

Centers for Medicare & Medicaid Services
Special Open Door Forum:
Templates and Clinical Data Elements (CDEs) for
Therapeutic Shoes for Persons with Diabetes
Tuesday, June 12, 2018
2:00-3:00 pm Eastern Time
Conference Call Only
Moderator: Jill Darling

Operator: Good afternoon, my name is (Chantell) and I will be your conference facilitator today. At this time I would like to welcome everyone to the Centers for Medicare and Medicaid Service Special Open Door Forum Templates and CDEs for Therapeutic Shoes for Persons with Diabetes.

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 number 1 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: All right thank you (Chantell). Good morning and good afternoon everyone, I'm Jill Darling in the CMS office of communications and welcome to today's special open door forum.

Before we get into today's presentation I 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 have enquiries please contact CMS at press@cms.hhs.gov. And now I will hand the call off to Kevin Young.

Kevin Young: Hello everyone, welcome to the open door forum for clinical templates and clinical data elements for therapeutic shoes for persons with diabetes. I'm the senior technical advisor for provider compliance group, we're part of the program integrity unit here at CMS.

So the purpose of this call is to allow physicians, DME suppliers, providers, professional associations and all other interested parties to provide feedback on the drafted templates and clinical data elements that we posted on our webpage. As you can see on the webpage, the presentation slides are also on the left side on the announcement – posted on the announcement column.

The – also posted if you scroll down under (DME) posts, you'll see therapeutic shoes for persons with diabetes. We're going to cover today draft clinical templates and clinical data elements that were developed for the order, the progress now and statement for the certifying physician.

So the CDEs they were designed for incorporation to a provider's electronic health record to be used to collect information during a patient encounter, placing an order, or to assist the physician in completing the statement for the certifying physician when they order therapeutic shoes particular to persons with diabetes.

So the value sets and data elements on the templates are our suggestions of requirements or information I should say that would help meet the requirements for Medicare eligibility and coverage.

The templates themselves are a visual representation of the CDEs and they may be printed, completed and made part of the patient's medical record in the event that the provider does not have an EHR or the provider's EHR capability does not support the suggested elements. Our whole goal for this was to help or is to help improper payments, reduce appeals, and reduce provider burden.

Now, we at Medicare here have always strived to pay right in every case the first time in other words when the initial claim comes in. We strive to pay correctly the first time to authorized; referring physicians for covered

correctly coded and correctly billed item and services ordered and provided to an eligible Medicare beneficiary.

The practice to pay the claim correctly the first time rather than adding medical review and appeal activities to the life of the claim is very cost effective.

So to help facilitate this practice of getting it right the first time, our group here at CMS focused on developing various avenues or methods used to improve provider compliance when billing for Medicare fee for service items and services, in other words to pay the claim correctly the first time.

One of the initiatives is to create templates and clinical data sets that would continue to educate and keep encouraging physicians in determining beneficiary's needs for and the utilization of DMEPOS items and services to adopt and participate in the electronic submission of medical documentation and communication with other suppliers, providers using EHR.

As we all know EHR has become a widespread activity in the public; VA uses it, DoD uses it, and of course the private sector.

So we're jumping in if you will to continue – and it's growing at a fast pace so we're trying to jump into this rapid growth. So we've developed a number of templates and CDEs to assist physicians in creating appropriate guidelines regardless whether their future use of EHR is present or not.

So the list of the CDEs that will help EHR vendors to provide appropriate data collection templates as part of their offerings, these templates are printable and fillable templates that can be completed and included as part of the patient's medical record.

The electronic templates that may, with appropriate support from the EHR vendor, be selected by the practitioner, can be pre-populated with clinical data already in the medical record to be readily available in completing the remaining elements that are not already part of that particular patient's medical record documenting an in-person visit.

From an educational standpoint, we hope that the information within these templates remind the providers of certain needed pieces of information required by Medicare when submitting a claim for these particular items and services.

So to do this, we awarded a contract to a company called Customer Value Partners (CVP). This contract was awarded in 2015 and two members from our contract are participating on the call to offer technical support. First of all we have Dr. Mark Pilley, he's the medical director for Customer Value Partners or CVP.

He's got or he has extensive inpatient and outpatient clinical experience as well as formal medical informatics training and expertise in standard terminology including ICD-9 and ICD-10. He's been involved in medical review and appeals for the last 28 years, has worked with CMS as well as Medicare Administrative Contractors (MACs) as a consultant in developing local medical review policies.

He served as either the medical director or medical officer for a number of Medicare contractors responsible for medical review, program safeguard and appeals. The next presenter is Robert Dieterle who is the owner and CEO for Enabled Care, a subcontractor who CVP has contracted with for this initiative.

His expertise and his company's expertise focuses on IT and EHR service solutions, consulting to support payers, providers, HIT vendors, and help information exchange organization.

Bob plays a critical role in assisting with the clinical document templates vocabularies and providing the name expertise for each data enriched template.

Enabled Care is also a key provider in other EHR support conducted by our provider compliance group. Bob Dieterle and Mark Pilley were the primary technical gurus that helped CMS develop the electronic submission of medical

documentation project or the ESMD project that was launched a few years ago and is now operating in Medicare fee for service.

So at this time I'm going to turn over to Dr. Pilley to continue, to give an overview approach regarding how we shaped the templates based on clinical application and Medicare regulatory requirements. Dr. Pilley.

Mark Pilley: Thank you Kevin. I want to take this moment to first thank everybody who's taken time out of the day to participate in this special open door forum regarding therapeutic shoes for persons with diabetes.

This topic was selected based on a CERT, contract error rate testing report of fiscal year 2017 that calculated an improper payment rate of 67.8 percent which equated to a projected \$92 million of improper payment for therapeutic shoes for persons with diabetes. 84.9 percent of those improper payments have been attributed to incomplete documentation.

The template documentation developed was broke into separate and different types of document forms that could be of value to providers, suppliers and people who order these particular types of therapeutic shoes for persons with diabetes. I hope you have the PowerPoint slide presentation up.

I'm currently on slide four, now I'm going to slide five which talks more about the different types of document types that have been developed in order to address this issue of incomplete documentation and to improve the provider's ability to document better. One objective is to assist in reducing documentation burden.

The templates themselves can be found on the cms.gov website and if you have the PowerPoint up you can see there is a link posted to this website on slide five. There are three different types of documents basically; the order, progress note, and a certification statement.

In addition to these, we've also included a set of appendices that provide important information to the provider regarding the different types of therapeutic shoes and supplies and additional type of documentation

information, and local coverage determination requirements, as well as Medicare and statute requirements.

All of our documents are based initially on statute, the code of federal registry, CMS rules and regulations and publications from CMS and they also take into consideration the local coverage determination rules and regulations as well.

The clinical data elements are a selection of specific kinds of clinical information that across walk to certain types of representations of information that can be incorporated into the electronic medical record.

And I'm going to turn this portion over to Bob Dieterle because he is the subject matter expert with regards to clinical standards of structured documentation and development of clinical data elements. Bob, I'm going to turn it over to you.

(Robert Dieterle): All right, Dr. Pilley, thank you very much and thank you Kevin for the introduction, and I would also like to thank everyone who's joined the call today and taken the time to listen to this special open door forum and provide feedback.

We're going to start on slide six and talk a little bit about the content of these clinical templates and the clinical data elements. On slide six we talk about clinical data elements, what they are and how you might use them.

Clinical data elements are really the content of a field you would on a form or a template. There are some examples on slide six of the characteristics of a clinical data element.

It needs to include a unique identifier, so you can refer to it anywhere in any template. It needs to have a name associated with it, the name should be descriptive of the purpose or intent of the element such as patient name, date of birth.

There should be a data type which determines how that information should be structured either when it's entered or represented internally or presented. This could be text, it could be as a date. It could be a number, including things that are really values from value sets. We'll talk about that in just a second.

Selection type refers primarily to value sets where you have a list of one or more items that could be selected. Depending upon the nature of the element it may be appropriate to select a single value when you're dealing with something such as gender or to select multiple values when you're dealing with things such as diagnoses.

The value set itself is just the list of allowed selections and this could be the list of items that could be ordered, it could be the relevant diagnoses. These are the items that we would have as part of a value set from which a selection could occur for a specific data element.

On slide seven we're going to give some examples of these clinical data elements. What you see here are some very simple examples. For example in the first one, patient/beneficiary demographics, we have the identifier PBD1, the definition as patient's first name, last name and middle initial, and the data type text.

If you look down to PBD3 you'll see patient gender where we're selecting from a value set a single selection in the value set of M, F or O (male female or other.) I won't go through the remainder of the examples but they're here for your use.

On slide eight we cover the convention that we have used in both templates and data elements to separate those items that we consider required if you're going to use these templates or data elements, those that are considered conditional meaning that they are required if the condition is met, and those items that are considered optional.

The optional elements are included for the sake of completeness and the ability to have providers document any relevant information from their encounter with the patient or the beneficiary.

If we go to slide nine, we have some general guidance and I believe Kevin went over much of this at the beginning, but I'll repeat it here now regarding the templates and the clinical data elements.

Medicare does not require the use of either the clinical data elements or the templates for reimbursement for DMEPOS therapeutic shoes for persons with diabetes. Clinical data elements are designed to be incorporated into providers' EHR templates to be used to collect information during the patient encounter.

The optional elements are present to assist providers in documenting the encounter and recording any pertinent information including, for example, information on patient comorbidities or other problems that are presented during the patient encounter with the provider.

The templates are primarily intended to be visual representations of these clinical data elements, so the context of the element can become clearer.

However, the templates can be printed and they can be used to supplement electronic record or in the event there is no electronic record can be completed and made part of a paper based record.

On slide 10 we're starting to look at the individual templates. As both Kevin and Dr. Pilley have mentioned, the templates involved for therapeutic shoes for persons with diabetes include an order template which is subject of slide 10, the progress note the subject of slide 11, and the statement for the certifying physician which is slide 12.

For the order template on slide 10, (the template itself is posted on [cms.gov](https://www.cms.gov)), you'll see a guidance section which helps to define what the various requirements are for documenting an order for therapeutic shoes for persons with diabetes.

Next, you'll see required sections or conditional sections and that includes the patient information, the start date if it's different from the date of order, the

actual order itself for the therapeutic shoes and supplies, the type of order that's being placed, an initial order versus a new order because of a different supplier, and the signature, name and date ordered.

There are a series of optional sections or optional elements, such as the patient's date of birth, gender and Medicare ID which are considered optional although recommended, the provider who performed the evaluation, the date of the in person evaluation and any other relevant diagnosis. All of these sections are considered optional.

On slide 11 we're covering the progress note and the clinical data elements related to the progress note. Again, we have a guidance section as part of the template talking about the information or documentation that's necessary to support the fact that therapeutic shoes for persons with diabetes are medically necessary and appropriate.

Within the template we have a series of required sections indicated by the black or the burnt orange font and these include patient information, provider information if it's different than the signing provider, the diagnosis, therapeutic shoes coverage questions that are specific to the documentation of medical necessity for therapeutic shoes for persons with diabetes, a treatment plan and a signature name, date and NPI.

Optional sections are elements that are included for completeness and to support the ability for the provider to document other related items or unrelated items of the patient's condition during the encounter. These include the patient's date of birth, gender, Medicare ID, chief complaint and related past medical history, medications, allergies, review of systems, physical examination, assessment and orders.

To the extent that any of these optional items are deemed necessary by the provider to support medical necessity of the need of the patient to have therapeutic shoes for persons of diabetes, then those sections should also be completed.

Finally, on slide 12 we have the statement of the certifying physician. Both the template and clinical data elements are posted to cms.gov.

The template includes guidance on the requirement for a statement for the certifying physician. The template has required sections for patient information, a certification statement, and the provider's signature, name, date and (NPI).

The only optional elements supported in the certification statement are patient's date of birth and gender. I'm going to jump to slide 14 and for those of you that have feedback on the presentation that we've given today, you can provide it at clinicaltemplates@cms.hhs.gov.

And now I'm going to go back to slide 13, hand it over to Jill, and she will open the session for questions from people that are participating in this special open door forum. Jill.

Jill Darling: Thank you gentlemen. (Chantel), will you please open the lines for Q&A please?

Operator: As a reminder ladies and gentlemen, if you would like to ask a question please press star then 1 on your telephone keypad.

If you would like to withdraw your question please press the pound key. Please limit your question 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 1 again to rejoin the queue. Again if you would like to ask a question, press star then the number 1 on your telephone keypad. Your first question comes from (Josh White) with (AMTA), your line is open.

(Josh White): Hello and thank you. Please provide some further clarification of the physical examination information necessary to include on the progress note as it is included in the optional sections.

But what I want to be clear on is what is actually required in order to support a diagnosis? So again if a diagnosis is made, is it optional or required that there be physical exam findings to support that qualifying diagnosis? Thank you.

Mark Pilley: Yes, this is Dr. Pilley. I want to make sure I understand your question specifically. This is a benefit for persons under Medicare that have a confirmed diagnosis of diabetes, and notice that it's diabetes in general it is not specific for type II or insulin treated diabetics. It is for diabetics that have problems with their feet basically that require special footwear.

So in the guidance sections of the section 1861 (s)(12) of the Social Security Act it says that this is a patient with a diabetic condition and the documentation shows that the patient has a peripheral neuropathy, evidence of callus formation or history of pre-ulcerative calluses, a history of previous ulceration, or foot deformity, or previous amputation, or poor circulation and the treating physician certifies, and the certifying physician is an MD or DO that confirms the individual needs such shoes under a comprehensive plan of care in terms of their diabetic care or diabetic condition.

Now let's go to the template itself. I think the section of the template that you're referring to that in terms of requiring information, I think this kind of information is essential. Well there are different sections of the template ...

(Josh White): It would be in the review of systems.

Mark Pilley: Review of systems, OK that's where I was going with this, OK. The reason why...

(Josh White): Actually it would be in the physical exam ...

Mark Pilley: OK, the physical exam. Well if you take a look at the template itself it – there is a section of course at the beginning for patient demographics and the name of the physician or non-physician practitioner who is evaluating and treating the patient in an area for diagnosis.

And then there is a section that has therapeutic shoes coverage questions and those questions are basically that there is a history of one or more of the different types of conditions that were cited in the statute: partial or complete amputation; previous foot ulceration; pre-ulcerative encounters; neuropathy; evidence of callus formation; foot deformities so on and so forth. This is a required section.

The next sections of course are in blue and are considered optional because we wanted to provide the expanse and the scope of information that a treating practitioner would need to have available in order to provide a good description of the patient's presentation.

Review of systems is put that way because there are a lot of different systems of questions. Review of systems is basically a subjective type of presentation from the patient on what's going on with them with various different systems including the musculoskeletal systems and any other kind of system that might be related to diabetic function.

The physical exam section is optional because we wanted to provide a place for whatever information was needed to be presented for a description and a good presentation of the patient themselves. I think what you're asking is, why isn't there a section that says these are the physical findings that you have to have?

(Josh White): Yes, like for example if a patient qualifies for shoes because of a structural deformity it doesn't appear to me that it's required that that structural deformity be documented in the physical exam even though the diagnosis for call it a bunion is a qualifying condition. So where is the support; for the diagnosis required if it's not in this progress note?

(Robert Dieterle): Mark, let me make a comment. This is (Bob Dieterle). If you go to the first page of the template itself, under therapeutic shoes coverage questions the guidance there asks if the patient has one or more of the following conditions and it states (the provider should) check all that apply and document in review of systems and physical exam section.

The template does give guidance that you need to complete it. Now, given your feedback I'm going to make an assumption that you find that the sections in the review of systems and the physical exam should be expanded to include more clearly documentation regarding problems or foot problems that the patient has. Is that correct?

(Josh White): The way I read it is that if it says optional it means if you leave out anything, everything – anything and everything in the blue you can still be compliant.

And in this section here that's therapeutic shoe cover CDEs where there's the check off, it seems as though it implies that you must check all that apply and document in the review of systems and act in black so there's an incompatibility there, an inconsistency.

(Robert Dieterle): OK. We appreciate that feedback and we'll take that back and look at what we can do to make that guidance clearer.

(Josh White): OK.

Mark Pilley: Yes. Very good, thank you.

Operator: Again if you would like to ask a question, please press star then 1 on your telephone keypad. Your next question comes from (Randy Loyce) with Central Texas, your line is open.

(Randy Loyce): Hello, I was just going to ask how you anticipate this is going to work if you've got a podiatrist who is the ordering physician and may have notes patient's condition, and then how you think this template would work or be involved as it relates to the diabetic physician or the physician that's overseeing the patient with diabetes.

Mark Pilley: Yes this is Dr. Pilley. The design of the template really was to provide an avenue whereby the treating practitioner be that physician or non-physician practitioner could incorporate the information into their medical record.

Now the goal of what we're doing here is to promote incorporation of the information in terms of clinical data elements into an electronic medical

record, but these templates can be printed off and can be used in paper form if so desired by the clinician.

It's not required that these templates be incorporated into the physician or practitioner's medical record. It is available for them to adopt in the way, shape or form that they feel is going to best suit their needs.

(Randy Loyce): OK, thank you.

Mark Pilley: Did that help?

(Randy Loyce): Not really but I understand.

Mark Pilley: OK. In other words what we did is we designed the templates to provide a home for pertinent required and important information, everything from what's required under Medicare to what would – the physician or the practitioner would want to have available in terms of clinical information to document their patient's condition and their presentation.

(Randy Loyce): No I understand. I was just saying I don't – I'm not sure how exactly this would work with let's say a podiatrist because that's a situation we have a majority of the time is the podiatrist is the ordering physician and he's the one that's got all the notes for the inpatient (inaudible) he may have to go ...

Mark Pilley: They would, yes. They could pick and choose the areas that are pertinent to what their clinical examination is and what they do and what they find. So in other words they don't necessarily have to incorporate all of the information because it's just available.

Now we wanted to make sure that the practitioner had as much information as they wanted to present but if their examination is you know as a podiatrist their examination is going to be focused on podiatric issues, it's going to be focused on the feet, it's going to be focused on the toes, focused on the lower extremity, vascular supply lower extremity, neural sentry presentation, presentation of skin findings, presentation of potentially of structural findings in terms of articulation and disarticulation of the metatarsals and the tarsals of

the feet and if there's problems with hammertoes and evidence of callus in pressure areas that have really they're abnormal pressures because of deformity or disarticulation.

So you would just use those particular areas of the template to describe patient's findings and presentation and the rest of it you wouldn't need so you wouldn't have to add anything to it.

(Robert Dieterle): Mark, let me ask a question if you don't mind.

Mark Pilley: No, go ahead please.

(Robert Dieterle): Were you asking how one would coordinate documentation between the provider that is treating the patient for their diabetes and the podiatrist who's worried about the therapeutic shoes?

(Randy Loyce): Yes, if I was to use a template like this and I was to give it to the podiatrist so the podiatrist could fill in whatever sections he wants, he's going to be the one I'm sure if he's filling this out to sign it and date it and whatever it is, then we still have to take that information to the physician that's seeing him for diabetes and he's got to be able to sign off on it.

So I guess what I'm saying is do you anticipate being able to have a form that can be used and be signed off on by the diabetic physician or have another area where the diabetic physician can sign off on? Do you understand where I'm going with that?

(Robert Dieterle): Yes, good question. We'll take that back and and look at what we can do to make that guidance clearer. ...

Mark Pilley: I have a response to that. We've developed three different types of templates here. One is the progress note, and one is for the order, and another one is for the certification.

And literally in order for the order to really be effectively covered in terms of reimbursement under the Medicare benefit, there has to be a certifying

document, a certification from the treating physician who's treating this person for their diabetes.

And I think if you go out and you take a look at the template the structure in the templates are similar in that you've got a guidance section and then you have the template section that provides you with basically a form and basically the information that the certifying physician needs to complete and present.

Now that being said, you know if there's a request for documentation for completing an audit on the therapeutic shoes, you know the certification is a separate document in and of itself. The treating physician's medical record still needs to confirm the statements on the certification itself and support the order as well.

(Randy Loyce): And they also have to sign off on the notes if it comes from a podiatrist?

Mark Pilley: I beg you a pardon?

(Randy Loyce): They also have to sign off on the note from the podiatrist.

Mark Pilley: OK, yes.

(Randy Loyce): If the treating physician does any type of a foot exam then he has to confirm or agree with the podiatrist so he still has to sign off of their notes, their findings.

Mark Pilley: Well I don't – I understand what you are saying. I don't know that there is a requirement under Medicare that the certifying physician which is expected to be the physician who is managing the patient's diabetes and it's specific in that it has to be an MD or a DO. I – and there has to be – there is a statement basically that they are treating the patient for their diabetes and that they need special shoes.

I don't know that there is a requirement that they sign off on the podiatrist notes. I don't think it's a bad practice to have that done and ask the treating

physician to sign off on that and making sure that the treating physician includes that information in on the certification.

It will also be anticipated that that information would also be collaborated with the treating physician's documentation as well if that should be considered important to present during an audit.

(Randy Loyce): Well I'm pretty sure that's in the local coverage determination.

(Robert Dieterle): Mark, why don't we take this back and review the feedback internally.

Mark Pilley: Yes, we'll take it and take a look at this and yes you got it. Thank you.

(Randy Loyce): Thank you.

Operator: Again if you would like to ask a question, please press star then the number 1 on your telephone keypad. There are no further questions at this time, I will now turn the call back over to the presenters.

Jill Darling: All right, well Kevin, Mark and (Bob) any closing remarks?

Kevin Young: Mark, Bob are you OK before I start?

Mark Pilley: Yes I just wanted to say thanks for your input, I appreciate you taking time to participate in this. We always find that this is a good exercise in quality improvement and these – as the templates are posted these are drafts, they're not finals so it's a work in progress and your input helps to make it better. Thank you.

(Robert Dieterle): Yes, this is (Bob Dieterle), I want to also thank those of you that have responded or will respond in writing.

But we are looking forward to your input to go and try to improve the templates and data elements to more appropriately represent a convenient and appropriate flow of information for the provider treating the patient and those that are supplying therapeutic shoes for persons with diabetes. Kevin.

Kevin Young: Yes, just a reminder that these are designed to assist providers and IT professionals with medical record documentation and data collection that was also a piece. And they were also designed to help reduce the risk for claims denials.

So we try to put as much – as many pieces of information that would, that are not only required by Medicare as far as statute, code of federal regulation et cetera but also in the blue sections, the optional sections pieces of information that we've gathered from viewing a number of different provider documentation records that have good documentation practice standards if you will that help support the necessity or describe the patient condition or state for (DME) services.

So not all the providers have the same due diligence we've discovered in supplying additional information that's why it's optional. I mean if it can be recorded within their own organizational standards of practice then it could just be embellished into the system.

If not it could help educate others that these pieces of information that are listed in blue are usually or not usually – have routinely been provided by other providers within their field when billing for Medicare. The two comments thank you, excellent. We will go back and revisit these issues and investigate it, and go from there.

In closing, please remember that these templates and CDEs are completely voluntary, all right. So let's see, these are drafts. So we ask that you please periodically visit our webpage, there we would post future topics with supporting CDEs and templates and any revisions that we would have made or will make to items currently posted on the website.

As (Bob) and Mark says, we encourage for you to submit your suggestions to our mailbox. So, thank you for your interest and time for attending today's events. That's all Jill, back to you.

Jill Darling: All right, well thank you everyone and you'll get some time back and have a great day.

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

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