

Centers for Medicare & Medicaid Services  
Special Open Door Forum:  
Templates and Clinical Data Elements (CDEs)  
For Respiratory Related Items  
Moderator: Jill Darling  
Thursday, April 19, 2018  
3:00pm Eastern Time

Operator: Good afternoon. My name is (Jesse) and I'll be your conference facilitator today. At this time, I'd like to welcome everyone to the Centers for Medicare and Medicaid Services Special Open Door Forum Templates and Clinical Data Elements for Respiratory Related Items.

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'd like to ask a question during this time, simply press star then the number one on your telephone keypad. If you'd like to withdraw your question, press the pound key. Thank you. Jill Darling, you may begin your conference.

Jill Darling: Thank you, (Jesse). Good morning and good afternoon, everyone. I'm Jill Darling in the CMS Office of Communications, and thank you for joining us today for today's Special Open Door Forum. Before I hand the call off to Kevin Young, 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 inquiries, please contact CMS at [press@cms.hhs.gov](mailto:press@cms.hhs.gov).

And so now, we'll begin our presentation with Kevin Young.

Kevin Young: Hello, everyone. My name is Kevin Young and I'm one of the senior technical advisors for the Provider Compliance Group. We're part of the

Center for Program Integrity. Melanie Combs, our office director, is not able to attend today. So, therefore, I'll be facilitating the business portion of it, of the call today. So first of all, thank you for your – by joining this call and therefore showing interest in these drafts that we're putting out there for comment.

As many of you were probably aware by now that our groups here at CMS have been creating a number of clinical templates and what we call Clinical Data Elements or CDEs. So these templates are designed to assist providers and IT professionals with medical record documentation and data collection to help support Medicare coverage for selected items and services. The art – sole intention right now is to help reduce the risk of Medicare claim denial and ensure that the documentation is more complete when you're Medicare or when your contract has received it from a solicitation for more information for the payment of your claim.

Let's see, these – I need to point out that these templates are completely voluntary, all right? So for today, what we're doing is sharing our drafted templates and CDEs for specific DMEPOS respiratory related items and services. There, you can – they're available. These templates and CDEs are available in the CMS.gov website, and it should be posted on these Special Open Door Forum announcement for this call.

The templates and CDEs are specific to positive airway pressure devices for obstructive sleep apnea, and the templates are specific to the order and the face-to-face encounter. The other topic would be – is respiratory-assisted devices. There, we have templates for the order, face-to-face encounter, and lab results.

The third topic is ventilators, and we have templates for the order and the face-to-face encounter. So we welcome feedback on these initial version one drafts.

And I'd like to introduce now our technical consults who are presenting today. And it's Dr. Mark Pilley. He is the Medical Director for Customer Value

Partners. They are a prime contractor for this initiative. And Robert Dieterle, He's CEO of EnableCare, who has the IT expertise to add to this initiative.

So I'm going to turn it over to CVP right now. And, Bob, would like to start?

Robert Dieterle: Yes, Kevin, thank you very much. My name is Robert Dieterle. I will be walking through the material that Kevin has described that has been posted at CMS.gov. If you're following along in the PowerPoint presentation, we will pick up on slide four. Slide four talks about information from the 2017 CERT report that in this case, we're looking at improper payment related to these specific covered benefits.

As Kevin had said, positive airway pressure devices for obstructive sleep apnea, which we'll go forward and refer to as PAP; respiratory assist devices which we'll refer to as RAD; and ventilators. So what we have for PAP is roughly a 59 percent improper payment rate or about \$495 million. Almost 88 percent of that is due to incomplete documentation, which is one of the reasons why it has become a subject of this Special Open Door Forum, and these templates and clinical data elements.

Respiratory assist devices, the RADs, the improper payment rate is 63 percent or about \$72 million annually, and 95 percent of that is due to incomplete documentation. Again, this is the purpose that we are focusing on is to address incomplete documentation of these services. And then finally, ventilators, where the improper payment rate is over 57 percent or about \$192 million annually. In this case, it's 25 percent due to incomplete documentation and roughly 58 percent due to medical necessity. Part of the guidance we're providing along with these templates and clinical data elements talks to the coverage criteria; in other words, the requirements to demonstrate medical necessity as well as completeness in documentation.

On slide five, we have the summary of the various artifacts that Kevin had described. So on CMS.gov, you will see under positive airway pressure devices or PAPs an order template and a face-to-face encounter template, and the clinical data elements associated with each. Under the respiratory assist devices or RAD, you'll see an order template, face-to-face encounter

template, a lab test results template, clinical data elements associated with each, and a set of appendices that will help to describe either the coverage criteria or the specific elements or items that can be ordered. And then finally under the ventilators, we have the order in progress note. And in this case, we are both the complaint and the clinical data elements. These are all available on CMS.gov by following the link as indicated in the PowerPoint presentation or in the announcement.

Moving to slide six. We can get a little bit of background on what clinical data elements are and how we use them. So the definition of a clinical data element is it has to have a unique identifier, which we listed here like (DDN01). It has a name which is typically the name that would be if you wrote in a field on a form or a template. So it's the patient's name or the date of birth. It has to have a data type. So it describes what type of information, what the structure is of that information. So it can be a text, it can be a date, it can be a number, or it can be a value from a set and we'll talk about that, where we have specific values set that could be as simple as yes or no or gender. It can be as complex as an extensive list of HCPCS code.

Then we have a selection whether it's single or multiple. So in the event, we have a list, can you select one item or many items from that list? It depends upon the nature of the particular element. And then as we said, the value set or the specific items that are part of the value set. So each one of these clinical data elements is associated with one would think of as a field in the template. So, wherever you might see a series of underscores where you would write something at it, if you're doing it manually, or have a field where can enter it if you're doing it electronically. That field would be associated with the clinical data element.

As we move on to slide seven, these are some examples of clinical data elements. So, for example, we have the clinical data elements associated with the beneficiary's demographics; so the patient's first name, last name, middle initial. All are expected to be text. The patient's date of birth, which would have a eight-formatted result with month, day, and year. Gender selection from a value set of male or female. This is just an example what we have in

almost all the template of clinical data elements as a third option. The patient's Medicare ID using a standard Medicare ID format along with the check digit.

And then we have examples down here for demographics for the provider, where we're talking about the provider's name, again, first, last, middle initial, suffix, as well as their NPI using the standard numeric format with the check digit, the provider's telephone number with the format for the number plus the extension, and for example, in the event we're trying to communicate, the providers direct address or secure email, the direct address in the direct address format. So these are the types of things you'll see at the clinical data element documents associated with each template. I'm not trying to be comprehensive here but trying to be exemplary.

The final thing you'll see when you look at the templates and the clinical data elements is the color coding. We're using three primary color codes. For those things that are considered required – and by the way use of the template is not required, use of clinical data elements is not required. But if you use them, these are fields that we would expect you to fill in because they're necessary to document for the patient's record or to show that something is medically necessary and appropriate for this specific service. So we have black Calibri, indicating that it's required. We have a burnt orange italic Calibri indicating that it's conditional. So, for example, if you asked a question and the answer is yes, then there may be a conditional question, if you will, and clinical data element associated with the yes response.

And finally, we have those things in blue Times Roman. These are intended – these are considered to be optional but the recommended where they are appropriate to describe the patient's condition or provide support of the fact that whatever service or device that's being ordered is medically necessary and appropriate.

If we move on to slide nine, here are some general guidelines for the work that we're doing. So as we have said and as Kevin has said, we do not require the use of templates. Medicare does not require that to get reimbursed, and it does not require that the CDEs be used again to get reimbursed. These are

intended to facilitate the collection of information during the patient's encounter with the provider, (the document of a) record, the patient's condition, and why the services or devices that are being ordered are considered medically necessary and appropriate.

The CDEs are really designed for in cooperation in the vendor's technology. They're not intended to stand alone. So these would be used inside of an EHR's forms or the equivalent of them would be used inside the forms. The reason we're providing them so the EHR vendors and others that are creating input documents can understand the type of information, the structure of the data that needs to be collected, and where it's appropriate list of selections, what those selections are.

As we said before, the option elements are there to assist providers in documenting the encounter and recording pertinent information. And you should consider the templates as visual representations of the clinical data elements. Yes, they could be printed, (sold), and made part of the clinical record. The intent was really to show how those clinical data elements could be represented in a template to collect information.

We're moving on to slide number 10 now. Here, we're going to walk through the various types of templates and clinical data elements that we had posted on CMS.gov. The first is for order-related templates, and what we've done is we have combined all three into one slide here. So we're going to talk about RAD, PAP, and ventilators, and talk about PEEP order templates for all of them.

So, there are similarities across all of them as noted here and there are differences, and we'll talk about each one of those. So we have patient information or beneficiary information that's required; we have a place where the provider can or the EHR can populate information on when the face-to-face encounter occurred and who performed it; the date of the face-to-face encounter or in-person evaluation; now in the case of ventilators, it's a progress note if not a face-to-face encounter requirement; and (any) diagnoses that are pertinent. Again, these are all optional elements here but it's a place

to go and provide the continuity in the order to point back to where that in-person encounter occurred.

There's a start date and time, which is considered to be conditional. So start date and time is different than the date of the order. So, in other words, if the start date is intended to be in the future. There is the type of order, the specific device. There are optional lists of HCPCS codes associated with those devices that if the provider knows which ones they want, they can check off. If they don't, then they can just textually describe the device that needs to be provided.

And finally a section for each one of these templates on supplies and accessories that can be part of the order or can be the sole order having previously ordered the device. And finally, we have the signature section where the provider would provide their name, the date of the order, their NPI, and their signature. And that signature could be physical signature on the document. It could be an electronic signature in the EHR records. It could be a digital signature, depending upon the nature of the technology that's used. And I should note on here, the NPI is required for the WOPD or the written order prior to delivery when that is a required order element.

Moving on to the next slide, slide number 11. We're going to go through the face-to-face encounter or progress note template. The progress note will be for the ventilator. The other two are face-to-face encounter requirement. As we walk through the documents, each one of these templates from front to back, we have patient information where it's required. We have encounter information that is conditional depending upon the nature of the encounter, where we've encountered solely for, for example, the purpose of evaluating the patient for the specific device or as part of some other encounter.

We have relevant diagnoses in each case. We have optional section again to allow documentation of the patient's condition and, where appropriate, those things that are necessary to describe why that device and services are being ordered. So we have the chief complaint, related medical history. We have medications. We have a space for allergies. We have review of systems and

it goes through all the systems. We have physical exam; now, in the case PAP and RAD, or specific required sections on the physical exam to support the face-to-face encounter. We have an assessment section. We have a required treatment plan to describe what the intended treatment is for the beneficiary. We have optional orders. The orders do not need to be part of the face-to-face, but they will be documented in the face-to-face or progress note. And finally, the signature, the name, the date, and the NPI. Now, one would assume that in the treatment plan that would indicate the intent to order a specific item, and then the order would be the documentation of the specific order of the device with the supplies or accessories.

Moving on to slide number 12. This is only for RAD, this of the test result template and the clinical data elements associated with it. And the thing I neglected to mention in each of these is there's a guidance section at the front of each of the templates not at the front of the clinical data element document but in front of the templates that talks about the conditions of coverage, talks about the required documentation, and provides background information on each of the templates.

So in the laboratory template, we have a guidance section, and then within the actual template itself, we have required patient information, we have information that can reference back to the patient visit from which this lab testing was ordered, we have required date of testing, we have an optional section for the individual or (laboratorian) performing the testing and the laboratory which it was performed, and then we have the specific sections for documenting the test results – I'm sorry, test conditions first and then test results; so test conditions such as patient was receiving oxygen via cannula and the test results related to arterial blood gas at rest, arterial blood gas during sleep or immediately upon awakening, and finally overnight oximetry results. And then we have an optional, in this case (some of) test results, signature section, which would be intended for the individual or the organization performing the testing.

So that's brief summary of each of the document you'll see posted. We encourage you to go through them in detail. We encourage you to provide

feedback on the templates on the guidance section or on the clinical data elements. And you can do so at the address in the PowerPoint which is [clinicaltemplates@cms.hhs.gov](mailto:clinicaltemplates@cms.hhs.gov).

At this point, I want to turn it back over to Jill who will initiate the Q&A portion of the Special Open Door Forum. Thank you.

Jill Darling: All right, thank you, Bob. Also, folks, on the announcement that was sent out, that email address is also on the announcement, [clinicaltemplates@cms.hhs.gov](mailto:clinicaltemplates@cms.hhs.gov).

(Jesse), we will go into our Q&A please.

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

Your first question comes from line of Carolyn Basford from Pulmonary Partners. Your line is open.

Carolyn Basford: Yes, thank you. In looking at the draft for the respiratory assist device order template guidance, under the indications for the use of the RAD divided into four categories, the section that you have for severe COPD, actually that information facility-based polysomnogram to rule out LSA is not required in the LCD for RAD. It is actually – you only need a polysomnogram if the – if the severe COPD diagnosis is not (bad) that – I mean it is (bad) and you have already ruled out. But you do not need according to the LCD a sleep study to get a RAD device covered for COPD.

So, totally, it's – it does not match with the LCD at all for RAD. Further, you have obstructive sleep apnea under – somewhere – I don't know, it's four categories but that's (not again). An obstructive sleep apnea should not have

– you do not get a RAD device. It is not classified as a RAD device under the LCD. It has its own LCD, which is the PAP, positive airway pressure LCD.

Mark Pilley: Right. This is Dr. Pilley. I understand what you're saying. I think there is – (that's a RAD device). There is some qualification – there is information in the LCD with regards to when, I believe, it's an E0470 would be used for patient with obstructive sleep apnea. We'll take a look at that.

Carolyn Basford: Well, the big thing is that – I mean – it really, I mean, where obstructive sleep apnea falls is if you truly – if patient has a obstructive sleep apnea and they have to go from an E0601, a CPAP, to an E0470, a bi-level, without a backup rate, I mean that's OK but where there's really – where it's problematic on your template and the progress note is the fact that you do not – you definitely do not need to have a sleep study because it says and actually E0470C, prior to initiating therapy, sleep apnea and treatment with a CPAP has been considered and ruled out. And then it has parentheses, note formal sleep testing is not required if there is sufficient information in the medical record to demonstrate that the beneficiary does not suffer from some form of sleep apnea as the predominant cause of awake hypercapnia or nocturnal arterial oxygen saturation.

Mark Pilley: Right.

Carolyn Basford: Because obviously if we're looking at RAD device, we're looking at a ventilatory issue. So – and that's in – we're looking at hypercapnia as the primary. So I just that – that was – that was just a glaring thing that I was hoping that we could rectify on the draft – on the template and the process of that template.

Mark Pilley: Yes, thank you, thank you. We will address that issue. Thank you.

Carolyn Basford: I appreciate that. Thank you.

Operator: Again, if you like to ask a question, please press star one on your telephone keypad.

There are no further questions at this time.

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

Kevin Young: Well, that was a – we certainly appreciate that last comment. So in order for us to – I mean there's transcripts to the call. Everything will be captured there. But if the last – the most recent person, if they could send in the comment to the mailbox that's posted on the open door announcement, that way we have no misinterpretation. We are clear on what your comment and suggestion would be. So that would help us immensely.

All right. Then that's about the only thing I have other than thanking everyone for joining this call, and please send in your comments. This is our initial draft so your comments are important. Any versions coming out of this or I should say we will refresh the website as needed. We usually give time for all comments to come in about three or four weeks and then go through making corrections or suggestions or I should say assessing the information at that point in time but it gives everyone a chance, too, in their busy day to send it suggestions and comments.

That's about it, Jill. That's all I have. Thank you.

Jill Darling: All right. Well, thank you, Kevin, and thank you everyone for joining today. Have a great day.

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

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