

**CENTERS FOR MEDICARE AND MEDICAID SERVICES**

**Special Open Door Forum: DMEPOS Accreditation – 2008 MIPPA Guidance**

**Moderator: Natalie Highsmith  
Conference Leader: Sandra Bastinelli  
September 3, 2008  
2:00 PM ET**

Operator: Good afternoon. My name is (Amanda), and I will be your conference facilitator today. At this time, I would like to welcome everyone to the Center for Medicare and Medicaid Services Special Open Door Forum on DMEPOS Accreditation Medicare and Permits for Patients and Providers Act of 2008 Guidance.

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, press the pound key. Thank you.

Ms. (Hasmith), please go ahead.

(Hasmith): Thank you, (Amanda), and good day to everyone, and thank you for joining us for this Special Open Door Forum on DMEPOS Accreditation related to the member 2008 guidance. This special open door forum is to provide guidance to DMEPOS providers on the Medicare Improvements for Patients and Providers Act of 2008 and how it affects you.

MIPPA Section 154(b) added a new subparagraph (f) that states, "Eligible professionals and other persons are exempt from having to meet the September 30, 2009 accreditation deadline until CMS determines that the

quality standards are specifically designed to apply to such professionals and other persons.”

Please remember that there will also be an audio recording of this call placed on the Special Open Door forum Web site, being accessible after September 10, and also the transcript will be posted that day, as well.

I will now turn the call over to Ms. Sandra Bastinelli, who is the director in the Division of Medical Review in the Program Integrity Group in our Office of Financial Management.

Sandra?

Sandra Bastinelli: Thank you. Welcome, everyone. Good morning and good afternoon.

Hopefully, all of you are safe considering all that has happened with Gustav and now with (Tana). I'm fortunate to be able to talk to you today to get you, finally, the guidance that everyone was expecting. Now, we'll repeat at the end of this session the Web site where you'll be able to find these materials and the (stack) that I'm speaking off of, and also the Q&A. The Web site is [www.cms.hhs.gov](http://www.cms.hhs.gov), and then it's forward slash, and this is all one word, Medicare provider SQP – like supplier, SQP – enroll, E-N-R-O-L-L. And I'll repeat that again. I just wanted to get to (serious) that – just in case we do forget that.

As was stated already, the purpose of this call, and only the purpose of this call, is to give out guidance as relates to the Medicare Improvements for Patients and Providers Act of 2008. We will not, at this time – and this is just for DMEPOS suppliers and providers – we will not, at this time, be giving any guidance regarding competitive bidding or any other roles that are either in rulemaking or final.

The Medicare Improvements for Patients and Providers Act of 2008, which is MIPPA Section 154(b), added a new subparagraph (f), as in Frank. This subparagraph states that eligible professionals and other persons are exempt from meeting the September 30, 2009 accreditation deadline unless CMS determines that the quality standards are specifically designed to apply to such

professionals and persons. CMS will work in collaboration with the Medical and professional groups to develop any specific quality standards in the future.

The eligible professionals, as was defined in Section (1848k 3&b) include the following practitioners; physicians, physical therapists, (educational) therapists, qualified speech language pathologists, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetist, certified nurse midwife, clinical social workers, clinical psychologists, registered dietitians, nutritional professionals.

Additionally, Section 154(b) of MIPPA allows the secretary to specify other persons that are exempt from meeting the accreditation deadline unless CMS determines that the quality standards are specifically designed to apply to such other persons. At this time, such other persons are only defined as the following practitioners. Now, again, this is in addition to the list that I just stated; orthotists, prosthetists, opticians and audiologists. In 2009, CMS will be issuing further qualifications or standards for orthotic and prosthetic suppliers, and these suppliers will need to meet in order to bill for those supplies.

Please keep in mind this will be a (NPRN). So since it's a proposed rule, you will have the opportunity to comment on that proposed rule. Although we do not have a date when that proposed rule will be published, we hope it will be sometime in early – in the first few – six months of 2009.

MIPPA also states that CMS may exempt such professionals and persons from the quality standards based on their licensing, accreditation or other mandatory quality requirements that may apply. At the present, CMS is not exercising their statutory authority to exempt suppliers solely based on their licensing, accreditation or other mandatory quality requirements.

Assisting DMEPOS suppliers, with the exception of the eligible professionals and other persons that I already mentioned, that are enrolled in the Medicare program are required to obtain and submit proof of accreditation to the National Supplier Clearinghouse by September 30, 2009. The NSC will revoke a DMEPOS supplier's billing privileges on October 1, 2009.

The accreditation process may take up to nine months to complete for an enrolled DMEPOS supplier that submits a completed application to the accreditation organization and also has no deficiencies to correct post onsite survey. Therefore, all enrolled DMEPOS suppliers, except those eligible professionals and preferred persons that I already mentioned, will need to submit a complete accreditation application to the accreditation organization by January 31, 2009. This is to insure that the DMEPOS supplier will receive an accreditation decision, provided they meet all the accreditation requirements, by the deadline of September 30, 2009.

If an enrolled DMEPOS supplier does not submit a completed accreditation application to the accrediting organizations by January 31, 2009, CMS cannot insure that the accrediting organizations will be able to accredit them by the September 30, 2009 deadline.

Since March 1, 2008, new DMEPOS suppliers submitting an enrollment application to the NSC, excepting those eligible professionals and other persons that I already mentioned, must be accredited prior to submitting the application for enrollment. The NSC will not approve any DMEPOS supplier's enrollment application if the enrollment package does not contain an improved accreditation upon receipt or in response to a developmental request. The NSC shall reject the enrollment application unless the DMEPOS supplier provides supporting documentation that demonstrates that the supplier has an improved accreditation. Keep in mind this is only for those individuals that are not exempt.

So to recap; one, there is a statutory deadline for all DMEPOS suppliers of September 30, 2009. Since this is set in statute, CMS does not have the authority to change this date. Two, the eligible professionals and other persons are exempt from these requirements unless CMS determines that the standards being applied are designed specifically to this group, and this group means the – all of the professionals that I listed. Three, there is an accreditation application deadline. Third point is there is an accreditation application deadline of January 31, 2009 to insure suppliers will meet the statutory accreditation deadline if they meet all requirements. That does not say that the accreditation organizations will not accept your applications; they

will. But CMS cannot insure you – insure you that the accreditation organization will have enough time if you come in after January 31. Four, all new suppliers since March 1, 2008 must get accredited prior to submitting their application, and that's their (855s). This deadline, again, does not apply to any exempt professionals. Five, and last, I just wanted to repeat the Web site, and in addition to what the document called a (fact) sheet and FAQs will be on the Web site, at least by early next week, if not by Friday, and that Web site is [www.cms.hhs.gov/medicareprovidersqopenroll](http://www.cms.hhs.gov/medicareprovidersqopenroll).

That concludes the – actually, topics of discussion, and we're ready for the Q&A session.

(Hasmith): OK, (Amanda), if you can just remind everyone on how to enter the queue to ask a question, and everyone, please remember, when it is your turn, to restate your name, the state you are calling from and what provider or organization you are representing today.

Operator: At this time, I would like to remind everyone, if you would like to ask a question, please press star and the number one on your telephone keypad.

The first question's from (Carolla Wright). Your line is open.

Sandra Bastinelli: Hello, (Carol)? OK, let's move to the next question, please.

Operator: OK, the next question's from (Karen Miller). Your line is now open.

(Karen Miller): Hi. We recently had a physician who required a new (DME) number in a new location, and we were told that because the location was not accredited, we could not get that (DME) number. But according to what you've just told me, I would think that he would be exempt from the accreditation need.

Sandra Bastinelli: That is correct. Ask the physician to resubmit his enrollment application. The National Supplier Clearinghouse has been given written guidance on this, so there shouldn't be a problem. Was this more than a week ago?

(Karen Miller): We've probably been fighting it, and most recently talked to them probably two weeks ago.

Sandra Bastinelli: That's why. So just resubmit it. If you have any problems, just let me know at my e-mail address is Sandra, S-A-N-D-R-A, dot Bastinelli, B as in boy, S – A-S and S is as in Sam, T as in Tony, I, N as in Nancy, E-L-L-I at CMS.hhs.gov.

(Karen Miller): And then can I just ask, when you talk about that CMS could determine that the quality standards do apply to those exempt providers, are we going to get a good leeway again to start working towards accreditation, should we not necessarily – my thought is we shouldn't necessarily be trying to work with an accreditation agency at this point for our positions because, at best, the standards may change for that group.

Sandra Bastinelli: That is correct. I would not be working with an accreditation organization if I was one of the exempt professionals.

(Karen Miller): And we can expect to get a long lead again if they decide to institute quality standards for the physicians?

Sandra Bastinelli: Oh, absolutely. They would have to go out for public comment, first of all.

(Karen Miller): Oh. Thank you very much.

Operator: Your next question's from (Scott Fullier). Your line is now open.

(Scott Fullier): Hi. This is (Scott Fullier). Thank you for this very concise conference, here. Let me ask if this exemption status for physicians is based on a default or an actual decision that has been made by the secretary.

Sandra Bastinelli: I apologize. I wasn't able to understand your question. Do you mind repeating that for me?

(Scott Fullier): Well, I'm a physician, and I'm a podiatrist, and the four categories of physician in Medicare include podiatry, and I believe I'm exempt, based on what you've said. However, is this exempt status based upon the fact that you have not gone through the process of thinking about whether we are exempt, or is it based on an actual decision that we are exempt?

Sandra Bastinelli: Thank you very much for the question. We are – we've received our general counsel opinion, and the acting minister has approved basically what was in the MIPPA law. So I wouldn't conjecture to say that such is due to the fact that we will be changing administrations in the next six months. I just wouldn't guesstimate that we have made a decision to, forever and ever, exempt all those professionals.

(Scott Fullier): Well, consider yourself hug and kissed, OK?

Sandra Bastinelli: You just made my day. Thank you.

(Scott Fullier): All right.

Operator: Thank you. The next question's from (Ron Bullock). Your line is now open.

(Ron Bullock): Hi. Can you hear me?

Sandra Bastinelli: Yes, we can.

(Ron Bullock): Great. Thank you. I just want to clarify, if you could, for a second. I'm a member of a 26-group physician group orthopedic group, and I think I may have misunderstood. Are you now saying that a physician group is exempt?

Sandra Bastinelli: Yes, we are.

(Ron Bullock): OK, that's all I needed to know. Thank you.

(Hasmith): Another hug and kiss.

Operator: Thank you. The next question's from (Alexandra Benowitz). Your line is now open.

(Alexandra Benowitz): Yes, thank you. I'm with the American Association for Homecare. I just wanted to clarify a statement that you made, Sandra, on the March 1, 2008 deadline. Could you repeat that again?

Sandra Bastinelli: Sure. Since March 1 of 2008 new – these weren't existing, but new DMEPOS suppliers, meaning that those – for example, someone with – the first caller

stated they had new locations and they needed to get an enrollment number. So it would be new DMEPOS suppliers, except the physicians and those professionals that I already talked about, and excepting those, all others new DMEPOS suppliers submitting an enrollment application to the National Supplier Clearinghouse must be accredited prior to submitting that application. The NSC, as you already heard, will reject your application if you're not one of the exempt categories professionals unless you have that proof of accreditation.

(Alexandra Benowitz): OK, and then by March 1? What was the March 1 ...

Sandra Bastinelli: That was – it had already happened, March 1 of 2008.

(Alexandria Benowitz): Oh, OK.

Sandra Bastinelli: And we submitted that. That policy's been – we stated that in the Open Door Forum in December.

(Alexandria Benowitz): That's right. That's right. I remember now. Thank you.

Sandra Bastinelli: Oh, great. You're welcome.

Operator: Thank you. The next question's from (Kelly Hipp). Your line is now open.

(Kelly Hipp): Yes, (Kelly Hipp) with the American Optometric Association. I think there's some confusion with National Supplier Clearinghouse. We've had optometrists making calls there yesterday and today, and they are being told that the accreditation has been lifted for physicians only, that optometrists are not considered physicians and still have to become accredited. Can you clarify that with NSC?

Sandra Bastinelli: (Kelly), thank you. Yes, we have already found out that that was an error. That direction was in error, and we have already corrected it, I believe ...

(Hasmith): Or in the process ...

Male: We're in the process of correcting that.

(Kelly Hipp): OK, thank you very much, and major hugs and kisses from us here, too.

Sandra Bastinelli: Thanks, (Kelly).

Operator: The next question's from (Debra Farley). Your line is now open.

(Debra Farley): Yes, I am employed by (Belford) Management Systems, a medical billing entity, and we have many podiatry clients, and again, I know this is probably redundant, but I just want to verify that a podiatrist in private practice who dispenses orthotics to only his or her patients is exempt. Thank you.

Sandra Bastinelli: You are correct.

(Debra Farley): Thank you.

Sandra Bastinelli: You're welcome.

Operator: The next question's from (Bret Ritchie). Your line is now open.

(Bret Ritchie): Hi. I'm a certified pedorthotist in Virginia, and I know that orthotists and prosthetists were listed, and I wanted to know – a lot of times, when orthotists and prosthetists are listed, they mean by referenced certified pedorthotists, as well, but I just wanted to clarify that.

Sandra Bastinelli: Thank you. We have not – as you know – yes, you can send that. However, please note that in the next year there will be public rulemaking to determine who is qualified to supply orthotics and prosthetics, and we will make those definitions known for those qualifications. But thank you very much for pointing that out, that we should make that distinction certification. Thank you.

(Bret Ritchie): OK, so just to restate, certified pedorthotists are also exempt now, as of ...

Sandra Bastinelli: Until such qualifications come out in 2009.

(Bret Ritchie): All right, thank you.

Sandra Bastinelli: You're welcome.

Operator: Thank you. The next question's from (Paul Kethlemann). Your line is now open.

(Paul Kethlemann): Hello. I am a podiatrist, and major hugs and kisses to you, as well. I had some – there seems to be, especially with the last call, there seems to be some confusion over an issue, such as who is going to be able to supply orthotics and prosthetics. Podiatrists do supply a lot of (O&P), and especially on an acute issue – need, rather, to their patients, and this is one of our greatest concerns regarding the need for accreditation. I was wondering if you could comment on that at this time.

Sandra Bastinelli: Sure. At this time – at this time, we, the orthotics – orthotists and prosthetists and any podiatric medicine physicians are exempt from meeting the current quality standards. That is correct. However, as it relates to (O&P), we will define – we'll later define what those requirements will be, but only for (O&P).

(Paul Kethlemann): I'm not quite sure that you answered the question. So what I'm going to do is follow-up with Sandra on an e-mail. Could you – can she possibly repeat her e-mail address?

Sandra Bastinelli: OK, this is Sandra speaking, by the way.

(Paul Kethlemann): OK.

Sandra Bastinelli: Sure. If you're asking for other accreditation standards, I will not be able to say anything because we're in rulemaking as to what those qualifications will take – what kind of shape they will take because we are in rulemaking. But you can certainly e-mail me at Sandra.bastinelli, B as in boy, A, S as in Sam, T as in Tony, I, N as in Nancy, E-L-L-I at cms.hss.gov.

(Paul Kethlemann): OK, thank you very much.

Sandra Bastinelli: You're welcome.

Operator: The next question's from (Brian Husky). Your line is now open.

(Brian Husky): Thank you very much. I have several questions. First of all, what's going to happen in my county, of Galveston County, when none of the participating opticians get accredited? Where are all the people that have benefits going to go?

Sandra Bastinelli: To the non-accredited opticians.

(Brian Husky): To the non-accredited opticians.

Sandra Bastinelli: They're exempt from meeting that deadline, so they don't have to be accredited. So what I'm getting at is nothing has changed, then.

(Brian Husky): All right. So in other words, I'm a certified – I'm an optician standalone business in Galveston County, and I don't have to go through this accreditation process?

Sandra Bastinelli: That's correct.

(Brian Husky): OK, and why is that reason?

Sandra Bastinelli: The – MIPPA has given – has give the secretary discretion – and of course that's delegated through CMS to consider those professionals, and if you look at those professionals under (1848k 3&b), it includes all of the physicians, and also we additionally have the discretion to determine such other persons, and we included such other persons to be not only orthotists and prosthetists, but opticians and audiologists. So basically, the secretary was utilizing his discretion.

(Brian Husky): Well, I was going to be one of those guys that said I wasn't going to give you a kiss. But I will pass this information on to the Certified Opticians Group in Texas and let them know, and I don't know if my current president is listening in on this, but I imagine she will be giving me a phone call shortly after we talk about this.

Sandra Bastinelli: Sure, and please note that we've been in coordination and communication during the last year with your – at least two of the national associations, so

I'm sure after this call they will also be putting messages out on the national forum, at least.

(Brian Husky): OK, I thank you very much.

Sandra Bastinelli: You're welcome.

(Brian Husky): All right.

Operator: Thank you. The next question's from (Roxanne Cook). Your line is now open.

(Roxanne Cook): Hi. We're from an ophthalmology office, and we have an optical department, and we are also curious as to whether or not we would be exempt.

Sandra Bastinelli: Yes, you are exempt.

(Roxanne Cook): Thank you very much. Even if – I'm sorry, even if we get in scrips that are not necessarily the doctor's patients from the outside?

Sandra Bastinelli: For any supplies, and this is post cataract glasses or lenses, I'm assuming, that you're talking about, because I'm – they're the only thing that you're supplying, correct?

(Roxanne Cook): Yes.

Sandra Bastinelli: OK. It's – you know, if you're billing for those supplies, you're correct. You don't, just by virtue of you being in an optical group, do not have to be accredited.

(Roxanne Cook): OK, thank you very much.

Sandra Bastinelli: You're welcome.

Operator: Thank you. The next question's from (Mitzie Watson). Your line is now open.

(Mitzie Watson): I think you've answered this, but just so I can say I asked and you answered it, we're a six-physician group and orthopedics, and our physicians don't have to be accredited, right?

Sandra Bastinelli: That's correct.

(Mitzie Watson): OK, and if we add another physician, he also does not have to be accredited.

Sandra Bastinelli: That's correct.

(Mitzie Watson): OK, great. Thank you.

Operator: Thank you. The next question's from (Kevin Nervin). Your line is now open.

(Kevin Nervin): Yes, I guess I just need a clarification. As far as – I'm a (CPED) in Iowa, and – or a certified pedorthotist, and just – you said something about the standard is going to be determined in later in 2009. I – there, again, is that referring to the accreditation standards? I should not be working with a current accreditation organization at this time, also?

Sandra Bastinelli: Well, I can't tell you what to do, certainly, regarding that, but you might want to wait until the ...

(Kevin Nervin): Standards come out?

Sandra Bastinelli: ... the (NPRM), the qualifications come out. Just in case there's a chance of, you know, things changing, I agree. But I can't tell you what – certainly, if you want to go through, you would be crosswalked into whatever new qualifications we have, if you should choose to go through accreditation today.

(Kevin Nervin): OK, that sounds fine. Thank you.

Sandra Bastinelli: You're welcome.

Operator: Thank you. The next question's from (Paula Ling). Your line is now open.

(Paula Ling): Thank you. We – when we enrolled our (DME) supplier, we enrolled as a (DME) supplier/supply company, even though we are essentially billing for a medical group of physicians. Would we then not be exempt?

Sandra Bastinelli: Do you mind sending me that e-mail? I'm not sure. I'm looking at my colleague, and I'm not sure that I can ...

(Barry): I think the question is what it is that – what it is that you're doing. If – I would – I'd venture to guess that if the physicians are billing for their own – you know, their own patients and things for things that they would be qualified to do, we would give them an exemption. However, if there – you know, if they're operating as a more general (VME) store and they have to see a physician owner, that would not give them an exemption, necessarily.

(Paula Ling): Well, what we're doing is only supplying CPAP and supplies to our own patients. We're not taking outside referrals from any other entities.

(Barry): Yes, but they can walk in the door with a prescription from somebody else.

(Paula Ling): Well, I think that technically they could, but that's not happening at this point in time.

(Barry): Yes.

Sandra Bastinelli: And just to clarify – this is Sandra. Your – the physicians are offering – or not offering, are giving the CPAPs as part of their – they've already done studies and ...

(Paula Ling): ... testing ...

Sandra Bastinelli: OK, and they're giving it as part of their treatment plans?

(Paula Ling): Yes. However, we're billing with an (MPI) for an entity called (LHSU) sleep disorders (DME). So I think that where my confusion comes out because we're not billing under a physician name, per se. We're billing with an (MPI) assigned to this (DME) entity.

(Barry): Well, I'm sure that that will create a problem; however, we will take care of such a matter.

(Paula Ling): OK, so should I still drop you an e-mail clarification?

(Barry): Yes, you can do that, and we'll take care of that. If that's what's going on, the physicians are exempt.

(Paula Ling): OK, so it's [sandra.bastinelli@cms.hhs.gov](mailto:sandra.bastinelli@cms.hhs.gov).

Sandra Bastinelli: Yes, and I'll forward it on to (Barry). He was the gentleman that was speaking.

(Paula Ling): Oh, thank you, (Barry) and Sandra.

Sandra Bastinelli: Sure.

Operator: Thank you. The next question's from (Tammy Klenny). Your line is now open.

(Tammy Klenny): Hi. My question is we're an ophthalmology practice, as well, dispensing post-cataract Rx. I had submitted an updated enrollment form to the (DME), and our supplier number came back deactivated because of the accreditation requirements. What can we do at this point going forward?

Sandra Bastinelli: I don't know when the last time you submitted it. Was it more than a week ago?

(Tammy Klenny): Oh, yes. It was actually in February when it – when it was, you know, deactivated.

Sandra Bastinelli: Oh. Yes, sure. Just resubmit your application.

(Tammy Klenny): Resubmit the application and it should be fine?

Sandra Bastinelli: Yes.

(Tammy Klenny): Great. Thank you so much.

Sandra Bastinelli: You're welcome.

Operator: Thank you. The next question's from (Caroline Picklo). Your line is now open.

(Wendy): Yes, my name is (Wendy). We're a podiatry office in New York, and Dr. (Palucci) was just clarifying that she doesn't need to have the accreditation. She has a (DME) number, and we do sell shoes and orthotics in our office.

Sandra Bastinelli: That is correct.

(Wendy): OK, so we do not need to do the accreditation.

Sandra Bastinelli: Not at this time, no. You're correct.

(Wendy): Not at this time. OK, thank you very much.

Sandra Bastinelli: You're welcome.

(Wendy): Have a good day.

Operator: Thank you. The next question is from (Marvin Aural). Your line is now open.

(Marvin Aural): I think the question's already been answered. Thank you.

Operator: To ask the next question's from (Jennifer Bedach). Your line is now open.

(Jennifer Bedach):Hi. My name's (Jennifer). I'm calling from Minnesota. We own a home healthcare agency up here, and we – our nurses and stuff prescribe equipment for our patients, and we're just wondering if we are exempt from anything.

Sandra Bastinelli: Did you say nurse practitioners?

(Jennifer Bedach):No, they're just RNs.

Sandra Bastinelli: Are you talking about home healthcare?

(Jennifer Bedach):Yes, we are a home healthcare agency ...

Sandra Bastinelli: No, you're not ...

(Jennifer Bedach): A Medicare-certified home healthcare agency.

Sandra Bastinelli: Yes. No, you are not exempt.

(Jennifer Bedach): No. So even for our patients, we – even if it's just for our patients that we're prescribing equipment for?

Sandra Bastinelli: Actually, the home health benefit is exempt because you're – you should not, unless you have a separate (DME) number, what you're ordering for your patients is under payment.

(Jennifer Bedach): Well, we have a separate – a separate number for – not a separate (MPI) number, no. Is that what you mean?

Sandra Bastinelli: Yes, or an enrollment number. Is that correct, (Barry)?

(Barry): Yes, if you have a separate (MSC) number, but I'm not sure you do, then there may be a particular. Some people do.

Sandra Bastinelli: If you don't have a separate number, then no. But if you – oh, we can ...

(Jennifer Bedach): We don't have like a separate – our own separate business apart from our home healthcare agency. It's our agency, but we supply the – you know, we also supply the (DME) supplies for our patients.

Sandra Bastinelli: Right, and you're not billing them separately? That's what we're trying to ascertain.

(Jennifer Bedach): No, it's billed our same (MPIs). We bill our home healthcare.

Sandra Bastinelli: Then this does not apply to you.

(Jennifer Bedach): It does not apply to us. What if we had people that came off the streets that wanted equipment? Is that ...

Sandra Bastinelli: You would need to be – you would need to be accredited as DMEPOS supplier, yes.

(Jennifer Bedach): OK, so technically, if we just cut out people off the streets and just supplied to our patients, we would be exempt?

Sandra Bastinelli: No. What I'm saying to you is as a home health agency, MIPPA doesn't even speak to you because it's already referenced in the (MMA) that you were exempt – these supplies were exempt as part of the home health agency treatment plan.

(Jennifer Bedach): Oh, OK.

Sandra Bastinelli: However, if you tried to go into business as a DMEPOS supplier separate and distinct from your home health agency, then, yes, you would need to get accredited, and you would fall – and no, you would not be exempt.

(Jennifer Bedach): OK. Is there like a special procedure you have to go through, or are we just set?

Sandra Bastinelli: You're set, yes.

(Jennifer Bedach): OK. All right, that was everything.

Sandra Bastinelli: Great.

Operator: Thank you. The next question's from (Tina Breathing). Your line is now open.

(Tina Breathing): Yes, I believe that you probably answered my question already, but we are an ophthalmology practice with optometrists, as well. But our practice and stuff is owned by one physician, and so we are exempt from – we do supplies after cataract surgery.

Sandra Bastinelli: Yes, you are.

(Tina Breathing): OK, and now – and I had supplied or submitted, because we built a new office, and we tried to get a new number, and they didn't give me – of course,

that was back in March, and which I think you referred to that earlier if I send it again now it should go through?

Sandra Bastinelli: Yes, it should.

(Tina Breathing): OK, thank you so much. I guess the hugs and kisses, as the other guys mentioned. You saved us thousands of dollars. So you're great.

Sandra Bastinelli: Understand.

(Tina Breathing): Thank you.

Operator: The next question is from (Shawn Bend). Your line is now open.

(Shawn Bend): Hi. I have a question. We are a new outpatient occupational therapy clinic. We are therapist-owned. We just got our Medicare number in January and our (DME) billing authorization as of April, and I just wanted to clarify we do make custom splints per doctors orders. A lot of it is post surgical, and I just wanted to make sure that we are exempt.

Sandra Bastinelli: Yes, you are.

(Shawn Bend): OK. Thank you very much.

Sandra Bastinelli: You're welcome.

Operator: The next question is from (Robin Wright). Your line is open.

(Robin Wright): Oh, hi. I'm a certified prosthetist, and I was listening to you speak to the other certified podiatrist, and you said orthotists and prosthetists, they are exempt, at this time only?

Sandra Bastinelli: Anyone – yes, by virtue of the fact that we included them in the professional group. However, as it relates to all orthotics and prosthetics, and that means anyone offering orthotics and prosthetics, we are doing rulemaking, and we will set in rulemaking the qualifications, or if you want to call them standards, by which all orthotics and prosthetics suppliers must meet. So that's what I meant by now.

(Robin Wright): So we're in rulemaking.

Sandra Bastinelli: Yes. And because we're in rulemaking, I really can't discuss what that's going to look like. But everyone will have the opportunity to comment during the public comment period in 2009.

(Robin Wright): And that's before January 31?

Sandra Bastinelli: Yes, the deadlines do not apply to you right now. So all the deadlines that are here, being January 31 for your application and the September 30, 2009 for accreditation does not apply to you. So don't worry about the deadlines.

(Robin Wright): OK, thanks.

Operator: The next question's from (Marcia Lawrence). Your line is now open.

(Marcia Lawrence): Hi. I'm a private practice physical therapist and certified hand therapist in Kansas City, and I do understand that I'm now exempt and don't need to do the accreditation. However, if I hire an additional therapist into my practice, will that therapist need to be accredited, or can they fall under my umbrella?

Sandra Bastinelli: No, even if they decide to not fall under your umbrella and you both have separate billing numbers, your – until such time we have orthotics and prosthetics standards, yes, you are all exempt.

(Marcia Lawrence): I can't thank you enough.

Sandra Bastinelli: Sure.

Operator: Thank you. The next question's from (Chris Derevo). Your line is now open.

(Chris Derevo): Folks, we're a (DME) supplier of a (class 3) device, a wearable cardiac defibrillator. We're the only producer of it in the world right now. I'm assuming we still have to go through the accreditation.

Sandra Bastinelli: The defibrillator device, is it external, did you say?

(Chris Derevo): Yes, ma'am.

Sandra Bastinelli: OK, so it is a (DME) supplier, but you – or supply. Sorry, I didn't catch the external part. And you're a physician supplier ...

(Chris Derevo): No, we are a producer and supplier. We are not a physician.

Sandra Bastinelli: OK. No, you are not exempt.

(Chris Derevo): Well, thanks for that.

Sandra Bastinelli: Sorry.

(Chris Derevo): That's OK.

Operator: Thank you. The next question's from (Stacey Reynolds). Your line is now open.

(Stacey Reynolds): I understand now since we're orthopedics, we're exempt, and if we had signed up with the National Board of Accreditation, since we don't have to do it, what would you suggest that we do now?

Sandra Bastinelli: You can – they will give you the option, I'm sure, as all the – any of the accrediting organizations that you may already are going through the accreditation process, they should give you the option to either keep on going because you have invested time, energy and money, or you could choose to not go ahead, and then lose that time, energy and money that you've already invested. So I can't certainly tell you what I would ...

(Stacey Reynolds): All we've done is paid the fee. We really haven't done anything else yet because they have not contacted us.

Sandra Bastinelli: OK, well, just call your accrediting organization and discuss with them what – you know, this still is the best option, and you will be able to make that determination. I really couldn't, as a CMS employee, make that determination for you. I'm sorry.

(Stacey Reynolds): OK, that's fine. Thank you.

Sandra Bastinelli: You're welcome.

Operator: Thank you. The next question's from (Jean Bowman). Your line is now open.

(Jean Bowman): I believe that part of my question has been answered. We are a multi-specialty medical group in Iowa, and we have an optical shop. We have an ophthalmologist on staff, no opticians. We do all the optical supplies, the glasses and such, and my understanding, from what has been said, is that that is exempt. The other half of my question, however, was we also have a surgery center here. It operates under a separate tax ID and a separate (MPI) number, and we, of course, will be dispensing some (DME) during surgeries there. Would that be exempt, or would we – the physician part be exempt and we'd still have to get it for the ambulatory surgical center?

Sandra Bastinelli: OK, that's a great question. Just keep in mind, follow the (DME) supplies, whatever you're billing for under the (DME) supplies. If during surgery, the physicians are doing is implantable device, for lack of better word, that is not covered under any accreditation regulations. However, if the supply is something that is covered, which is post cataract glasses or lenses, then you would still – you would be exempt. So just keep in mind that there are some. Anything that's implantable does not have to – there are no accreditation – quality standards, rather, that even speak to implantables. They were exempt in MMA, Medicare Modernization Act.

(Jean Bowman): OK, thank you very much.

Sandra Bastinelli: You're welcome.

Operator: The next question is from (Ray Jackson). Your line is now open.

(Ray Jackson): Yes. I was wondering what the projected processing time would be for a new DME application now for an exempted individual?

Sandra Bastinelli: For an exempted individual?

(Ray Jackson): Yes.

Sandra Bastinelli: Or a non-exempt?

(Ray Jackson): That's obtaining a new DME number.

Sandra Bastinelli: Well if you're exempt, oh, you mean the enrollment application? I'll have to refer that to (Barry). I'm sorry.

(Barry): We'd like to think that it shouldn't take much more than about 60 days. On occasion it will and depends if you've made any mistakes on your application or how many applications we get, it may – many cases it goes a lot quicker than that.

Right now it might take a little bit longer especially now that we have all these people who listen to this phone call who may be bombarding us with applications, but hopefully it will be shorter than that.

(Ray Jackson): I'm sorry, I had trouble hearing. Did you say 390 and ...

(Barry): No. No.

(Ray Jackson): ... 60 and 90 days?

(Barry): I'd like to think that it would be done in 60 days. However, if we get backlogged as we may because of our, this change, it may take a little bit longer. We hope not. Normally it'll actually take considerably shorter than that.

(Ray Jackson): Thank you very much.

Operator: Thank you. The next question is from (Susan Mestras). Your line is now open.

(Susan Mestras): Hi, my name is (Susan Mestras). I'm calling from a podiatry office in Ohio and I realize that podiatrists are exempt, but subject to the new qualifications that may come out in 2009, is that correct?

Sandra Bastinelli: Yes.

(Susan Mestras): OK.

Sandra Bastinelli: Again, it's the same, may not apply to you, but I – because we're rule making I really can't ...

(Susan Mestras): Can't answer that. OK. But right now we're exempt.

Sandra Bastinelli: Yes.

(Susan Mestras): No deadlines for us.

Sandra Bastinelli: Yes.

(Susan Mestras): Thank you very much.

Sandra Bastinelli: You're welcome.

(Susan Mestras): Bye-bye.

Operator: The next question's from (Peggy Tooms). Your line is now open.

(Peggy Tooms): Good afternoon. I just wanted to clarify that pharmacies dispensing the immunosuppressant drugs but not doing diabetic supplies do not need to be accredited.

Sandra Bastinelli: That is correct.

(Peggy Tooms): OK. Thank you.

Operator: Thank you. The next question's from (Tammy Ferguson). Your line is now open.

(Tammy Ferguson): I'm with a podiatrist group in Wichita, Kansas and – Central Kansas Podiatry. I have a quick question. Does the DME, once we have our DME number does it ever expire? I'm just worried that forget and lost in between the two.

(Barry): You're required to be re-enrolled very three years. We send you out a package to get re-enrolled. On occasion if you do not bill then we will deactivate you

and it usually takes about a year worth of non-billing and then we will deactivate you.

(Tammy Ferguson): OK. Thank you.

Operator: The next question's from (Lee McCree). Your line is now open.

(Lee McCree): We are an orthopedic group in North Carolina. My question, I have two questions, the first one is when do you anticipate the rule making and the standards to come down for the exempt providers? And the second question is, now that we do understand we're exempt, we just continue business as usual providing – billing under our DME provider number?

Sandra Bastinelli: Yes, thank you. This is Sandra again and we don't have any, as I believe I stated, we don't have any intention at this point to – we haven't looked at designing special quality standards that are designed specifically for the exempt professionals so I couldn't give you a date on that.

And your second question was should we just business as usual for the exempt professionals? That is correct.

(Lee McCree): All right. Thank you.

Sandra Bastinelli: You're welcome.

Operator: Thank you. The next question's from (Mari Savickis). Your line is now open.

(Mari Savickis): Thanks, Sandra and (Barry). This is (Mari Savickis) with the American Medical Association. We also want to applaud your decision to exempt the physicians and licensed healthcare professionals from having to get their accreditation. As you know, that's been something that we've had a lot of concerns with so we greatly appreciate that.

One question I do have for you is just listening to the call over the past hour or so it sounds like there's still a lot of questions and I was wondering if you were planning on putting anything up on your Web site? And if you would be sending out any LISTSERV announcements because we plan on advertising

this decision widely and think it would be useful to have that information out there so that we can pull from it directly.

Sandra Bastinelli: Sure, (Mari), we – and thank you. Thank you for everyone's assistance in getting us to this day. We will have our fact sheet up, hopefully by no later than Monday. And we will also have FAQs at that same time, hopefully no later than Monday.

(Mari Savickis): OK. That would be great because we'll get it around to all the specialties and obviously moving forward we continue to oppose the you know any level of accreditation and want to continue to keep the lines of communication open should that change.

But it sounds like right now, as you said, to reiterate what I think I heard was at this time there's not movement at CMS to I guess go down this road of accreditation later.

Sandra Bastinelli: That's correct.

(Mari Savickis): OK. Thank you, Sandra.

Sandra Bastinelli: Yes.

Operator: Thank you. The next question's from (Peter Thomas). Your line is now open.

(Peter Thomas): Hi, Sandra, this is (Peter Thomas). I wanted to clarify a couple things but some of the questions very recently may have answered them, but you just said that you don't plan on going forward with any additional quality standards in the future for exempt professionals.

But I also heard you say in the beginning of the call that you would work in collaboration with medical groups and others to – I think I heard to kind of define these standards? Can you clarify that please?

Sandra Bastinelli: Yes. At such time that CMS would feel that we needed to design and need to look at our specific standards or design specific standards for all those exempt professionals we would certainly work in collaboration with the industry as we hopefully have done in the past.

And (Peter), as it relates to hopefully clear, as it relates to the orthotics and prosthetics supplies that we still have, we still owe a regulation based on HIPAA.

(Peter Thomas): Right.

Sandra Bastinelli: OK.

(Peter Thomas): In terms of the statement that you made I was just unclear about that. You said something along the lines of that you would not – you were making the decision to not exempt anyone for licensure or licensing at this time. Could you clarify that please?

Sandra Bastinelli: Yes. There was a statutory provision that was actually the last statutory provision that said the secretary may exempt these professionals and persons from their, just by virtue of their licensing, accreditation and other such requirements.

What I'm saying today is they are exempt from the quality standards today. Not by virtue of their licensing, certification or other, meeting other qualities of accreditation requirements, but by virtue of the fact that the secretary, that the statute states that we shall exempt these professionals and other persons until or, excuse me, unless we can design or find you know standards that would apply to such professionals and persons.

(Peter Thomas): So specifically it says that unless the secretary determines that the standards being applied are specifically designed to be applied to such professionals. So then the secretary made an affirmative decision that in fact the standards that currently exist were not specifically designed for every one of the professionals that you mentioned?

Sandra Bastinelli: That is correct.

(Peter Thomas): Thank you.

Operator: Thank you. The next question's from (Paie Grey). Your line is now open.

(Paie Grey): You guys already answered my question.

Operator: Thank you. The next question's from (Alex Pinkston). Your line is now open.

(Alex Pinkston): Hi there. My name's (Alex) from Medicine Shop in Georgia, and the question we have several categories of required accreditation. Of course the diabetic testing supplies and we also provide orthotics in our store and DME so the accreditation's going to cover several categories. I'm just wondering how this – our situation's a little unique compared to most of the callers.

How the, –well, I have a certified orthotist on staff. Is that category not necessary for me to cover during accreditation pending the new guidelines that are going to be coming out?

Sandra Bastinelli: Thank you for the question. It's actually – you're not an unusual question. Any DME post supplier billing as a DME post supplier is not exempt. Because you have a certified podorthist or orthotist, unless they're billing and under their own billing number and they have their own enrollment number, they would be exempt.

But if they are – just happen to be your employees, you are not exempt because you happen to be offering O&P (inaudible) September 30th deadline.

Male: OK, and – OK that makes sense, appreciate the help.

Sandra Bastinelli: Oh sure.

Operator: Thank you. The next question is from (Carola Wright). Your line is now open.

(Carola Wright): We are a larger ophthalmology group with optometry and ophthalmology, and I think you've answered most of our questions, except that we had a denial on a new office that was opened in March. We now want to resubmit that application. What's the possibility of us using today's date as the retroactive date, or is there a possibility of even making it retroactive longer than that?

Sandra Bastinelli: Thank you. It – I don't know what you mean by retroactive. You will only be able to bill to the point where you got your enrollment number, because you

can't retroactively bill when you didn't have an enrollment number, from what I understand, (Barry).

(Barry): That's absolutely correct.

Sandra Bastinelli: So I would talk to the NSC as to what you know what dates you're supposed to put on it. But I – we can't you know we, I can't answer what date that should be on, but just can't retroactive. In other words, you know back to January or February, because you did not have an enrollment number for that new office.

(Carola Wright): No, the question is, OK, CMS has a standard that when you're getting a new provider or supplier, that you don't send the application prior to a month before that supplier/provider's effective date.

For example, since this is a new situation you know, for example we sent our application March 12th because the supplier, that practice location was going to be opening April. Now so in other words, we realized that the processing time can take 60 to 90 days on average.

So if I – what I'm asking is, we want, we've always wanted this office to be a supplier. We – before it was rejected, so now we're anxious to get it as a supplier. So if we send in the application this week, can we request today, 9/3/2008, as the effective date?

(Barry): No, you cannot. Basically, the effective date for any new supplier is the date the supplier numbers issued. You'll get a notification in the mail and it will say when that, you'll see exactly when it was issued.

(Carola Wright): Right. But like, so usually on the application it asks, there's a place where you put effective date. And so in other words, you've got it in the application as the effective date, and when they get – and that's the date they do issue the supplier number, because the realization with NSC and CMS is that applications can take 60 to 90 days to process. So they, usually they're – it's either the date that the provider or delegated official signs it or the effective date requested.

(Barry): The effective date, if it was in the future, certainly we would not have anything done. It would not enroll you before the effective date that you said you were going to be open. But we never backdate it.

(Carola Wright): Right. But – I know, and I realize that. But this is a different situation in that the office opened you know six months ago, and so now we're having to go after the fact to become a supplier.

If I contact NSC now, because I was one of the individuals who called them yesterday and was told absolutely not, that we weren't exempt. If I call NSC today or tomorrow, are they going to be onboard with this, to ask questions about resubmitting an application?

(Barry): Well we'll try to process it as quickly as reasonably possible. But we will not backdate it to the date that you put down as an effective date.

(Carola Wright): So, OK, so my only other question was, so now that we're having this phone conversation and everyone's being told that we're exempt, when is it that NSC, because I called them yesterday and was told that we were not exempt, when is it that NSC, their provider enrollment, their, those people that you discussed with processing application, when is it that they're going to be onboard and aware of all this, resubmitting application?

(Barry): I am pledged to issue a technical directive to tell them this within five days of today.

(Carola Wright): Oh OK.

(Barry): I will do that.

(Carola Wright): OK, so 9/8. OK. Thank you.

(Barry): You're welcome.

Operator: Thank you. The next question's from (Julie Sanders). Your line is now open.

(Julie Sanders): Hi, I have a question as far as when we're looking at the (DME) numbers, like for radiology. How do you do that that's assigned to a physician?

(Barry): Well first of all, the physician is down on the application.

(Julie Sanders): OK, so as long as the physician is listed on applications, we're exempt.

(Barry): Yes, the physician, if the physician is the owner, yes.

(Julie Sanders): OK. And then we went through the process with a O&P facility, and we got our accreditation and then we submitted our application. Are we going to have a second CMS inspection or does the first inspection cover it?

Sandra Bastinelli: Thank you. That's a great question. We – you will not have to get reaccredited by no means, but to the extent that there are new standards and qualifications for O&P services. The (crediting) organization will be much like we did when we implemented accreditation.

They will come back to you and see to the extent that you do not meet any of those new qualifications, that you would be you know ask us to become compliant within you know so many months.

(Julie Sanders): Yes, but – no, our ABC certification already came out after March 1st.

Sandra Bastinelli: Understand, but you asked me, I believe, unless I didn't understand, that at such time that we have new standards.

(Julie Sanders): Oh, no. My ...

Sandra Bastinelli: (inaudible).

(Julie Sanders): ... CMS application is currently in your guy's hands, waiting to be processed. Am I expecting a second inspector to come out from CMS?

Sandra Bastinelli: You mean from the National Supplier Clearinghouse.

(Julie Sanders): Yes.

Sandra Bastinelli: (Barry)?

(Barry): You said you're an O&P supplier?

- (Julie Sanders): Yes. My application's been there seven weeks.
- (Barry): Yes. Generally for an O&P supplier, we generally do (inaudible) somehow.
- (Julie Sanders): OK. So if I haven't seen an inspector, we're still waiting.
- (Barry): That's correct.
- (Julie Sanders): So any new supplier's going to end up with two inspections?
- (Barry): Well I wouldn't say that. I'd call it, you get an (accreditation) or accreditation review. And then you get a review, an enrollment review, which tends to consist mainly of review of, that you're meeting supplier standards.
- (Julie Sanders): OK. And you're expecting 60 days from when we applied?
- (Barry): Generally that's about what it takes. It can take longer. We cannot guarantee any processing time. Many cases it's shorter, but some cases it's longer. Depends on a variety of factors; how many applications we get in at once. Sometimes it could even depend upon your location. If we don't have anybody, if you're in a remote location, it may take us longer to schedule a visit.
- (Julie Sanders): OK. So are we just supposed to keep calling back for the status of our application?
- (Barry): You can do that. The MSC probably will not be happy (inaudible) that, but you can do that.
- (Julie Sanders): OK, because we're like the other (gal), we're waiting to bill, so we're holding up our revenue. Thank you.
- (Barry): You're welcome.
- Operator: Thank you. The next question's from (Patty Lariza). Your line is now open.
- (Debbie): This is actually (Debbie). I'm a pharmacist at a small rural Vermont ...

Sandra Bastinelli: I'm sorry, (Debbie). We can't hear you.

(Debbie): I'm sorry. Is this a little better?

Sandra Bastinelli: Yes, that's better.

(Debbie): OK. I'm a pharmacist in a rural Vermont pharmacy, but we're part of a federally qualified rural health center. Are we exempt?

Sandra Bastinelli: What do you supply in your pharmacy that you bill Medicare for?

(Debbie): Most diabetic supplies, some Ensure, some incontinence products.

Sandra Bastinelli: If you don't mind, I'm not aware that you exempt, but I'm not the expert on the federal health you know clinic. So if you don't mind, I can send this up to you know to our policy folks to see if there are any exemptions.

But as far as I know, we don't have – the (inaudible) that actually part of MMA, which was Section 302, did not give us any – and this, (NIPA) did not give us any new sections. And in the existing sections, there were no exemptions for any types of providers such as yours.

But I'd be happy to take that back, to get back with you. If you don't mind, e-mail me at sandra.bastinelli. That's C, as in boy, A, S as in Sam, T as in Tony, I, N as in Nancy, E-L-L-I.

Female: OK. Thank you.

Sandra Bastinelli: (inaudible).

Operator: Thank you. The next question from Harry Goldsmith, your line is now open.

Harry Goldsmith: Thank you. This is Dr. Harry Goldsmith, from the American Podiatric Medical Association, and I have a couple questions. Number one, I just wanted to clarify and make sure that there will be no automatic reprocessing of any applications that have been rejected from either the July 1st or the March 1st deadline.

The doctors would have to reapply?

Sandra Bastinelli: That's correct.

Harry Goldsmith: OK. Second question, I have a podiatrist in Southern California that was given a letter demanding, because it was a demonstration project in Southern California, that he be accredited. He was given 120 days to get accredited. At this point, would he also be exempt from accreditation standards and not have to comply with accreditation?

Sandra Bastinelli: Yes.

Harry Goldsmith: He'll be very happy to hear about that. And lastly, I'd like to thank everyone that we had met with. Sandra, thank you very much, hugs and kisses from the American Podiatric Medical Association. You guys did a good thing. Thank you.

Sandra Bastinelli: Thanks, Dr. Goldsmith.

Operator: Thank you, the next question is from (Charles Abericus), your line is now open.

(Charles Abericus): Yes, I have a couple of questions. When it comes to orthopedic surgeons, in their offices, do the fittings of braces have to be done by qualified people and what is qualified people, according to Medicare?

Sandra Bastinelli: Great question. And since we have (inaudible) on from (ONP), they'll be happy to hear this answer once again. We do not have a definition yet for certified, for qualified orthotists and prosthetists, who can bill Medicare because we are needing to do rule making to determine that.

And that's the rule making that I have been talking about for 2009. So at such time that we – since we do not have specific (inaudible) qualification guidelines out there, either in our quality standards or otherwise, your – first of all, your group is exempt by virtue of the fact that you are a surgeon. So, but just stay tuned to see if there are any (inaudible).

(Charles Abericus): Right. Well, my question was you know can receptionist put on the brace and the doctor bill for it?

Sandra Bastinelli: I would hope not, Dr.

(Charles Abericus): That's what I'm hoping too. We'd like to see some standards within the medical community about who can actually fit the brace in the doctor's office since 99 percent of the time, it's not the orthopedic – in orthopedics, it's not the orthopedic surgeon doing the brace fitting.

Sandra Bastinelli: We will get those in place. Make certain that you give us public comments within the public comment, some comments during the public comment period. We'd love to hear from you.

(Charles Abericus): Is (CMS) aware of the term orthopedic technologist?

Sandra Bastinelli: Actually, I am not. But I'm not proclaiming to be the specialist in this area. If you'd like to send me any information, I'd be happy to hear from you.

(Charles Abericus): Sure, and I – you spelled your name a little bit too fast for me to write it down.

Sandra Bastinelli: I'm sorry. Sandra, S-A-N-D-R-A.

(Charles Abericus): OK.

Sandra Bastinelli: And then dot, I'll spell it phonetically. B as in boy, A, S as in Sam, T as in Tony, I, N as in Nancy, E-L-L-I, Bastinelli at [cms.hhs.gov](http://cms.hhs.gov).

(Charles Abericus): I thank you very much.

Sandra Bastinelli: Oh, you're welcome.

(Charles Abericus): Bye now.

Operator: Thank you, the next question is from (Marylyn Blum), your line is now open.

(Marylyn Blum): I'm with a clinic in Texas. And our clinic is comprised of physical and occupational therapists and we have one podiatrist on staff. So our DME number is for our clinic. I'm a little confused on your comments regarding the

quality standards. I understand that the occupational and physical therapists are exempt.

But the podiatrist, I gather falls into that second item in the new paragraph F, the secretary may exempt instead of shall exempt. So when my therapists are making custom splints, or if the doctor orders a prefabricated one to be dispensed by the therapists, they would be – is our clinic (PTN) number still going to be exempt?

Sandra Bastinelli: OK, I just want to clarify first. Are you billing – do you have a billing number for (DME)?

(Marylyn Blum): Correct.

Sandra Bastinelli: OK. If you are – if the only folks that are providing services under that billing number are occupational therapists, physical therapists and podiatrists. You are exempt, yes.

(Marylyn Blum): OK. And then secondly, when – since the podiatrist is that other category, when you address the (OMP) standards next year, then that status for the podiatrist potentially could change. To where he would need accreditation?

Sandra Bastinelli: (inaudible) it could, yes.

(Marylyn Blum): But if it takes six months for the ruling to get finalized, that may not leave us time to get the clinic accredited.

Sandra Bastinelli: The deadlines do not apply to any of those groups. And that would not apply to the (ONP) as well. We understand that you would never be able to meet the September 30th deadline if we're just coming up with some qualifications that are new and distinct from what you have already. So we understand that.

(Marylyn Blum): OK. And if the (ONP) rulings don't affect what my therapists are doing, but it does affect what my podiatrist is doing, it's then – it's not just he who needs the accreditation, it's the whole clinic, isn't that correct?

Sandra Bastinelli: If in fact, we have accreditation standards, yes. It will not be without – again, we're going through rule making. But just please note that we will be very

specific in the categories of professionals and also in the services that those categories of professionals can provide.

So we'll be very inclusive of services and that would be products that they're dispensing, fitting, whichever the case maybe and who can fit or provide and bill for those products and services.

(Marylyn Blum): OK. And you expect the (ONP) rules in draft form to go out early next year? And then there's time for responses?

Sandra Bastinelli: Well, we – not sure about early next year. But yes, we're working very hard to get them out as soon as we can.

(Marylyn Blum): OK. All right, thank you.

Sandra Bastinelli: You're welcome.

Operator: Thank you. The next question is from (Robbie Upaday). Your line is now open.

(Robbie Upaday): Yes, thank you. Just quick questions on your policies for accreditation for pharmacies, we missed the first few minutes of the call. Could you tell us whether in your interpretation, (MIPA) exempts pharmacies from the accreditation requirement?

And as a follow up question, previously, CMS had a policy where they established a 25 store threshold to define large suppliers, with respect to an earlier accreditation deadline, if they open new locations on or after March 3rd of 2008. Wondering if that policy is still in place?

Sandra Bastinelli: Yes, I just want to clarify, are you a pharmacy that are billing for those supplies that are covered in the (MMA) for accreditation, meeting the quality standards?

(Robbie Upaday): Yes, (DME) supplies, right? Diabetic strips and those things, yes.

Sandra Bastinelli: OK. So there's nothing of what I said today that exempts you from meeting the current quality standards. As it relates to your second question, I believe

and please let me know if it's not correct, you wanted to know if there has been anything changed?

If there has been any change in what is considered a chain in that policy that we stated any new suppliers as of March 1, 2008, have to become accredited. No we have not changed that deadline for any new suppliers that are not exempt.

(Robbie Upaday): OK. Could you also tell me if that applies to new locations or reenrollments, or?

Sandra Bastinelli: Yes, all of the above, yes. New suppliers are considered anyone that is requesting a new supplier number.

(Robbie Upaday): OK, great.

Sandra Bastinelli: Unless you are a chain, if you're a chain, if you have more than 25 or more, then no. You're considered a part of that chain. So you're just opening another location. But if it's anyone that's not considered a national chain, by virtue of that definition, then yes, you would need to get accredited before you get a (inaudible).

Male: Great, and it's just I believe a transcript of this call will be made available, because we missed the first few minutes.

Sandra Bastinelli: Yes.

Male: OK, thank you.

Operator: Thank you. The next question is from (Lisa Odom). Your line is now open. Looks like her line is not in queue. The next question is (Tammy Bradley). Your line is now open.

(Tammy Bradley): Hello. I'm from a small optical shop in Wisconsin. Our DME Medicare number was deactivated in March. We sent in an application for reenrollment. Will we get reactivated back to that date?

Male: Generally it's – if you've been deactivated, if we reactivate you, we usually reactivate you back to the date that you were deactivated.

(Tammy Bradley):OK, so we can go back and bill from these last few months, then? As soon as our number gets reactivated.

Male: Yes. Generally we reactivate you back to the date you'd been deactivated.

(Tammy Bradley):OK, and I know you can't answer this, but we are, you know halfway through the accreditation process. Do you suggest we keep going you know?

Sandra Bastinelli: And you're an optical shop?

(Tammy Bradley):Yes.

Sandra Bastinelli: I would. You know it certainly is up to you, because I don't know how far into the process you are and how much time, money or energy you're already invested. I would suggest that you call your accrediting organization...

(Tammy Bradley):OK.

Sandra Bastinelli: ... and maybe you know, talk it over with them to see if they can give you an idea as to how much more you have to do, because I don't know that. I really can't tell you. Some people, I will tell you, have already – they're in the process and they want to go ahead.

(Tammy Bradley):Yes.

Sandra Bastinelli: Even because they thought maybe they want to go ahead because they believe in the accreditation process and believe that credential is helpful for other billing other than Medicare.

(Tammy Bradley):OK.

Sandra Bastinelli: So I really – that's why I really do not want to say, as a CMS employee, whether you – what you should do, because I don't know your business.

(Tammy Bradley):OK, and the other thing was I talked to the National Supplier Clearinghouse about an hour before we got on the conference. They still say that we are not exempt, so I just – you know how important it is when they get our applications that they don't get rejected again.

Sandra Bastinelli: I just did. We agree.

(Tammy Bradley):OK. Thank you.

Operator: Thank you. The next question's from (J.D. Pathke). Your line is now open.

(J.D. Pathke): Good afternoon. We are a physician – multi-specialty physician group in Wisconsin and we own pharmacies throughout the northern part of Wisconsin, and what our question is – our DME certification is issued to the clinic, and one of our – one of the services that we have listed is that we provide is that we have a pharmacy.

And so is that exempt because it's owned by the physician group?

Sandra Bastinelli: No, and I apologize if you got the wrong impression from Barry. He was stating in another context that it was physician-owned. Because you are billing under Medicare, I'm assuming you're billing for diabetic supplies, enteral or parenteral nutrition. That generally is – are the only three things, but if you're applying any other DME like walkers, canes and then like there are no exemptions for pharmacists.

(J.D. Pathke): OK (inaudible). We – one of our locations is also considered an (FQ8C) site, so – and at that site they are dispensing diabetic supplies, ostomy supplies and surgical dressing, so would that be exempted?

Sandra Bastinelli: We had another caller ask that question. Since we've had two I'll be happy to get back with you after I speak to our policy folks and see if there's any – we're not aware of in our division that there are any exemptions for those clinics; however, I'd be happy to get back with you.

And then on our subsequent open door forums for DME home health (inaudible), which I believe is September the 17th, we'll just put out a full statement. If there's two of you with that question there may be others.

If you'd like to give me an e-mail I'll be happy to at least address your question, though, as soon as I can.

(J.D. Pathke): Great, I will do that. Then I wanted to verify; I believe that what I heard you say is that if it's a DME item, an item that's considered DME that would go to the DME carrier, and it's dispensed by an ambulatory surgery center that it's exempt. Is that correct?

Sandra Bastinelli: No, it's not. I'm sorry for...

(J.D. Pathke): OK.

Sandra Bastinelli: Yes, no. Only those eligible professionals that I discussed, but it's not based on where they sit you know, so if you want clarification you certainly can e-mail me and you can describe what services you're billing for.

It's related to you know, who's providing services and the services you're billing for.

(J.D. Pathke): Right, well, I hadn't gotten any information that I read previously, but I thought that that's what you had said earlier when somebody asked about ambulatory surgery.

You talked about the fact that if it's implanted it's going to go the – our local carrier and if it's an external item it would be DME, and I thought at that point you said then it was exempted, but I must have misunderstood.

Sandra Bastinelli: Well, I don't know what you're – yes. You didn't misunderstand me. It's just the caller was telling me what they were doing. They were an ophthalmology clinic and surgical center, so I knew from that – ophthalmologists are...

(J.D. Pathke): OK.

Sandra Bastinelli: You didn't tell me who – what kind of surgery center or ambulatory center you were, so I can't make the assumption that you – the physicians are providing the service or care to the patient, and yes, ambulatory – excuse me – implantables are not even covered under any of these statutes.

They're exempt totally, but (inaudible) cataracts, glasses, that the ophthalmologist – in this case I believe you're talking about physicians, but optometrists and opticians are exempt currently, yes.

(J.D. Pathke): Right. I did understand that, and then I guess my last question is, is there a listing of all of the accredited organizations out there that would be available for Medicare beneficiaries if they have to start going to new suppliers?

Sandra Bastinelli: You know, (inaudible) that anything here effective October 1 would ask (inaudible) beneficiary to go to another supplier unless it was a (inaudible) and a non-exempted professional, but we certainly would expect that the supplier – and we certainly will roll that out to the extent that they do not get accredited.

We don't think that's going to happen, however, and their Medicare number is deactivated – excuse me – is withdrawn, the National Supplier Clearinghouse certainly will – and through CMS – certainly will get the word out if the supplier does have the responsibility, however, if they are no longer able to bill Medicare, that they have to give notice to the beneficiaries.

So that actually is a requirement, and if the beneficiary chooses to continue to utilize that supplier they have to give notice as well, and that's advanced beneficiary notice, so there's a lot of things that are outside the realm of this call, however, and we (inaudible) we can certainly remind suppliers what their requirements are if they choose not to get accredited for Medicare billing.

(J.D. Pathke): OK. Thank you very much.

Sandra Bastinelli: You're welcome.

Operator: Thank you. The next question is from (Gloria Crouch). Your line is now open.

(Gloria Crouch): Hi. Thank you. I'm (Gloria Crouch) from Connecticut (inaudible). I actually believe my questions were answered, but would just like to sum up my understanding.

Physicians, certified (inaudible) are exempt from accreditation and you have a fact sheet, because what I was looking for was an official notification stating that the physicians are exempt for accreditation for the DME application.

You speak to different reps and you get different answers (inaudible), so I understand that that will be available come Monday, for Barry?

Sandra Bastinelli: Yes. The fact sheet will become available through the web site, and I believe Barry stated that he will get the – the technical direction letter, by the way, is where we have contractors. In this case we need to give them, as you say, you know a formal direction to – on policy.

So that's basically what a technical direction letter is, and that will be going out as soon as possible, within the next five days, yes.

(Gloria Crouch): OK. That's wonderful because I needed to get word out. I'm a clearing house and I deal with many podiatrists, and we needed an official notification so we can get the word out instead of getting the word out before we go the official notification that accreditation is not required for physicians.

Sandra Bastinelli: OK.

(Gloria Crouch): Thank you very much.

Sandra Bastinelli: You're welcome.

Operator: Thank you. The next question is from (Jill Boping). Your line is now open.

(Jill Boping): Oh, hi. My question was is I wanted to clarify, for a podorthist – I have a podorthist that works with me and I understand that I do not need to be accredited, and he works through me for my patients.

If I have a patient that is not my private patient as a podiatrist, but is sent to me from their primary care because they want me to provide them with diabetic shoes, does that – am I still covered under the exempt from accreditation?

Sandra Bastinelli: You are because you're billing, so yes.

(Jill Boping): OK, but the podiatrist, when you get your final rulemaking done, if he wanted to break away from me and work separately, would have to probably, depending on the rulemaking, be accredited.

Sandra Bastinelli: I don't know.

(Jill Boping): OK. I understand. Thank you so much. I want to do the hugs and kisses too. Thank you.

Sandra Bastinelli: You're welcome.

Operator: Thank you. The next question is from (Pat Stevens). Your line is now open.

(Pat Stevens): My questions were answered. Thank you.

Operator: Thank you. The next question is from (Faye Frankfort). Your line is now open.

(Faye Frankfort): My question's been answered as well. Thank you.

Operator: The next question is from Cherie McNett. Your line is now open.

Cherie McNett: Hi. This is Cherie. First the Academy of Ophthalmology would very much like to thank Sandra and all the staff at CMS for all the time you took to meet with us and listen to our concerns on this important issue.

And we are doing a happy dance here and hugs and kisses to you, too, and I do have one question, though. A lot of my questions were answered, but I wanted to clarify if ophthalmologists will be included in the new standards that you're going to be working on for next year. Thank you.

Sandra Bastinelli: Did you say ocularists?

Cherie McNett: Yes.

Sandra Bastinelli: No, we would not be. We're talking about O and P, and that's orthotics and prosthetics supplies.

Cherie McNett: OK. The ocularists are those individuals who make and fit prosthetic eyes.

Sandra Bastinelli: OK, sorry. Yes. I haven't had anything to eat.

Cherie McNett: That's OK.

Sandra Bastinelli: I know (Peter) is laughing at me right now if he's still on the line. Yes. We would. You're absolutely correct. I apologize. I'm thinking eyes and something else. You're absolutely correct. Yes.

Cherie McNett: OK. Great, Sandra. Thank you. We'll look forward to working with you on that issue also.

Female: OK. We'll take one final question.

Operator: The next question is from (Candace Gonzalez). Your line is now open.

(Candace Gonzalez): Yes. I work for orthopedic surgeons and podiatrists and they – we also have OTs and PTs that work under the doctors. My question is – I understand that the physicians and the OTs and PTs are – do not need to be accredited, correct?

Sandra Bastinelli: Yes. That's correct.

(Candace Gonzalez): We work in a large medical building. There are other primary cares who, not often, but occasionally will send their patients down and say go see Dr. So-And-So. He's got one of these braces I want you to have.

Do we need to stop doing that because we're not going to be accredited, or can we continue to do that?

Sandra Bastinelli: You can continue to do that until further notice. Yes.

(Candace Gonzalez): OK. Thank you very much.

Sandra Bastinelli: You're welcome.

Female: OK. We have almost closely approached our 3:30 hour here on the east coast and I'll turn it over to Sandra for her closing remarks.

Sandra Bastinelli: Thank everyone for listening so intently and thank you very much for your questions. This certainly has given us more opportunity to understand what more clarification we may need. I've already received many e-mails from you during this call and (Ninnette Hardouin) and I will respond to them as quickly as possible.

And I'll just forward them to (Ninnette) as you know, we usually play tag team there. I really appreciate all of your feedback in how the (inaudible) guidance does or does not affect you and those – any further comments that you want to give me, please feel free to do so.

I do like to think that we are responsive and also protect the Medicare trust fund as is our requirement for the Office of Financial Management, so please if there's anything positive or negative that you have related to the guidance that I've given today I would like to hear them, either on the phone via voice-mail or e-mail.

The question that I was not – the one question I was not able to answer, regarding the (inaudible) qualified clinic, I will put that on the agenda for the September 17th call, and that's the regularly scheduled open door forum call.

And again thank you very much. I apologize to those that may have not gotten in the queue, but again please e-mail me at [sandra.bastinelli](mailto:sandra.bastinelli), B as in boy, A-S as in Sam, T as in Tony, I, N as in Nancy, E-L-L-I; [sandra.bastinelli@cms.hhs.gov](mailto:sandra.bastinelli@cms.hhs.gov), and again thank you very much and good luck.

Female: (Amanda), can you tell us how many people joined us on the phone lines?

Operator: Six hundred and thirty-nine.

Female: Six thirty-nine. Wonderful. Thank you everyone. See you all then.

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

END