

Centers for Medicare & Medicaid Services
Special Open Door Forum
Revisions to DMEPOS Quality Standards for Therapeutic Shoe Inserts
Moderator: Jill Darling
November 28, 2017
2:00 p.m. ET

Operator: Good afternoon. My name is (Tiffany) and I will be your conference facilitator today. At this time, I would like to welcome everyone to the Centers for Medicare & Medicaid Services Special Open Door Forum, Revisions to DMEPOS Quality Standards for Therapeutic Shoe Inserts.

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.

Jill Darling, you may begin your conference.

Jill Darling: Thank you, (Tiffany). Good morning and good afternoon, everyone. I'm Jill Darling in the CMS Office of Communications, and thank you for joining us today for the Special Open Door Forum.

Before I hand it off to our speakers today, I just have one brief announcement. This Special Open Door Forum is not intended for the press and the remarks are not considered on the record. If you are a member of the press, you may listen in but please refrain from asking questions during the Q&A portion of the call. If you do have any inquiries, please contact us at press@cms.hhs.gov.

And so, now, I will hand the call off to Melanie Combs-Dyer, who is the Director of the Provider Compliance Group.

Melanie Combs-Dyer: Thank you. This is Melanie Combs-Dyer. I am the Director of the Provider Compliance Group within the Center for Program Integrity at CMS. And there are going to be three speakers here today, and I'll have the other two introduce themselves now.

Joel Kaiser: Hi, this is Joel Kaiser, I'm the Director of the Division of DMEPOS Policy in the Center for Medicare.

Thomas Kessler: And I'm Tom Kessler. I'm a Senior Technical Advisor reporting to Melanie. And I did want to convey that if you want to follow along with the slides that we're using for today's session, you can go to [cms.gov](https://www.cms.gov), and under the Research, Statistics, Data & Systems tab, on that page, you'll actually find another subcategory called Medicare Fee-for-Service Compliance Programs.

And by clicking on that, you will then see the Reducing Provider Burden web page. And once on the Reducing Provider Burden web page, you will see the recent initiatives. The first of which is a discussion about these proposed changes to the quality standards. And within that section, there are four bulleted documents that are available. The third of which is the Special Open Door Forum presentation slides.

Melanie Combs-Dyer: Thank you, Tom. This is Melanie Combs-Dyer again. And for those of you who had trouble following Tom, you might try it my way, go to Google and type in reducing provider burden, and usually that's the first link that comes up. Once you get to that reducing provider burden page, the bullet after that first section, third one down says Special Open Door Forum presentation.

The title of the presentation is Documentation Requirement Simplification Project. And on slide two, you can see the charge that we got from our CMS administrator, Seema Verma, as we began to set up this initiative. She really wants to make sure that we simplify our requirements, that we make them easier to understand and get rid of requirements we no longer need and that we really challenge the way we've always done things, and finally to make sure that we have input from external stakeholders. And it was an external

stakeholder who actually alerted us that we may need to make some changes in this area, that being the proposed – the DMEPOS Quality Standards for Therapeutic Shoe Inserts.

On slide three, we've listed our agenda for today. I'll be giving you a little bit of background, and talking about the recent activity and innovation. We'll review the current language and the proposed language. We'll then talk about our consultation period. That's where we'll hear from you. We'll talk a little bit about payment method and then talk about next steps and questions.

So on slide four, we'll begin with the background. The Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, or DMEPOS, as we like to call it, Quality Standards were first published in October of 2008. And in Appendix C, the definitions, there are two definitions that are pertinent to these conversations. The first one is the definition of custom fabricated and number 12 is the definition of inserts.

There's been some recent activity and some innovation that we thought we should talk about. The current standards require the use of a physical mold of the foot for molding a model of the patient's foot. But there had been a number of technological changes that really eliminate the need for a physical model. It can allow that the mold be directly carved using scan technology and all the other new electronic modeling that's out there. They can be very patient-specific. And that new technology is not accounted for in the 2008 quality standards.

I'll now turn it over to Tom to talk about the current language and the proposed language.

Thomas Kessler: So with regard to the current language, the definition is at number one, it's the definition of custom fabricated. And that currently talks about the fact that these are individually made for a specific patients; that the fabrication use – is done using calculations, templates, et cetera; and it then conveys that there's really a substantial amount of work that goes into creating these custom fabricated models. From there, there's a definition at number 12 for inserts. And the current version of the quality standards details that those are directly

molded to the patient's foot or as Melanie indicated they're a model of the patient's foot in some regards.

So moving on to slide seven. What we're proposing is that we make some changes to that definition number one, custom fabricated. And one of the first things that we're doing is in the current version, there's two additional definitions, specifically for molded to a patient model and positive model of the patient. Those were actually numbers two and three. We're actually subsuming those under the definition of custom fabricated model. And we're breaking those out to show the different ways that you can actually create those types of models. And within that, we're now adding in basically a third method, which is the use of the computer-aided design, computer-aided manufacturing software. So, that you can actually mill from the electronic version of the model.

So, those are the primary changes that we're making to the definition of the custom fabric. Now with that, we are also making a change to definition number 12 for inserts. A simple change is going to be (there) because we've moved two of the definitions under number one, (where) renumbering it is number 10. And then we're actually accounting for the fact that another method of creating these models is that you can actually use this CAM – CAD/CAM software, Computer Aided Design, to electronically transmit for milling the data necessary to create the insert.

And so, those are the specific changes that we've proposed to the DMEPOS Quality Standards. Moving on to the next slide, Melanie mentioned that the process that we're using with regard to consultation. And that's an outgrowth really of the statutory requirement in Section 1834 of the Social Security Act. And it actually requires that if we're going to make changes to these quality standards that we need to do so in consultation with representatives of relevant parties.

And so, the process that we have used to carry out or effectuate that consultation is, first, we've actually – we're conducting this Special Open Door Forum. And then second, we actually have put the draft, DMEPOS Quality Standards, out there for a comment period. The draft standards have

been up since on or about November 9th, and we are going to accept comments on the draft quality standards until December 11th, 2017, with the goal that we are going to make a final decision on the final version of the quality standards before January 1st of 2018.

Now just to make sure everyone knows where any comments should be sent, we do have an e-mail address and it is on the slide but I'll say it here, ReducingProviderBurden@cms.hhs.gov. Your comments can be sent to that e-mail address. We have staff that are specifically looking out for any e-mails associated with the draft changes to the quality standards, and we will get to a response denoting that we've actually received the comment once we get the e-mail.

Joel Kaiser: So this is Joel Kaiser. I'm just going to go over the payment rules for therapeutic inserts. Should this new category of inserts be added to the quality standards, payment for inserts is governed by the Social Security Act, a couple of different sections, Section 1833(o)(2)(A) and Section 1834(h).

Section 1834(o) is the section under which we paid for therapeutic shoes and inserts beginning in 1993 through 2004, I believe. There are statutory limits, specifically in the statute for therapeutic shoes that we paid under 1833(o). With the Medicare Modernization Act of 2003, there was a slight change, in that – the law was amended under 1833(o) to mandate that the inserts and the shoes be placed on the DMEPOS fee schedule. And the rules for calculating fee schedule amounts are under 1834(h) of the Social Security Act, which mandates that we use our historic payments from the 80s updated by covered item update factors to establish fee schedule payment amounts. And so, assuming that the proposed changes to the quality standards are finalized, our anticipated fee schedule amount based on the rules of statute for this category of insert is \$38.67. That is a fee schedule amount that is per insert. Thank you.

Melanie Combs-Dyer: Thank you, Joel. Slide 10 talks about the next steps we really like for you all to review and submit your comments no later than December 11th. Again, your comments go to ReducingProviderBurden@cms.hhs.gov. And CMS

plans to make its final decision and post the revised quality standards on or before January 1st of 2018.

So, with that, let's open it up for questions and hear any comments that participant may have.

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

Your first question comes from the line of Joe McTernan with AOPA. Your line is open.

Joe McTernan: Thank you very much. And Melanie, Joel, and Tom, we appreciate you getting some folks together to talk about this. (Inaudible) we saw this information come out on the quality standards, we're pretty excited about it. We felt that you guys were doing the right thing, recognizing the advances in technology. And we know the DME MACs were looking for a signal out of CMS to basically say, it's OK to pay these as positive model inserts as long as the custom fabricated devices were either as good or better than what was provided before.

What came of concern was in the FAQ, and Joel, you maybe able to address this, where the payment amount, and I think it was \$38.67 per insert, was kind of arbitrarily put out there. And then – and without any real stakeholder input on that, and that ends up being essentially a 14 percent toll, for lack of a better term, from providers if they use the direct milling process which I've been told is equal or better way to ensure a truly custom fit.

This seems to be contrary to what's in the claims processing manual when it talks about exploding codes, that if you explode one code into two and they're similar that the fee from the original code should be crosswalked over to the new code as well. Is there any reason for that or any reason why the decision

wasn't made to simply accept or allow the inserts to be billed under A5513 when they were direct mills at the same reimbursement rate as in currently in place for A5513?

Joel Kaiser: From the diabetic shoes and inserts, the history under the Medicare program is in the 1990s, there was a massive amount of fraud and abuse, particularly related to all different types of inserts that were being billed under the benefit. Based on that severe abuse, the agency took the position that we needed to tighten up and control this benefit. And one of the ways of doing that was to have very specific description of the inserts and the process for fabricating the inserts.

At the time, it was direct formed or made over a positive model of the patient's foot. Those were the two techniques. We split the code. The statute had one payment amount for inserts. We split that into two in very specific wording so that you could not deviate in any way from these techniques and come up with creative ways to create inserts that you would then bill Medicare. And that was a major problem.

So that – you know, the solution for that was to create very specific codes and very specific descriptions for the process of fabricating the insert. And so, what we have here now is a new and distinct process. It is neither direct formed A5512 nor is it made over a very positive model A5513. It is a third fabrication process and very specific process.

So it is not a 5513 nor is it a 5512; so it's its own. And based on that, the rules of the statute are applied in calculating the fee schedule amounts. And it is an exclusive payment rule, it's a mandatory payment rule, and that was what was used.

Joe McTernan: OK. Just as a follow-up to that – and was that Joel or Tom, I'm sorry?

Joel Kaiser: This is Joel.

Joe McTernan: But Tom answered the question, correct?

Melanie Combs-Dyer: No, that was Joel that answered the question.

Joe McTernan: Oh, that was Joel, I'm sorry. So just a quick follow-up then, Joel, I mean as far as the – where you get to the 3867, I'm curious where did that come from? Has there been efforts to collect data from manufacturers, from central fabricators? I understand the whole (capital) process, but I guess I'm trying to figure out where the base amount came from? It just seems kind of arbitrary, and it just seems like it's a little bit of a punishment for using this new technology when we already have the productivity adjustment built in to the fee schedule every year. We're not built in to the fee schedule, we're not built in to the reimbursement as a reduction every year.

Joel Kaiser: The fee schedule amount is, like I said, I've quoted the section to the statute to get very specific. In 1993, we began paying for therapeutic shoes and inserts, and we pay based on the limits and the statutes. Those limits are based on average reasonable charges from 1988. So those initial shoe insert limits were based on Medicare average reasonable charges from 1988.

I know the statutory limits were updated every year until the Medicare Modernization Act required a shift. And the shift was to put the inserts' allowed amounts – the payment amounts under a fee schedule. And so, we were switched to 1834(h). These are the – your very – I'm sure you're very familiar with these because they're the fee schedule payment rules for prosthetics and orthotics.

Joe McTernan: Right.

Joel Kaiser: So we're now subject bound by the exclusive payment rule of 1834(h) for calculating fee schedule amounts, no longer statutory limit, but fee schedule amounts for these items. And the fee schedule amounts, as you also probably are very well aware of are based from on average reasonable charges from 1986, 1987, updated by an annual update factor.

So, since we had 1988 average reasonable charges for inserts that were paid. Those were used to – and updates were applied in accordance with 1834(h). And that's how we arrived at the amount. It's exactly what the statute

mandates for therapeutic shoe inserts. And so it's 100 percent in accordance with the law.

Joe McTernan: OK. So the difference is more in how things were calculated because you're using 1988 as a base year for the "new insert," while the A5513 was based on statutory increases through, I think, 2003, you said, and then subject to the CPI update after that. So, is the \$5 or \$6 difference in reimbursement is a trick or the result of the different methodology for calculating then?

Joel Kaiser: No. The Medicare Modernization Act also had a provision that allowed us to establish limits, fee schedule amounts that were low lower than the 1834(h) amounts. And so, we did that. It was the intent of Congress that for the cheaper inserts on the market that we have a lower amount, and we establish a lower amount that the amount for A5512 for direct formed inserts.

By the same token, for those made with a positive model, there was a lot of – we got a lot of inputs from the suppliers about all the work that's involved in making a positive model. And so, we created the fee schedule amount for the ones created over positive model such that they would be higher than the historic reasonable chargers; whereas, the direct formed would be lower.

Now, we're talking about direct milled inserts where you don't have a positive model. So, that fee schedule amount would not apply in this situation. They are not direct formed. So, that fee schedule amount would not apply in this situation, the \$29 amount. So, what we have is (go) based on what exactly the statute mandates for the amount, you calculate that amount, and that's what you have for these inserts.

Joe McTernan: OK. Thank you.

Operator: Your next question comes from the line of Robert Gaynor with Dia-Foot Florida. Your line is open.

Robert Gaynor: How are you today?

Melanie Combs-Dyer: I'm good.

Robert Gaynor: My first question is – so A5513 will be the positive model custom diabetic inserts and CMS is proposing a new code for the direct milled diabetic inserts, a new CPT code?

Joel Kaiser: Well, (currently) it's just a way of processing a claim. If there's not a new code added, it would be processed under a miscellaneous code.

Robert Gaynor: Do you think it will be confusing to the suppliers of diabetic inserts to have two different types of inserts, especially for the manufacturers?

Joel Kaiser: Well, we already have two.

Robert Gaynor: (And lastly) ...

Joel Kaiser: This will be adding a third.

Robert Gaynor: And lastly, in August, CMS proposed a redetermination project for the custom diabetic inserts, whether they'd be made positive model or now maybe the direct milled inserts. Will that still carry on? Will all manufacturers of custom diabetic inserts have to have all their diabetic inserts approved by PDAC?

Joel Kaiser: Yes. Currently, that's what the contractors are requiring. They're requiring a product verification. If you are going to be classified under A5513, which requires a positive model – you use of a positive model in fabricating the insert, then you must be code verified. And I think the contractors are currently looking at existing products and are going to be making code verification decisions, I believe, by June.

Robert Gaynor: So, even if you're approved for a direct milled diabetic insert, you will have to get it approved again under the redetermination project?

Joel Kaiser: No. That's a project that's specifically related to A5513. Those are diabetic inserts that are made over a positive model.

(Inaudible)

Robert Gaynor: And lastly, a lot of suppliers don't even know the difference between a direct milled and a positive model diabetic insert. So, will there be some education given to the suppliers?

Joel Kaiser: Well, the industry that came to us pointing out the technique. So, I'm assuming the industry knows what the technique is that they brought forward.

Robert Gaynor: All right. Thank you very much.

Operator: Your next question comes from the line of Paul Kesselman with APMA. Your line is open.

Paul Kesselman: Hi. Good afternoon to everyone. Tom, thank you very much in the past for speaking with me on the phone. I do have one question regarding the quality standards. This is even more important I think than the pricing issues and other issues that have been brought up. One thing that has not been addressed by the proposed quality standards is the taking of a negative physical impression, by the way, of a cast or a foam impression and then converting that into an electronic image.

We have using CAD/CAM to scan the body. We have foam impression or cast impressions. But we do not have this other methodology, which by the way is probably the way most physicians and suppliers are taking an impression. So, my question, I guess, is why was that left out?

Melanie Combs-Dyer: This is Melanie. And I'll start and see if Tom or Joel want to add anything. I wasn't aware of that foam impression to an electronic model was new way of doing this. And we appreciate your comment. We'll certainly look into it.

Paul Kesselman: Thank you.

Operator: Your next question comes from the line of (Stephan Fletcher) with (American Board of Certification). Your line is open.

(Stephan Fletcher): Thank you very much for the opportunity to ask questions. My question really has been somewhat covered, but I just wanted to make sure I understand why there is a need for a new code or a new way to bill this type of insert that's direct milled. It appears that the proposed revisions to the quality standards changes the definition of what a positive model of the patient is by including in the new language the ability to make a model that is on the computer rather than a physical model. And so, it's somewhat confusing why there is a need for a different payment or different code, if you will, for a custom fabricated diabetic insert when the definition in the quality standards appear to now have provided an opportunity for suppliers to be able to use that type of fabrication technique in order to make a custom fabricated device.

And I'm just – if you could sort of maybe just reiterate why is this technology now mean that it's not A5513 is my basic question, if it's still the end result is a custom fabricated diabetic insert made to a model of the patient's foot, whether the model be a virtual model on the computer or a physical model on their bench. I – could you explain why that now creates a requirement to pay it in a different way?

Joel Kaiser: Well, the one – the one thing to just to make crystal clear is that the payment amount for A5513 is a payment amount that is for a technique that involves using a positive model. So the insert limit and statute historically was for inserts, period. At the time that we created the code and the lower limit, the lower fee schedule amount for direct formed, we created the code and the fee schedule amount for the positive model. You have to have a positive model or that fee schedule amount doesn't apply.

If we're talking about we're not – the technology is such that we're not using positive models anymore, then I would think that we would just eliminate 5513 and we would pay the statutorily mandated amount of 3867, which is what is mandated in the statute. The only other amount that the statute speaks to specifically is a lower amount, a lower amount for inserts of appropriate quality. The secretary has discretion to set lower amounts and we did that for the direct formed.

So, if we're talking about a technological evolution and the amount that we establish for positive model is no longer applicable because we don't use a positive model anymore, then that fee schedule amount goes out the window. And so, we are left with the statutorily mandated amount. So, one – either way, whatever direction you take it from, it's the statutory mandated payment amount applies in this case. And there's really no discretion here.

(Stephan Fletcher): I appreciate that clarification. And just as a brief follow-up, my question really was not about the amount that's paid. It was really about the rationale behind revising the quality standards' definitions to say that a way to get a positive model of a patient is this new way. But now you're going to say it doesn't qualify to be a positive model even though it's not a physical model. And I guess I would encourage CMS to perhaps view this from a different perspective that this is just a different fabrication technique, and there's still a model of the patient's foot used to fabricate the actual end result, which is a custom-made insert for the diabetic patient. And so, I guess, I would encourage that.

I have a last comment before I give up the floor. I would strongly encourage for the sake of the suppliers who are trying to care for these beneficiaries that there be an actual code for this instead of a miscellaneous code because I that creates a whole other set of issues, but just – I'll leave it there. Thank you very much.

Operator: Your next question comes from the line of Peter Thomas with OPA. Your line is open.

Peter Thomas: Thanks very much. This is Peter Thomas. I'm representing the Orthotic and Prosthetic Alliance. And I have been listening intently, Joel and Melanie. In particular, I don't want to rehash a lot of the territory we have already covered, but I'm afraid I'm going to have to. First off, I want to thank you for reviewing this whole issue and not going forward with the decision to code these inserts as non-covered items. That's a critical and very beneficial step forward.

We have – we submitted a white paper, comprehensive white paper. I hope you were able to see it. And ultimately, what we're hoping to do is follow up with a meeting at some point in the future. I think the issue around molded to patient model is an important one. We basically said in our paper that you could take the language that is in the existing code descriptor of 5513 and simply interpret it in such a way that the – especially now that the quality standards have been changed the way they have been or they are proposed have been changed – to be changed. You could interpret the existing language to completely cover these inserts.

Now, FAQ number 13 refers to the inserts in question as being different types of therapeutic shoe inserts, but we don't really believe that that's true. The inserts are, in the end, the same inserts. It's just we're talking about a process, a fabrication process, more than anything. And really that is something that goes to the productivity adjustment that was discussed earlier. You could basically interpret a virtual model of the digital scan of a patient's foot to qualify under the phrase, model of patient's foot, in that code descriptor of A5513. And you could interpret the term custom molded to include direct shaping of a finished diabetic foot insert from the virtual model through the use of CAD/CAM or similar technology.

So, we're unclear as to why, as it's already been mentioned before, why a new code really needs to be created if you've got the new definition in the quality standards, which we support. We do think that, that allows CMS to make the determination that these inserts through a new process, if you will, ultimately the same inserts can continue to be reimbursed under 5513 and interpreted to qualify into that descriptor.

So, that's our ultimate position, I guess, and I'm just – I'm grappling with how – with the previous callers, with (Steve Fletcher's) same basic question, that now you've defined the quality standards to include these inserts, why we – why CMS could not use the existing descriptor of 5513 to allow this to qualify under that code?

Joel Kaiser: Yes. Hi, Peter. 5513, you know, what we had, and I alluded to this earlier -- this is Joel, by the way -- there was a mass amount of fraud. There were FBI (stings). There were a lot of criminal activities that was going on in the 90s related to all types of inserts that were being billed to Medicare. And so, we had to become very specific in describing the inserts that fall under the benefit. And the codes specifically described those types of inserts. And it's not just a brand or a product. It is a fabrication process.

And so, we had -- we were very specific, which is why we have to update the quality standards because the quality standards were written in a very specific way because we had to close the door on the fraud and abuse. So, now that we know that there's a new type of technique that we believe is appropriate for inclusion under the benefit, we're proposing to revise those standards to recognize that. And that's what needs to be done.

If we were going to go away and go in a reverse direction, if we felt that the fraud and abuse problem was no longer a problem and we were going to go in the opposite direction, we might potentially go back to one code for inserts, which is where we started. But for now, we have very specific codes.

Now, with regard to A5513, our understanding is that there's still going to be inserts made over a positive model. If that's not the case, then we might think about eliminating code A5513 and we might think about eliminating that definition in the quality standards. But our understanding is that that's still an insert technique, fabrication technique, that's still in use. But if it's not, then, of course, that might change things.

But if it is still in use, then we would have a code and fee schedule amount that was specifically calculated based on molded to patient model with positive model. And I have all my files and everything related to that. But this simply is not that fabrication technique. And so, if the fee schedule amount for A5513 does not apply. So, the rules of the statute apply, and the amounts calculated in accordance with that, those rules would apply here.

So, we're not, number one, creating a lower amount than the amount that the statute requires, which is what we did for direct formed, nor are we

calculating, applying the amount that was specifically established for over a positive model to this insert because it's not made over a positive model.

Peter Thomas: Yes. So, what – thank you for that. I appreciate that. What is the purpose of the productivity adjustment then? People's wages are not going down. Rent is not going down, materials, insurance, taxes. Those are the kinds of things that providers are paying every single day, every single year. What I would assume the productivity adjustment was passed and enacted to accommodate changes in fabrication techniques, changes in technological ways of doing things that would become more efficient. And that productivity adjustment is spread across the entire fee schedule and limits the amount every year that the fee schedule has increased based on the rate of inflation.

That is, I believe – unless I'm completely missing the purpose of the productivity adjustment – that is very nub of why a productivity adjustment was created in the first place. And if you've got basically exact similar products at the end of the – that doesn't make sense – if you've got exactly the same inserts at the end of the process just made in different ways, it strikes me that, that sounds like the very definition of why the program is exuded, why providers are exposed to a productivity adjustment in the first place. So, I'm trying to understand the underpinning for why would providers be enduring that every year if not to accommodate the very situation we're talking about with respect to these set of codes.

Joel Kaiser: Yes. Peter, these are two different items and services. They're not the same. They're two different items and services, right? I don't know how, I can make that; any more clear.

Peter Thomas: OK. I do appreciate your comments, Joel. Thank you very much. And, Melanie, same with you. Tom, thanks very much. I'll pass the gavel.

Operator: Your next question comes from the line of Randy Stevens with Pedorthic Footcare. Your line is open.

Randy Stevens: Yes. This is Randy Stevens from the Pedorthic Footcare Association. Thank you very much for putting this together today and bringing in the stakeholders

that truly have an interest in here. Naturally what we come out with the outcomes here definitely affect the patients in which our members serve. One of the things is if we take a look at the whole issue while this was initially designed was to prevent lower limb amputations.

And my concerns is some of the all encompassing language here it seems like (Steven) said a little bit on – everybody's hit a little bit on everything here yet, be it at the same time, the new definition doesn't really clarify and meet what's being actually done out there by those individuals that are currently doing this through the CAD/CAM process. One of the other things I wanted to question is or make a statement, do not get rid of the mold of the patient model and impression or anything. A lot of PFA's members Pedorthic Footcare Association members, still currently produce and manufacture just as a lot as a small business practices currently do a lot of stuff in-house and they are actually fabricating themselves, and they are still creating their own positive model and then molding that A5513 over top of it.

So back to you, Joel, Tom, or Melanie, my question is what do you see about coming to some type of – come together with the group here and maybe try to define a better definition of number three that's more encompassing of what's actually being done there? You know – and go ahead and answer that first if you could, please.

Melanie Combs-Dyer: Sure, this is Melanie. And I want to make sure that I first understand your point and then see if I can answer your question. We're very clear, do not get rid of the A5513, I got that. I'm not sure if you're suggesting that we postpone or delay or give up on trying to change the quality standards. Are you suggesting that maybe they're OK as is? Or you think we should proceed with our proposed change?

Randy Stevens: No. I see we have to do something that's all inclusive of these inserts that you were basically going to negate and say – and have them resubmit. My thing is the definition for the inserts with therapeutic shoes that third – that new definition you came up with is not truly all encompassing the way the

fabrication process is actually being made for those individuals that or doing CAD/CAM or using CAD/CAM.

Melanie Combs-Dyer: OK. So, it sounds like your comment is not about the quality standards, rather your comment is about the addition of an additional code.

Randy Stevens: Or just additional definition that you have proposed that you're looking at entering into the quality of standards. It doesn't truly still match the way things are currently being done at this point in time.

Melanie Combs-Dyer: And so how would you recommend we change them? Which word should we take out or what words should we add in?

Randy Stevens: When you're looking at this, you're still saying that digital image is – the body part is being made and then something else is being made over top of that model. Is that truly reflecting everything that's actually occurring today? But we go back to what (Steven Fletcher) had also said and modern technology when you take a look at it today for the rest of the quality of standards for orthotics and prosthetics. You've got this issue where we have technology here describing those areas though they're all inclusive. Nobody's being penalized for that, but yet at the same time there's a penalty here for using modern technology to create the same type of product whether it's over a positive model or it's a plaster mold or if it's being done through CAD/CAM.

Melanie Combs-Dyer: Randy, I'm not sure I understand exactly which section of the quality standards you think we should revise, but ...

Randy Stevens: I'm under the – I'm in the definition section, the one that we're actually talking about. The definition section of custom fabricated and positive model, you know. I'm looking at those two definitions right now.

Melanie Combs-Dyer: And so, is it 1A little three for inserts ...

Randy Stevens: Right.

Melanie Combs-Dyer: ... used with therapeutic shoes for diabetes and digital image of the patient's body part is made with CAD/CAM system software. Is there something wrong with that sentence or is that sentence OK?

Randy Stevens: It's number three, that's the one – the small Roman numeral three. That's what we're looking at, yes.

Melanie Combs-Dyer: And are you suggesting that we delete it or take out some words or add some words?

Randy Stevens: We're looking that we add some words to be all inclusive here. This isn't including within the manufactures. I think we need more input from the manufacturer in this. I want (one that) necessarily make that or sells, but we have PFOLA out there who accredits the labs. If we could use them with some of this in reviewing some of these definitions; that would probably be very helpful.

Melanie Combs-Dyer: Absolutely. Are they on the phone today? Can I suggest the words that I should add here? Or do they want to send me an e-mail?

Randy Stevens: I don't know if PFOLA is on this call that I know of, but since they're the ones that accredit the labs here in the fabrication process, I think it would be very good to take their input in there. But that's something – if you could reach out to PFOLA where we could get them in contact with you or whatever we need to do, we'll do that.

Melanie Combs-Dyer: I would appreciate it if you could get them in contact with me.

Randy Stevens: OK, all right.

Melanie Combs-Dyer: Again, ReducingProviderBurden@cms.hhs.gov.

Randy Stevens: OK.

Melanie Combs-Dyer: Thank you.

Randy Stevens: All right.

Operator: Your next question comes from the line of (Pam Peg) with (RMCI School).
Your line is open.

(Pam Peg): Hello, everyone. Can you hear me?

Melanie Combs-Dyer: Yes, we can.

(Kim Peg): Wonderful. I'd like to speak on the behalf of Medicare. I'm going to do a role reversal here. I'm listening to this conversation. I understand we got a lot of issues at hand, but I'd like to talk about the elephant in the room if we could for a second. I think the problem that we, educators, if I'm going to call myself an educator, or us, clinicians, have with of the way that pedorthics are being manufactured in today's world is that the arch heights are not matching the feet of our patients that we're serving. And so I'm frustrated with what I see in the industry and that's why I'm on this call today.

And I think that what Medicare needs to do is first of all recognize that a positive model is a positive model. I mean you'd recognize that, but I think your callers are using the word positive or trying to take away the term positive model. Positive model means that we are actually putting that in our hands and hoping something that is truly custom and unique for that patient. And while I'm not saying that that can't be done with direct milling, I'm saying that direct milling is not a positive model so that's the problem with that statement.

Secondly, when we make feet orthotics and you referenced PFOLA and that's Prescription Foot Orthotic Laboratory Association, and the company that we owned, Allied OSI Labs in the 1980s was one of the top five podiatry manufacturing labs in the country. My husband and I set on a mission to start a school so we could kind of teach how to make feet orthotics correctly, and asking PFOLA to put in answers and responses to this diabetic shoe insert is perhaps a good idea but that's a podiatry lab. Most podiatry labs receive a positive model, a negative model of the cast of the patient's foot in a non-weight-bearing position. So that's going to produce a higher arched product than a Bio-Foam or total weight-bearing product.

So, the next thing that I want to say is Medicare needs to make some standard that says total weight-bearing cap cannot be performed in Bio-Foam or scanning as that's going to produce a lower arch product. And we're trying to support arches that are low or support arches that are high, and we truly need to have products that are made for that individual's patients' foot. To have a patient stand on their product and there be a finger or two-inch distance between the contours of their arch on the plantar aspect to the supporting surface of that insert is negligent.

So, Medicare needs to realize that there is a number of techniques that are out there. And until you get to where you dictate what arch (right) and what manufacturing technique is going to be used in that direct milled product, where they are – all feet orthotics are not the same. And if you make them out of a negative model turning into a positive model non-weight-bearing and you do a total weight-bearing cast, which is ludicrous that the patient doesn't have a rigid foot, you're not going to get the same product. So with that said, I have the ReducingProviderBurden@cms.hhs.gov. I got a detailed letter that I'd like to send representing the comments that I'm making here today. And so ...

Melanie Combs-Dyer:(Kim), thank you so much for being on the call today, and we really appreciate your input and look forward to receiving your detailed letter. If you would let us know exactly which parts of the quality standards we should revise or if you've got suggested new sections we should add, please feel free. Now is the time. We'd love to hear from you.

(Pam Peg): Thank you.

Operator: As a reminder, to ask a question, please press star followed by the number one on your telephone keypad.

Your next question comes from the line of Paul Kesselman with APMA.
Your line is open.

Paul Kesselman: Yes. I've been listening very intently. The last caller, I'd like to address that issue primarily now, and that is that I don't believe that therapeutic inserts and

I would say up to 35 years of clinical practice and speaking with the vast majority of podiatrists and orthotists and pedorthists out there, I don't believe that a functional foot orthotic is the same thing as a therapeutic shoe insert. And so, I don't think we should be discussing the ins and outs of different weight-bearing versus non-weight-bearing versus semi weight-bearing position for diabetic patients who – our intent really is to offload a specific area of the foot and not functionally correct it.

My primary concern has to do with the quality standards and the fact that if you're going to use CAD/CAM imaging. Again, the most important step has been left out of the quality standards. I have a connection at PFOLA. I'd be happy to have PFOLA contact you at CMS, but the issue here really is that the way that the vast majority of people take impressions whether it be through plaster or through a fiberglass cast mechanism or a Bio-Foam. That is a key step that has been left out of the quality standards proposed mechanism. And I can't urge you strongly enough to have that included.

I think that's pretty much – I just want to reiterate what I had said before because it really seems to have been the lost on a lot of the call here, so.

Melanie Combs-Dyer: Paul, we appreciate your comments. Would you like to tell me today or send me an e-mail about what specific sentence in the quality standard we need to sustain.

Paul Kesselman: Well, there is – OK, so, (Cynthia), here's the thing. In the quality – the proposed quality standard itself, that exact mechanism that I mentioned is absent. It talks about taking a physical negative impression and – I'm sorry, it doesn't talk about it. It talks about doing a CAD/CAM or taking a scan of the body part and then creating a virtual positive, OK. It talks about taking a negative impression and then talking about making a positive physical mold. But it doesn't talk about taking that physical negative impression and converting that into a digital image which is then used as a physical as a – sorry, as the positive for creating the device. That step, that unique step, which is again the primary way that most manufacturers and most people are getting their inserts done, has been it's been left out. I don't understand why that is the case, but I can't emphasize how strongly I feel about this.

Melanie Combs-Dyer: Thank you, Paul.

Paul Kesselman: Because all – without this, most of what we're talking about here is going to be moot because, again, most manufacturers who are making things custom milled are doing it in that fashion. And at some point in the future, if this is not included, OK, then all the devices that are made this way are not going to be acceptable either. So I think if we're going to be – if you're going to be correcting this, I think you need to start from the very process by which the impression is taken. If you don't do that everything else is as I said. It's just a moot point, and I'll be more than happy to send you something in writing.

Melanie Combs-Dyer: Well, I really would appreciate that. I try to write as fast as I could, and frankly I'm still not clear if you're asking me to change some of the language in 1A little 2 or if you're asking me to add four that says for inserts use with therapeutic shoes where you take a mold using foam – I'm just not – I'm struggling with the words, you're talking so fast. It really would be helpful ...

Paul Kesselman: I'm sorry. I'm sorry. It's my New York and emotional feelings about this whole issue, so I apologize. Let me do this. Let me put it in writing and send it to you, but in essence it is an additional – you left out a step so we need to add something. I don't want you taking anything out. I want you to actually add something.

Melanie Combs-Dyer: Great. And you want us to add to both 1A and 1B or we only need to add to 1A?

Paul Kesselman: I'm not looking at the proposal documents right now so I can't tell you. But when I look at it and I send you an e-mail I'll let you know.

Melanie Combs-Dyer: Excellent. Really appreciate it.

Paul Kesselman: In essence, the methodology by which the impression is taken and then converted to a virtual positive is what needs to be – that needs to be addressed.

Melanie Combs-Dyer: Wonderful. Thank you. I appreciate. We'll be looking for your comment.

Paul Kesselman: OK. You're quite welcome.

Jill Darling: (Tiffany), we'll take one more question, please.

Operator: Your next question comes from the line of (Jeremy Genais) with Doctor Comfort. Your line is open.

(Jeremy Genais), your line is open.

Your next question comes from the line of Robert Gaynor with Dia-Foot. Your line is open.

Robert Gaynor: I just wanted to discuss what Dr. Kesselman was talking about. And we are a manufacturer of custom diabetic inserts using both positive model and direct milled. And what he's asking for and that would be under definition of term, number one, where it says custom fabricated going down to number three. Diabetic inserts first needed is either a foam box impression of the patient's foot, or plaster cast, or a fiber cast, or a digital image from a scanner. So, one of those four things need to be done first before you can make digital positive image of the foot. And that's the step that Dr. Kesselman is talking about under that definition.

So when we receive orders from customers, they either send us a foam box and then you can scan it into the system, or they'll send us a digital image from an iPad scanner, or they may send us plaster cast or a fiberglass cast. And that's the first step. And I think that's what he is indicating in the quality standards.

Melanie Combs-Dyer: And, Robert, you're suggesting that, that addition of the taking of the negative mold, the creation of the foam box or the plaster cast scan or the fiberglass cap that can all be added to number three or that should be a number four?

Robert Gaynor: That could be added because right now it says, "For insert use with therapeutic shoes for diabetes, a digital image of the patient's body part is made." So, that body part right now needs to be made either using a foam

box, fiberglass cast, a plaster cast, or a scan of the foot. It is through an iPad scanner or any other scanning that they do in the office. So that's the first part.

(Inaudible)

Robert Gaynor: And then from that, then they do the – then they create the digital image on a computer.

Melanie Combs-Dyer: Got it. Thank you very much for your comments. I appreciate it.

Robert Gaynor: Thank you.

Melanie Combs-Dyer: This is Melanie and I would just like to thank everybody who participated in today's call. We've got a lot of great ideas and suggestions. I'm sure when we get to ReducingProviderBurden@cms.hhs.gov, we'll find even more comments. We really appreciate you guys taking the time and giving us such thoughtful feedback. And please stay tuned to our website where we will be posting updates. We may have some more FAQs. We may have some revised language. Really appreciate everybody's time. Again, watch that website for updates. Thank you.

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

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