

Centers for Medicare & Medicaid Services  
Special Open Door Forum:

Suggested Electronic Clinical Template for Lower Limb Prostheses

Wednesday, July 31, 2013  
1:00pm – 2:00pm Eastern Time  
Conference Call Only

CMS will host multiple Special Open Door Forum (ODF) calls to allow physicians, prosthetists, and other interested parties to give feedback on clinical elements for the Suggested Electronic Clinical Template for Lower Limb Prostheses for possible Medicare use nationwide.

In order to enhance physician understanding of medical documentation requirements to support orders for Lower Limb Prostheses, CMS is exploring the development of an electronic clinical template that will assist providers with data collection and medical documentation. These templates may also facilitate the electronic submission of medical documentation. While not intended to be a data entry form per se, the template will describe the clinical elements that CMS believes would be useful in supporting the documentation requirements for coverage of Lower Limb Prostheses. CMS will work in collaboration with the HHS Office of the National Coordinator for Health IT (ONC) and the electronic Determination of Coverage (eDoC) workgroup which is focused on developing the standards necessary for an electronic clinical template.

You can find the proposed document by going to:

<http://go.cms.gov/clinicaletemplate>

Comments on the document can be sent to [eclinicaltemplate@cms.hhs.gov](mailto:eclinicaltemplate@cms.hhs.gov).

Special Open Door Participation Instructions:

Dial: **Participant Dial-In Number(s): (800) 603-1774**  
**Conference ID # 14359495**

Note: TTY Communications Relay Services are available for the Hearing Impaired. For TTY services dial 7-1-1 or 1-800-855-2880. A Relay Communications Assistant will help.

A transcript and audio recording of this Special ODF will be posted to the Special Open Door Forum website at [http://www.cms.gov/OpenDoorForums/05\\_ODF\\_SpecialODF.asp](http://www.cms.gov/OpenDoorForums/05_ODF_SpecialODF.asp) for downloading.

For automatic emails of Open Door Forum schedule updates (E-Mailing list subscriptions) and to view Frequently Asked Questions please visit our website at <http://www.cms.gov/opendoorforums/>.

Thank you for your interest in CMS Open Door Forums.

Audio File for Transcript:

<http://downloads.cms.gov/media/audio/073113LLPSODFID14359495.mp3>

**CENTERS FOR MEDICARE & MEDICAID SERVICES**

**Moderator: Melanie Combs-Dyer**  
**July 31, 2013**  
**1:00 p.m. ET**

Operator: Good afternoon. My name is (Steve). And I will be your conference operator today. At this time, I would like to welcome everyone to the Lower Limb Prosthesis conference call.

All lines had 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 questions 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.

I would now like to turn the conference over to Melanie Combs-Dyer. Please go ahead.

Melanie Combs-Dyer: Thank you, (Steve). My name is Melanie Combs-Dyer. I am the deputy director of the provider compliance group here at CMS, the Centers for Medicare and Medicaid Services.

I'm joined today on the call by Dr. Handrigan who is the medical officer here at CMS in Baltimore, the central office as well as by Dr. Brennan and Dr. (Hughes), two of our contractor medical directors who work for the Durable Medical Equipment Medicare Administrative Contractors, DME MAC.

And I would like to start with a thank you to Dr. Handrigan, Dr. Brennan and Dr. Hughes for joining us today. Dr. Handrigan, could you start by reviewing any of the comments that may have been received from the public through our e-mail address since the last time we spoke to the group.

Michael Handrigan: Thank you, Melanie. First, let me just say, thank you to everybody that's joined the call today to give us your feedback and to help us with this effort which we think is going to be very helpful.

In terms of comments that we have received so far on the data element project, we have really received very few comments. But there is I think probably some common confusion that we are focusing on for a couple of minutes. And it really bears on the focus of this effort and the intended outcome of this effort.

It seems that there is some confusion that we are attempting to develop some kind of form that can be filled out. And it's worth spending a minute to say that that's not what we are trying to do here.

What we are trying to do is to relieve some of the documentation issues that have resulted in payment error specifically with respect to some DME items like lower limb prosthesis. As you know, physician documentation has been a challenge for DME items and particularly for lower limb prosthetic DME.

This effort really is intended as an educational effort to help physicians understand what it is that they need to document in order to satisfy the coverage requirements for lower limb prosthesis. It's been named the electronic clinical template because we are working with the office of the national coordinator for health information technology to develop the electronic background that will assist in standardized electronic template and electronic health record development not necessarily by CMS or ONC.

But if we can identify the right data elements that will help ONC create the electronic standards then that will allow industry to develop the right electronic tools to insert into electronic health records.

I hope that helps to frame the intent of our effort and what this call is going to be about, and what the ultimate products of this effort will be. The ultimate products will be a list of data elements that CMS believes, with the help of folks like yourselves on the phone, to be the right data elements that need to be documented in the electronic health record or in currently paper medical records to satisfy the documentation requirements as it relates to the overall health status of individuals receiving lower limb prosthesis.

As such, it's important that we direct this effort to physician documentation. And not direct this effort to the documentation created by the prosthetist per se. I think that that relates to most of the comments that we have received. But I'm hoping that, you know, with your help additional comments can be generated and sent in to the e-mail site. And we will provide that to you later in the call, to help us to refine these data elements. And make sure that they are the right data elements for the physicians to document.

And I will turn it back over to Mel.

Melanie Combs-Dyer: Thank you, Dr. Handrigan. So just to recap, what we are about during this call and then the next couple of calls that we have is identifying the data elements that a physician needs to document during a physician face to face visit with the beneficiary who is about to receive a lower limb prosthetics.

We will turn over that list of data elements to the office of the national coordinator who will work on the standards that will eventually turn that in to some kind of an electronic clinical template that the physician will be able to pull up optionally in his or her electronic health record. And just to remind them of all the things that they need to document during that face to face visit.

Let me turn it over to our operator, (Steve), who can give you the instructions for how you can open up your line and ask a question. (Steve), can you tell the group how to ask questions?

Operator: Sure. As a reminder, if you would like to ask a question that's star then the number one on your telephone keypad. So again, star then the number one if there are any questions.

And your first question comes from the line of (Dennis Riva). Your line is open.

(Dennis Riva): Hello. I got a question regarding K Level documentation. And in the previous meeting it was mentioned for the physicians to specifically state the K Level. We have spoken recently with NGS and they were stating that as long as there is activity mentioned of specific K Level that that would be sufficient. I was just curious on your feelings on that.

Michael Handrigan: Yes. I guess let me clarify. CMS doesn't expect the physician to specifically state the K Level. The documentation that the physician provides with respect to functional capabilities and general health status needs to support the ultimate K level device that's delivered. Does that make more sense?

(Dennis Riva): Absolutely. It was mentioned during the previous meeting that if there was – if the doctor was not levels then he shouldn't be prescribing. But I understand if as long as the supporting documentation is there. We just didn't know how critical it was going to be to have that specific K Level. But, thank you for the clarification.

Operator: Your next question comes from the line of (Andy Luis). Your line is now open.

(Ken Myer): Hello?

Melanie Combs-Dyer:(Andy), go ahead with your call – with your question.

(Ken Myer): This is (Ken Myer). (Andy) was my office manager and I was with the patient at that time. I'm a certified prosthetist and orthotist. And I first would like to address specific comment that was made during the last meeting when doctor, sorry if I butcher his name, (Hustol) had suggested that physicians not be let off the hook to provide the information necessary for documenting K Levels and functionality levels on the amputee.

I was wondering if any further conversation in taking place with Dr. (Hustol) in aiding and developing this electronic documentation template further.

Secondly, I would like to go back to that same conversation. And doctor, I believe it has Handrigan has suggested that this would not going to be mandatory to require physicians to fill this documentation. Now, I would like to have that thought addressed again hoping that maybe this would become mandatory as our industry definitely needs that documentation and collaboration with the physicians to get the necessary information.

And then I would like to suggest that our profession also be allowed access to the electronic medical records so that our assessments could be inputted to that – into that record so that the physician could literally review our recommendations and our assessments. And could literally possibly use that data to either simply sign off on it or use that to collaborate with the electronic template to possibly assist them to make their jobs easier and quicker, and more efficient.

And with all of that information and being electronically stored possibly CMS could access that information totally from all parties. And would save a lot of gathering of that information and possibly expedite the entire process.

Melanie Combs-Dyer: This is Melanie. I will start – that was a long three-part question. And I will start with part of the answer. And then I will ask Dr. Handrigan and others to jump in with some of the other parts of the answer.

You first talked about was it mandatory for the physicians to provide this documentation. It is mandatory for the physician to document the condition of the patient, the full condition of the patient. And why they think the patient needs a lower limb prosthesis and what their level of need is. And so that part is definitely important for the physician to document in the medical record.

The part that is not mandatory, the part that is optional for the physician is whether they choose to document it in a paper record or in an electronic record. And should they choose an electronic record, someday we hope that there will be an option to pull up the electronic clinical template for the lower limb prosthesis for a Medicare patient.

Perhaps there will be other templates for other types of health insurance. Perhaps there will be other templates for other types of durable medical

equipment prosthetic orthotic supply, cast and other things that a physician may order for a Medicare patient. So clearly, it would be optional if a physician chooses to use EHR. It would be optional for physicians to choose to use an electronic template in that EHR.

But documenting the patient's medical needs for what the physician is ordering, that part does not change. That is still something that we expect physicians to do. Now, on your point about you think that prosthetist have access to electronic health record, we fully support all providers moving away from paper medical records and moving to electronic health records, whenever they believe it's in their best business interest to do so.

And we are working with ONC to develop the standards that would allow one provider to send their electronic health records to another provider. For example, when a physician writes a prescription for an item of a DMEPOS and needs to send that to the DME supplier with the prosthetist, we would love for that to happen electronically.

And when the prosthetist or the DME supplier needs to document something perhaps the detailed product description or some other piece of documentation, maybe a visit to the patient's home and a home assessment, and they would like to send that to the physician. We would love for that to happen electronically. And ONC is working on those standards so that will happen.

Finally, you talked about perhaps all EHRs could be stored at CMS. We are not intending to develop a storage system here at CMS. But we do have a system called electronic submission of medical documentation or ESMD that does allow providers either upon request or prospectively if they are submitting a prior authorization request to send documentation to the review contractor, to the (inaudible) who has asked for the medical record.

And we will continue to build and grow, and expand our ESMD system, the electronic submission of medical documentation system. And hopefully, we will be able to get all providers who are interested in submitting electronically to be able to do that.

Now, I think you did have a question at the beginning something about (Dr. Hustol), I'm not sure that I have spoken to a (Dr. Hustol). But I will ask Dr. Handrigan if he has had a conversation with the (Dr. Hustol).

Michael Handrigan: (Dr. Hudol), I think it was, was a caller on the previous call that suggested as you said that the physician be responsible for selecting the K Level. And I think that's the same question as the caller before you. And CMS is not expecting the physician who writes the order to select the K Level per say.

But what is required is that his or her documentation supports the K Level of the device that's ultimately delivered to the patient. And I think that that's an important distinction that should be made.

I also want to add to Melanie's comment on the use of the prosthetist notes in physician's documentation. It's important to note that as the prosthetist, the orthotist-prosthetist that is participating care of the patient is certainly providing a valuable service. But they are billing CMS as the DME supplier.

And our rules and instructions to contractors are very clear about documentation generated strictly by DME supplier. Because of the relationship as a supplier, documents that are generated by the prosthetist or the orthotist are not stand alone documents. That is to say, you couldn't fill that document out and send it to the physician for signature. And have that stand in isolation to satisfy medical necessity.

The ordering doctor must, in their own medical records, substantiate the medical necessity for the item that they are ordering. Did that help clarify the issue?

(Ken Myer): It does, and we understand that. However, many physicians don't feel adequate in making those types of assessments we find. And what I'm really suggesting is not so much stand alone as collaboration that they may review the assessment and therefore documentation that we provide on a given patient. And they would maybe concur with our findings stating that they agree that they also see a patient performing at a certain functional level. Therefore, that would substantiate a K Level rating.

And by doing that, they may not necessarily do the assessment test themselves or make that specific assessment. But they would concur with the fact that they also see that individual functioning at that level.

Michael Handrigan: I think that's really helpful comment. And let me say something, and then I will boot it over to Dr. Brennan and Dr. Hughes. CMS fully expects that the prosthetist and the ordering physician communicate and collaborate on the medical needs for the individual.

And I think – well let me just leave it at that and ask Dr. Brennan and Dr. Hughes to step in and give their thoughts.

Dr. Stacey Brennan: OK. Well, this is Dr. Stacey Brennan from National Government Services Jurisdiction B. (Mr. Myer), I think you have some interesting points to make. And it seems to me that maybe you were concerned that as the prosthetist and supplier that somehow you would not be able to read the full report from the physician either from the electronic template or in a paper record.

I think in a review situation with us who would serve the role as auditors from time to time, we would still be getting those records from you although it is possible of course that you as supplier or prosthetist can send this in electronically, if not today, we hope in the near future. But nonetheless, it will be expected that, yes, you have that opportunity to review what the physician has said. And consult back with this person who is the person ordering the prosthesis if you think it's insufficient. And it doesn't get (across) to general medical condition as we would like it to.

And that's the beauty of this template even if it's not working. Electronically it will still provide some guidance to physician. Paul?

Paul Hughes: Yes, I agree with your comment. It's not that we don't have access. I think just allowing this profession to have the input electronically directly expedites the entire process as supposed to doing things either through the mail or fax electronically then the physician can see ER assessments immediately. And we can see the physician's assessments immediately, and we can collaborate much more efficiently that way.

And then with all of that, then the CMS can then access not necessarily store but access that same data wherever it's maybe stored at would then expedite even CMS's reviews or the auditor's reviews. And then they can respond even quicker just making the system completely more efficient.

Melanie Combs-Dyer: This is Melanie. And I will say that we have looked at the privacy rules and the legal rights that we have, the medical record. And we think that it works better given today's, you know, the laws and statutes that are in place today for the contractor to request the records and for the provider to submit the records.

What we are working towards would be a day where that could happen even more quickly than it does today electronically where the request could go out from the contractor, the electronic system that the provider can automatically find the needed record. And can automatically send it back through CMS and to the review contractor.

So are you laying out sort of a vision that we have for the future. That all sounds wonderful. But the purpose of this call is really to identify the data elements that need to come in, in that medical documentation. And that's really why we have set up the series of open door forum calls.

(Ken Myer): OK. Thank you.

Melanie Combs-Dyer: You are welcome.

Operator: Your next question comes from the line of (Joel McTermans). Your line is now open.

Melanie Combs-Dyer: (Joel), go ahead with your question.

(Joel McTermans): Can you all hear me OK now?

Melanie Combs-Dyer: Yes, we can. Go ahead.

(Joel McTermans): OK. I just want to thank everybody for allowing me on the call today. And I think I want to just follow-up on (Mr. Myer's) comment. I know it is

not necessarily relevant to exact purpose of this call. But I think what's (inaudible).

What we are finding from our member is that it's all very well and good to (rate) this template and this electronic template that's has been (inaudible) the physician to document what they need to document. But the ultimate (inaudible) that our members face now and will continue to face for the future is that there is absolutely no accountability to physician if they either refuse or they don't document appropriately to support what they have been prescribing.

Dr. Handrigan said several times that it's mandatory (or they have been doing it). Several times that it's mandatory for those physicians to document what they are prescribing for however all of the liabilities falls back on the provider in this case the prosthetist to ensure that that documentation is in the physician's file. That's the source of our frustration. It's been the source of frustration for years and will continue to be even with (inaudible) templates because it makes it more and more difficult when there is no liabilities (inaudible) to physician as to what they document, how they document and how well they document.

So with that, I will go offline and I'll listen to the response. Thank you.

Melanie Combs-Dyer:(Joel), thank you for your comment. It is a little off topic given the statutory authority that we have. We can only pay or not pay claims that come to us from the submitter and that would be from the prosthetist in this case.

We encourage you to work with your member of Congress. If you would like to see the law change, and we will go from there if it does. Is there anybody else that has a comment or a question about the data element for an electronic clinical template?

Operator: We have few other questions in queue. And as a reminder, its star then the number one if you would like to ask a question.

And your next question comes from (Raymond) (Inaudible). Your line is open.

(Raymond): Yes, I'm a certified prosthetist in Arizona. And I have so many questions but I know that you want them specific to the data that you are collecting. And I'm really distressed by this because I'm starting to see physicians, I've had it happened twice now, amputating surgeons say, "I will amputate your limb but under no circumstance will I write a prescription for prosthesis."

I mean, your efforts are gallant but you are creating a monster that they are just not going deal with but that's off topic. The data elements that you want to collect, I think the CMS is missing the fact that they will pay and they do pay physical therapist to collect about 80 percent of this data. But a physician (asks) a prescription to that therapist who doesn't have a financial interest to do a functional level analysis that CMS pays them to do that, and we utilize that service.

So that physician, lots of independent prescription to this therapist, they get about 15 page exhaustive report that the physician now can make an educated decision on prosthesis. Just like if you needed blood work, he writes a prescription to a lab. So now, with this using the physical therapist, it's a win-win-win because the therapist doesn't have a financial interest. I as a prosthetist give a second opinion and the doctor gives a third opinion.

And we are trying this to be the answer to collecting this gargantuan amount of data. And we are finding that really quite frankly discriminatory to amputees because you can be put on quarter of a million drug with much less paper work, and then what you are asking for in this template.

So my question really is, will CMS divert their attentions from our financial interest to get collecting a lot of this data from physical therapist?

Melanie Combs-Dyer: This is Melanie. And I will say that I think that there is no prohibition on the physician referring a patient to a licensed clinical medical professional like a physical therapist who can conduct and evaluation, and refer the patient back to the physician to analyze that information and decide whether or not to write an order.

I may defer here to Dr. Brennan or Dr. Hughes, or Dr. Handrigan but I don't think there is a prohibition against the physician referring the patient to a physical therapist, is there?

Paul Hughes: This is Dr. Hughes. No, that's perfectly allowed.

(Raymond): Wonderful. That is wonderful news because it – like I said again it's a win-win-win scenario because I'm being perfectly honest with you when I tell you that surgeons telling patients, "I will amputate your leg but I will not under any circumstances write a prescription for prosthesis. You can get there from your general practitioner or your physiatrist down the line."

They are just dodging your template and they are not going to do it, if they can get away from it. But we are referring it to the physical therapist, we are finding that the surface can gather almost all of the data that's not already contained in the doctor's chart which includes, you know, all the vital information and co-morbidities. So it really seems to fix it.

So what I'm really asking the panel is if CMS can really expand on that, and really focus on it to say, "OK, everybody stop panicking." because we are in the state of panic, the doctors and us because we got to get that educated information to the doctor because they are not specialist in our field. They know the patient needs a prosthesis but they have no idea. We can't even keep up with our own technology. Just to focus on spreading out this workload.

Michael Handrigan: Let me just jump in and say that regardless of who actually accumulates the information for the medical record be at licensed physical therapist without financial relationship to the prosthetist or the physician themselves. The issue for today is, what is the relevant information that would support medical necessity for ultimately delivering a prosthetic device.

And so, thanks for your comment. With that, let me send it to the next caller.

(Raymond): Thank you.

Michael Handrigan: Thank you.

Operator: Your next question comes from (Michael Fenner). Your line is now open.

(Michael Fenner): Thank you. Have you all looked at the (Osher and Auto Bacher), two of our big manufacturers. And they both have information that they have worked up that tries to go over the kind of information they think the doctor wants. My question is, have you all seen those?

Melanie Combs-Dyer: I have not. I'm not sure if others in the group have but we would love it if you could send it to us.

(Michael Fenner): Well, I would be more than happy to. I think these are the points you are looking for. And then I've got one more observation. I think my biggest concern is that the more – my concern is it seems like the (RACs) are looking through it point by point. And if you missed a point, they deny it. In other words, the more detailed it is, the more they are looking – it's like a "gotcha" type of situation.

I'm not saying that's the intention, I'm saying it seems like that's what we are getting right now. And that's where a lot of the panic is coming in. the doctors – I've got notes that look to me excellent. And yet, there may be some little detail and that's why I think the template is a really good idea. And I will send this information to someone if I can somehow figure out where to send it to.

Melanie Combs-Dyer: Yes, let me give you that e-mail address now. And this will be the same e-mail address that anyone could use. So if you want to send us comments or a questions or suggestions on our electronic clinical templates for lower limb prosthetic. The e-mail address is eclinicaltemplate, all one word, @cms.hhs.gov. Again that's eclinicaltemplate@cms.hhs.gov.

(Michael Fenner): Is it all small letters or ...?

Melanie Combs-Dyer: I don't think capitalization matters. I think if you just use all small letters, E as in electronic, eclinicaltemplate at C like centers, M like Medicare, S like services dot HHS like health and human services dot G-O-V like government. It will get to us.

(Michael Fenner): OK. I will be happy to do that. And then if you could address the second point which is the kind of the – it seemed like the audits are kind of "gotchas" right now. And even though I feel like I've got a really good, I mean the doctor did what I asked him to and he wrote kind of analysis and yet, they missed the point somehow.

OK. That's it. Thank you.

Melanie Combs-Dyer: Well, in that particular point I think we will – you can certainly put that in your e-mail. You can e-mail us that question if you would like. The purpose of this call is to focus on the data elements for the electronic clinical template for the lower limb prosthetics.

And we would really like to try to keep that front and center in all of our minds. So you can feel free to send any questions that you want to that e-mail box but we are going to try to keep the call focused on our data elements.

(Steve), who is our next person (inaudible)?

Operator: Our next question comes from the line of (Matthew Rungirth). Your line is open.

(Manny Rivera): Hello. This is (Manny Rivera). I know it's about the data point form the elements. However, have you guys considered separating us from DME? We don't just give out canes, crutches and walkers. We provide a service with the prosthesis. That's my question.

Melanie Combs-Dyer: Sure. That's a question that you would need to bring up with your member of Congress. The way that the statute is written right now, patients can only receive items at Durable Medical Equipment prosthetics, orthotics and supplies on the order of a physician, and based on the documentation of the physician.

(Steve), who is our next question from?

Operator: Our next question comes from the line of (Claude Doctor). Your line is open.

(Claude Doctor): Hi folks. Regarding the data elements, is it the expectation that this all coming from a single physician? We work in a healthcare environment where I've got primary care physicians that I don't have all of the review of systems as it relates from the medical standpoint in cardiovascular and neurological, and skin and such.

And then we work very closely with a physiatrist that can attest to all of the qualifications from the mobility standpoint and need for the prosthetic device. When I showed her this template, she became quite anxious if the intent is that she has to document this every time that we are providing a replacement socket or a new prosthesis.

So I just kind of would like some insight from you folks as to what is the intent with the data elements, does it all have to come from the ordering physician who is prescribing the prosthesis or can it come collectively from those that are associated with the care but ultimately when we are defining what the patient's functional status is that has to come from the physiatrist that's ordering the prosthesis. If I could get your input, please?

Michael Handrigan: Yes, this is Dr. Handrigan. I think it's absolutely fair for an ordering physician to rely on consultation from other licensed certified medical providers or other physicians.

Melanie Combs-Dyer: And on the question of, do you need to complete all of the data elements for a replacement prosthetic or a socket replacement. Dr. Hughes or Dr. Brennan, could you answer that one?

Stacey Brennan: Hi. This is Dr. Brennan. Well, as far as that goes if there is a physiologic change if for instance there is clear, it's clearly documented that the new replacement will enable the beneficiary to have a higher functional level or for that matter perhaps even lower. We would want to know the general medical condition that would allow that.

So I would not see it as a reiteration of many of the bullets that we have in the template in front of us that we are looking at for Dr. Handrigan or whatsoever. But we would expect to see if there is a change in that physiological functional level. You know, what is it? Why did it happen? You know, what

was it that happened with the beneficiary that now this type of change in the prosthetic is necessary?

Melanie Combs-Dyer: Caller, was that responsive to your question?

(Claude Doctor): Yes. Thank you very much. I appreciate the input.

Melanie Combs-Dyer: You are welcome. (Steve), who is our next call from?

Operator: Your next question comes from the line of (Jan Stakosa). Your line is now open.

(Jan Stakosa): Thank you. It's (Jan Stakosa). I'm a prosthetist in Michigan. In the template background to start with, there is a comment concerning CMNs. To what degree is the CMN necessary for custom prosthetics? I believe that is mostly for DME. That's the first question, I've got more – and I would go one at a time instead of laying them all out.

Melanie Combs-Dyer: Sure. Thank you, (Jan). Dr. Brennan, can you answer? Are CMNs needed for lower limb prosthetics?

Stacey Brennan: My understanding is that they are used loosely in the industry. But we don't have an absolute requirement that there will be one. I'm going to ask Dr. Hughes to correct me if I'm wrong.

Paul Hughes: Well, yes. Dr. Hughes here. In Medicare speak, CMN is a specific document designed by the agency and approved by the office of management and budget. So it's a very specific thing. There is no CMN associated with the payment for prosthetics.

Lots of folks in the industry created documents that they call certificates of medical necessity or CMNs in an attempt help organize the material that they ask the physician for or submit to us, you know, arose by any other name with regards to that, you know. But in terms of an official approved CMN, there is not one that's associated with prosthetics.

Melanie Combs-Dyer: Thank you, Dr. Hughes. Go ahead, Dr. Handrigan.

Michael Handrigan: The point of adding that into the introduction of the template was not to indicate that the CMN was necessary. It was to describe the kinds of documents that are not allowed to stand alone to demonstrate medical necessity. And it comes from PIM, our Program Integrity Manual guidance to the contractors about what documentation is necessary to demonstrate medical necessity. So it was not intended to identify requirement.

Melanie Combs-Dyer:(Jan), was that responsive to your first question?

(Jan Stakosa): Yes, it tends to be confusing. I might make a suggestion if you want to do that parenthetically because a number of colleagues have asked me. They have been doing CMNs. They don't really know the purpose of it. They thought it was only for DME but they are doing it anyway in conjunction with a written order and functional assessment by a medical practitioner.

It seems to be confusing. It seems like there is one more level of paper work required that they believe to be required. So it's – fundamentally it's confusing, that wasn't my point.

Michael Handrigan: Yes, that's helpful. We will clarify that.

(Jan Stakosa): The other thing is minor but I'm going to throw it out and I will probably e-mail the site. I have done this before as a comment. Prosthetic is an adjective not a noun. And the use of the word prosthetic here in the background information is a little bit inappropriate.

Melanie Combs-Dyer:Thank you, (Jan). Let me just make sure if we are going to use the word prosthetic, it should always be followed by the word device. Is that correct?

(Jan Stakosa): Well, device is more DME intending, if you imagine that. This is purely custom for the person. It is a device because the person uses this for their mobility activities as well as transferring et cetera, et cetera. So prosthesis instead of saying lower limb prosthetic is a lower limb prosthesis.

Michael Handrigan: That should need to change.

Melanie Combs-Dyer:Got it. Thank you.

(Jan Stakosa): Next is the paragraph on page one, just below that now. For Medicare care payment purposes, lower limb prosthetic devices are categorized. Lower limb devices as far as I'm aware are not categorized. Amputee's functional ability that is categorically, numerically here in this five levels.

So, are we taking a prosthesis and saying it has a functional level of this or are we saying a person has a functional level of this? And therefore, certain functionally descriptive component elements of the foot, ankles and, knee, thigh, et cetera are more applicable for those individuals who have a functional level of.

Michael Handrigan: Yes, I think that the fundamental question really is that certain prostheses required that they fall into the K Level function as ordered. So while the prosthesis themselves is not necessarily categorized by the K. And they fall under the requirements of the K Level function. So I guess that's the point that we are trying to make in that language. But there is probably a better way to say that as you are indicating.

(Jan Stakosa): Really the prosthesis is the entirety of it that becomes a useful component for the person. So if you are talking about a particular foot or knee which I believe you are referring to that is a component element of the prosthesis comprised of many elements. And the foot, ankle, knee has a functional component requirement. You must be a functional level three ambulatory to have this particular foot, ankle or this particular knee.

So it's not the prosthesis as a whole. It interface the socket design, the suspension by mechanical alignment, the connectors, et cetera, are not – are separate of that. So you are really wanting to say that the person who has a low functional level is not necessarily going to be made available for a higher functional level knee or a foot, or an ankle that ultimately, ultimately also has higher cost involved.

Melanie Combs-Dyer:(Jan), perhaps it would be helpful if you could mark up those couple of sentences to how you think it would flow better if it would be more accurately worded. And you could submit that to our e-mail box.

(Jan Stakosa): I will do that.

Melanie Combs-Dyer: That was very helpful.

(Jan Stakosa): And now, the last, I think I've got on page four, I believe. Page four under G, the beneficiary assessment. Another semantic thing that I might do in e-mail as a corrective thing, the last sentence. Please keep in mind that the activity level support that this exam must be consistent with the level of device. Again, we are not talking about the level of device. We are talking about maybe their component, the functional level of the person matching the functional, equal of the foot or the knee. That's confusing there. So I will reduce that to e-mail communication.

Melanie Combs-Dyer: That would be perfect, (Jan). Thank you so much. Did you have (inaudible) this questions or did we get to all of your questions?

(Jan Stakosa): I think everything else would be – I think the components or the elements that you call the data elements, I think what we have been doing as prosthetist, I know I have for the last 40 some years is now just becoming very specific that all of these data points must be their physicians typically will not cover all of them. They will cover some of them in their quickness to free up and get this done because we have to have this as a requirement.

I think this is – I think it's good that it becomes, you know, put down in paper that we need 17 points to make a determination as whether or not this person's functional level matches the component elements of the prosthesis that are being submitted in the claim for payment. So I think this is very good.

There are few things I'm going to add in there, I will put it in e-mail but nothing that we have to talk in the phone right now.

Michael Handrigan: I think it's worth focusing on that comment. It's a very good comment. As we have under efforts and that we have under weigh here at CMS for this electronic clinical template process. And this is not intended to create a list of things that the physician must fill out in its entirety.

It's intended to highlight the important areas that can support medical necessity for the device that's ordered. That will certainly depend on the specific device the physician is ordering.

For example, if the cardiovascular system is an important aspects of the overall health status then, you know, these are the data elements within that section and we feel are important for the physician to fill that. Whereas, if the patient obviously doesn't have cardiovascular issues that are important to their functional abilities, we wouldn't expect the physician to think as a paper document that fill in all the blanks.

It's really intended to create the electronic backdrop for an electronic system that ultimately in the future will be able to walk the physician through the right elements to enter, not necessarily all of them on any particular patient.

(Jan Stakosa): Who is speaking? I'm sorry.

Michael Handrigan: This is Dr. Mike Handrigan.

(Jan Stakosa): Handrigan, thank you. Yes, and I think one of the issues that we have with these audits that are going on is that of the list of certain data points that were referenced earlier in the Dear Physician Letter, for example. Physicians did that yet in an audit they find one point that was not there but it really is not significant that affects the mobility aspects of this person with their general activities.

You know, physically all the vital elements, everything is – the person is very physically fit. But they are very critical that this one point wasn't there therefore, we are denying it. And so, it kind of counters what you just kept on saying.

The last part of that was to create a picture, last part of the Dear Physician Letter of 2011 was to create a picture of this person's functional capabilities which would give us an idea. And that's what I would repeat and educate physicians that referred to us. You've got to put something in here that what's this person doing every day, et cetera, et cetera.

Then when we get an audit, they are saying, "Well, you didn't do this." So therefore, this is going to be denied. And that counters what you just kept on saying.

Michael Handrigan: We will weigh on it. I think that's helpful. But it's difficult to speak to generalities here. If there are specific claims that have been audited and denied (like that) that you would like to share with us via the e-mail, we will be happy to take a look at that.

(Jan Stakosa): OK. I would be happy too.

Melanie Combs-Dyer:(Steve), can you give us our next question?

Operator: Sure. Your next question comes from the line of (Matt Bailey). Your line is open.

(Matt Bailey): Hello. This is (Matt Bailey) calling from Florida. I'm a licensed prosthetist orthotist. I have a few questions for you and hopefully some clarification maybe just some discussion. I feel strongly that we have some good objectives going on trying to get the data points.

I do feel, I hope that you guys can hear us commenting that we need to simplify this into a system that is actually doable. Because otherwise it's going to be the kiss of death if it's too big. And I appreciate that what you are saying is this is just, this is just a loose format for them to consider for the physicians.

However, when it's interpreted on the other end, they are very critical to every point. And if one eye isn't dotted, it is the reason to deny. And denying for us is much different than it might be for our systems because we have already paid for everything. And you can realize it's a big burden for us especially if we purchase a \$20,000 knee component. We are paying all our staff. We have, you know, rent and bills as you can imagine.

So I appreciate, I think that this is we needed it for a long time. We really need to have some good correlation between just the case in the prosthetics and what they need. And with going through your list in regards to a specific

data points, I think all these things relate well to whether a prosthesis will be beneficial or not.

I'm sure we could debate some small items on there. And maybe as – I don't know which physician was just speaking a minute ago but he said, they don't have – if it doesn't pertain, they don't have to fill it out. If there was a form, and they could just say going to a section where it says review of constitution.

If there was – I realized it's a not a form but if it was, and they could just say, check a box that said, nothing to interfere with the use of a prosthesis or nothing. And just check it and they could skip the section, it will be a quick – they could address quickly that, you know, respiratory or rest quickly musculoskeletal. And if there are any specific things that did relate, add them in very quickly.

If we make it easy, they can use it. It would be beneficial to everybody because we don't want Medicare go to bankrupt. When we see people prescribing inappropriate prosthetics, it makes us good guys angry also because they are hurting the system. And honestly, I don't think Medicare has a good system so far on our system.

The second part of it, I'm sorry I guess this is all comments, isn't it? The second part I have here is if we could use this quote template that we are talking about. The burden that we have as prosthetist, someone else has this information. It's going to be judged that at later date after we have made everything, after we have built everything, and it's subjective. It's not clearly defined as what everything needs to be, here is a suggestion for the physician but someone else judge that later. And who's holding the bag is us and we have already spent the money. And it's precarious situation.

If we could do prior authorization with this form, and I will put that in an e-mail but the same form could be the justification. It could be decided in advance. Medicare would then be saved from paying for legs that are inappropriate. And we would be saved from carrying a burden on something that subjectively someone else might say, you know, I don't know if this

qualifies because this one I wasn't dotted regardless of whether it's really perfect for the patient.

Do you have any comments on this?

Melanie Combs-Dyer: We appreciate your comments particularly about prior authorization. And we will take it back to our leadership and let them know your thoughts.

I do think that we are getting to the end of our time. And I would like to turn it back over to (Steve) to give our closing remarks.

And I would also like to remind everyone that we will be having another open door forum call on September 11th at 4:00 p.m. Eastern Time. The details will be posted on our website. But if you would like to mark that down on your calendars now, you can. Again, September 11th at 4:00 p.m.

(Steve), I will turn it back to you to close the call.

Operator: Great. Ladies and gentlemen, this does conclude today's conference call. A recording of the call will be available later this afternoon. To listen to the recording, you will need to dial the toll free number and that's 855-859-2056. And you will need to reference the ID, 143-59485.

Thank you very much. And you may now disconnect.

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