's office, an outpatient department or a Sub-Q at home to try to change that as it works for them. That's not our goal at all. Next question, operator?

Operator: Your next question comes from (Michael Bliff) from Immune Deficiency. Your line is open.

(Michael Bliff): Hi.

(Jodi Blatt): Hi.

(Michael Bliff): There were some – I'm a physician and a question -- sort of addressed physicians, I think most of them have been answered. But certainly, there are advantages to Sub-Q, there are advantages to IV depending on the individual patient situation and I think we always have to think about what is the patient situation and what is best for them.

I think the doctors need to be involved in making the decisions about what is the most appropriate site of care and certainly about the most appropriate product. As you know, there are reactions – are generally experienced (and so) there are fewer reactions and fewer significant reactions in patients that are receiving their immunoglobulin subcutaneously as opposed to IV. But there are certainly some patients who have significant reactions to subcutaneous and just won't tolerate it, so I think have to be able to, again, decide on what to do based on the patient's tolerance and what is best for our patients.

Certainly, distance to travel, all of the other things that have been raised are important considerations in making the site of care decisions and I really

applaud this demonstration project because care in the home for particularly people in the rural areas is a very important aspect.

So, from a physician's point of view, I think this is a great program. There are many issues that are going to be coming along to be discussed. But I think most of them have been (heard) in the previous discussion.

(Jodi Blatt): Great. Thank you. And again, we're hoping to just make – for those patients for whom the administration and across the administration has been a detriment or barrier to receiving at the home, we're trying to lift that barrier. We are not looking to change where they're getting services for any other reason or change the nature of their medication. I don't get involved in that decision at all. It's – we're purely trying to remove a barrier that may be currently there now. So I thank you for your thoughts.

(Michael Bliff): One of the (issues) I think is important to recognize and I think you're going to be supporting this is that the access to individual products is very important and there are many reasons why a particular product is favored over another.

With the products of immunoglobulin replacement, there are differences in the excipients, whether is high concentration of sodium, a high protein concentration and the osmolality. All of those things – sugar content that may be present – all of those things have to be considered in choosing a product that's appropriate.

You don't want to give a high sugar-containing material to someone who has diabetes or renal disease, for example. And so, you know, this – the idea that a number of insurers – third-party insurers are introducing formularies that exclude some products is something I hope that will not occur in this particular space.

(Jodi Blattk): We are really not looking to interfere at all or change at all what the Medicare Part B benefit is. If, over the three-year course of the demonstration, that new drugs developed that have occurred under the current Medicare Part B benefits for IVIG, then, those would be available. Any changes, we would just piggyback.

Again, what we're looking to do is, for those people who are eligible to receive IVIG in the home who are not homebound to now pay for the administration of it. We're not – you know, we're not looking to interfere, change – or change the current drug benefit. And again, should the current drug benefit change, we updated the new J Codes. The new drugs that they come on the market, adapt to that.

(Michael Bliff): Thanks very much.

Operator: Your next question comes from (Rich Lane) from Alternative Infusion. Your line is open.

(Rich Lane): Hi. This is (Rich Lane).

(Jodi Blatt): Hi.

(Rich Lane): I guess I have something back with regards to the coding. I understand conceptually why you would want to move to a single code, maybe during that demonstration project. So if your intent also – the pump, the supplies, everything else is all bundled with the nursing. Is that correct? Is that what you're looking at?

(Jodi Blatt): We are looking at a single bundled code for the administration of medically-necessary supplies.

(Rich Lane): OK.

(Jodi Blatt): This is not – we are not making any statement about the pump which – and durable medical equipment which, I don't believe, is covered not under Part B.

(Rich Lane): Right. So is that something that you anticipate that would potentially be unbundled at the end of the demonstration project where you would use the EO 781, 84, 22, et cetera, those type of things, those types of codes...

(Jodi Blatt): We're not making any suppositions or assumptions about what will happen at the end of the demonstration or (coverage upon). We're looking at...

(Rich Lane): OK. I would just – I would concur with some of these then, depending on what rates and what structure you're going to come up with, whatever that fee is really going to make an impact as to what providers are going to do in the long run.

And the only other reason I asked the question was because competitive bidding is also impacting on the re-compete with external infusion pumps and it's going to impact your Sub-Q IG patients that are potentially going to have to switch providers because those pumps were included, EO 7 to the 9 was included on that. So again, just something to keep in mind that they impact down the road and I just wanted to make sure that was out there.

(Jodi Blatt): Again, this demonstration per se is not going to change anything in terms of the coverage of the drug or the pump if it's administered subcutaneously. We're not changing that.

(Rich Lane): Right. I understand that, but...

(Jodi Blatt): ... is a competitive bidding reimbursement may have an impact on people's choices.

(Rich Lane): Correct. I – anyway, OK. That's great. Thank you.

(Jodi Blatt): Thank you.

Operator: Your next question comes from the line of a participant whose information we could not gather. If you've queued up for a question, please state your first and last name. Your line is open.

(Jodi Blatt): Go ahead.

Operator: Hello? Your line is open. Your next question comes from (Lisa Vetch) from Walgreens. Your line is open.

(Lisa Vetch): Hi. Can you hear me?

(Jodi Blatt): Yes, we can. Go ahead.

(Lisa Vetch): Wonderful. I have two comments and two questions. One is the suppliers themselves. I do agree that we need to be able to identify and make sure the suppliers have accreditation, have the geographical scope of service to reach patients in the rural areas, that there's a competency and training program for the IG nurses. There's a lot of side effects in this patient population for IVIG.

Also, you had mentioned, and here's the question, data outcomes are also going to be part of this demo and I wanted to identify what that would be.

(Jodi Blatt): We haven't really defined the full scope of the evaluation at this point. The statute provides for us to specifically look at some questions and to update the report that the department prepared about five or six years. We will probably, sometime in the middle of 2014, be putting out a solicitation for an independent evaluator to look at the demonstration.

If you've got some thoughts about questions we should look at, data we should be collecting, we'd be happy to hear any suggestions you have. And we also, by the way – I want to – why don't we – while we're doing this, I'll just move to slide 10. I want to make all of you aware that we do have an IVIG demonstration mailbox.

When we end this conversation at about 15 minutes or so, that isn't the end n we want to receive your input. We appreciate your comments and thoughts, so if you leave this call and have additional thoughts or comments, please give them to us. This last – slide 10 also has our demonstration website and we will post on the website more information as we get it.

And there's a LISTSERV there which you can sign to get notified whenever anything new is put on the website. In addition, my name and number is there. But we do run monitor the mailbox. I have several staff who work with me. We monitor the mailbox. So if I'm out of the office, (then) e-mail box is probably the quicker way to get us your feedback and comments so we don't play telephone tag. Operator, again, if we continue to take question for – some question.

Operator: Yes. Your next question comes from Andy Copeland from ARG Infusion Service. Your line is open.

(Tom Shonafig): Thank you. This is (Tom Shonafig) and there were a few items that I just wanted to either have a question or comment on. I guess, going to the eligibility question, you know, who should be eligible and so forth and kind of the process around that, will there be an administrator of the – I guess taking in the, you know, applications and so forth or will that be handled by your office?

(Jodi Blatt): Well, we anticipate at this point is to hire what we call an implementation support contractor that we will work closely with. We will work with them to develop an application form that, based on what I'm hearing, not only will beneficiaries complete and give us their name and basic demographic information and perhaps answer a couple of question; but they will also have the physicians co-sign it.

Then, we anticipate it being sent back to this implementation support contractor that will be responsible for tracking all of the applications that come in. And again, that's where we come in too at the end of – let's say, we have a one-month application period. If we don't have 4,000 applicants who are eligible, then, great. They will all be enrolled and we will notify to that effect.

If we have more than 4,000, we will have to make a decision about prioritizing them, whether that's random or whether we do it based on any of the factors suggested. At this point, that's what we will be considering over the next couple of months as we finalize the design of this demonstration, so will be working with an independent contractor.

(Tom Shonafig): Yes. And then, just to your point, as far as – you know, if you do get more than the 4,000 eligible, I mean, just a thought, a part of the eligibility – I mean, once they're cleared as being eligible for the demonstration project, you know, you've got more than 4,000 applications that falls in that category. I mean, you might look at just a random lottery situation, you know, where people are assigned, the number and they're picked out at random basically.

(Jodi Blatt): And that is definitely one option if we don't think there's a good equitable way to prioritize.

(Tom Shonafig): Right. And then, the next one goes – my next question is just, from the nursing reimbursement standpoint, I know that there is some differentiation between, you know, reimbursement from Medicare depending on if you're in an urban setting versus a – you know, a suburban or rural setting. You know, there's different kind of cost structure and reimbursement structure for physician services and so forth.

Would that may be, you know, looked at within this setting as well? You know, where, you know, nursing visits are compensated in New York City at a higher rate versus...

(Jodi Blatt): Sure.

(Tom Shonafig): You know. So that might be something to consider as well. And then, the other thing is just a little bit about, you know, the comparison cohort. You know, can you speak a little bit about what you're envisioning or, you know, what your data from this is going to be compared to?

(Jodi Blatt): At this point, as I mentioned, we don't have the evaluation contract on board. It's part of their test to develop the design for the evaluation and what an appropriate comparison group is.

(Pauline): This is (Pauline) from (inaudible) and also comparison group will be driven by our actual demonstration population. So since we're not sure how many would actively enroll, we cannot say with certainty right now what our comparison would look like. So it depends on how many eventually enroll.

(Tom Shonafig): So – and I know that – I know just from, you know, reviewing past demonstration projects and so forth and the outcomes of those projects, I think the comparison group is an extraordinarily important aspect of, you know, what is home infusion being compared to. So I think that's going to be, you know, a real big thing that hopefully I think we'll have some opportunity to have some input on in the future. So,

(Pauline): Sure. And as (Jodi) mentioned earlier, there is a mailbox, the [ivigdemo@cms.hhs.gov](mailto:ivigdemo@cms.hhs.gov), that you can certainly send in any suggestions or

thoughts after this (call). But again, until we are sure of what our actual demonstration population site looks like, it would be hard to come up and define our comparison group.

(Tom Shonafig): Understood. Thank you very much.

(Pauline): Thank you.

Operator: Your next question comes from Logan Davis from Vital Care Inc. Your line is open.

Logan Davis: Hi. Thank you, again. I wanted to comment on the bundled payment rate has been spoken of several times through the call as a flat rate and I know that's the intent of you all moving forward as you put this rate together. As we look at the patient population that are receiving IVIG --, of course, we want to make sure are ensuring access.

Would you consider looking at a payment rate that varies based on the length of the infusions the patients are receiving to make sure access is ensured for patients, so maybe have long infusions; six, seven, eight hours?

(Jodi Blatt): We haven't finalized anything on the payment at this point. We'd be interested in any -- if you've got some specific proposals or thoughts, I'd like to hear them.

Logan Davis: OK. Great. And I'll throw one in there. There are several nursing kits that several of the pharmacy providers use currently in the commercial side. They're CPT codes 99601 and 99602.

These codes are for nursing, so they don't currently cover supply and so that would be added on. But the way those work is that the 99601 covers the first two hours and then 99602 covers subsequent hours. And that would mirror many of the billing for nursing that we see in the commercial side.

(Jodi Blatt): Can you provide for us sort of a mix of how long the infusions take, for example, what percentage of them may be three hours or less, one -- what percentage of them three to five years, et cetera? You...

Logan Davis: Yes. I'm probably not in a great position to give, you know, (hard part perspectives) on that. I just know – we've had experience with these patients, you know, that have – that maybe have reactions to IVIG. You know, the typical protocol is to slow their infusion down.

And so, we've certainly experienced patients that, you know – and they have six-, seven-, eight-hour infusions and they're less tolerant, of course, but (they're) better in the four-hour range. But I would just hate for that, you know, if there's a patient in rural area where there aren't very many suppliers if that becomes a sticking point, it could limit access for those patients...

(Jodi Blatt): What I would like to ask of everyone on the call is, after the call is over, for those of you who are suppliers and are currently providing this service now, if you could send to the e-mail box any percentages you have on duration, you know, of your average patient, particularly if you have older patients – what – that has PIDD. So patients that are most likely the people we will be serving, what the mix is of – currently of the timeframe.

So – and then, I realize I don't want to put people on the spot now. But if you have that information that you could share with us, I would very much appreciate that.

Logan Davis: Thank you.

Operator: Your next question comes from the line of a participant whose information we could not gather. If you've queued up for a question, please state your first and last name. Your line is open.

(Jodi Blatt): Go ahead.

Patrick Collins: Patrick Collins from CLS Behring. Can you hear me?

(Jodi Blatt): Yes, we can. Thank you.

Patrick Collins: Excellent. Thank you. A question and a comment. I'll start with the comment just with regard to IVIG supply. This is my personal opinion based on what Marcia Boyles from the IDF said earlier that I would completely

agree with her that, as previous reports have illustrated with the (wood worth) is that this should not have any impact on supply, whatsoever. Plus, from my understanding with CSL Behring that a product is (plentifully) available, so we do not anticipate any impact at all in supply.

A question with regard to the project itself. I know the legislation identified it as a three-year demonstration project, I believe. Could you confirm when that project would start? Is it from the enactment of the statute or is it from the beginning of the actual demonstration when the first patients are enrolled?

(Jodi Blatt): We are measuring it from the beginning when the first patients are covered for services.

Patrick Collins: Excellent. Well, thank you very much.

(Jodi Blatt): ... we're behind the schedule on that. Can you hold on just one moment please? OK. We have one question we'd like to put out for the group to get some input.

(Bill): Hi. This is (Bill). I'm with the evaluation group and I just want to give the – people on the call had some examples of commercial payers that do pay on – that do pay based on the alternative methodology that's been discussed, if they – you know, if you could send your story to our e-mail box with some examples of who those payers and maybe some more specifics about how they pay.

(Jodi Blatt): Thank you, (Bill). So again, we're willing to consider your thoughts as we finalize our formulations. So please, the information that you can provide to us would be very helpful. Operator, I have about – 2:25 – and we have time probably for another two or three questions.

Operator: Your next question comes Larry LaMotte from (Knee) Deficiency. Your line is open.

Larry LaMotte: Hi. Yes. I just wanted to clarify something that you – I'm not sure I heard right; I'm not sure what I've heard and with regard to the use of DME pumps

in this project and demonstration. Did I hear that you – that the demonstration will pay for DME pumps?

(Jodi Blatt): No. The DME pumps, it is my understanding, if the drug is administered intravenously, our current coverage decision is that those are not medically necessary and we would not be changing our current coverage decision about that.

Larry LaMotte: Because my understanding is I thought that, most especially – most of the people infusions – are you just talking about, like, dollar flow or is that – with the kind of gravity type of infusion? Because I'm concerned about what kind of safety – patient safety – and what is – really what is out there in the normal world. I really like to hear other people talk about that with regard to the pumps.

(Jodi Blatt): Thank you. If there are other people who have thoughts – again, we're not changing current coverage decisions regarding the pumps per se. That's not within the statutory purview at this point.

Larry LaMotte: I understand what you're saying. I'm just saying is we wouldn't want to have this fall down because people would not recommend that they have (no) infusions if it was not going to be done with a safe pump.

(Jodi Blatt): Thank you.

Operator: Your next question comes from (Lisa Vetch) from Walgreens. Your line is open.

(Lisa Vetch): Hi. Thank you. I have one question in regards to the reimbursement structure. I understand that it's going to be a bundled per-visit payment rate with nursing and supplies with the code.

And I do agree with the other caller that, you know, we should have the ability; just like with the 99601, 99602; to be able to have these patients receive care throughout the whole infusion and not just two hours or four hours or six hours. So, you know, we should have the ability to build based

on length of infusion. We do require our nurses to stay out there throughout the whole infusion.

But I also understand from the LUPA payment system that there is a five-visit, 60-day episode of care with those same – and then the reimbursement level goes to a different structure...

(Jodi Blatt): Yes. It's confusing. The statute says it's based on the LUPA, but that – the LUPA is part of the home health payment system. Again, this – we're not tied to the LUPA literally.

We're using it as a guideline as we develop the reimbursement structure. The beneficiaries that are covered under this are explicitly not covered under the home health episode of care payments.

So (while) those issues regarding these are the LUPA and the number of visits and things like that that relate to episode of care are separate and relate to patients who are home-bound and covered under a home health episode of care. We're using the LUPA more the guideline for developing the payment rate, but not as a rigid structure of following it literally.

We also agree with you that the nurse should be with the patient during the full length of the infusion. And we don't think that's necessarily mutually exclusive with developing a payment rate that's based on an average period of time. So whatever that is, if the patient is – it ends up being slightly longer, we would still expect the nurse to be out there just like our DRG rates that they've done on average.

And even if the average length of stay is four days for a particular DRG, the patient get services (as their benefit today). Similarly, the hospital pays the same amount as the patient but they are only (three days). Again, I would appreciate any data you have on the distribution of patients by hours in terms of how long the infusion takes so that we can consider that in developing our payment rate or the payment structure. As I said, we're here to get input and that would be very valuable inputs for us to have.

(Lisa Vetch): OK. Thank you.

Operator: Your next question comes – go ahead.

(Jodi Blatt): No. We'll take one – two more calls, if we could, because I know we're getting to 2:30.

Operator: OK. Yes. Your next question comes from the line of a participant whose information we could not gather. If you've queued up for a question, please state your first and last name. Your line is open.

(Matt Smith): Hi. This is (Matt Smith). I just had two quick questions to go back. The open enrollment course then with the 4,000 people, I agree with the previous callers that, you know, everyone should have access to it, but with the one stipulation that I think, unfortunately, if you do get past the 4,000 limit and, say, you have 5,000 or 6,000 people, I just think that the goal of this is to get access to IVIG patients in the home that don't currently have it.

And I think if push comes to show, it might be looking at the IVIG patients first versus the Sub-Q just simply because the standard for IVIG patients is nearly all of them need nursing throughout the entire length of care, whereas at least Sub-Q patients have the capability of self-infusing.

(Jodi Blatt): Thank you.

Operator: Your next question – your next question comes from (Debra Apalooski) from Henry Ford. Your line is open.

(Debra Apalooski): Yes. Our question was in regards to administration with a pump. I believe it's best practice to deliver IVIG with pump. That is our routine procedure. If we dispense IVIG, we also dispense an infusion pump. That's the safest way for do it as both for IVIG and Sub-Q IG. I believe most other infusion companies follow that suit.

(Jodi Blatt): Thank you. I have that it's a little past 2:30. I want to thank everybody very much for participating and for your active attention and questions. Again, I – we do have an e-mail box. Please, if you have additional comments or questions, send them to the e-mail box. We will try to respond within 24

hours or one business day. And again, we have a website where we will be posting more information as we progress with our implementation.

Thank you very much and, operator, thank you very much for your assistance today.

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

**END**