Centers for Medicare & Medicaid Services
Special Open Door Forum:
Home Blood Glucose Monitor and Supplies
Templates and Clinical Data Elements
(CDEs)
Moderator: Jill Darling
Thursday, March 15th, 2018
3:00 p.m. ET

OPERATOR: Good afternoon. My name is (Tiffany) and I will be your conference operator today. At this time, I would like to welcome everyone to the Centers for Medicare and Medicaid Services Special Open Door Forum, Home Blood Glucose Monitor and Supplies Template and Clinical Data Elements conference call.

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 then the number one on your telephone keypad. If you would like to withdraw your questions, press the pound key. Thank you.

Jill Darling, you may you conference.

Jill Darling: Thank you, (Tiffany). Good morning and good afternoon, everyone. I'm Jill Darling in the CMS Office of Communication and thank you for joining us today for this Special Open-Door Forum.

So, before I hand it off to our speakers, 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. And now, I will hand the call over to Connie Leonard.

Connie Leonard: Thank you, Jill. And thank you, everyone for joining. This is Connie Leonard. I'm the Deputy Director of the Provider Compliance Group in the Center for Program Integrity at CMS.

And we're very happy to present to you today the Home Blood Glucose Monitor and Supplies Templates and Clinical Data Element Special Open Door Forum.

And our purpose of today's call is to give you physician, suppliers, providers, associations, and all other interested stakeholders an opportunity to provide feedback on the templates for Home Blood Glucose Monitor and Supplies and the clinical data elements that have been posted to our CMS.gov website.

We have the following templates and clinical data elements on the website. We have one for orders, one for the face-to-face encounter, and one for the lab test results.

CMS and PCG in particular believe that the use of these templates and clinical data element can reduce improper payments, reduce appeals, and most importantly, reduce provider and supplier burden.

You might ask how? We believe that the use of these templates, which are somewhat more than a simple paper template. Some may use a paper form like a checklist, in my mind, and/or the clinical data elements in an EHR system.

We believe by using these templates, that providers and suppliers can ensure that they have these proper elements in the medical record. And so, if they get a request for additional documentation they know that they've submitted the proper elements to help ensure that the claim gets paid.

Helping CMS with these efforts is a contractor Customer Value Partners, or CVP. CMS has tasked CVP with helping to create these templates and these

clinical data elements based on CMS' statute, regulations, and policies in the various CMS (manuals).

Today, helping CMS with this presentation are two of CVP's technical support, Dr. Mark Pilley who is the Medical Director for StrategicHealthSolutions, and (Bob Dieterle) who is CEO of (EnableCare).

CMS chose to focus on home blood glucose monitors and supplies because it's an area that has seen a high error rate over the past years. For example, in fiscal year 2017, the comprehensive error rate testing program reported that glucose monitor improper payment rate is 47.9 percent. And a lot of that, 70.1 percent was because of incomplete documentation.

So, that means that while for a lot of that 47.9 percent, accurate services were probably provided but we couldn't determine that based on the documentation in the medical record. And so, CMS believes that the use of these templates and clinical data elements can help providers submit the necessary required information to help lower that improper payment rate.

If that improper payment rate is lower, we reduce the provider burden, we reduce the administrative cost for CMS and the Medicare program on appeals if we have a lower improper payment rate.

That 47.9 percent improper payment rate equated to $131 million. So that's certainly a lot of money in the Medicare trust fund and a lot of burden that we put on the provider community that we believe could be fixed somewhat by the use of these templates.

With that, I'm going to turn it over to (Bob Dieterle). He is going to talk specifically through the templates and the clinical data elements, and then we will come back around to have additional questions that any of you may have. (Bob), I turn it over to you.

(Bob Dieterle):   Thank you, Connie. For those of you that are following along, I'm going through the presentation that was posted on cms.gov for this particular Special Open Door Forum. The presentation is entitled Home Blood Glucose Monitor

and Supplies Templates and Clinical Data Elements, CDEs, and we're on slide five.

What we have posted on cms.gov are a set of documents that are CDEs, a list of clinical data elements, and templates, draft templates for each of the following:

- the Basic Home Blood Glucose Monitor and Supplies Order;
- the Specialty Home Blood Glucose Monitor and Supplies Order;
- the Basic Home Glucose Monitor and Supplies Face to Face (F2F) Encounter.

I'll make a point right now that the F2F Encounter template and clinical data elements can also be used for progress notes for the Specialty Blood Glucose Monitoring and Supplies.

And then, finally, for both the basic and specialty home blood glucose monitor, a template and data elements for the laboratory test results. These are intended primarily where we have a newly diagnosed beneficiary not for one that has of substantiated history of diabetes mellitus.

On page six, we're talking about slide six. We're talking about the nature of clinical data elements. Clinical date elements are really the content of an individual field in a template that has several characteristics.

The first is the unique identifier, and we listed a couple here such as PDNO1, that identifies a specific element, across all of the templates that we may create.

There's a name associated with that element that can frequently be the identifier of the field or the elements on a template, or in the EHR and that for example is patient, date of birth.

Each of those (CDEs) has a data type. The data type describes the expected response structure, such as text, a date, a number, or maybe one or more values from a set.

Then where there are multiple values from a set, there is a selection type. We may say that from the set you can only select one (value), so it is a single selection. Or you can select multiple (values), and that will be a multiple selection. And you will see all of these, by the way, in the data elements that were released with the templates.

Finally, where we have a defined list which we call a value set we have the content of that list that is bounded. (to the specific values) So, for example, you may have all of the HCPCS codes and the descriptions of the device or devices that may be ordered.

You might also have all of the relevant diagnoses and their ICD-10 codes for all of the diagnoses that may be relevant to the patient's condition.

On slide seven, we have some examples. We chose to use Patient or Beneficiary Demographics and Provider, or NPP Demographics. You will see some examples here such as the name of the patient defined in PBD1 as an element.

That's the patient's first name, last name and middle initial, all of which are text fields. We may have the patient's date of birth, and here is a date as an example of the structure. So, month as two digits, day as two digits, and year as four digits.

You can see other examples here such as the patient's gender, where we use abbreviated list of genders such as male and female. So, we're saying it's a single selection from the value set that is male or female.

On slide eight, we have a little information on the use of color and fonts in the templates. This (use of color) is true in both the template itself and the clinical data element documents.

What we've done is take all of the, if you will, fields that's required if you choose to use that template or incorporate of data elements and wish to conform to CMS or Medicare FFS documentation requirements. Those are indicated in black Calibri.

There are burnt orange Italics Calibri elements that are conditional, meaning they should be considered required if the condition is met. So, for example, you may have answered affirmative on the prior question and now you may need to define what you mean by picking from the list.

And then, finally, there are a large number of elements in blue Times New Roman. These are considered optional. They are recommended where they make sense. They are not required.

They are used primarily to allow provider's to document the various conditions of a patient that are either relevant to the management of their care or relevant to the specific device or service being ordered.

We are on slide nine. However, we want to make a couple of points before we go into the specific templates. The first one is Medicare does not require the use of these templates or clinical data elements. It's up to you to use (them). It's up to an EHR vendor to incorporate.

CMS does not require them for reimbursement, for home blood glucose monitoring, or for any of the other areas that we're creating clinical data elements and CDEs for as part of this program.

The clinical data elements are designed for incorporation into the provider's EHR templates. They're used to (facilitate) collecting information during the patient encounter, recording laboratory results, and specifying elements of an order.

We suggest adding the documentation requirements to the provider's workflow by incorporating the information into the templates that are used as part of the provider's documentation within the EHR medical record that they're using in their practice.

The optional elements as we said are here to assist providers in documenting the encounter and recording any pertinent information. They obviously would be used based on the particular patient's presentation, and based on the

provider's decision to document specific elements that are necessary to support the fact that a particular device is medically necessary and appropriate.

The templates themselves are actually visual representations of the CDE. The focus here is to put clinical data elements into a provider's workflow. But we understand there are situations where there may still be a paper record or the EHR does not support all the elements that are necessary.

In that case, a provider may wish to incorporate portions of these templates into their templates. They may wish to print them, fill them out, and incorporate them into the patient's medical record.

These are done for completeness because there's an expectation that the paper or the printed version of these templates will not be used in most situations.

On slide 10, we're going to start going through the individual templates. I'm not going to talk about the data elements, per se, they're in the documents that are associated with each one of the templates. And if you have questions, you can certainly raise them either in the Q&A session or you can write any comments or questions and submit them to clinicaltemplates@cms.hss.gov .

So, first, the basic Home Blood Glucose Monitor and Supplies order, this is something that is covered provided the practitioner has completed a face-to-face encounter with the patient, and it also requires a written order prior to delivery (WOPD).

What you see here are a list of sections. The first section is guidance. Each of these templates include the guidance section. It talks about the purpose of the template. It talks about coverage requirements for the particular device, in this case, the Home Blood Glucose Monitor and Supplies.

(The guidance) covers what needs to be on the order, and it will address who can complete the basic Home Blood Glucose Monitor and Supplies order. The guidance really helps the provider to understand the purpose of the template and what portion of it is important.

Within the template itself, there are a series of sections. We've listed them on slide 10 for the Basic Home Blood Glucose Monitor and Supplies Order. The ones in black are the ones that are required. There are none in burnt orange or conditional and they're several that are in Times Roman blue or optional.

For example, the patient information, the order itself and the signature are required. The face-to-face provider information is optional but useful to point to when the face-to-face occurred to tie the order back to the actual face-to-face encounter.

The diagnoses are useful to describe the diagnoses of the patient. In this particular case is the diabetes mellitus insulin treated or non-insulin treated which has an impact on the supply order.

Training is an optional question that has to do with whether or not the patient or the caregiver is capable of, has been trained to and is capable of using the glucose monitor and the testing supplies.

And then, finally, there are some sections here on the frequency of use of the diabetic testing supplies and the supplier itself to the extent those supplies are being ordered at the same time.

On slide 11, you have a template for a Specialty Home Blood Glucose Monitors, these are not covered by ACA or do not require a face-to-face; however, they do require the documentation in the medical record or a progress note that substantiates the needs for the Home Blood Glucose Specialty Monitor, and the testing supplies. And in this case, there would be a detailed written order, order prior to submission of a claim.

If you look at the list of sections (between the F2Fl encounter and the progress note) they are basically all the same with one difference. There is no face-to-face reference here. The face-to-face template can be used, as we said, as a progress note for documenting the encounter.

There is a start date and date of order that are art of the next templates section The signature date is expected to be at the bottom of the template. Where the signature date is different from the order date, or the order date is different from the start date, we have the ability to have the provider specify (the actual dates for the order and start of service). Other than that, the sections are the same as for the Home Blood Glucose Monitor and Supply Order.

Slide 12 summarizes the information related to the face-to-face encounter template for the Basic Home Blood Glucose Monitor and Supplies. Again, there is a guidance section that talks about the face-to-face encounter requirements. And then there is a series of template sections to document the face-to-face encounter.

In this case, the required section is the patient information. The encounter information is considered conditional; for example, if the person that actually conducted the face-to-face encounter is different than the signing provider. There is a space to indicate it.

The diagnoses section is there, where you can indicate if this is insulin treated or non-insulin treated diabetes mellitus. Then there are a series of optional sections related to laboratory validation information for a newly diagnosed beneficiary.

The chief complaint and related past medical history (provide space for the provider) to describe why the patient has come in or any other symptoms associated with their visit, including medications and allergies. Next is a review of systems, assuming the review systems are done and there is space to provide the results for physical information.

Finally, there is a required section for the assessment and caregiver specialty monitor sections. These sections document any particular specialty needs such as vision or manual dexterity that would require a specialty monitor.

There is a conditional treatment plan section where the provider can document why a particular specific requirement exists for supplies above and beyond the normal. There is an order section which is optional, and finally, signature.

On slide 13, we've included a template of clinical data elements to document laboratory test results for the diagnosis of diabetes mellitus. This is for a new diagnosis or a reconfirmation of an existing diagnosis.

While most laboratory test results report this adequately, what we chose to do here was to indicate those things that really should be part of a laboratory report, and in particular for testing that is performed in office.

We have required patient information, and then, depending upon whether this is an initial test or a confirmation test or both, we have sections to indicate the type of testing that was performed. This includes the ability to document glucose levels, random plasma glucose level, glucose stimulation tests or an A1C test; depending upon what was chosen to be performed to verify the diagnosis of diabetes mellitus.

We have confirmatory test (results) because in general we do a confirmatory test after we've done the initial screening. Finally there's an optional signature section as well as information that could be provided on who performed the test and where it was performed.

I think we've covered all of the templates that are part of this special open-door forum, and we talked about the clinical data elements. I'm going to turn this back over to Connie to make additional comments and start the Q&A session. Connie?

Connie Leonard: Thank you, (Bob). And, hopefully, everyone was able to follow (Bob), and (Bob) did a great job of going through. And you can actually pull up those templates if you're in a computer in case you had any more detail questions for us.

With that, Jill, I think we are ready to open it up for the Q&A portion of the call.

Jill Darling: All right. Great. Thanks, Connie, and thank you, (Bob).

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

Operator: At this time, I would like to remind everyone. In order to ask a question, please press star followed by the number one on your telephone keypad. We will pause for just a moment to compile the Q&A roster. Again, that is star one on your telephone keypad to ask a question. There are no questions over the phone at this time.

Jill Darling: All right. Connie or (Bob), any closing remarks?

Connie Leonard: Sure. I would like to say that we, if you look at these templates in the future, if you thought that you have additional comments, we do have a web address that's out an email address box, that's out on our website.

It is clinical templates – with an S – at CMS.hss.gov – G-O-V. That's clinicaltemplates@cms.hss.gov . We'd be very appreciative of any comments or questions, or concerns that anyone would have or may have about these templates.

The process next depends on what comments that we get in. We would then go right ahead and have another call if need be, or we'd move forward towards going to the official approval process for the templates.

That can take some time to go through the official process. And so, that's why we have the draft version up there for providers and suppliers if they chose to go ahead and begin using that now. Certainly, it's there for your use. (Bob), any last-minute discussion for the group?

(Bob Dieterle): The only thing I'd like to do is, again, remind people that we have created (these templates and clinical data elements) to be used primarily with EHRs within their templates and within their clinical workflow.

The printed version or the version that may be printed is there for use when you can't use the EHR or the EHR has not incorporated all the elements.

So, the goal here is to minimize provider burden my making this part of the normal process of recording information from a face-to-face visit or a face-to-face encounter with a patient. Thank you.

Connie Leonard: Jill, that would be it for us, unless there are some questions in the queue.

Operator: As a reminder, to ask a question, please press star followed by the number one on your telephone keypad. Your first question comes from the line Of (Bernadette Jacobs) With National Federation. Your line is open.

(Bernadette Jacobs): Yes, Ma'am. I have a couple of points to make. First of all, I'm curious to know who you present to be as caregivers. Are you talking about doctors? Are you assuming that most diabetics have people who take care of them? I'm curious to know that.

Secondly, I'm also curious to know how you perceived the error rates. There are equipment and things out for the diabetics. For one thing, as people know, diabetes is the leading cause of blindness these days. Secondly, the diabetes also affects the – well, the very young, of course.

But the elderly population is, you know, the baby boomer is – this is huge. And therefore, the Medicare roster with the baby boomers in it is huge. And that I'm well aware of. However, if there is a lot of equipment out there that simply is not accessible to the blind diabetic, and to me that is very, very wrong.

And the reason it is, is because if you're talking that diabetes is a leading cause of blindness, what sense does that make to have none of the equipment accessible so that the blind diabetic can take care of him or herself effectively and independently. I have, I have some real great – quite frankly, I have some grave concerns about a lot of these. Is there any way to address that?

This is why we, the National Federation of the Blind have formed a working group for a medical, accessible medical equipment because it's not just the diabetic that have the problem with inaccessible equipment.

It is people that are veterans. They use sleep apnea aids. Those machines aren't accessible to the blind, you know, the blinds out there. There is really

nothing, and we haven't received much cooperation from anyone. I mean, is it…?

Connie Leonard: Is your question more…?

(Bernadette Jacobs):   Well, I just… I'm sorry?

Connie Leonard: I want to know if your question was more directed that there were not, if there was not equipment out in the market that is suitable for blind beneficiaries? Or is your question more that this equipment (is best) but it's not covered by Medicare? Or both?

(Bernadette Jacobs):   It's all of it. It's all of it. It's both. It's not accessible and it's not available through Medicare. So, it's a combination.

Connie Leonard: So, we can't get into necessarily that's the policy on this call. If; you'd like to submit some feedback to the email address, we can certainly get it to the right policy staff so that they can be aware and make sure that they're aware of these issues that the blind community and that the National Federation of the Blind is working towards. Was someone else going to say something? I did want to over-speak.

(Bob Dieterle):   Yes. This is (Bob). Do you mind if I comment?

Connie Leonard: Absolutely, (Bob). Go right ahead.

(Bernadette Jacobs):   Sure.

(Bob Dieterle):   You asked basically two broad questions. One was what we meant by caregivers and by caregivers in the context within these templates we mean someone that is assisting a beneficiary usually in their home.

So, the questions are related to training for either the beneficiary or their caregivers not intended to be in general license provider but could be. So, that was where caregiver came from on the specialty monitor side and in the face-to-face.

And there was a question around specialty monitors, we do have questions regarding visually impaired.

The second point you were making is regarding access to devices that can be used by a visually impaired or the blind that we couldn't agree more that this is an important area.

I assume you're aware that there are actually a number of voice / talking blood glucose monitors in the market now that can be used effectively by the blind. There may not be generally known but they do exist.

(Bernadette Jacobs): Well, I understand we're agreeing with some of that but being a blind person myself and having seen a lot of that (something) is out there, there's only one totally and completely accessible, glucose monitor out there, only one I assure you because I've used, I've used some of the other ones.

And it talks but you can't, you can't completely use them without (signing assistance). That's the only place I beg to differ with you. But, again, having said that, I understand where you're going and a lot of – because a lot of people think along in those lines.

(Bob Dieterle): Well, thank you for the comment that, even though there are (monitors for the visually impaired), they may not be terribly accessible for people that are legally blind. That's a valuable comment. Thank you.

(Bernadette Jacobs): OK. Now, one last question. Is the email address on the website?

Connie Leonard: Yes. The email address is on the website.

(Bernadette Jacobs): OK. All right. That's what I needed to know. Thank you.

Connie Leonard: Thank you.

(Bernadette Jacobs): Now, do I (still have one) to not ask any more questions or…?

Jill Darling: Yes, please because we're – there might be some other folks.

(Bernadette Jacobs):   OK, thanks.

Jill Darling: Waiting in the queue. Thank you.

Operator: There are no further questions in queue at this time.

Connie Leonard: With that, I think we would like to thank everyone for your participation today. And again, just email us if you had any suggestions or questions or comments for us. Jill, (Tiffany), I turn it back to you.

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

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