

Centers for Medicare & Medicaid Services  
Special Open Door Forum  
Templates and Clinical Data Elements (CDEs) for  
Vitamin and Metabolic Assays  
Moderator: Jill Darling  
Tuesday, June 26, 2018  
2:00 p.m. ET

Operator: Good afternoon, my name is (Jack) and I will be your conference facilitator today. At this time, I would like to welcome everyone to the Centers for Medicare & Medicaid Services Special Open Door Forum Templates and CDEs for Vitamin and Metabolic Assays.

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 1 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 (Jack) and hi 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 topic, I have one brief announcement from me. 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 any inquiries, please contact CMS at [press@cms.hhs.gov](mailto:press@cms.hhs.gov). And now I will hand the call off to Kevin Young.

Kevin Young: Good afternoon and thank you for joining us. Today we're going to have an open door forum on the drafts that we developed for clinical templates and

clinical data elements for vitamins and metabolic assays. We want to share the drafts with you and solicit comments.

We believe that that these pieces of information will help support documentation requirements for the coverage of vitamin metabolic assays, and the drafts you see are tailored for the order and the progress notes.

When you take a look at these templates and CDEs or I should say the clinical data elements, the CDEs were designed for incorporation to providers electronic health record templates used to collect information during a patient encounter or when placing an order.

They reflect particular information needed to help meet Medicare requirements for eligibility and coverage. The templates are the visual representation of the CDEs and may be printed, completed and made part of the medical record in the event the provider does not have an EHR system in place.

Our goal is to help to reduce improper payments, reduce appeals and reduce provider burden. As background, at Medicare we continuously strive to find ways for paying for a submitted claim correctly and for the right amount the first time.

As a regulatory agency we strive in every case to ensure that the program pays an authorized ordering or referring physician or supplier for covered items and services which are correctly coded and correctly billed, and the items and services were ordered and provided to an eligible Medicare beneficiary.

It's pretty clear cut to say that the practice of paying the claim correctly the first time is indeed more cost effective as opposed to paying after adding on to the life of the claim the high costs and labor-intensive activities of medical review and appeals. And, of course, from the other side of the coin, these safeguard activities also heavily burden the provider community who bill for these services.

So, one of the initiatives that we took up here at CMS is to create templates and clinical data elements that would, from an educational perspective, remind the provider upfront that they need to report certain pieces of information required by Medicare when submitting a claim for the particular item or service.

Also, we encourage the participation in the electronic submission of medical documentation and communication with other providers and suppliers using EHR.

Use of EHR has become widespread activity in the public and the private sector, and we've seen that it continues to grow at a steady pace in today's healthcare industry. So, we developed these templates which you'll see in multiple drafts on our webpage. In addition to the metabolic assays and vitamins but there's a list of other templates there.

(The templates and CDEs that )we will present today on specifically vitamins and metabolic assays will help vendors to provide appropriate data collection templates as part of their own product offering and services.

For example, with appropriate support from an EHR vendor the electronic templates can be selected by the practitioner. It can be pre-populated with clinical data already in the medical record to (prompt the provider to) complete the remaining elements that are not already part of the patient's records.

For those who do not have an EMR, these templates can be printed, the information may be completed and included as part of the medical record.

So, for example, a practitioner or their office staff may add a link to our cms.gov web page to his or her iPhone, laptop, desktop to quickly remind him or her of the needed information that Medicare requires from patients for payment.

To push forward this initiative, we put together a contract called the medical review documentation compliance and technology contract, and in 2015

Customer Value Partners was awarded the contract to investigate and develop these templates and CDEs.

We have two members who are part of the contract participating on the call today. The first is Dr. Mark Pilley, he's the medical director for Strategic Health Solutions. Dr. Pilley has extensive inpatient and outpatient clinical experience, as well as formal medical informatics training and expertise in standard terminologies such as ICD-9, ICD-10.

He's conducted medical review for over 28 years and he's also been a part of the Medicare reconsideration and (peer) activities and reviews. He's been either the medical director or medical officer for a number of Medicare contractors responsible for Medical review program safeguards and appeals.

The next presenter is Bob Dieterle or Robert Dieterle as you see on your slides. He's the CEO of EnableCare. His expertise focuses on IT and EHR service solutions, and consulting support to payers, providers, (HIT) vendors and health information exchange organization.

Bob plays a critical role in assisting us with clinical documentation templates, the vocabulary, content exchange and providing the domain expertise for each of the templates you see on our website. EnableCare is also a key player for our group here at CMS in the area of template development and consulting with EHR support.

Bob and Dr. Pilley together helped put together the esMD project that was launched a few years ago. esMD stands for the electronic submission of medical documentation. I'm going to turn it over to Dr. Pilley now who will provide an overview of how we got to where we are today. Dr. Pilley.

Mark Pilley : Thank you Kevin. First, I'd like to thank all the participants for taking time out of their day to attend this Special Open Door Forum. I hope you've accessed the slide deck on the cms.gov website regarding the Special Open Door Forum (for Vitamins and Metabolic Assays) and I'll start on slide four.

We chose multiple topics based on the comprehensive error rate testing or CERT report which provides information regarding improper payments. For vitamins and metabolic assays, the improper payment rate was 29.2 percent with a projected improper payment of \$187 million.

What was particularly important about this is 96.6 percent of the improper payment rate was attributed to incomplete documentation, and that's why this was a topic that was selected for development of the templates and the crosswalk association with clinical data elements.

Now let's go to slide five. It gives you the link where you can access these clinical templates and other topics as well. We have three basic categories of information out on the eClinical templates section for vitamins and metabolic assays that of template order and template progress note.

We also have attached an appendix which provides information with regards to what is currently published in terms of coverage for vitamins and metabolic assays which are largely coverage determinations made by the AB MACs and have been published and implemented as Local Coverage Determinations and supported by local coverage articles that have gone through the formal comment and notice period.

Our task was not to develop policy templates and these templates are optional and voluntary. They can be used by the practitioner physician or non-physician provider to document the clinical information they feel they need to for their patients. The listing of diagnoses in terms of the appendix is what's considered supportive of paying for these particular claims but not all inclusive.

The templates are not designed to be used for claims processing or for establishing medically unlikely edits, they are for informational purposes and for the use of the practitioner.

Next – let's go to the next slide, slide six vitamins, metabolic assays, templates and clinical data elements. The definition of clinical data elements, I'm going to turn the presentation over to Bob Dieterle at this point in time because he is

really the expert and the person who's been the key character in the development of the clinical data elements. Bob, I'm going to turn it over to you.

Robert Dieterle: All right Dr. Pilley, thank you very much. I would also like to thank everyone who's taken time out of their busy days to attend this Special Open Door Forum. I'm going to start out by defining what a clinical data element is and how one would recognize it. The fields that are in a template can each be represented by what we call a clinical data element.

Each clinical data element has a set of characteristics, those characteristics include a unique identification; this is an ID by which that element is known for example (PVNO1). A unique name that might be patient name, date of birth, it's a representative name for that element. You could consider it the label of that field on a template.

The data type, this is a representation of the information that would go into that particular field or into that data element. It could be text, it could be a date, it could be a number, or it could be a selection from what we call a value set.

The value set is a list of items. If we have a selection from a value set, then we can indicate as part of that clinical data element whether you're allowed to make one or multiple selections. You may make only one in the case of, for example, gender; but you may make multiples in the case of diagnoses.

The value set itself is the list of appropriate selections for that particular element, so it may be a list of appropriate diagnosis, it may be a list of appropriate HCPCS codes for a particular type of device.

On the next slide, number seven, we have some examples of clinical data elements. I'm not going to spend a lot of time going through this. I will point out PDB3 which is patient's gender and is indicated as a single selection from a value set where that value set is M, F or O -- male female or other.

That is an example of how selection from a value set might look. If you look at PND3, that is the provider's telephone number and it includes a structured definition of the format of the telephone number including its extension.

On slide eight you'll find the way we define whether particular elements are considered required, conditional or optional. In the case of required elements, we use black Calibri as the font to indicate that that element is considered required if you choose to use a template.

If it's burnt orange italics Calibri; that is considered conditional meaning if the condition is met then it should be treated as required. And finally, we have Times Roman – Times New Roman blue which is the font we use for items that are considered optional.

Optional items are typically used to document the patient's condition, comorbidities, and items that are not required by either regulation or policy but may be important to document for the sake of having a complete record of the patient's condition at the time they are seen or they might be optional items that are relevant to documenting the need for that particular service or device.

On slide nine we talk a little bit about general template and CDEs and how they should be considered and treated. Medicare does not consider the use of templates or the clinical data elements as a requirement for reimbursement for vitamin and metabolic assays, these are optional.

CDEs are designed for incorporation into the provider's EHR. They allow the EHR vendor to add these elements in so that during the time that the provider's in front of the patient, they can record whatever information is necessary to have a record as to why a particular service or device is being ordered and show that the device or the service is medically necessary and appropriate.

As we said, the optional elements are there to assist the provider in recording documentation related to the patient's condition that may or may not be relevant to that particular service or device.

And finally, the templates themselves are visual representations of the clinical data elements. As Kevin went over at the beginning of the call these templates can be printed, and there are fillable versions. They can be used to document the encounter or the order and made part of a medical record.

But in general, if you already have an EHR and that EHR supports equivalent templates that allow you to document all of the relevant items, then there's no need to consider or use the template themselves.

On slide 10 we have an overview of the sections that are part of the order template and its related clinical data elements.

Within the template there is a guidance section and that guidance section provides information on the purpose of the template, the order requirements that may exist, any issues related to patient eligibility, other information that is recommended to be included in the order and information on who can complete the order.

The sections within the template itself include the required or conditional sections; patient information, patient diagnosis and clinical indicators, priority of the order and the specific order for various vitamin and metabolic assays that are covered by this particular topic that we're discussing today. It also includes information for the provider's signature, name, date ordered and NPI. Optional sections include the patient's date of birth, gender and Medicare ID, and provider contact and address information.

On slide 11, this is an overview of the progress note and the associated clinical data elements.

Again, we have a guidance section and that guidance section covers the purpose of the progress note, patient eligibility and information on who can complete the progress note template.

The sections of the progress note include required and conditional sections: patient information, provider information if it's different from the provider



signing the progress note, diagnosis, clinical indications relevant to the order of vitamin and metabolic assays, chief complaint and related past medical history, relevant medications, relevant review of systems, relevant portions of the physical exam, relevant portions of the assessment, relevant portions of any treatment plan and relevant orders in addition to the signature, name, date, and NPI of the signing provider.

Optional sections include the patient's date of birth, gender, and Medicare ID as well as allergies. We have a large number of conditional sections here primarily because the topic of vitamin and metabolic assays is broad.

There a number of clinical indicators that may be documented as part of review of systems or as part of the physical exam. So, we've colored those as burnt orange indicating that where they're relevant to documenting the need then they need to be completed. At this point I'm going to turn it back over to Jill Darling to ask for questions. Jill.

Jill Darling: All right, thanks Bob. (Jack) will open the lines now for Q&A please.

Operator: As a reminder ladies and gentlemen, if you'd like to ask a question please press star then 1 on your telephone keypad. If you'd like to withdraw your question, press the pound key.

Please limit your questions 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, that is star 1 to ask a question by phone. There are no questions at this time.

Jill Darling: All right everyone, I'll hand the call back off to Kevin, Dr. Pilley and Bob for any closing remarks.

Kevin Young: Hi this is Kevin again, thank you for joining us. Let's see, we – as reminders these templates and CDEs are completely voluntary.

They are intended to help reduce the risk of claim denials and ensure medical record documentation is more complete when billing for Medicare items and

services. So, we encourage you to submit comments and suggestions through our mailbox which is listed on our webpage, and we thank you for your interest and time for attending today's event. Dr. Pilley, Bob any closing remarks?

Mark Pilley: No, I just want to thank everybody for their participation and if you have any other comments please send them to the cms.gov email. Thank you.

Robert Dieterle: This is Bob and I will reiterate Dr. Pilley's comment, thank you very much for attending the call today and we look forward to any comments that you have to help us improve the quality of the templates, the clinical data elements, and the way the provider would use them or incorporate them to improve their documentation to support the clinical appropriateness of the order for vitamins and metabolic assays, and the ability to ensure that they get covered by Medicare without any denials due to lack of documentation.

Kevin Young: Great Bob, Mark thank you. Back to you Jill.

Jill Darling: All right, well thank you again everyone and have a wonderful day.

Operator: This concludes today's special open door forum. Participants may now disconnect, have a wonderful day.

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