Centers for Medicare and Medicaid Services
Special Open-Door Forum
DMEPOS Dietary Related Items,
Templates and Clinical Data Elements
Moderator: Jill Darling
Thursday, May 31, 2018
2:00 p.m. ET

Operator: Good afternoon. My name is (Thea) and I will be the conference operator today. At this time I would like to welcome everyone to the Centers for Medicare and Medicaid Services Special Open-Door Forum DMEPOS Dietary Related Items, Templates and Clinical Data Elements.

All lines have been placed on mute to prevent any background noise. After the speaker's remarks, there will be a question and answer session. If you would like to ask a question during this time, simply press star and the number one on your telephone keypad. If you would like to withdraw the question, press the pound key. Thank you.

At this time, I would like to turn the conference over to Jill Darling. Please go ahead.

Jill Darling: Thank you, (Thea). 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 question during the Q&A portion of the call.

If you have any inquiries, please contact CMS at press@cms.hhs.gov. And now I will turn the call over to Kevin Young.

Kevin Young: Good afternoon folks. My name is Kevin Young. I'm substituting for Connie Leonard. She's our Deputy Director for our group, the Provider Compliance group. We're part of the Centers for Program Integrity at CMS. I'm one of the senior technical advisors with the group.

So the purpose of this forum call is to allow physicians, DME suppliers, providers, suppliers, professional associations, and all interested parties to provide feedback on draft templates and related clinical data elements that have been – that we've develop for certain dietary related items and services such as was posted on our website, parenteral nutrition and enteral nutrition.

For parenteral nutrition, you will see templates on the order, the face-to-face encounter and lab test results. For enteral nutrition, you'll see templates for the order and face-to-face encounter. The goal of these templates is to help reduce improper payments, reduce appeals and reduce provider burden.

So, Medicare, we've always strive to try and pay the right amount in every case to the authorized ordering or referring practitioner and supplier the first time out. In other words, the practice is quite effective, cost-effective of paying the claim correctly the first time rather than adding medical review and appeal activities to the life of the claim.

So to help achieve this goal, our group focuses on improving provider compliance with billing for Medicare free-for-service items and services. One tool or initiative we started about two years ago is to create templates and clinical data elements that would continue to educate and encourage practitioners in determining the beneficiary's medical need for the utilization of DMEPOS items and services eligible for coverage and payment, and to adopt and participate in the electronic submission of medical documentation and communication with other providers and suppliers using EHR or I should say Electronic Healthcare Records, which are becoming – which are growing and becoming widespread in the private sector.

CMS has developed multiple templates as you can see in our website. These technologies or these templates that we put together is to assist practitioners in

creating appropriate documentation regardless of their current or future EHR technology status.

So that's why we've included list of clinical data elements that will help EHR vendors to provide appropriate data collection templates as part of their services or their offering, but we've also added printable and fillable templates that may be completed and included as part of the medical record.

The electronic templates that – with appropriate support from the EHR vendor can be selected off the menu of the CMS.gov webpage and pre-populated when working when their EHR vendor. They can pre-populate clinical data that say maybe missing from an already submitted or previously submitted data element from another template or previous template that's already – that's not part of the medical record. So Bob Dieterle or our technical gurus can speak to more of that as we get on with the call.

So, these templates and (CDEs), they are voluntary and these particular ones are to assist the practitioners in documenting the face-to-face encounter progress, completing the DMEPOS order for parenteral and enteral nutrition and incorporating a laboratory test results as part of the beneficiary's record.

So when we went off with this initiative, we put out a contract and Customer Value Partners in Fairfax, Virginia. They won the contract they were tasked with providing services to better facilitate healthcare provider medical record documentation as well as information coming into the Medicare contractor medical review and appeals area.

So, we kicked around and developed attack of using printable clinical templates and to push to EHR mission associated clinical data elements, all right. So, again as I mentioned, these were developed to support coverage to help reduce the risk of claim denial and to add more completeness to the information that one would submit for coverage. Helping us on this call will be technical support from CVP or Customer Value Partners.

The medical director, Dr. Mark Pilley will be helping or assisting us with this. He has extensive background in inpatient, outpatient clinical expertise as well as formal informatics training and expertise in standard terminologies

including ICD-9 and ICD 10. So, he has conducted medical review over the past 28 years not only in the public sector but also the private sector.

He has also helped with application of Medicare policy. He has worked with CMS many years in helping to shape LMRP, local coverage determinations. He's worked with contract – Medicare contractor to do such he's oversaw the appeals, review workflow, et cetera.

So, he has been a long time advocate for provider compliance. He, along with another presenter who is part of CVP, actually they are subcontractor to CVP. He is Robert Dieterle, OK. Robert Dieterle is the CEO of Enable Care and his services were formed, well, his business was formed back in 2004 and focused on services and solutions and consulting to support payers, providers, HIT vendors and health information exchange organizations. So Bob plays a critical role in assisting with clinical documentation, templates, vocabularies, as well as providing domain expertise by template.

They, both Dr. Pilley and Bob, were instrumental in the development of our ESMD project which was launched a few years ago. So ESMD is our Electronic Submission for Medical Documentation system which allows providers and Health Information Handlers (HIHs) to electronically send the documentation is response for Additional Documentation Requests (ADR) for additional documented information received from the Medicare review contractors during the claim process and/or review process.

Alright, what I'm going to do is turn it over to Mark Pilley, Dr. Pilley, to cover the portion of an overview of how these are developed in the first place and the efforts that they lend to us to improve documentation. Dr. Pilley?

Dr. Mark Pilley: Hi. Good afternoon. I want to thank all the participants for taking time out of the day to dial in and to listen and provided some input. We certainly welcome your questions and input. We have developed a process of identifying topics and information under Medicare that would best be served in terms of reducing not only improper payments but in providing improved documentation process for providers to reduce documentation errors or incomplete documentation.

These two subjects, the parenteral nutrition and enteral nutrition were selected because of their high improper payment rate that was determined by the fiscal year 2017 error rate report. I would invite people to go out to the CMS website and pull up today's PowerPoint presentation. We'll go through that and there will be a lot more clear what our discussion is about.

The parenteral nutrition, the improper payment right was calculated to be 30.4 percent with an estimated $70 million of improper payments and 50.2 percent were due to incomplete documentation. Enteral nutrition improper payment rate was 37.0 percent with an estimated $73 million in improper payments and 76.7 percent was considered to be incomplete documentation.

In selecting these particular topics, there are a set of templates that have been developed to support providing across the board documentation types that providers and suppliers can use particularly providers can use for ordering and documenting the services. The template for parenteral nutrition, we have an order template, progress note template, lab testing template because some of nutritional elements that are covered under Medicare do require some lab testing results.

And in this is a set of appendices that provides additional information and references that I think is optimal to use with the templates in completing them. The enteral nutrition, we have an order template, progress note template, and also in appendix that will help assist with providing additional clarity and references regarding that particular Medicare coverage topic.

These templates and clinical data elements which are categorizations of data elements or elements of information that crosswalk to clinical information that Robert Dieterle is going to discuss on the next slide in just a moment to provide for the clarity, but this presentation and the templates as mentioned earlier, are available on the CMS.gov website.

I'm going to turn the presentation over to Robert Dieterle at this time. Bob, your turn.

Robert Dieterle: All right thank you very much, Dr. Pilley. My name is Bob Dieterle. I'm going to walk us through the remainder of the presentation, focusing on the actual nature of clinical data elements, the templates themselves, and how the elements and templates can be used in the documentation process during the patient encounter or in the process of getting lab results or creating orders for services.

On slide six, we have an overview of clinical data elements. The clinical data element is the content of an individual field of the template. The clinical data element has a number of characteristics. It has a unique identifier that differentiates it from any other element. They have a name. The name we're using is the one that would commonly be seen on the template and that is patient name, date of birth, something that is human recognizable.

The data type is the definition of the structure of the information within the data element. It could be could be text, it could be a date, it could be a number or it could be an item from what we call a value set. It would also indicate selection – can you select one or more items -- that would only be true if you have a value set. So, I can pick one item off a list or I can pick multiple items off the list.

Value sets are list of appropriate answers for the particular question asked by that data element. This may be a list of appropriate diagnoses or may be a list of appropriate HCPCS codes or items to order. And so the value set is the list from which you can select in certain environment.

On slide seven, you'll see some examples. In this case we're using simple examples, for example patient or beneficiary demographics. So you see here PBD1 is the identifier for the patient's first name and last name and middle initial all represented of text.

If you look further down (the list) PBD3 is the patient gender, which is a selection, a single selection from a value set of male, female or other. In this case, we use abbreviation M, F or O. I'm not going to go through the rest of the slide but have some additional examples here for provider demographics including (NPI).

On slide eight, we are pointing out a convention that we use when we create template and data elements, and that is to identify by color and font style whether an items is considered to be required within the context of that template or it is conditional, meaning if the condition is not met, the item is not considered required. Finally, there is optional (or blue), meaning there is no specific requirement for that element but we included it for the sake of completeness or for the ability for a provider to document information related to the patient's condition during an encounter or during an order.

On slide nine, you see some general concepts related to the work we're doing with templates and clinical data elements. First, Medicare does not require their use for reimbursement for any of the DMEPOS dietary related items. These (templates) are optional. You may use these templates or you may incorporate the data elements into an EHR's documentation platform. That is your choice.

Clinical Data Elements (CDEs) are designed to be incorporated into the EHR. They are not a standalone concept. We create them so EHR vendors and suppliers of order systems can take a look at the various information requirements (required, conditional, optional) and ensure that they have within their template all of those elements represented.

And when they don't, we provide them with a general definition of that element so that they can incorporate it into their product and into their template than the provider will use during the patient encounter or in the process of order or documenting lab results.

The optional elements, as we mentioned, are there to assist the provider in creating the full set of clinical documentation if necessary for the encounter with the patient. These are items that are not required by regulation and are not required to support that a particular device or service is medically necessary and appropriate, but do substantiate and document the patient's condition.

Finally, it's important to understand the templates were created as a logical representation of the clinical data elements. The goal ultimately is to have the

elements incorporated in the provider's EHR so providers can document within the context of their clinical workflow.

However, the clinical templates are there so that if a provider is not using an EHR and have a paper based record or if the EHR does not support all of the elements necessary to show a particular service or device is medically necessary and appropriate, they can use these templates. They could print them, fill them out, and incorporate them as scanned document in the EHR, (Electronic Health Record) or within the paper record.

On Slide 10, we'll start to talk about the individual templates and clinical data elements. Slide 10 is an overview of the various sections of the order template and order related clinical data elements. Included in the template is a guidance section which covers the conditions under which this particular service is rendered and particular the order requirements. The template itself has a number of sections, some of which, as we mentioned, are required, conditional or optional.

In the case of the order for dietary related items, we have required sections for patient information, diagnosis, signature (that include the name, date ordered and NPI), and if it's a specific order type. The type of order may specify an initial order or an order to change the dietary requirements. It also can be a new order if the supplier has moved from one organization to another.

Next, we have the start date if it is different from the date of the order so one could place the order today and have it start next week if that's appropriate for that particular beneficiary. We have the place of service. This is indicates whether it's at home, in a long-term care facility (or other location). These are coded and we have the ability to specify additional detail on the location. The additional detail is considered optional.

And finally, we have the dietary order and associated device and supplies. There is an optional section for the provider who performed the evaluation, so we can tie the patient's need for particular dietary supplies and devices that to the in-person evaluation of the patient. It is optional, and not a requirement.

Our next slide, slide 11, we have the progress note template and clinical data elements. Again, we have a guidance section. It talks about the requirements for documentation, to show that the service is medically necessary and appropriate. We have template sections that are identified by color as required, conditional, or optional.

In this case, the required sections or conditional sections are patient information, the provider information, the provider that actually performed the evaluation if different from the signing provider, the diagnoses, the dietary therapy coverage questions which is specific to the parenteral or enteral nutrition and questions related to need for that particular service. We have a treatment plan that is required and then the signature, name, date and NPI.

There are optional sections to support documentation of patient conditions related to chief complaint, related past medical history, medications, allergies; review of systems, physical exam, assessment and orders. Again, these are optional sections that are there to be used when it's appropriate to document the patient's condition.

On slide 12, we are covering the lab test results template and clinical data elements. This is for the parenteral nutrition template. Again, we have a guidance section indicating the lab testing requirements in the template. We have some specific required sections related to patient information, data testing and then the individual test results, in this case fecal fat and serum albumin.

We also have optional sections to indicate when the in-person encounter occurred, the person performing the testing, and finally a signature; and those are all considered optional for the testing and the testing template. I believe that concludes my portion of this presentation.

I'm going to hand the session back over to Kevin Young. Kevin.

Kevin Young: Hi Bob. Jill, are there any – maybe it's time to solicit questions from the audience.

Jill Darling: Sure. Sure Kevin, no problem. (Thea), can you please open the lines for Q&A please.

Operator: At this time, if you would like to ask a question, please press star one on your telephone keypad now. Again, that is star one for any questions. We'll pause for just a moment.

There is a question from (Kelly Falone).

(Kelly Falone): Yes. I'm wondering on slide 12, on I guess why the serum albumin is required.

Robert Dieterle: Mark, you want to take that?

Dr. Mark Pilley: Yes, I'll take that. That's actually conditional. That's for particular types of parenteral nutrition. It can be supported as indicated for particular conditions. It's is required if it is specific for that particular use in treatment.

I'd really have to go back to the policy detail itself and pull it up and find what the diagnosis would be indicated for that, but by conditional requirement means as it is indicated for a particular diagnosis and a particular nutritional element is then ordered, then there is a requirement for that particular test to be present. Does that help?

(Kelly Falone): Yes, it helps. We used to use serum albumin to identify malnutrition, but now it's not really something that we're following. So it just seems like in addition, like sense in laboratory depending on what they're utilizing it for.

Dr. Mark Pilley: OK. I always think it would be a particular laboratory test that would be commonly obtained to establish malnutrition and indication for certain parenteral formulas or to establish a diagnosis.

Operator: We do have a question from Lillian Harvey-Banchik.

Lillian Harvey-Banchik: Hi. It's Dr. Lillian Harvey-Banchik. I'm representing the ASPEN public policy committee. I want to reiterate also albumin has basic – serum albumin as pre-albumin had basically been moved out as markers of

malnutrition for hospitalized patients so we really don't use it. Also fecal fat is basically not done anymore. There are other tests that can be done such as Sudan stains testing for fat, but the 72-hr fecal fat test is not done. I can't think of anybody who has done it in an extremely long period of time.

It might be worthwhile to go back and check the current literature on what the recommendations. I know that the national and regional care determinant, they list those test, but they are out of date.

Mark Pilley: Thank you. That's a very important point and we will make note of that. We also invite you to send in your comments into CMS into the e-mail and then we can make sure we provide a response to that.

You are correct, the requirements and additional requirements for these templates do have a relationship and do crosswalk to indications for coverage published in Local Coverage Determinations (LCDs) and Local Coverage Analysis (LCAs) and that becomes a requirement. We include that because it is reflected in those particular policies.

If the standard of care changes in those particular indications and you don't feel they are appropriate or needed anymore, there is a process where you can actually request that there would be a reconsideration of a Local Coverage Determination in order to update other types of testing or not require certain types of testing for coverage.

Lillian Harvey-Banchik: Thank you.

Mark Pilley: Thank you.

Lillian Harvey-Banchik: As I said, I'm part of ASPEN public policy and we have put in a request for that and to date, we had no positive response, but review of the literature now shows that basically the same don't do these things anymore. So, it's a bit redundant to just have them on the sheet on your template.

Mark Pilley: Understood. And it's key that when we make those kind of request, and I'm sure you have, is to provide the published literature that supports your request.

Lillian Harvey-Banchik: OK, thank you.

Operator: The next question will come from (Andrea Hansen).

(Andrea Hansen): Hi. Thank you for hosting us. With respect to the template, I'm looking at the parenteral nutrition one. So as the physician is filling this out, presumably they already have documentation in the medical record that's going to substantiate all of this. Is this something because you indicated it can become part of the medical records, if we were to get say an additional documentation request we could provide that in addition to the material that supports it, and would weight be given to the template?

For example, when the reviewer looks at that initially to kind of help direct where they look in the records that we send them? We find we often have to really spell things out and direct the reviewers to, OK, on this date this test showed this. Is this – would that be more beneficial or does that cause more confusion?

Mark Pilley: Well, the template itself is, hopefully been designed so that the provider could use the clinical elements in it and incorporate them as clinical data elements in a progress note that will provide all the information clearly.

Now that being said, we do anticipate and certainly the way medical records are developed that there is going to be some sections of the patient's medical record that may be separate from the progress note and that would be a lab test of some sort or may be even a consultant note in addition to that.

And I think – there again, any kind of clinical information that's in documentation that supports the parenteral nutrition order, I think it all has to be presented. We did this in anticipation that we could provide sufficient amount of information within the template that the provider could use – the clinical provider could use that to incorporate all the information they need to reflect the patient's condition and need for the treatment. We think we have captured that but are there elements of the template you feel have some deficiencies or could be additions made to that same report or the template?

(Andrea Hansen): Not as such. As I'm looking through it, it basically, I mean it follows the LCD and policy articles to the letter. It actually opens up a few spots for physician's document further. I guess my thought is, many of the physicians that we work with, they're very versed in this.

They understand that there's Medicare criteria but they have a very difficult time documenting clearly in the record exactly what needs to be documented and oftentimes we're having to call them and say, well, you know you've documented test of permanence, but you haven't documented whether there is – you could adjust an enteral diet or do a tube trial.

If they were to fill this out in its entirety and in the description areas that are conditional say, OK, well it can't be managed with changing the enteral diet because XYZ – is that sufficient documentation or at that point is it just enough on the template, but we would also have to offer corresponding additional information from the medical record?

Mark Pilley: Well, it might be some instances where it might the need for additional information. I think there are specific types of testing. Do you have a specific section that you're referring to? You said you were looking at the template itself.

(Andrea Hansen): So, basically, I was starting at the top just kind of getting an idea where it talks about parenteral nutrition therapy coverage questions and it's got the required test of permanence documentation there. I could see a patient's physician saying, well, yes, it's a permanent condition.

And then in the conditional section, it talks about yes, is there sufficient insufficient absorption of nutrients to maintain weight and strength commensurate with the patient's overall health status.

If they answer no, can this be managed with alteration of compositions to an enteral diet and answer no pharmacologic means answer no and they have to describe down in the next field. I can see a physician saying, well, the patient's condition is such that it has XY or Z disease process that precludes these treatments. That's all a physician might state in that area because the physician in his or her head understands that the condition is one that you

can't try those things with – I'm just trying to make certain that if they do write that there, then I have to go back and say, well, you need to elaborate on this. If that's what needs to happen, I wanted to just make sure I'm understanding this clearly. Do you follow?

Mark Pilley: Yes, I do and I would think that that would be sufficient if there was accurate and understood communications as to exactly why those justifications for treating a patient's condition in the manner that the clinician wants to do.

(Andrea Hansen): OK.

Mark Pilley: I would say that would be sufficient. I guess the question would be, if the reviewer takes a look at that and they don't think that that's sufficient, will they be requesting additional documentation on that? Right? I don't think we can actually answer that on this particular time.

(Andrea Hansen): OK.

Mark Pilley: Because you would think that with sufficient information that that would be an acceptance of that information in the document itself, and that's why we developed this in this manner to follow certainly the parameters of coverage – indications of coverage under Medicare as published in the LCDs and published in the statute and Medicare rules and regulations and provide a place for that information anticipating that the clinical information gets documented, it's accepted by the reviewer.

(Andrea Hansen): OK.

Mark Pilley: And I think that – I'll tell you, if a physician provides account information, I think that's very credible and I think that from my standpoint as a reviewer, I look at that I consider that credible and complete.

(Andrea Hansen): OK.

Mark Pilley: And I think that that's really kind of what we're hoping to provide assistance with in terms of resolving some of the insufficient documentation that has been found in the CERT error rate report. So, we're really trying to provide a

house – a home for all the information that's needed in one particular type of template on the progress note and anticipate that that will be sufficient.

(Andrea Hansen): Excellent, thank you. That helps me out quite a bit.

Mark Pilley: Yes, thank you.

Operator: The next question is from (Lisa Kelly).

(Tom Hancock): Hi, this is (Tom Hancock) from (Inaudible) listening in with (Lisa Kelly). My question and statement are related to the new ISO standard for enteral feeding new connectors. It doesn't appear like there's any commentary about the use for either encouraging use of the new safer connectors in the – looks like the template on page six. These are safer connectors to avoid tubing mis-connections.

And then one more specific question, kind of two-part, the more specific question as it does ask about medication, what types of medication are used, but it doesn't necessarily request what delivery route for the medications to be delivered orally or enterally.

If it is enteral, the syringe would be required to currently it's (directs) only and a syringe would be required to deliver enterally and that it would need to know whether that would be an ISO standard connector to be able to deliver the medication enterally. I don't know if that made sense, but hopefully it does?

Mark Pilley: I understand what you're saying in terms of the ISO standard and these are particularly – they're FDA approved, correct for their indicated use. They do have their own separate HCPCS code, correct?

(Tom Hancock): They would fall under the same HCPCS as far as I know so I don't think the HCPCS also designate the difference.

Mark Pilley: Well, that's important to know because if they fall under the same and similar HCPCS code to another type of connector, I guess what you're saying is that that may be a point of denying the claim, but I don't know that that actually is

part of the process in terms of medical review. This is for documenting clinical indications for coverage and you're really talking about the application of specific devices for delivery as a considerable ISO indicated for.

But that being said, they fall under the same HCPCS code as other connectors at a particular client and you wouldn't be able to differentiate that specifically on that claim.

(Tom Hancock): Right and I think that itself may be at the landmark or could be problematic for someone that is seeking reimbursement and making sure that they are getting the right supplies that would be compatible and avoiding any disruption of therapy.

Mark Pilley: Well, in a way it's a little bit off topic, but is there a cost difference between the connectors that you're referring to, these ISO connectors and those that precede them or is that on ISO connectors.

(Tom Hancock): For my perspective, technically we're not supposed to discuss cost because it's really up to the manufacturer and what they deem the cost should be, but a lot of indications out there are that the cost should be no different or immaterial difference.

Mark Pilley: Right, right, and that's really kind of – that's really very separate kind of issues than what we're talking about here, but I do appreciate you bringing it up for discussion.

(Tom Hancock): OK.

Mark Pilley: Thank you very much.

(Tom Hancock): Thank you.

Operator: The next questions comes from (Diane Manible).

(Diane Manible): Yes, hi. The original CMS invitation for the Open-Door Forum came with the description of Open-Door Forum for durable medical equipment, orthotics and supplies for dietary related items, and it seems like the focus of this conversation and the link that's on the CMS website is specific only to the

dietary related items. Is there any templates out there currently for actual DME or orthotics of a more of an orthotic nature?

Because all I'm seeing on the website is a lower extremity prosthesis template, but I don't see anything in regards to like custom orthotics and – we're a podiatrist office so obviously we're not going to be involved with much of the DME related to dietary disorders. I was just curious if you were going to touch at all on the orthotics issue or durable medical equipment other than the dietary related items?

Mark Pilley: This particular special open-door forum is specifically about the nutritional coverage particularly enteral and parenteral nutrition for this particular meeting, but that being said and you're being podiatric office, we will probably – we will be having an Open-Door Forum in the future I believe on therapeutic shoes for diabetics.

(Diane Manible): OK, perfect. Thank you.

Mark Pilley: Yes, you bet.

Operator: There are no further questions.

Jill Darling: Kevin, do you have any closing remarks?

Kevin Young: Hi, this is Kevin over at CMS. So, again, let us thank you for taking time to attend. We hope the session was educational and informative. Please keep monitoring our webpage for updates or revisions of templates and further open-door forum topics that we have in the coming months.

That's about it, Jill. Thank you. Our mailbox is clinicaltemplates@cms.gov.hhs.gov. So clinicaltemplates – that's a plural – @cms.hhs.gov or you can see slide 14 on your handout. Thank you. Jill, back to you.

Jill Darling: Thanks everyone for joining today's Special Open-Door Forum and have a great day.

Operator: Ladies and gentlemen, thank you for participating at today's conference call. You may now disconnect.

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