



## HIT Standards Committee Implementation Workgroup Transcript June 23, 2014

### Presentation

#### Operator

All lines are bridged.

#### Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you. Good afternoon everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee's Implementation Workgroup. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Liz Johnson?

#### Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation

I'm here.

#### Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Liz. Cris Ross? Anne Castro?

#### Anne Castro – Vice President, Chief Design Architect – BlueCross BlueShield of South Carolina

I'm here.

#### Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Anne. David Kates? Gary Wietecha? John Travis? John Derr?

#### John F. Derr, RPh – Health Information Technology Strategy Consultant – Golden Living, LLC

Here.

#### Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, John. Joe Heyman? Kenneth Tarkoff? Kevin Brady?

#### Kevin Brady, MS – Group Leader, ITL Interoperability Group – National Institute of Standards and Technology

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Kevin. Michael Lincoln?

**Michael J. Lincoln, MD, FACMI – Director General Standards – Veterans Health Administration**

I'm here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Michael. Nancy Orvis? Sudha Puvaadi? Tim Morris? Wes Rishel?

**Wes Rishel – Independent Consultant**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Wes. And Udayan Mandavia? And from ONC, do we have Erica Galvez?

**Erica Galvez – Community of Practice Director, State HIE Program – Office of the National Coordinator**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Erica. And Scott Purnell-Saunders?

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator for Health Information Technology**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Scott. Mike Lipinski, are you on? Are there any other ONC staff members that I missed?

**Lauren Thompson, PhD – Director, Federal Health Architecture – Office of the National Coordinator for Health Information Technology**

Lauren Thompson's here, Michelle.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Lauren. And with that, I'll turn it back to you Liz. Liz, one more comment, I apologize. For this task, we've invited a small vendor to join, which is iPatientCare, and that is Udayan Mandavia. I believe that he is on – that he's at least on the web conference, so I'm not sure why we can't hear him yet, but hopefully we'll be able to – he'll be able to join the speaker line soon.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

All right. Thank you. So thanks everybody for joining today. What we are doing is we've been asked to look at the C-CDA and exactly what we need to do in that process is going to be explained to us, and

that's really what we're going to get done today, so that we can be ready to report in the July meeting on our charge. And I really think that we don't need to take any more time than that and we can move forward. I believe you said Erica will speak first?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

She will. And just a reminder, if you aren't speaking, if you could please mute your line, it would be appreciated; we're getting a bit of feedback today.

**Erica Galvez, MA – Community of Practice Director, State HIE Program – Office of the National Coordinator**

Okay. This is Erica Galvez. I think we can probably move to the next slide – and perhaps the next one. So I serve as the Interoperability Portfolio Manager for ONC and I think most of you are aware that we are continuing a really deep focus on interoperability, how to make that happen, advance interoperability across the care continuum and in many respects, broadly to support both healthcare delivery and health of the population. Content, as you know, is a key part of that both the semantics and the syntax of the actual data that we want to share and that we want to be interoperable.

The consolidated clinical document architecture is the cornerstone of the exchange requirements in Stage 2 Meaningful Use. And again, I'm not sharing anything that you all are unfamiliar with. Since 2014 certified products are creating care summaries using the document architecture, and will be for some time, and providers are exchanging those to meet MU Stage 2 requirements, there's a lot of focus on the Consolidated CDA right now.

**W**

Give me a call or text if you want –

**Erica Galvez, MA – Community of Practice Director, State HIE Program – Office of the National Coordinator**

It sounds like there might be a little bit of background noise from somebody. At any rate, there's been quite a bit of feedback from the field, both through tools like the standards and implementation testing environment, some of the ConnectaThons that we hold, other educational activities that we've been engaged with, in terms of implementers and providers for Stage 2. We've been hearing feedback from the field that the Consolidated CDA is not constrained enough at this point. So a key question that continues to come to the forefront is how should the C-CDA be constrained to address the implementation issues that we've been hearing about as 2014 edition certification standards have been implemented?

There are a couple of additional questions that kind of beg after we ask that first question, things like, what are the key areas in which the standards should be constrained to be more interoperable? Does the existing companion guide that is intended, I believe, to further constrain the C-CDA, get us to where we need to go, given our bold interoperability goals? What additional work needs to be done and what is the best task forward? And so we thought it would make sense to tee up that companion guide. Again, this is actually an implementation guide that was developed through the S&I Framework at ONC that further constrains implementation activities around the C-CDA that was part of the 2014 edition certification regulation. Thought that would be a good starting point given that's already been developed, that's something we have been pointing implementers to and really key the conversation from there.

So Mark Roche is not only a physician but a subject matter expert on Consolidated CDA, has done a lot of work with the companion guide. He is going to do a deep dive for us today on the companion guide and some of the key questions that we've been hearing with the feedback about where constraint could be added, hopefully to tee also the conversation amongst this workgroup that will be helpful in answering some of the questions that we've teed up. Let me pause there, see if there –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

So Erica – yeah, as you – this is Liz Johnson. As you have been doing this work, have you gathered the questions or comments that have been given to you as a part of the certification process, so that we're not starting with a blank page?

**Erica Galvez, MA – Community of Practice Director, State HIE Program – Office of the National Coordinator**

Yeah, actually I think we've got several sources of feedback, some of which I believe Mark has synthesized. He can correct me if I'm wrong.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Okay.

**Erica Galvez, MA – Community of Practice Director, State HIE Program – Office of the National Coordinator**

And if there are additional pieces of feedback that I – that have not been included in what he tees up today, we can certainly synthesize those for you guys.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Okay. Does anybody else on the workgroup have any questions related to sort of the charge itself?

**Wes Rishel – Independent Consultant**

Well I think – this is Wes Rishel, I think at some point – I thin – I guess we have to wait until we see the presentations, but I just think we may find ourselves going back to be careful we understand the definition of interoperability that the regulation calls for. And whether there are some key topic areas that are operating at acceptable levels of interoperability and others aren't, or whether we have sort of a systematic issue that is not specific to one topic or another.

**Joe Heyman, MD – Whittier IPA**

Also – this is Joe Heyman, I'm wondering if this – if the definition of constraining is sort of the opposite of finding a place where you could put past history and family history, is th – are those – that would make it worse rather than better?

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Yeah, that's a good question, Joe. That's why I wondered when we – as we open the charge up, I had the same kind of process going through my mind of, is that meant we should send less information, is that what the concept is? Or, again, the word constrained is – really needs to be defined and I'm hoping –

**Wes Rishel – Independent Consultant**

This is Wes, if I could add on to that, is that okay?

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Absolutely.

**Wes Rishel – Independent Consultant**

Yeah, so I think we've got two different qualitative forms of interoperability that each has benefits and we will need – one of the reasons I was thinking about the necessity to go back to the definitions relates to the two forms. One form is that if you put some text material in a C-CDA, the other system, the receiving system, will be able to find that text appropriately labeled and so forth, and display it. And the second level of interoperability is if you put coded data in a C-CDA document, that the receiving systems can pull that coded data out and put it into the structured data of the receiving EHR. So, for example, family history we could look at at two levels, one, the prior version the C32, there were issues with some topics where it was ambiguous where to put information in the document, even if it was only text. And, excuse me, I'm going to have to go on mute for a second here – I apologize, I have no idea what happened there. But –

**Caitlin Collins – Junior Project Manager – Altarum Institute**

You need to turn off your computer speakers if they're on.

**Wes Rishel – Independent Consultant**

I've turned them off twice and they're coming back on. Let me just pass on this and I'll figure out my technical problem and come back.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Okay. So let's – I don't know that we have an answer yet, Joe. Let's see what the rest of the input looks like and then I think your question is critical for us to come back to.

**Joe Heyman, MD – Whittier IPA**

Okay.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

And then we'll let Wes get his echo issue – so why don't we con – Erica, are you going to continue on or are we going to switch?

**Erica Galvez, MA – Community of Practice Director, State HIE Program – Office of the National Coordinator**

I think we'll actually pass it over to Mark. Actually, just one stop before we hand it over to Mark, though. As we have been contemplating these questions, and thinking about how to tee them up to the workgroup, sending less information was not the first thing that we were thinking about, when we were thinking of the term constrained. And I don't think that's generally the feedback that we've heard from the field. I think it has been more a question of having more defined information and more reliable information, to get to a couple of the things that Wes was just describing, so –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Okay.

**Erica Galvez, MA – Community of Practice Director, State HIE Program – Office of the National Coordinator**

Let me pause there and make sure that Mark is on the line, I think there may have been a couple of challenges with the dial-in. But Mark will walk you through details and I think maybe bring some clarity to a few of the questions that have been teed up.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Can you hear me? This is Mark.

**Erica Galvez, MA – Community of Practice Director, State HIE Program – Office of the National Coordinator**

Yes.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

I can.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Perfect. Thank you very much for inviting me. This shapes up to be a very good discussion, I think, and the – how do we do – do I bring up the slides or present or is that something that you will drive?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

We'll bring them up; just let us know when we should go to the next slide.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Okay. So the objective of this slide is to provide you with some specific examples that will hopefully provide a – some foundation for further discussion and hopefully some clarity. Maybe we can advance to the next slide.

So the – what I was thinking of talking about today is just generally explaining the word constrained. Provide a little bit of overview of what it means from a technical perspective in Consolidated CDA, bring a couple of examples, address a couple of benefits and drawbacks of these constraints, show a couple of levels that we can target in the Consolidated CDA to make it more constrained. We're going to discuss a little bit about the use of companionshi – a companion guide and what it did. And maybe at the very end, address some constrains, opportunities and managements of those constraints and show you some explicit examples of how Consolidated CDA has been constrained in one of the upcoming templates for cancer implementation guide for Centers for Disease Control. If we can advance the slide.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Mark, this is Michelle if there's any possibility, it sounds like we might be on a speaker phone, if you could use a handset, that would be a little bit better, it's kind of hard to hear you.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Okay, I mean, sorry to – move my computer closer – for a second. Okay, can you hear me now, is this better?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

A little better, thank you.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Okay. So, in terms of constraints and how it relates to the HL7 structured document and Consolidated CDA, which is one of its derivative, it's simply a set of rules imposed on data that is being collected and/or exchanged. An example of those rules is, a data element shall or must be present. If a data element cannot be provided, then the nullFlavor must be used. NullFlavor is used to indicate when information is not available. The data element values shall be drawn from one or more code systems, so you can specifically tie a particular code system or value set to a data element that you're trying to capture. And sometimes the word constraint is used synonymously with optionality, I hear both flavors being used interchangeably and they're inversely related. Next slide.

So technically, in Consolidated CDA, what you see here are words that are used in Consolidated CDA to constrain or to provide definitions on which sections need to be used, which data elements need to be used, which vocabularies. So there are three levels of these conformance verbs that are used to constrain something, SHALL, SHOULD and MAY. SHALL is the most restricted and it states that something is really required. SHOULD is, it says it's a best practice, you really should provide that information, but in end effect it's optional. It's not going to cause any errors, the electronic health records system will not complain if you don't provide that data element. If you received Consolidated CDA from somebody else, your EHR will not complain. And then there is a third level, which is the MAY and that's the most optional one, this is true optionality. And it means that, if you really have that data element or section or information, you can provide it and here is the placeholder where you can do so. But it's really not required and we haven't looked at it, as a – we don't consider it as a best practice.

And then there are a couple of other ways to constrain something. If you cannot provide a data element, then you can use something, which is called a nullFlavor. So whenever a data element is required, such as if you don't know the patient's last name or patient date of birth, you can actually use a nullFlavor to say, no information is available or unknown and so on. And then there – the attributes in any data element in Consolidated CDA can use nullFlavor, unless it is specifically prohibited to use. And then some data elements also have attributes associated with them, which use negation indicators. And that's a little bit more detailed for this discussion. Next slide, please.

So here is an example of Consolidated CDA. On the left-hand side, this is an excerpt from procedure section and in green circles you actually see how these constraints are applied throughout the document. So in the yellowish section, this is where you provide – this is where the Consolidated CDA stipulates which procedure codes should be used, from which coding systems. So in this case it specifically said if you use a procedure code for a patient that code should be selected from LOINC or SNOMED, may be selected from CPT-4 or ICD-9 or ICD-10. On the right-hand side you actually see an example of how the nullFlavor is used. So again on the left-hand side there is a data element called the method code. So if you indicate a procedure for a patient, you can indicate the method that was used to perform that procedure. And in this instance, the binding is "may," so you may communicate the

method code, and if you don't have the method code, you can apply a specific nullFlavor and say, "I don't know what the method is that this procedure was performed with." Next slide, please.

This is an example from companion guide. This is an example of how companion guide identifies the data elements that you have seen previously in –

**Wes Rishel – Independent Consultant**

Did we lose him?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Mark, are you still there? It sounds like he accidentally disconnected. We're having some technical difficulties today.

**Erica Galvez, MA – Community of Practice Director, State HIE Program – Office of the National Coordinator**

We're giving the –

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Yeah, but wait a minute –

**Wes Rishel – Independent Consultant**

I wonder what the nullFlavor is for that.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Oh, Wes.

**Wes Rishel – Independent Consultant**

So, you had some surgery, huh?

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

I did, I had a retina reattached.

**Wes Rishel – Independent Consultant**

Oh.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

I heard you had surgery, too.

**Wes Rishel – Independent Consultant**

Yeah –

**Joe Heyman, MD – Whittier IPA**

Hey guys, it's a public call, don't forget.

**Wes Rishel – Independent Consultant**

Yup.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Is that PHI, are you trying to tell us something?

**Wes Rishel – Independent Consultant**

I believe as patients we're allowed to say what we want about our PHI.

**Joe Heyman, MD – Whittier IPA**

But not necessarily about each other.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

We should know that Dr. Joe would come to the rescue.

**Wes Rishel – Independent Consultant**

So, how long will he speak before he realizes that no one is listening?

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Did you ping him Michelle or Erica, to let him know we don't have him?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

I think that he is getting pinged as we speak.

**Erica Galvez, MA – Community of Practice Director, State HIE Program – Office of the National Coordinator**

Right.

**Joe Heyman, MD – Whittier IPA**

One of my – just listening to him, one of my questions is about CPT. I mean every physician uses CPT for coding procedures, nobody uses any of the other things, at least not physicians, maybe pathologists use LOINC –

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Hello, can you hear me?

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

You're back.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Mark.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Hi, I think I dropped off the call, I'm very sorry.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

You did drop off, but thank you for joining back.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Yeah, so you had just started on the slide on the companion guide when we lost you.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Okay, okay. So I'll repeat. So this slide shows you an example of how the constraints are articulated in companion guide. So the – you will notice that this slide is much more simplistic compared to the previous one, in terms that on this slide you don't see all the noise from the actual Consolidated CDA, you just see the data elements identified and then the constraints, shall, should and may. And the sections in red are sections where companion guide indicates and ties the Meaningful Use Stage 2 data requirements and information to Consolidated CDA. In essence this is where companion guide says, if you're implementing Consolidated CDA, you need to focus on these data elements from your Consolidated CDA and these are the cons – these are interpreted from Meaningful Use Stage 2. Next slide.

So here I'm trying to kind of – a couple of pros and cons and think most of you are probably familiar with this. A couple of pros of having constraints are improved consistency of structured document contents. It improves semantic interoperability. So for example, if you have a data element that contains the value from one coding system, it is better than a data element that contains values from multiple coding systems and a good example is procedure. Procedure allows SNOMED CT, LOINC, ICD-9, CPT, and ICD-10, that Consolidated CDA release 1.1, which is basically you can put any of the five coding systems. If one coding system generates the procedure codes in SNOMED, the other one in LOINC, there is little semantic interoperability, there are some gaps that are going to be present.

The constraints improve predictability and reliability of the information available to the user. Basically, if you – if a data element is required to be communicated, and if the data element is not available if you – that a nullFlavor must be used, then a physician looking at a patient summary form will know that certain information is either reliably present or that a reason for its absence is stated always. Basically you won't see a blank on your chart, you will actually see a data element specified and it will have a value or if it doesn't have a value, it will have an explanation why it doesn't have a value. And the constraints also improve consistent implementation of standards across vendors.

And a couple of cons, a couple of drawbacks. The data elements requirements will differ based on clinical or administrative content – intent. Certain data elements in certain clinical scenarios will be more relevant than in other clinical scenarios and that also goes for clinical disciplines. What a primary care physician – the data elements that a primary care physician requires will be a little bit different and more general than the data elements than an ophthalmologist will require.

Now these requirements will – if we constrain data elements in specifications that means that if we say that a data element is absolutely required. That means that if that data element does not exist in existing electronic health record systems, then the vendors need to extent their databases and the graphical user interfaces to capture those fields that are required in addition.

And there's also possibility of something called semantic and structural overload of C-CDA templates. Sometimes if we put a lot more constraints, we're actually adding a lot more complexity to a Consolidated CDA document itself and I think one of the examples at the very end of this – very end of these slides will actually show you how complex the wording in Consolidated CDA gets once you apply more constraints. Next slide, please.

So this slide is trying to summarize the different levels, where can you apply the constraints. We can apply the constraints on a section level, you can say that a procedure section or a history of past illnesses section is required or not. For each of the sections you can say that the entries should be coded or not. By default, all entries must contain free text or narrative section, but some of the entries must be coded. An example is the results section, if you indicate a result – a laboratory test result, you should not only free text it, but it should be encoded as well. Free text narrative is more targeted for the human consumption, coded sections within the entries are required for machine processing, so basically to facilitate computers to talk to one another.

We can further constrain data elements, we can constrain the values for those data elements or we can – by specifying vocabularies. And if the data elements are not available, we can also specify that the nullFlavor must be specified. We can also specify the data element attributes. So for example if you communicate a procedure code for a procedure that you performed on a patient, then you must not only tell me the procedure code, but you can also tell me the code system, where you – where that code generates – where that code is derived from. And you may also need to specify the display name from that coding system where you're pulling the code from. Next slide.

This slide graphically shows all of the different levels and I didn't address the document type. One thing that's important is that the constraints that we place on a particular document type, such as Consolidated CDA or discharge summary may be different than a set of constraints that you place on another document, such as progress note, which means that you cannot easily parse the – you may not easily be able to parse the document from discharge summary into progress notes and vice versa. If, for example, procedure code is required in discharge summary, but it's optional in the progress note, if your system refused the progress note and it can transcribe – if you kind of like pull all the information from progress note and try to generate a discharge summary, you won't have all the information required. So there is – one of the things to consider is, as we apply the constraints for a particular document type, we need to think about the consequences that those constraints will have across the spectrum of all the documents such as CCD, discharge summary and so on. Next slide.

So here I'm trying to address a couple of things that the companion guide did. The companion guide provides guidance to a vendor on how to implement Consolidated CDA using or in light of 2014 certification requirements. It's an informative document and it does not impose any new constraints beyond those that already exist in Consolidated CDA and certification requirement. Basically all it does, it says, here are the data elements that are in Consolidated CDA, here are the data elements that are in Meaningful Use Stage 2, here is how they map to one another. And it basically tells the vendors if you're implementing the Consolidated CDA for these data elements from Meaningful Use Stage 2, you should apply these set of requirements. This basically implies, and I'll go through a couple of examples, that in some cases C-CDA is not – does – is not the ultimate source of truth for the vendor, it is actually less constrained and the companion guide then clarifies constraints from the Meaningful Use Stage 2 perspective. Next slide.

### **Wes Rishel – Independent Consultant**

Excuse me, didn't you just state two opposites? This is Wes Rishel. Didn't you just say on the one hand it doesn't impose new constraints, on the other hand it does impose new constraints?

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

The – it doesn't impose new constraints, the companion guide imposes constraints, not new constraints, imposes simply constraints that are already stipulated in the Meaningful Use Stage 2, and it says how those constraints apply to Consolidated CDA. But it doesn't say, in addition to Consolidated CDA and in addition to Meaningful Use Stage 2, here are additional constraints that you need to apply.

**Wes Rishel – Independent Consultant**

Okay. So if I understand it, the C-CDA is not sufficiently constrained to meet the requirements of Meaningful Use Stage 2, you need to further constrain the C-CDA by the contents of the companion guide in order to meet the requirements of Meaningful Use Stage 2. Is that correct?

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

That is correct. That is correct and the next slide will actually – next three slides will actually show explicit examples.

**Wes Rishel – Independent Consultant**

Thank you.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

So, this may be a little bit difficult to read, but the green arrows basically link the left and the right side. The left side is the Consolidated CDA, it's a snapshot from the actual document. The right side is a snapshot from companion guide, and this entire – this snapshot talks about the header data elements. The header contains typically administrative and demographics about the patient and his care providers and so on. So in this specific example, you see how companion guide maps in red the Meaningful Use Stage 2 elements and then maps them to the Consolidated CDA. And in this instance, you see that the constraints are all the same, shall contain ID, shall contain address, shall contain name, and shall contain administrative gender. Now there is one constraint that should contain marital status code, right, so in this instance, there is no difference between the – what companion guide said and what the Consolidated CDA says. Unlike the next example, on the next slide –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Hang on just a second before you go there. So, for the vendor whether it says shall, should or may, my interpretation is they would have to have the ability to do any one of those three conditions.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Correct. Yes.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

And then as a provider, we would need to be able to populate the "shalls" – we would have to populate the "shalls" for sure. The "should" or "may" is a choice.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Correct.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

All right. Thank you.

**Wes Rishel – Independent Consultant**

And if I would just add one thing to that, as a user, receiving such a document, your workflow has to allow for the possibility that the “shoulds” and the “mays” are – have no meaningful value, they might have a nullFlavor that says why it wasn’t collected. But you can’t assume that that other provider filled in any of those fields, so –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Right, but you’re absolutely right, it’s as simplistic as, you have to have a catcher’s mitt that can catch all, right?

**Wes Rishel – Independent Consultant**

Well yeah, but I was adding, in addition to that, you have to have a procedure for dealing with, what if they didn’t put it in.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Right – .

**Wes Rishel – Independent Consultant**

So for example, if you’ve got rules that are going to fire based on the contents of some field that’s a “should” or a “may,” you have to allow for the fact that you may have to collect that data yourself, or you may – the rule may not fire. I mean, it’s just –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Right, right. And yeah, and what we’re finding in the field is based on what the vendor built, the vendor may – that product may or may not even accept it, it may reject the whole thing.

**Wes Rishel – Independent Consultant**

Right.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

I mean, we’re seeing that in the field today. Okay.

**Wes Rishel – Independent Consultant**

Okay.

**Joe Heyman, MD – Whittier IPA**

This is Joe. I just want to make sure I understand one thing that Wes said and he got a yes answer to. Wes said that the areas that have “may,” the vendor has to be able to do all of those areas. He got a yes.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Umm, the vendor has to implement all the “shalls.” The “shoulds” and “sha – the mays,” the vendor is not required to implement.

**Joe Heyman, MD – Whittier IPA**

Okay, that’s what I –

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

The user – good point, yeah.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

That’s a different answer than you gave me originally, this is Liz.

**Joe Heyman, MD – Whittier IPA**

That’s right, that’s why I re – .

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

I asked you, yeah, I asked you very specifically because in the past, when we gave options, the vendor had to be capable of doing all options, so they would have to be able to do “shall, should or may.” And you’re saying they only are required to be able to do “shall.”

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

The Consolidated CDA specifies for each data element what the vendor has to implement. So if it’s a “shall” data element, then the vendor must provide you with that data field so that you can document that information. If it’s a “should,” the vendor – it’s – should be able to provide you –

**Wes Rishel – Independent Consultant**

This is a real binary situation here.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Yeah.

**Wes Rishel – Independent Consultant**

Does the ve – it’s often said that when it comes to vendors, “or” means “and,” if –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

That’s right.

**Wes Rishel – Independent Consultant**

– the specification allows for “A” or “B,” then the vendor must do “A” and “B.” And it has been our understanding up until now that fields that had optional values it was the user’s option whether to send

the value in there, not the vendor's option whether to enable sending the value. Now we're getting a different message from you.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Yup.

**M**

Okay.

**Udayan Mandavia – President and Chief Executive Officer – iPatientCare**

Even as a vendor, again, this is Udayan – our perception is also that we would build “A” and “B,” even though it was “A” or “B.”

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Right. So again, when we're talking here, there are obviously two sides of this, one is the person who builds the software that we then buy from them and use for our purposes of communicating with each other as providers. So our question is strictly about what does that software – what is required to be done? And like Wes said, all along we've been told, it doesn't matter whether it says “and” or “or,” both pieces must be present for use.

**Wes Rishel – Independent Consultant**

The system must be capable, must be demonstratable –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Right. Correct.

**Wes Rishel – Independent Consultant**

– in certification of being able to send any – use any of the options.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Right.

**Wes Rishel – Independent Consultant**

So if it says, you have to use CPT codes or ICD procedure codes to send procedures, then the system has to be able to do both of those.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Right.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Okay. So I was looking at it strictly from the conformance perspective in terms of when the document is generated, an actual instance whether it's going to validate or not. If that has been the com – if from the implementer perspective, from the perspective of designing the actual field and providing the capability,

if that's what you've been told so far, then that still stands. If a "shall," "should" and "may," if – no matter what it is from the vendor perspective then if what you've been told is you have to provide that field, then it still stands true. And then if the user – on the user side, if the – if a data element has a "shall" constraint, that data element needs to be provided, if it has "should" or "may," does not need to be.

From a document validation perspective, an instance of a document, once it's completed, if the document data element has a "shall" constraint and the element is not provided, the validation will fail in that – document. If the document instance contains a "should" constraint on a data element and if that element is not provided, then the validation will trigger an error – it will trigger a warning that the information should have been provided, but the document is still valid. And if the document contains a data element that has a "may" binding, then the document is valid and there will be no warning. So, I was looking at it from a different angle, not necessarily from a user and from a vendor implementation perspective, but strictly from a document validation perspective.

**Joe Heyman, MD – Whittier IPA**

This s Joe. I think that it would be good to have a reaffirmation at the next meeting by the folks from ONC to be absolutely certain that we're interpreting the way we've been doing it up to now as still being correct when it applies to the C-CDA.

**W**

Great.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

So – if you'll put that on our list, please.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Okay, I'll make sure we come back to you with reaffirmation.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Okay. Did you want to go on to another example?

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Yes. So in this example, you can see on the left-hand side the Consolidated CDA for a specific section such as functional status section, immunization section provides the "may" binding, so it's optional. On the right-hand side you see how the companionship guide clarifies or interprets the Meaningful Use Stage 2 requirements and states that the functional status is required, so it's not optional, it actually has a "shall" binding. And the immunization section also has a "shall" binding and the entries are required. So this is where the companionship guide, it doesn't really constrain the Consolidated CDA, it only explains how the Meaningful Use Stage 2 requirements should be interpreted in light of the Consolidated CDA. Next example.

And this is where the companion guide recommends that the – certain sections that are currently not present, be included. This is not a requirement, this is just a suggestion or recommendation. Next –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

So how does that work in terms of what the software vendor is required to do? And my interpretation would be for the purpose of certifying for Meaningful Use, this is not required, so this would be an area where this is truly optional.

**Wes Rishel – Independent Consultant**

Well I – I think we need to ask the same question about sending and receiving.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Yeah.

**Wes Rishel – Independent Consultant**

So if it's truly optional, even though the sending system has it in its database, it's not obligated to put it into the document. And if it comes in in a document, even though the receiving system has a place in its database, it's not obligated to put it in there, or is it? I mean, is it obligated to deal with it if it comes in when it's a "may" or not. This focus –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Yup –

**Wes Rishel – Independent Consultant**

– on validating the document is a very narrow focus that doesn't serve well the interest of making sure that interoperability happens and is meaningful and serves the medical purpose that it's meant for.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

So is that question – I mean, I think, Wes that the same question could be asked of "should."

**Wes Rishel – Independent Consultant**

Oh, I agree, I agree. I mean this whole – I just – this whole thing, we're learning right now about what a companion guide is and how it relates – how it fits into the conceptual layers associated with Meaningful Use by creating further constraints over the HL7 document in order to meet the requirements of the Meaningful Use Stage 2 regulations.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Uh huh.

**Wes Rishel – Independent Consultant**

But, we have to look at the bigger issue of what happens when two certified, interoperable systems attempt to interoperate and what data can be expected to be there and what can't. And that's my big concern, I'm looking forward to, if we let the poor fellow talk, maybe we'll find some examples that have been discovered in operation that points to needs to improve this, or maybe we'll find that there are no such problems in implementation. I've never heard of any system that didn't have problems in implementation, but it could happen.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Okay, keep going please.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Okay. Next slide please. So the opportunities for constraining are listed here and they basically reiterate the possibilities to constrain not only for data elements and nullFlavors, but also on sections and entries, code systems and code – and attributes as well. A couple of examples in the next set of slides will show how these constraints have been applied to a different implementation guide that’s coming out. Next slide, please.

So what this shows is an example of, on the left-hand side is a Consolidated CDA and this is release 2, this is not release 1.1. On the right-hand side is a new cancer implementation guide that’s currently being under design for Centers for Disease Control. And here is an example of how the birthplace for the patient has been further constrained or clarified for the user or for the vendor in terms that the birthplace does now only have a “may” requirement, it is required. A nullFlavor is – it is specifically articulated in the guide that the nullFlavor is allowed and there may be one or – zero or one nullFlavors. And based on the cancer specifications, the – if the birthplace is known, then the place, address, country and state must be provided and consequently, if the birthplace is known, then the nullFlavors cannot be used for place, address, country and state. However, if the birthplace is not known, then the nullFlavor must be used only at the birthplace level and will not be used for place, address, country and state. Basically this eliminates the cases where one vendor can say if they don’t have the birthplace, well I don’t have the place, I don’t have address, I don’t have country, I don’t have state and another one just saying I don’t have a birthplace.

**Wes Rishel – Independent Consultant**

Well, so what about – I mean, I know I was born in Chicago, Illinois, I have no idea what the address is or the hospital where I was born. What – are you saying that they can’t send it – they can’t send the fact that I said I was born in Chicago because they don’t know the address of the hospital?

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

If you – if they don’t know the address of the hospital, then they provide that information as a nullFlavor in a birthplace element.

**Joe Heyman, MD – Whittier IPA**

And could you give an example of a nullFlavor in the birthplace element?

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

No information –

**Wes Rishel – Independent Consultant**

But I’m asking the question –

**Joe Heyman, MD – Whittier IPA**

In other words, no information or somebody would select no information from a template?

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

It's – a nullFlavor has a specified list of values that can be used as a nullFlavor, one of them is UNK, unknown, the other one is NA, not available, NI, no information and there are four or five others.

**Wes Rishel – Independent Consultant**

Yeah Joe, some of them are actually useful and distinguishable, unlike those, for example, we didn't ask or the patient declined to answer are possible. I mean it's really a reason why we don't have the information. But I'm just asking a more basic question, can I see – can the vendor collect and send only Chicago, Illinois or is the vendor required to either say null or include the address of the place?

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

For this – make sure I understand your question, from this – from the Cancer IG perspective –

**Wes Rishel – Independent Consultant**

Um hmm.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

– if you know the birthplace, you need to provide the country and the state, that's required. And if you don't know either one of them, then the birthplace is –

**Wes Rishel – Independent Consultant**

Okay, so for example, if –

**Joe Heyman, MD – Whittier IPA**

If he doesn't know which hospital he was born in, but he knows he was born in Chicago, Illinois.

**Wes Rishel – Independent Consultant**

Yeah, so he says that's okay. He does say that if I – it would be – if, in fact, I said I was born in the United States, but I don't know what state, then they would have to send no information, they couldn't send the fact that I was born in the United States. But he does say that they don't have to know the hosp – the address in order to –

**Joe Heyman, MD – Whittier IPA**

Supposing you know that you were born in Illinois, but you don't know what city?

**Wes Rishel – Independent Consultant**

That's good, that's okay, I think, country and state he said is what's required.

**Joe Heyman, MD – Whittier IPA**

Okay.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Yeah, country and state are part of the address. This is – the indentation of this ladder section of the implementation guide is not as visible, it's not as intuitive, they couldn't indent it all the way to the right. So the country and state actually are part of the address. Can we move on to the next slide?

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Yes please.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

So in this instance we've tightened data vocabulary for a specific data element for the city. The Cancer IG actually has a separate list of permissible values for city name. So on the left-hand side you see the Consolidated CDA release 2, on the right-hand side the draft Cancer Implementation Guide.

**Wes Rishel – Independent Consultant**

I'm sorry, could you – you're saying that separately from many a general place elsewhere, there's a committee that's maintaining a list of cities that's legal to say you were born in in the cancer report?

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

We are drawing the city value set from US Geological Society website.

**Wes Rishel – Independent Consultant**

So, city may be – city – very often addresses and so forth are validated by the postal system's data. The people who represented what's good for the user in developing this said, it's better to use a dif – a separate database, have the system have to have two different databases of cities, have the user deal with the possibility that a city name is in one database but not in the other and deal with the errors that arise from that. That's a decision that was made on behalf of our users in developing this implementation guide, is that correct?

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

You said that a city was, I'm sorry, I didn't understand.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

I think he's asking if the postal – why aren't we using the cities listed in the postal system.

**Wes Rishel – Independent Consultant**

I'm pointing out that –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Yeah, I know.

**Wes Rishel – Independent Consultant**

– there have been a lot of sources for cities, when there are multiple different sources, operational issues arise whenever they're inconsistent that's the reason for using one source instead of multiple sources. And saying that someone has apparently made the value judgment that it's better for

healthcare to use the Geological Survey with the difficulties of multiple sources for cities, than it would be to just use the same thing that the systems use wherever else they edit cities. And that we – I just wan – I was leading up to asking what was the process that went through to decide on that particular bit of benefit?

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Well the Centers for Disease Control they wanted to make sure that the values that are provided for the city data element is act – first of all valid and it's just not a random set of characters and that it comes from a specific value set.

**Wes Rishel – Independent Consultant**

Right. And so the decision was made, during a consensus process, to pick this particular value set, without reference to what other value sets were used to populate cities in other locations, is that correct?

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Well, I would have to go and ask CDC how they came to the decision to use that particular city value sets and what other options were available and how they came to that decision –

**Wes Rishel – Independent Consultant**

Yeah, I'm thinking on what seems to be a small inconsistency here to get to an issue of process.

**Joe Heyman, MD – Whittier IPA**

Well the only – it actually could be a big deal, but of course a doctor like me is not going to know. But for example, my EMR it defines every city by using the zip code.

**Wes Rishel – Independent Consultant**

Right.

**Joe Heyman, MD – Whittier IPA**

So –

**Wes Rishel – Independent Consultant**

You use the postal service database, that's what most –

**Joe Heyman, MD – Whittier IPA**

I put the zip code in – .

**Wes Rishel – Independent Consultant**

– most systems do.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

So guys, I'm going to ring you back pretty quickly because while I think this is an appropriate point and was discovered and we should include it as sort of a discovery point that somehow we've managed to have CDC go one way when the rest of us have gone another way and that that could certainly impact interoperability. But I want to get us back to the subject of how we work on the constraint issue.

**Wes Rishel – Independent Consultant**

Yeah.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Okay.

**Wes Rishel – Independent Consultant**

Of course.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Thanks, guys.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

There's some motherly aspect to this, Liz.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Yes, I know Joe. I mean it's just one of those things where I think the point is very well taken and it –

**Joe Heyman, MD – Whittier IPA**

Oh no, I agree with you 100%, we're way off.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Yes, yes. So let's continue Mark, going forward.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Okay. Next slide, please. So we can also tighten vocabulary options, and this is an example from Consolidated CDA release 1.1 and 2. The difference is that the ICD-9 has been dropped as one of the coding systems to indicate the procedure. And the other opportunity is SNOMED CT is a coding system that contains about more than 400,000 terms, not all of them pertain to procedures so it may be more beneficial if the procedure code was used that the SNOMED CT code be limited to just those SNOMED CT codes that are descendants of a SNOMED CT procedure. As opposed to right now where basically a SNOMED CT code for problem or finding or symptom can be used in a field for a procedure code and nobody would know. Next slide.

So this is an example on the left-hand side, again it's a Consolidated CDA, on the right-hand side is the Cancer Implementation Guide. The Cancer Implementation Guide we decided to specifically call out the attributes that are part of a data element in blue, and we're still working on the constraints, so even the display name may have a "shall" requirement. But we've found that the instances of the Consolidated CDA documents or some other templates that were developed sometimes contain some of these additional attributes or not. Some of the attributes are required by default and if you don't provide them, then the schematron or the validation tool automatically generate an error and will automatically say that that document is not valid. But there are a lot more attributes than even what you see on the

right-hand side that could be used and if they're specified in an implementation guide, could improve consistency of how the document actually look like. Next slide.

So here what I'm trying to do is to outline three different levels of how the constraints are communicated so far. And how the constrain – further constraints can be applied. One can constrain the actual CDA, which is the very underlying base standard that the Consolidated CDA is based upon. One can constrain the Consolidated CDA, which is the derivative of the consolidated – of the clinical document architecture standard. The problem with that approach is that the balloting happens only three times per year at HL7 and moving from one Consolidated CDA version to another is a – can be a lengthy process. The July 2012 is the Consolidated CDA release version 1.1, the update has just been – the ballot has just passed through, several weeks ago for the Consolidated CDA release 2.0.

The problem with that approach is that if we update the underlying standard such as CDA or Consolidated CDA it's likely going to be Consolidated CDA, then there are other things that are updated within that standard, not necessarily the constraints. And one runs into a danger that if we improve the constraints and everybody agrees to that, then for other things other than constraints such as new sections, removed sections, renamed sections and some other things that are being updated that are independent from constraints may not pass the ballots. So, in essence the passing of the ballot is tied to the entire content of the ballot and the content of the ballot is mixed.

The companion guide also has to go through the balloting process in HL7, but here we have more – kind of more freedom to target specifically constraining data elements. And not necessarily discussing the CDA or Consolidated CDA structure – from – and then there's – .we can also constrain directly in CFR by specifying directly in the CFR what data elements are required, what value sets are required. But in that case, that may require implementation guides such as companion guides to tie the CFR requirements to the actual standards. So, that brings me to the end and open up the floor for discussion.

**Wes Rishel – Independent Consultant**

Well, I guess I'm – we've learned something about the implementation guides here, but – and the one thing I heard that I had forgotten, if I knew it, was that after these go through the IS&M process, they're balloted in HL7, is that right?

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Yes.

**Wes Rishel – Independent Consultant**

Okay, so that means my concern about process is a little less strong. But I think we're still wondering why are we here, at least I am. Having heard this, what are we being – what's the ask for us?

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Yeah, why don't we go back to the – at the beginning, where Erica had a charge slide, and then let's work and use that –

**Wes Rishel – Independent Consultant**

Okay.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

– based on our knowledge and see if we can respond. Okay, so – .yeah. So it appears to us that – at least it appears to me that what is being asked is could we look at the implementation guide, I guess would be the easiest place to go, tied back to the C-CDA and suggest or make recommendations around changing “shalls” to “shoulds” or “mays” or vice versa. I am concerned about the body of work that this might entail and the timeline, if I were just going to kind of give my immediate gut. Wes?

**Wes Rishel – Independent Consultant**

Can I add some concerns?

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Yes, you may.

**Wes Rishel – Independent Consultant**

So, this slide mentions implementation issues that have been expressed by industry –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Right.

**Wes Rishel – Independent Consultant**

– as 2014 edition certification standards have been implemented. Well what are those implementation issues?

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Yeah, that was what I –

**Wes Rishel – Independent Consultant**

Do we have –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Yeah, that’s what Erica, I’m sorry to intrude, I’ll let you talk in just a second. Erica, that’s what I was asking about in the beginning of the call is, do we have that list or whatever format it might come in, and to be able to understand what has been expressed. Keep going, Wes.

**Wes Rishel – Independent Consultant**

Well I think probably the questions that are listed on the charge slide, what should be constrained to be more interoperable? That’s pretty open-ended and –

**Joe Heyman, MD – Whittier IPA**

Actually, before you go further Wes, when it says what should be constrained more; if our interpretation has been correct all along, it’s already constrained as far as it can be constrained.

**Wes Rishel – Independent Consultant**

Well, we don’t – I mean, the reason for constraints, Joe, is that without them, you can get into a situation where the sending system in good faith is filling in data and the receiving system has had such a wide variety of different ways to pick – to interpret the data, based on the “ors” and the “mays” and

the – that they’re actually not able to be assured of processing the information put in by the sender in good faith. And the constraints are supposed to narrow that range of what can be sent to give the implementation of the receipt a reasonable target to build it on.

**Joe Heyman, MD – Whittier IPA**

Right and what we’ve been told before is that, or at least my understanding and maybe I’m just not understanding. But my understanding from before is that whether it says “may,” “should” or “shall,” the vendor is responsible for including all of them. So –

**Wes Rishel – Independent Consultant**

Yes, but if it says, for example, you “may, should or shall” use this data element and it must be coded using SNOMED CT, then you know you don’t have to implement the – specification to deal with something coming in in this data element.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Yeah, there’s a – yeah.

**Wes Rishel – Independent Consultant**

Go ahead.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Well there’s another piece about the constraining question so, let me throw this out to the group and others, please correct me. The way I understand it is the constraints are almost required descriptors. So if we change more things to “shall,” then the companion guide and the description would be more constricted, frankly, I believe. I understand the “shall” and the “may – I mean ”should” and “may,” but I do believe that if we list – if we change some of the “mays” to “shall,” then Joe you or I could count on receiving additional information consistently.

**Wes Rishel – Independent Consultant**

Yeah, but we could also get into the situation where pediatricians are saying –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

I agree –

**Wes Rishel – Independent Consultant**

– the system is telling me I have to collect the smoking history for 2 year olds because there’s a “shall” in there somewhere.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Right.

**Wes Rishel – Independent Consultant**

The – my feeling is that I’d like to know why this is being brought to us. Is there a list of issues that have been demon – that have been raised, if so, what is it? If we’re asked a question such as, given what we’ve heard – given information presented from industry, is there a need for more constraint, we can

answer it. But short of that, we'd have to have hearings to find out how people are doing in the implementation, what interoperability they're having to begin to answer these questions.

**Erica Galvez, MA – Community of Practice Director, State HIE Program – Office of the National Coordinator**

So this is Erica, just a couple of quick thoughts. We can absolutely pull together feedback – specific feedback from the field. I think one of the reasons we're bringing this question to you is to engage you and get your help in figuring out, is this really an issue? Right, are there enough specifics coming through in the feedback, and based on the companion guide that's been developed to warrant additional effort in looking at further constraints to this aspect of interoperability. And you may come back and say, no. It's actually – what's there is fine. But I think your wisdom and doing this in a transparent manner is important for us.

**Wes Rishel – Independent Consultant**

Well I –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

I think that gets down to the kind of the bottom line though is that, and I agree – thank you for helping us much better understand how this works and how the companion works. I think what's missing for us to even begin the work is what have the complaints been? Or concerns or suggestions or however one may categorize them.

**Erica Galvez, MA – Community of Practice Director, State HIE Program – Office of the National Coordinator**

Yes, that's reasonable.

**Mark Roche, MD, MSMI – Vocabulary and Terminology Subject Matter Expert – Office of the National Coordinator**

Yes, I agree.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

So I would say for all the folks on the workgroup, what we need to do is get that list out quickly and let us look at it and then we can come back together and say, how do we actually move this from, either this is – given that list, where do we go from there. I'm not going to try and conjecture on what the right answer might be. I though again am very concerned about the timeline because if HL7 only ballots three times a year and we have to get this – I'm trying to figure out why we feel that we have to complete this work by the July implem – workgroup meeting or Standards Committee?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Actually Liz, this is Michelle. There's a work plan slide that we should look at, we've updated that because we had to cancel the last meeting.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Okay.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

And so we were proposing that by the August meeting, and if we need more time, we can plan for that.  
And –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Okay. Yeah, because

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Sorry.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

I'm just thinking that if we know when the – we can work backwards from when the balloting would take place. And again, without seeing the list of concerns, I'm not sure the amount of work, the time we'll need and so on. So, we're a little bit hamstrung, but that's okay. Let's look at – at least the timeline allows a little more time. Again, the other thing I worry about, of course, is that during the summertime getting folks scheduled – working through schedules is always a challenge, but we will certainly make every attempt to complete the work, once we understand what the work is. So we can take a look at that –

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

This is Michelle, one more thing I wanted to add was that we were proposing, and we can certainly think through this and maybe have another planning meeting before the next call –

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Okay.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

– that possibly we have presentations at the July 9 meeting of people that are having challenges, like current HIEs or somebody like that, and invite a number of people to present and share their experience.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

That would be very helpful because if we knew both ways, if we knew what the vendors were challenged with, as well as those who are receiving the data, like Joe or I or others, if we understood. And early in the call Joe brought up the concern about history, which we've talked about many times and it really is important. I think if we knew – I'm hoping that the list you will bring us will come from the certification process, therefore we would have more of the vendor input. And by doing some field experiences, we could understand what either HIEs or other ways of the portal folks that are now receiving these and its providers or even patients, what they're struggling with. That's a very good idea.

So, I don – let’s have a planning meeting so that we can assure that we understand what the list is consisting of, and then we can plan for the July 9 meeting, to determine whether or not we need to review that list with the group. And come up with a plan and can we also fit in field experience, are we ready to ask for field experience? Because if we’re going to ask for field experience, we need to tell the folks that would be talking with us what information we are seeking. Other comments from the workgroup? Other suggestions as to how we might better define our charge and get the right information?

**Udayan Mandavia – President and Chief Executive Officer – iPatientCare**

We just – what we’ve talked about would certainly help.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Okay. Well I think – again, I thank you Erica and Mark both for – I’m sure like everyone, had no idea and so this is very, very helpful. And I think that if we can get the list of the certification – concerns that have been raised during certification or after, then we can have a planning meeting prior to our next workgroup meeting and actually look at those concerns as well as get further input and then really refine our charge and timeline. So I’ll give you minute to say, okay or not and then we’ll go to public comment. Okay –

**Wes Rishel – Independent Consultant**

Who do you want to say okay?

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Yeah, any one of you – you can either say okay or –

**Wes Rishel – Independent Consultant**

Okay, okay, okay.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Okay, thank you –

**Udayan Mandavia – President and Chief Executive Officer – iPatientCare**

Okay.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

– okay. Okay, all right. So Michelle, can we go to public comment please?

**Public Comment**

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Sure. Operator, can you please open the lines?

**Rebecca Armendariz – Project Coordinator - Altarum Institute**

If you would like to make a public comment and you are listening via your computer speakers, please dial 1-877-705-2976 and press \*1. Or if you are listening via your telephone, you may press \*1 at this time to be entered into the queue. We have no comment at this time.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

Great. Well thanks everybody and thanks for the information shared and now we'll go to the next step and take that information and apply it to our response to the request. So everybody have a great day and we'll talk to you on June 28 – or the –

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, everyone.

**Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation**

– bye, bye.