Centers for Medicare & Medicaid Services
Special Open Door Forum:
For Durable Medical Equipment, Orthotics and Supplies (DMEPOS) Drug Related Items
Templates and Clinical Data Elements (CDEs)
Moderator: Jill Darling
Thursday, May 3, 2018
2:00 pm Eastern Time

Operator: Good afternoon, my name is (Amy) and I will be your conference facilitator today. At this time, I would like to welcome everyone to the Centers for Medicare and Medicaid Services Special Open-Door Forum DMEPOS Drug-Related Template.

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, please press star then the number one on your telephone keypad. If you would like to withdraw your question, please press the pound key.

I would now like to turn the call over to Jill Darling. You may begin.

Jill Darling: Hi, yes, thanks, (Amy), and good morning good afternoon everyone, thanks for doing it today for the Special Open Door Forum. I'm Jill Darling in the CMS Office of Communications and 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 do have any inquiries, please contact CMS at press@cms.hhs.gov. And now, I will hand call off to Kevin Young.

Kevin Young: Good afternoon folks. Welcome to all of you who have made it – made the effort to participate in this forum call. My name is Kevin Young as Jill

mentioned and I'm one of the senior technical advisors for provider compliance group. So we are part of the Center Program Integrity. So again, thank you for your time and valuable attention.

As many of you know, our group here at CMS has been creating a number of clinical – of clinical templates and what we call clinical data elements or CDEs. They're value sets associated with fields in the principal clinical template formats that you see.

Our intention is to help reduce provider burden pretty much overall, to also get with the EHR movement, electronic healthcare record movement going on in the public sector and also to help address certain items and services that are CERT error rate as pushed to the surface of items and services that are related to a denial reasons due to lack of documentation.

So hopefully, these templates can help get your claims a little bit more wholesome and comprehensive by providing you certain pieces of information that we feel is necessary that we suggest when you submit a claim. So your documentation is much more complete when you submit for – for payment.

So today, we are going to present our drafts on external infusion pumps and within that topic we have the order, the face-to-face encounter and lab test result. We have the nebulizer which is the next topic and that is for templates we have and CDEs we have the order and the face-to-face encounter. And this – the third, it would be immunosuppressive drugs and there we have the order and the face and face – face-to-face encounter.

So all of these templates are available on our CMS.gov website, which can be accessed through the link by searching CMS.gov E-clinical templates and you'll find them in the compendium that drops out of that. Let's see. I need to do introduce some people. I like to first of all, introduce Mark Pilley. Dr. Pilley is the Medical Director for our contractor that has offered a technical support to produce these templates and that is Customer Value Partners located in Fairfax, Virginia.

Other people particular to this call would be Robert Dieterle is a president and CEO of Enable Care. Enable Care was – is into the healthcare technology business and both Dr. Pilley and Bob Dieterle have been instrumental in the development of the ESMD project that CMS now is operating across the country with different HIHs providers.

So let's see. Mark, I'm going to turn it over to Dr. Pilley and Dr. Pilley will run into how we develop these topics or the building out of these templates. Dr. Pilley?

Mark Pilley: OK. Thank you. I want to thank all the participants for taking time out of their day to attend this special door forum and we really welcome your feedback and responses and comments through this presentation. First off, the topics that were selected for development of templates and associated clinical data elements were selected because of a high improper payment rate particularly related to incomplete documentation.

It was taken from the fiscal year 2017 CERT error rate report. Of the three that we're discussing today as Kevin Young mentioned, are external infusion pumps and related drugs, nebulizers and related drugs and immunosuppressive drugs. The improper payment rate for external infusion pumps was calculated by the CERT contractor at 23.1 percent with an estimated improper payment of $148 million of which 76.7 percent was due to incomplete documentation.

Nebulizers and related drugs, improper payment rate was calculated at 13.4 percent, with an estimated $106 million of improper payments, 88.5 percent considered due to incomplete documentation.

Immunosuppressive drugs, the improper payment rate right was 34.3 percent or estimated $93 million, 57.4 percent was due to incomplete documentation.

Now the basis for the templates themselves are based on statute, code of registry, national coverage determinations, national coverage analysis, Medicare Internet only manuals, and Medicare rules and regulations. Taking into account also, those particular contractor discretionary policy requirements

that are published in the local coverage determinations and local coverage analysis.

So the information that's in the templates itself come from what is already in statute and in Medicare policy and claims adjudication today. And those particular references are also included within the templates themselves. The template has different sections.

The first section of the template is really a guidance section be it for a face-to-face or progress note, order, or for lab testing results. The guidance section presents the purpose, patient eligibility, and the qualification of who can or cannot or should or should not complete the documentation.

And then there is a section that represents what would be considered the clinical information section that is within electronic medical record which is very similar to what many clinicians and those of us who read medical records are very familiar with. And that is the information regarding demographics, diagnoses and presentation and the different the particular items within the plan of care that the physician may want to order or want to provide for that patient.

The clinical information that is selected and identified as either being required, conditional, or optional. Bob Dieterle will talk about these categories a little further. This information is used to develop the clinical data elements. Now if we go to slide five, there is a listing of the external infusion pumps, nebulizers, and immunosuppressive drug templates that are out there on the CMS.gov website.

And if you have access to the slide the website address is www.CMS.gov/research-statistics-data-n-system/computer-data so on and so forth. We encourage you to access the website which houses the latest drafts posted by CMS. And I also want to say, as a qualifier, these are drafts. They're for voluntary use. They're not required and they're optional for the provider to make use of.

Now, I would like to refer to slide six and that this open door forum itself can also be found on the CMS.gov website after this meeting. I want to turn it over to Bob Dieterle who discussed clinical data elements and – and how they are selected and the definition of such. Thank you. Bob?

Robert Dieterle: All right. Thank you Dr. Pilley. First thing I'd like to do is talk a little bit about clinical data elements. What are they? How are they defined and how we use them in this template and data element work

The clinical data element is a detailed definition of what you would see as a field in the template form. It includes a unique identifier for that particular element such as PDN 01. It includes a name for that element such as patient name or date of birth. It includes the data type of the element. It could be a text field, a date field, a number, or it could be a selection from what we call a value set.

When we go to selecting from value sets, we have the option of selecting a single entry in a value set up or multiple entries. So there is a selection type and finally the value set itself will limit what is appropriate to select for that particular data element. So this might be a list of appropriate diagnosis.

It might be a list of items that are appropriate to order in virtually all cases. There will also be the ability to go and write-in in text additional items that may not be in the selection list or in the value set. We use these clinical data elements so that we can have them incorporated into electronic health record templates or in the templates that we are creating here.

As an example of a data element, if you are looking at slide eight we see for patient or bene sorry, patient/beneficiary demographics, PBD one would be the patient's first name, last name, and middle initial all in text.

To give you an example of selecting from a value set, patient's gender, which is PBD 3 would be a single selection from the value set (PM) for all male, female or other. We have some additional examples here that will allow you to look at yourself, but that's a general concept of the clinical data element.

As Dr. Pilley mentioned what we have done in the clinical data elements, document and in the templates is to separate the items that are considered required for that particular benefit from those that are conditionally required from those that are optional. And to do that, we have used both color and font characteristics to separate them.

So anything that's considered required is black Calibri. Anything that's considered conditional is in burnt orange italics Calibri. And anything that's considered optional although we, in many cases, suggest that you use the optional field to qualify the patient's condition and their need for a particular service or device that is in blue Times Roman.

Some general template information that we would like to cover is on slide nine – ten excuse me. And some of this has already been covered by Kevin Young. Some of it has been covered by Dr. Pilley. But I'll go through it again because it is extremely important.

First point is that Medicare does not require the use of these templates or clinical data elements for reimbursement for DMEPOS drug-related items. These are considered completely optional. We encourage their use because it helps to make sure that the important information to which – to describe a patient's or beneficiary's need for the device in the medical record to support the fact that it is medically necessary and appropriate.

These CDEs or clinical data elements are designed for incorporation in the EHR's templates. They are used in the templates that we have presented on CMS.gov as a visual representation of how they might look in a template in the EHR. In the event that you do not have an EHR, the provider does not have one or the EHR does not support all the necessary elements to appropriately describe the patient's condition and need for particular devices or service, the templates that we have on CMS.gov may be printed or filled in and incorporated in the medical record.

The optional elements that are defined in each of the templates of the clinical data elements are to assist the provider in recording all the detail about the patient's encounter. So we make provision for a number of things that are not

necessarily required by policy or by regulation, but makes sense to record to substantiate other aspects of the patient's condition that are documented or should be documented during the patient encounter.

Moving to slide 11, this will give a general overview of how we are approaching each one of these templates and clinical data element sets. As Dr. Pilley described, the first thing will be guidance in the template itself. Not in the clinical data element document.

Secondly we'll have sections within each of the template and the clinical data elements where the section is considered to be or contains required conditional or optional information. And they'll be color-coded as we described with the appropriate fonts.

So the first thing we'd like to go over are the order templates for all of these drug related DMEPOS items and we'll talk about the commonalities and differences as we go through each one of the template types. So for the order template, required information is the patient's information, the diagnosis and the signature name, date ordered, and NPI.

Conditional information depends upon whether or not it's appropriate or required based on patient's condition or who else may for example have performed part of the documentation or ordering. It's start date if it's different from the order date, the type of order whether it's an initial order, subsequent order or an order being placed, for example, because the supplier has changed and there are other reasons in the template that are documented based on the policy for that particular item.

And then finally, the actual order itself. So in most of these, we are ordering based on a particular patient's condition or diagnosis or problem in a specific drug or pharmaceutical and we're ordering that drug along with all of the other information that's necessary to describe it, such as route, concentration, volume, duration, frequency, refills. Those are defined specifically in each template.

For those that also have an associated device, this (would true with) nebulizers and external infusion pumps. The specific device that is appropriate to the drug that is being ordered is also made available to order as part of that section of the template.

And then finally, we have optional items. Whether this is – if it's a face-to-face encounter or an in-person encounter and the date of the face-to-face or in-person encounter if one was required by ACA.

Next, we will talk about the face-to-face encounter or progress note template. Again, we have the same sections indicated by color and font, the required and conditional sections, as well as optional sections. In the face-to-face encounter, we have required sections for patient's information, patient's diagnosis, the treatment plan, the signature name, date …

Jill Darling: Hi Bob, are you there?

Robert Dieterle: Yes I am. Can you hear me?

Jill Darling: Has Bob's line dropped?

Robert Dieterle: Can you hear me?

Jill Darling: Mark or Kevin, would you be able to continue for Bob?

Mark Pilley: I can hear him.

Robert Dieterle: Can you hear me?

Mark Pilley: Well, the answer is yes, I can. I can hear – Bob, can you hear me?

Robert Dieterle: I can hear you. Can you hear me?

Mark Pilley: OK. I can hear you.

Robert Dieterle: OK.

Mark Pilley: Can anybody else hear Bob?

Jill Darling: Yes we can, you may continue.

Mark Pilley: OK. Go ahead. For some reason we couldn't hear you.

Robert Dieterle: I apologize.

Mark Pilley: You were on slide 12 I believe. We're getting ready to go on slide 12, talking about nebulizer external infusion pumps associated devices and drugs – OK. Yes.

Robert Dieterle: All right. Well, I apologize for people on the call. I'm not sure exactly what happened. So on the face-to-face encounter or the progress note, we again have sections that are considered required or conditional and optional sections, each of which is indicated by the appropriate color and font.

The required or conditional sections include patient's information, patient's diagnosis, the treatment plan, signature name, date and NPI. And next specific patient qualifications or conditions based on the benefit whether it's a nebulizer, the external infusion pump, and the drugs associated with it or the immunosuppressive drugs.

So each of those will have qualifying questions and answers to go and ensure that that patient's need for that particular drug and device is documented in the medical record. There are optional sections to support documentation of chief complaint, related past medical history, medications, it was the patient is currently on, may have been on or being prescribed, patient allergy – known allergies, a review of system section where the provider can document in particular those items that are needed – those items that are needed to be or device, a physical exam section and there are pieces of that that are actually required for both – We have a documentation here on the side, I apologize.

So the physical exam section, the assessment section, and then the order. So we have a place to document the order information in the face-to-face documentation as well as in the order template.

Moving on the lab test results template, we have a single template defined for the external infusion pump only and the drugs associated with it. This particular template has required sections or conditional sections for patient information, date of testing, testing information related to fasting plasma glucose, C-peptide, beta cell – auto-antibodies, A1c, and creatinine clearance.

And then there are optional sections in here that can be used to document the provider that has performed the face-to-face to tie this back to the original provider as well as individual performing the testing and the signature if the – if the be performing into the organization or individual wishes to sign.

So this completes the overview of the templates you'll find on CMS.gov. We're looking for feedback on those templates, comments on the both their structure, completeness, and usability and you'll be able to both feedback on this call when we turn it back over for questions as well as provide information via email at clinicaltemplates@cms.hhs.gov.

So I'm going to turn this back over to Kevin Young. Kevin?

Kevin Young: All right, any questions from the – I guess Jill will need – I should turn it over to you to handle any questions.

Jill Darling: All right. Thanks Kevin. (Amy), can you please open the line for our Q&A please.

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

Your first question today comes from the line of Gerald Rogan from Rogan Consultant. You're line is open.

Gerald Rogan: Hi, good morning everyone. I would like to suggest that some elements are required that are now considered optional and those would include the diagnosis, the patient identification number, and the name of the physician who provided the face-to-face service. And these are all for purposes of ensuring program integrity that the item or service is reasonable and necessary.

Also, I would like to suggest that how long the medication might be needed is important. Any ongoing documentation about the benefit of the treatment in case the drug needs to be changed and a requirement for periodic reevaluation of the patient to be sure that the patient continuously needs the item, the benefit. So those are my comments. Thank you.

Kevin Young: Dr. Pilley, any comments?

Mark Pilley: Yes, Dr. Rogan, thank you for your comments. We understand the importance of that information that on the order and in any other kind documentation what we are bound by, we are bound by the rules and regulations of the statute to the registry and NCDs, program integrity manual and other benefit manuals, claims processing manual and of course the LCDs and LCAs.

So where we have been able to apply those particular elements of that information that is required. We have done so. Where we have thought it was important that that information be considered to be included. We have also include that in the documents but of course color-coded those two optional because were not able to categorically require those unless there is a requirement under Medicare to – to demand that the provider provide information.

So where we have applied requirements we have where we have applied – we wanted to apply requirements that were – but had to optional, we color-coded those blue but the other ones the burnt orange or bronze were conditional and that it was – if it was a particular diagnosis or particular situation, that information should be definitely included.

I would encourage you to go ahead and put together, maybe some examples of what you're referring to and send that in an email to the clinicaltemplates.gov.hhs email and we will – we will take those into consideration in response to other comments and correspondence related to this special open-door forum. Thank you.

Gerald Rogan: Thank you, Dr. Pilley. What an excellent job you've done. A very complicated situation. I will do what you say. Thank you.

Operator: And again ladies and gentlemen, if you would like to ask a question please go ahead and press star then the number one on your telephone keypad.

Your next question comes from the line of Sam Giordano of US COPD. You're line is open.

Sam Giordano: Thank you and good afternoon. I am focusing on the nebulized – nebulizer assessment plan aspect of the template and there's – there seems to be an opportunity to add and I understand from previous explanation, it would be optional, but since the patient's ability to cooperate with the use of the nebulizer, in other words, using it properly needs to be assessed during the face-to-face visit.

I would recommend that we add an element that speaks to their ability to demonstrate their use of the device at the face-to-face so that the attending physician could assess that patient's ability to really get the drug delivered in an effective way.

Kevin Young: Dr. Pilley, any comments?

Mark Pilley: I'd, yes, I think that's a – that is a good suggestion and we will – we'll go back and take a look at that and see where we can incorporate that. It isn't – certainly an optional element but I do agree with you from a clinical standpoint certainly and from a standpoint of completing documentation that that is not just for payment purposes.

But documentation that's for communicating to other healthcare providers, particularly if you are looking at transitions of care type of information documents. So we'll – we'll go back and take a look and see where we can incorporate that. OK. Thank you.

Sam Giordano: Thank you.

Operator: And there are no further question thank you. At this time, I turn the call back to the presenters for the closing remarks.

Operator: Sorry, we do have one further question. Thank you. From the line of Gerald Rogan, you're line is open.

Gerald Rogan: Thank you. I forgot, could you explain why EO574 is not on the list that's nebulizer that's handheld and is a benefit with the drugs that go with it.

Kevin Young: Go ahead, Dr. Pilley.

Mark Pilley: Yes, I am thinking about EO547 you said?

Gerald Rogan: Yes, that's ultrasonic electronic aerosol generator with small volume nebulizer, EO574. It's in the same family as the other nebulizers. It's commonly used for certain drugs like for cystic fibrosis to inhale the drug.

Mark Pilley: Got you. Let me – let me – it maybe because it was a must – I do not remember if it was listed in the LCD or not.

Gerald Rogan: OK. So would you – could you do – my recommendation is just to check and see whether or not this template should apply to that particular code as well.

Mark Pilley: OK. EO574, I'm looking it up right now. It relates to …

Gerald Rogan: I think they're in some – I think there are EO574s in nebulizer policy of the DME MACs in the nebulizer LCD.

Mark Pilley: It is. That is a – that's a good observation. Good pick up. Not including it was an inadvertent oversight. We'll fix it. Thank you.

Gerald Rogan: Thank you. Mark?

Mark Pilley: Yes.

Gerald Rogan: It is included in here but only for pulmonary artery hypertension. Yes, correct. OK.

Gerald Rogan: It's already in the order template for that. If it should be included for something else, we can certainly do that but I believe that's the only specific condition and drug combination that it was specified for in the LCD.

Mark Pilley: I think EO574 is used for cystic fib – to inhale K – to inhale for – maybe for cystic fibrosis for some drugs.

Gerald Rogan: Then we can go ahead and look at that and we'll review it and add it if it's approved.

Mark Pilley: Yes, the LCD says that the diagnosis that are associated with that are primary pulmonary hypertension, secondary pulmonary hypertension other specified pulmonary heart diseases. That is what I am reading right now. We will – we'll go ahead and go back and take a look at. There is the drug for cystic fibrosis – I mean the nebulizer associated with that was the J7682, but that is OK. We'll still – and what else? J7639.

So those two are associated with delivery of drugs for cystic fibrosis. But we will go back and we'll double check that and make sure – just to make sure that we have done a good thorough job of including all appropriate nebulizers. OK.

Gerald Rogan: Thank you.

Mark Pilley: Thank you.

Operator: And there are no further questions thank you. I turn the call back to the presenters for their closing remarks.

Kevin Young: OK, this is Kevin – Kevin Young. In a sense that this – we had some really good points made. So thank you for your recommendations. Again, we – we hope that these suggested fields or value sets or pieces of information which makes it way – will hopefully make its way to the medical record will help ensure coverage when documentation submitted to support a claim and forms do not guarantee coverage but it only offers to help support coverage of the items and services billed.

Now with the website itself, if there are significant changes based on the recommendations that we received from our mailbox as well as information obtained from this call, we will post another version – a revised version – version two if you will up on our CMS.gov website. We'll definitely ensure that we market and announce all of the different version or the newer version. Other than that, thank you for your attendance today. Back to you Jill.

Jill Darling: Well, thanks everyone for joining today and have a great day.

Mark Pilley: Thank you.

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

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