

**HIT Policy Committee  
Certification/Adoption Workgroup  
Transcript  
January 10, 2014**

**Presentation**

**Operator**

All lines are bridged with the public.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Thank you. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Certification/Adoption 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. Marc Probst? Larry Wolf?

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Mike Lardieri? Joan Ash? John Derr?

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

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Carl Dvorak? Paul Egerman?

**Paul Egerman – Businessman/Software Entrepreneur**

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Joe Heyman?

**Joseph M. Heyman, MD – Whittier IPA**

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Hi, Joe. George Hripcsak? Stanley Huff?

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Hi, Stan. Liz Johnson?

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

I'm here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Hi, Liz. Don Rucker?

**Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation, CEO IDEA Studio, OSU Wexner Medical Center – Ohio State University College of Medicine**

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Hi, Don. Paul Tang?

**Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation, CEO IDEA Studio, OSU Wexner Medical Center – Ohio State University College of Medicine**

Hi.

**Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation**

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Hi, Paul. Micky Tripathi? Maureen Boyle? Jennie Harvell?

**Jennie Harvell PhD – Senior Policy Analyst – Office of Disability Aging & Long-Term Care Policy**

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Hi, Jennie. Marty Rice?

**Martin Rice, MS, BSN – Deputy Director, Office of Health IT & Quality – Health Resources and Services Administration**

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

And I know there are quite a few ONC staff members on the line, so I'm going to list the ones I know about. Liz Palena-Hall.

**Elizabeth Palena-Hall, RN, MIS, MBA – Office of the National Coordinator**

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Elise Anthony. Judy Murphy?

**Judy Murphy RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator**

Here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

And Scott Purnell-Saunders.

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

Scott's on.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Is there anyone that I missed?

**Elise Anthony – Senior Policy Advisor for Meaningful Use – Office of the National Coordinator**

Michelle, I think you said Elise; I'm here as well.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Okay, thanks Elise.

**Tara McMullen. MPH, PhD – Gerontologist, Health Analyst – Centers for Medicare & Medicaid Services**

Tara McMullen from CMS is here.

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Hey, Tara. And I think that's everyone now Larry, so I'll turn it back to you.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Okay. Let's go on to review the agenda. So we've got a pretty robust slide deck, a lot to cover. We're going to be continuing our work on LTPAC EHR certification. We're going to begin with a presentation on the current Certification Program and I think this might be an opportunity for us to explore the notion of a test kit that's come up in several of our discussions already, and maybe understand how it might be like or not like what's already in the Certification Program. And then we're going to sort of dive into what we heard at the hearing and how it maps to the certification criteria. Much of the material here has been organized sort of around the existing certification criteria. And so you'll see as we go through those slides that there's been an attempt to align what was said at the hearing to those criteria and then where we might go with that as a potential for how that criteria might apply in this setting.

We have a second call on January 17 as follow up to the hearing to sort of wrap up this first pass on LTPAC. Then we'll have behavioral health hearings, meetings and they'll also be a half-day hearing, virtual hearing. And then finally a chance to review our framework and our overall recommendations in light of what we've learned, with recommendations going to the Policy Committee at their March meeting. I think that's about it for an overview of what's on deck for today and where we're going. So, why don't we dive in? Scott, do you want to take away the first piece of this?

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

Great. Thank you for the transition. Next slide, I think it just shows the list – which you just went over.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Yes, let's keep going. So, the slide after that.

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

Great. Next slide. Good morning everybody, I'm Scott Purnell-Saunders from the Office of Certification. I'll be walking through the current ONC Health IT Certification Program. I'm explaining some of the key partners and participants in the program, as well as how things are operated currently and how we can describe some of the differences between what has been indicated as a test kit for some other care settings being able to leverage a certification program or other efforts in this realm. Next slide.

This is a list of the major ONC certification program participants. ONC is at the top, obviously, with the Office of the National Coordinator for Health IT and the Office of Certification manages and operates the program as a whole. NVLAP, or the National Voluntary Laboratory Accreditation Program, administered by NIST, accredits the testing labs, so they are the governing body that certifies that the testing labs are operating in the correct fashion. The ONC-AA, which is the ONC Approved Accreditor, accredits and oversees the ONC ACBs, those are certification bodies; currently there's only one ONC-AA at this time and they happen to be ANSI or A-N-S-I.

The ATL, which is the next grouping, is the Accredited Testing Laboratory. Currently there are six testing labs, and we'll review those and list them by name towards the end of the presentation. The next grouping is the ONC-ACB, which is the certification body. And we'll go on the next slide and show how all these various organizations coordinate to develop and facilitate our testing and certification program. And finally, the developer vendor or the organizations that create and build the certified electronic health record technology, which pass through our program and are used in the public sector. Any questions here?

**Paul Egerman – Businessman/Software Entrepreneur**

This is a good – this is Paul Egerman. This is a good summary. The one thing I would just add is developer vendor, people need to keep in mind that there is open source software and so that sometimes the certification is coming from the – the process is coming from a healthcare organization as opposed to from a vendor.

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

That's correct –

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

And to Paul's comment, there also could be provider-developed software, so in those cases, the providers in some way are more or less actively involved in building the software.

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

Great. Next slide. So this diagram basically gives an overview and shows how products are tested and certified in the overall program, as we just indicated. We use the term developer vendor to really list anyone who's developed or designed a product that has been passed through our certification program, so that even includes self-certifiers as well, small businesses, large businesses, educational organizations as well.

So if we start at the very top of the chart, you'll see that ONC approved NVLAP, which is the National Voluntary Lab Accreditation Program, which we just talked about. And the ONC-AA, which happens to be ANSI right now, to operate and approve and accredit the various testing labs and certification bodies, which are indicated in the blue boxes towards the middle of the diagram. What you'll see indicated in the middle between the ATL and ACB is a firewall, I mean, it's kind of a crude drawing, but it actually is a wall and it's on fire that shows some segmentation between the testing lab and the certification body. In the temporary certification program, the ATLs and ACBs were typically one organization and were called ATCBs, of the Accredited Testing and Certification Body. In the ONC HIT Certification Program, or the permanent program, those organizations were separated to allow more flexibility in the marketplace.

So developer vendors or – and companies were able to partner with the testing lab to get their product tested and then partner with a different in order to have that product certified before being submitted to ONC for publication and inclusion in the certification program as a whole. So in some cases the ATLs and ACBs are the same organization or are managed by the same organization, but the firewall just indicates that they're not joined together in one way. You'll see at the top ONC approves the NVLAP and ANSI accreditors and authorizers and then we support the authorization of the ONC-ACB to operate the administrative portion of the program.

You'll notice at the bottom of the diagram, the developer vendor submits their product to the ATL, which is included in the first left box. Once the product successfully passes the various tests that were submitted and tested through the ATL, it's then passed back to the ACB, which is included in the second box. ACB reviews those test results and then provides certification that that product has passed all the test successfully and been approved to that. That product is then sent back to ONC for review. We have a lengthy review process for all products that are tested and certified in the program, before they're then published to the ONC-CHPL, which is indicated in the tan box on the right-hand side and the three various boxes in the corner.

So essentially, there are multiple organizations that participate in the program. It was designed this way to allow some isolation in the overall process so that we manage and maintain the program. But we're using organizations that are accredited and approved outside of the scope of what we directly manage to allow some independent opinion on how things operate as opposed to the government deciding how everything has to be directly managed and maintained. Any questions here?

**Joseph M. Heyman, MD – Whittier IPA**

Yeah, this is Joe. What's the difference between accreditation and certification and do the same people have to go – do the same vendors have to go through both processes or do some just go through one and some go through the other? Or, how does that work?

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

So the accreditation happens to the actual testing laboratories. So we, working through our accreditors, test and certify the products, so the accreditation happens with the testing labs and the certification bodies. They then do the testing and certification of the particular products that are submitted by the vendors and developers. So a self-developed product would only go through testing and certification if they're not accredited through our program that happens a level above that.

**Joseph M. Heyman, MD – Whittier IPA**

So nobody is both accredited and certified, they're either –

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

That's correct.

**Joseph M. Heyman, MD – Whittier IPA**

– certified or accredited.

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

They're certified, so products are only certified. The accreditors are the certification bodies themselves.

**Joseph M. Heyman, MD – Whittier IPA**

Oh, I see.

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

So the testing and certification happens to the products themselves. The accreditors and the testing labs are accredited and approved and the certification bodies are as well, so that happens a level above that.

**Joseph M. Heyman, MD – Whittier IPA**

So the people, who are on the left side of this screen, are they doing the certifying on the right side of the screen or I'm not understanding this.

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

Not a problem. So, the two bodies that are doing the testing and certification are indicated by the blue boxes. So the testing labs are the six that we'll go through in a second and then the certification bodies are the other, I guess four at this point, that do the certification of the products. So there's essentially you could – go ahead.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

This is Larry. I think Joe's asking for clarification about the difference between testing and certification.

**Joseph M. Heyman, MD – Whittier IPA**

No, now I understand, because –

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Ahhh.

**Joseph M. Heyman, MD – Whittier IPA**

I guess what I misunderstood was it said accreditation and then its – one side accredits and the other side certifies, but really one side is testing and the other side is certifying.

**Paul Egerman – Businessman/Software Entrepreneur**

So Joe, this is Paul. The accreditation is sort of like the Joint Commission accrediting the hospital.

**Joseph M. Heyman, MD – Whittier IPA**

Yeah, that's why I was confused –

**Paul Egerman – Businessman/Software Entrepreneur**

This hospital has good stuff and its – it's not the same as the patient getting tested, hopefully the patient only goes to an accredited hospital, one that went through that process. This is an excellent presentation Scott. The question I have, I don't know if this is the right point for the question, is, as you show this diagram where you show the separation between the testing process and the certification process. One of the issues that I had raised about the whole – the entire process that we are considering is, would there be any benefit to having a testing process only, without certification because certification carries with it some implications. And that perhaps we could have a more flexible program where we had a whole series of different things and people can simply say these are the things that I passed testing on. Do you have any observations about that kind of an approach?

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

I mean, certainly do and that's one of the reasons why I wanted to make sure that we presented this slide today. So I had some conversations about just that topic and I think that the partnership between testing and certification, it's usually important not only in what we do with Health IT certification, but certification programs in general and testing programs in general. There are a lot of ways that people can self-test and say that I have participated in this process and I can prove to you that I passed these tests and got these results. And that can work, in some instances and some cases, but the certification gives kind of everybody a level playing field and everybody a unique underst – the same understanding that, we all passed the same tests and this outside organization said so.

And sometimes that – having that extra seal of approval, as it will, or that extra support, levels the playing field a bit so that everybody knows that they're starting from the same place. Without it, you do open the gates a little bit for some misinterpretation and a lot more concerns about if people are actually doing what they say they're doing. I mean, it's not to say that there isn't some sort of gamesmanship involved in any of these programs, but the oversight that's provided by the partnership between testing and certification gives everybody a little bit better comfort with the overall program. And I think that certainly some of the proposals that I think have been discussed concerning just developing a test kit that says, we are going to test to these particular layers and levels, is a good idea. And that's certainly what we currently have in our testing certification program, which was developed through our – in a pretty mature test method which includes various test procedures, test data and test tools that are used. And I'll describe that and some differences between our 2011 program and the 2014 program as we move forward in this as well. But the certifica – go ahead.

**Paul Egerman – Businessman/Software Entrepreneur**

I'm sorry, Paul, Joe if I got you out of sequence. If you're covering this later, that's fine.

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

Yeah I mean, I can preface it here, but we'll show some of the differences and the advantages of that. But certainly it's the idea that the certification gives a certain – it's like a – I mean some people would kind of call it a Good Housekeeping Seal, but we look at it as it gives a second look, because a lot of people can test and say that we've done this. But without it, you don't really to have that separate accreditation or whatever saying that this is –

**Paul Egerman – Businessman/Software Entrepreneur**

Well, that last comment is perhaps answering my next question, is, when you pass through the part on the left and you do your testing, do you get anything like a certificate or a letter or something that says, you just passed the Federal Emissions Test for your car. In other words, do you get anything that sort of says, yes, here's a little – here's the official okie dokie?

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

Right. You do get that and that pass to the certification organization that then – or certification body, that then reviews that. So the testing lab, once they finish testing, shows – creates a very large test report that's extremely detailed, and then they submit that to the various certification body that shows that in this process, by the developer vendor and they pass that to them and say, we've – we can assert that this product has passed these tests. That certification body goes back and reviews that test report and ensures that that's right, so it gives it a second set of eyes and I think that second set provides a lot more comfort in the marketplace. Can it happen without it? I mean, certainly it can, but I think that you need that partnership to first – I mean sometimes products are tested – I mean we have this – I think at this point six test labs. Certainly we ensure that they are doing everything as best they can and are almost exactly correct and the same, but undoubtedly we have different organizations, it's not always done exactly the same way. So it's good to have a second sort of organizations that can review and say, we assert that this is happening in the right way and this is done right. But we'll go into that in a little more detail as we move forward.

**Judy Murphy RN, FACMI, FHIMSS, FAAN - Deputy National Coordinator for Programs & Policy – Office of the National Coordinator for Health Information Technology**

Hey Scott, this is Judy. If you could also talk, just real briefly, about the logo stamp of approval that the vendor is then eventually able to put on their product.

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

Thanks Judy, I will. So we've – starting with – in the Fall, 2014, the Office of Certification worked with the Office of Communications and other organizations at ONC to develop an accreditation seal. So products that are certified through our program receive what we liken to be that Good Housekeeping Seal. So developer vendors can put products – can put this seal on their products once they pass a certification program and have received that approval and they're then posted to the ONC-CHPL, so they can market that on their products on their websites and in their literature, indicating that they have passed through our certification program.

And through the last few years, our program has been – has worked very hard to attain a certain level of maturity and recognition in the marketplace so people understand that this program does mean something and it's not just something that people then pass through and it's not a rubber stamp. I mean, it's certainly extremely rigorous, and we'll go into some of those details in a second, but that seal does indicate a lot of oversight and work that has been done by the developer vendor to get that product through our testing program.

**Paul Eggerman – Businessman/Software Entrepreneur**

Yeah and – this is Paul. I appreciate those comments. I have some observations about that, what people call a Good Housekeeping Seal of approval. I don't want to hang up your presentation. I do want to make one observation though, before you go onto the next slide, which is, this testing process is entirely objective. In other words, either you pass or you fail, there's no subjectivity; this is very different than like meaningful use where you're allowed to attest to do things. There's no attestation here, this is just, and you've got to pass the test. Am I right?

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

I mean, that's correct. In some cases, we've worked to make this program more rigorous. In the 2011 edition of the program, there was some attestation available where it said, show me how you do this. We've worked to limit that so it's more – it is more rigorous because it passes individual tests, because that subjectivity, as it were, allowed a lot more nuance and inconsistency in the marketplace, from our opinion. And essentially, if you ask someone, can you do this? And they say yes, we do it this way, and then you ask someone else, can you do this? And they say yes, we do it this way but it's completely different. They may be able to operate it in that way, but that removes a lot of the standard – the consistency that you would need to see in a program. So we've tried to ensure that things are being done the right way and as close to the same way as possible. Certainly there is some flexibility, as always with anything, but we've tried to limit that as best we can to try to develop a more robust program.

**Paul Egerman – Businessman/Software Entrepreneur**

Since there's no subjectivity, there's no evaluation – this is easy or hard for a user to do or this vendor has happy customers, that's not part of the process. It's just –

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

That is –

**Paul Egerman – Businessman/Software Entrepreneur**

– I mean, in accordance to the specific requirement.

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

That's correct and that –

**Paul Egerman – Businessman/Software Entrepreneur**

(Indiscernible)

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

– that's correct and that's been developed based on our – what's been processed through our rules and regu – rule and regulatory process and that that's what we're currently attesting to. Certainly I think that including some of those other topics that you just mentioned are things that we would like to get to in the future. But we have to start with a place that's easy, and when I say easy, I mean you can show it consistently across testing results and test processes to ensure that people are doing it the right way. And certainly an evaluator can say, well we think this is easy, but you ask another evaluator is this easy and they'll say, well we think this is extremely difficult. So you need that consistency in the testing program to understand that you're speaking the same language.

**Paul Egerman – Businessman/Software Entrepreneur**

Yeah and also because this is the government and we don't want to have any concern that there's bias, that there's some reason why some vendor has a better relationship with the politician and therefore they pass the subjective test.

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

Right, and that other point is also why you see a lot of other organizations involved where the government so – we approve the National Voluntary Laboratory Accreditation Programs and we accredit or approve the accreditors as in ANSI. So those are organizations that are not – we don't manage them, they do this and bid to offer their service to us through this program. So we do not directly manage them and how they approve and accredit the various testing labs and certification bodies themselves.

**Paul Egerman – Businessman/Software Entrepreneur**

So basically this diagram is really a way to show that this entire process is totally and completely objective and it is simply based on prior approved tests.

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

Correct and also you'll see the various standards that I included on the left-hand side with the NIST 150, ISO/IEC 17025 and what not throughout, showing the standards that we've used in this program.

**Judy Murphy RN, FACMI, FHIMSS, FAAN - Deputy National Coordinator for Programs & Policy – Office of the National Coordinator for Health Information Technology**

I will say – this is Judy Murphy again, the – what we're talking about right here in terms of the objectivity and I think you all know that we had very few test tools at Stage 1 certification and we have lots of test tools at this Stage 2 or the 2014 edition. However, I will also, full disclosure; say that we've gotten a lot of criticism because of it. It has been very difficult in many cases, most cases, for the vendor community to get certified and so we definitely need to look at what's the right balance here between, and I'm not going to call it subjectivity, but I am calling it optionality. Because of the way it's designed right now, it's very constrained and so for example, with the transition of care document, we really only passed one way of doing it during certification, but out in the real world, after the product's installed, of course there are lots of different ways to execute a transition of care document transfer. And in fact, probably in many cases the individual providers are not using the one that the vendor actually got certified. And so there's been some criticism in the industry related to that, and some of you might have heard it as well. So, just thought it was helpful to say, there are some disadvantages to the way we do it as well.

**Paul Egerman – Businessman/Software Entrepreneur**

Yes some specific – good comment Judy, it's also a comment about the challenge of having what I call one size fits all.

**Judy Murphy RN, FACMI, FHIMSS, FAAN - Deputy National Coordinator for Programs & Policy – Office of the National Coordinator for Health Information Technology**

Yeah, yeah.

**Paul Egerman – Businessman/Software Entrepreneur**

When you have one testing objective process that has to work for everybody, and it works for some people in some circumstances very well, but there might be other circumstances in which it's – there are more things that are annoying than are important.

**Judy Murphy RN, FACMI, FHIMSS, FAAN - Deputy National Coordinator for Programs & Policy – Office of the National Coordinator for Health Information Technology**

Yeah.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

So, I'll comment – this is Larry. I'll comment a little bit on this as well. I've heard some comments from the industry that while the test tools have been very helpful and having a very specific, this is the bar you've got to get over, there were some initial glitches with the test tools themselves. Not to be unexpected, actually in a major testing program, but that created some delays in the startup of people being able to get through the MU2 certification testing.

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

This is Scott, I can speak to that, we've – our program has matured from even the beginning with the 2011 edition program. So, having to make updates to our testing tools and test procedures and test data is something that we work through all the time. Certainly with the startup of the 2014 edition, as Judy indicated earlier, it was a lot more difficult than folks expected it to be from the very beginning. And I mean I'll go to – I mean I have a slide in here that explains just the number of differences between the test tools and test procedures even between the 2011 and 2014. So, we do understand that with a much more challenging program there are going to come other issues that you'll see throughout this process. And certainly there were some – revisions that had to be made to the test tools, just like the vendors and developers were going through the testing program; we were building a brand new program essentially from scratch. So, a lot of the advantages we had in 2011 were replaced with more difficult challenges in 2014, so just the industry was growing, we're growing as well. So that had to happen for us to try to build this mature program.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Scott, maybe we could move on to the next slide.

**Carl Dvorak – Chief Operating Officer – Epic Systems Corporation**

I was going to ask a question, this is Carl. As many of you might remember, I was the Chair of the EHR Association for some time, so I still participate in Executive Committee calls and such. And I know that there's a fairly high level of dissatisfaction with the process around certification, and in particular, a sense that real concerns fall on deaf ears. And I wonder if maybe you could comment do you foresee a process to have more structured input from the people who actually go through these processes? I know even John Halamka sort of kind of blew a gasket on some of this stuff and I wonder if maybe we should consider some sort of formal relationship with a group like the EHR Association, which does represent, I think, the vast majority of all attestors in the country from a product perspective. I just – I guess I wanted to comment that the emotion on the other side of the fence for those people who have to go through this, and the customers that depend on them to have certified products is probably at a peak level that I've ever seen.

**Judy Murphy RN, FACMI, FHIMSS, FAAN - Deputy National Coordinator for Programs & Policy – Office of the National Coordinator for Health Information Technology**

So, I'll go ahead and comment on that. Its Judy again.

**Carl Dvorak – Chief Operating Officer – Epic Systems Corporation**

Hey, Judy.

**Judy Murphy RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator**

Yes, thank you Carl, because I feel the same way. I've heard lots from people and have had several conversations, including one with John Halamka and I think that we have to really pay attention to this issue. Now, have we decided exactly what way we're going to get input? No. Do we need to though? Yes. And as recently as yesterday, Steve Posnack and I were having this exact conversation about what are some of the ways that we can go ahead and get input related to what worked, what didn't work, looking at suggestions that folks might have in terms of how to do it differently.

We obviously have a full cadre of ways to get that kind of input, everything from a formal hearing through working group and the FACA process, right on through going directly to organizations, like the EHRA and having a conversation. And maybe we need to do a little bit of both of those kinds of things. But we, Steve and I, were talking about maybe activating a summer school, again, to really look at getting tangible ways, based on the feedback, within the guidelines that we have for the way this program actually needs to occur, okay. Based on regulation, what are our options in terms of ways of doing this differently to correct those problems that people are having with the 2014 edition certification.

So it is definitely on radar. We're committed to making a change and I mean we've been talking about creative things. And I think in the past we've talked to the EHRA about hey, how about if you guys gave us some of the testing scenarios that you currently use internally for your products, and we use that as a source of some of this, instead of coming up with it on our own. So, anything and everything is fair game in terms of suggestions at this point. But we're looking at trying to wrap something up probably this summer. So get –

**Paul Eggerman – Businessman/Software Entrepreneur**

These are good questions – Judy and Carl, as this relates to the whole certification process, because I think we're trying to focus on this sort of new concept. And it's important to keep that in mind though because it's also important, I think, to keep in mind the feedback that we got during the hearing from the vendors –

**Judy Murphy RN, FACMI, FHIMSS, FAAN – Deputy National Coordinator for Programs & Policy – Office of the National Coordinator**

Yeah.

**Paul Eggerman – Businessman/Software Entrepreneur**

– which was – ?

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

This is Stan Huff. Yeah, I really like the idea that we could create a mechanism for the people who are being certified to feedback to the process ways improve it. And in that I would just, please remember provider developers, like Intermountain and others, along with the more standard vendors that are part of that process. I think we have, as provider developers; we have some challenges that aren't the same as the challenges that might exist for the other commercial vendors.

**Judy Murphy RN, FACMI, FHIMSS, FAAN - Deputy National Coordinator for Programs & Policy – Office of the National Coordinator for Health Information Technology**

Yeah, really good point, not to forget Intermountain and Beth Israel and some of the other folks that are going on this journey on their own. And yeah, the kind of input I think we'd get from you is probably really valuable as well.

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

Great. So I thank everybody for their feedback and we'll try to continue on. Great. Next slide. So this is what I was alluding to before, showing the difference between the 2011 edition and the 2014 edition program. And as you can see, the big number at the bottom, the 2 test tools that we used in 2011 versus the 9 that were developed for 2014 is a significant difference between the two programs. Certainly we see some other differences as far as the certification criteria that had test data that was 29 in the 2014 edition versus the 14 in the 2011 edition. And the overall number of certification criteria only increased a little bit, but as you can see with the increased number of products with test data – I mean criteria with test data, excuse me, and the increased number of test tools, the 2014 program was significantly more rigorous than the 2011 program.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

So, would you comment on the criteria that don't have standards and don't have test data, these – can you give us a general sense of how those criteria get assessed?

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

In most cases they are done through some sort of attesting, so we ask, show that this works this way. So the testing lab then – the test proctor at the testing lab then asks for these various processes to be demonstrated. Those are then demonstrated and recorded and the records of that test is then saved, then reviewed and included in the test results – not test result summary, but the testing results for that particular product and then passed to the certification body, ensuring that it was done in certain way. So generally we've – to try to add in a little more transparency to that process, one thing that we worked on including with products certified to the 2014 edition, which was just launched – recently were the inclusion of the test result summaries for some of these products. We received a lot of feedback from the industry in general asking about how things were tested and how things were certified. And we were not able to provide any sort of view into that, as those test results were – are very, very large and not always the easiest things to through, because each testing lab does it a little bit differently. But we worked with other entities in ONC and the public to work through this test result summary piece to include a little more detail and view into how things were tested and certified.

**Paul Egerman – Businessman/Software Entrepreneur**

Could you give – ?

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

So, it sounds like there may be some maybe gray isn't the right adjective, but that there's – the things that have sort of a cut and dry, here's a set of test data, we expect a very specific result. To maintain problem lists, there could be many, many ways to maintain a problem list and you need to do a couple of key functions, but how you do them and how they're verified is open.

**Paul Egerman – Businessman/Software Entrepreneur**

I was wondering, is that a good example? I'd like to understand this a little bit more. Can you give us one or two examples of certification criteria that do not have testing?

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

That's certainly a good example of that. Others would be, for example, showing how data is passed through one particular process to another, so if we were to use the problem list. So once a problem list is created, it's then being able to pull that problem list back up in another portion, so not having to – so once it's been entered in one place, then showing it somewhere else. You can't necessarily just say well, yes, they passed this test, you have to actually see that list then be incorporated and included, and then that same list be used again in reference later in the process, say for medication reconciliation.

**Paul Egerman – Businessman/Software Entrepreneur**

So what does the vendor do? The vendor just demonstrates that –

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

That's correct.

**Paul Egerman – Businessman/Software Entrepreneur**

– the problem list is here and it is also here, and the testing lab says, that's good enough and checks the box?

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

That's correct. That's correct.

**Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation**

Is there a counter example of something that's very constrained that causes angst both for the developers as well as, as you pointed out, or Judy pointed out, is not actually the way people use the system? So what's the counter example to tho – in that category?

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

I'd probably say some of the testing results relating to the clinical quality measures the first time – I mean, certainly for Stage 1 or 2011 certification edition, clinical quality measures were attested to, so you just had to show that you did them in this way. We included a tool in the 2014 edition, project Cypress, which is a very rigorous testing tool, which the developer vendor can choose which measures to then test against in Cypress and they have to meet the exact qualifications that Cypress requires of the testing – excuse me, the certification criteria requires for that particular measure, in that way.

And in some cases we've heard from folks that because of the optionality allowed in providing care, Cypress and in some cases, some of the other test tools are too narrowly focused in the way that they predict an answer. So in some cases, that – the way that that specific answer is derived is required for testing, as opposed to just getting an answer. And some cases you need that sort of consistency, and that can be an advantage, but it can also be a disadvantage because people feel like, I do it this way and that's not the way that the test looks at, so why am I being forced to do it this way? I mean, we certainly heard that and understand that, but our perspective is, the test has to be administered in some way. And we have to start with one sort of method through this, but as we can develop and mature the program, that does not dissuade us from trying to allow some optionality in testing in the future, that allows a multiple pass through a process, instead of one or two single prescribed paths.

**Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation**

That's certainly an example we've heard a lot about, including over in the CQM area. Is there another exam – I'm just trying to – because that is such a well-known and really is something we have to deal with, is there another example of an objective where testing is pretty constrained?

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

Say again please, where testing is what?

**Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation**

Very constrained and it causes essentially hard-wired workflow processes, it's – I certainly understand how that's happening in CQM, trying to get another example as well.

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

I mean I wouldn't really describe it as hard-wired per se. Certainly when, like I said, with some of the test tools that were developed say for transport and others, the tools, because they are – they're pieces of software, are developed with certain prescribed methods, and they may not be the way that everybody does it. So I wouldn't say it has to be done and hard-wired and pre – because I think you're alluding to well developers and vendors are preloading for just the test and then they're doing something different after that. Is that what you're trying to allude to there?

**Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation**

No. No, that's not what I meant, it's when you follow – so one scenario is, you have test scripts and vendors have to program to that test script, that almost prescribes what the workflow has to be in order to populate the right – in the CQM example, populate data in the right fields that are being tested against. And that turns out not always, and probably not many times, to be the actual workflow that's needed by customers. So I'm trying to look for another area where the test script is so constrained that it almost forces vendors to go right against that test script when that's actually not how it's – the consideration of workflow hasn't been invoked enough. I'm just looking at another example of a constrained test script that causes vendors to program something that's not actually used in real life.

**Paul Egerman – Businessman/Software Entrepreneur**

Well, the last part – this is Paul, I think there's a lot of examples of if you look at the self-developed situations, BIDMC, Intermountain, I mean, they – the entire concept of certification is still one size fits all and so they may have to certify their system for functionality that they just never use.

**Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation**

Right.

**Paul Egerman – Businessman/Software Entrepreneur**

And they can still meet meaningful use criteria, there's a lot of optionality in meaningful use, but they have to certify things they may never use, and that includes say interfaces for example, that they just don't do. Or you could picture some organization that has to; the favorite example is the pediatric growth curves –

**Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation**

Right, right.

**Paul Egerman – Businessman/Software Entrepreneur**

– but some organizations just don't need that functionality, but they have to certify it anyway.

**Carl Dvorak – Chief Operating Officer – Epic Systems Corporation**

This is Carl. One of the odd ones that we're grappling with is there's a workflow where you want the provider to be able to edit the CCDA on the fly, and it's really kind of convoluted because you're altering another version of the source of truth. And that one, it's not exactly what you're fishing for Paul, but that's one that creates a tremendous amount of awkwardness because you're really creating two versions of records now for patients, and then how you deal with that and how you save it and how you use it in a discoverable situation in court later. All those sorts of things are really, for me a good example of somehow that must have sounded easy at a FACA committee and gotten through a certification step, but it's certainly an odd one.

**Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation**

So let's – so that's a good te – so what was the objective that motivated that response or test?

**Carl Dvorak – Chief Operating Officer – Epic Systems Corporation**

You're catching me off guard; I don't remember specifically, Paul. I'd have to go dig through some stuff.

**Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation**

Yeah, I'm trying to understand the full – it's almost these unintended consequences. I'm sure the tests were designed with good intent and then, so I'm trying to even figure out like what objective motivated that test or that requirement. And I'm then – test – go ahead.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Yeah, this is Stan Huff. I can give an insight from Intermountain about an unintended consequence basically. There was a – is a requirement that you be able to exchange immunization information with a Public Health Department, and it specifies an HL7 interface to do that. At Intermountain, we worked with the state for a long time and we actually have implemented that, the sharing of the information through a shared database. So essentially we access their application and we access their database and services rather than through an HL7 interface. And so we're meeting the requirement, but – so, we asked the certification guys, look, the intent of this is that Intermountain's immunization data is available to the state, and that you're sharing that information. And we're sharing that through services; do we have to certify an HL7 interface to do that? And they hummed and hawed a little bit and then they said yeah, you actually have to put the HL7 interface in there to meet certification.

**Carl Dvorak – Chief Operating Officer – Epic Systems Corporation**

Stan, we had a similar one to that, just let me jump in because it's almost identical, and that was for an ePrescription to count, it had to be transmitted through an NCPDP standard, and yet we had some organizations, Kaiser in particular, had an internal pharmacy operation that they interfaced with HL7. So in that situation, we now run two interfaces, one transmits it to pharmacy and NCPDP and then goes into the bit bucket and the other one also transmits it in HL7, which is the one they use, because it's got some higher end two-way things that they can do to modify prescriptions. So that was another contortion that was an issue of certification and compliance. Paul, the answer to your question, it was bundled into the provide a clinical summary to the patient at office visits on the editability of a CCDA.

**Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation**

Okay. Thank you.

**Carl Dvorak – Chief Operating Officer – Epic Systems Corporation**

Sorry Stan, I didn't mean to cut you off there, but, I just wanted to –

**Paul Egerman – Businessman/Software Entrepreneur**

This is the other Paul. I think your comment, Carl, about the medications is important, because that is something that we're going to be facing up with in this LTPAC situation, because there are some organizations that basically run their own pharmacy. And so, some of the ePrescribing requirements might not be appropriate or might not be – might have workflows that are not appropriate.

**Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation**

So let me ask a question, and Larry, tell me if this is off topic. So in the example that Carl raised, yes, Kaiser could do with an HL7 interface, but wouldn't Epic have to do an NCPDP interface anyway with some other customers? And I know that's just –

**Carl Dvorak – Chief Operating Officer – Epic Systems Corporation**

(Indiscernible) – and they exactly do that Paul, but the HL7 interface had better two-way features so that they could modify and work more collaboratively from the pharmacist back to the clinician, HL7 allowed them to do things that NCPDP couldn't. Now for external-facing stuff, they use NCPDP, so they actually do have use cases for both and they have implemented both, but the problem was, they couldn't count their internal ePrescribing as being valid unless it also used the NCPDP, even though it really had no bearing on the external world, where they already used NCPDP, if that makes sense.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

So, to try another summary of what you're saying Carl and Paul, in this case, Kaiser's docs are writing prescriptions, in order for it to count, they have to be sent using NCPDP standards, but in actuality, the operational interface for the internally filled prescriptions is HL7. So we're driving throw away work in the case of Kaiser and there's some oddness, if you will, at the tech level of why are we sending this interface that isn't going anywhere?

**Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation**

But can I –

**Paul Eggerman – Businessman/Software Entrepreneur**

And then – and also to bring back the Intermountain example of the immunizations, when you have a single site that goes through certification, these problems can be more severe. So the immunization standard makes perfect sense for an organization like say Epic to do, but Intermountain didn't need it because they had an alternate solution to that same issue that was operational. And so basically they had to create – to get certified, they had to create some software to pass some testing that they would never use.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Yeah.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Right.

**Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation**

So let me ask something from a different perspective, and this really is giving credence to Judy's and Steve's though about having a separate hearing or process to drill down on this. But in both of these cases, whether it's Intermountain or Ep – Kaiser, couldn't it be thought of as, well you need an NCPDP interface to deal with the outside world period. In addition, it's okay that Kaiser used HL7 for its internal interface. Same thing for Intermountain, well, if they want to talk to public health, other than Utah, they may need an HL7 interface, but in addition, it's okay that they use their web services to the database. I mean, is that one way to look at it? And then the fix really is, well we want to make sure everybody can talk to everybody else or like most people, but, it's okay not to ding them for having done something for an internal case. Is that an approach?

**Carl Dvorak – Chief Operating Officer – Epic Systems Corporation**

Yeah, you would think so.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

It's an approach, but I mean, I mean it's actually not accurate in the sense that we don't need – I mean, we have all kinds of other HL7 interfaces to the state, so it's not like – we're passing them death certificate information, we're passing other things and we don't have to talk to other states, as a matter of fact. So, requiring us to have an immunization interface that talks to a state public health organization is work that we should never have to do, it's just work we should never have to do. I mean, in the cases that you say, if there really was a need, that we needed to talk to another state, hey, we're fine, okay? But there are two situations where you're absolutely just making us make software that has no use and in fact, you could argue was architecturally less useful than what we already have in place. And that's the waste that just drives me crazy.

**Carl Dvorak – Chief Operating Officer – Epic Systems Corporation**

And it – as well Stan, the solution here is, because we don't want to burn computer time and space and storage and people time doing two interfaces, we are now doing a custom extension to NCPDP to allow Kaiser to do the over and above two-way work that it used to do with the HL7 interface. Because they're – when the certifiers and the audit people say you must, the compliance lawyers say, oh my God, we're at huge risk if we don't. Even if it takes 300 hours, 200 hours, 100 hours, do it because we don't want to be at risk from a compliance perspective sometime later down the road if someone comes in and declares us having been out of compliance.

**Paul Egerman – Businessman/Software Entrepreneur**

Yeah, I mean to me the fundamental source of the chal – of this whole thing is, has two parts. One is, you have a process that is necessary to the objectives, so there's like no exceptions, everybody goes through the same process and coupled with that you have a concept of one size fits all, everybody's got to do this the same objective process and the one size fits all doesn't always work. So you've got the Kaiser and Intermountain examples where there was waste and there's no way to get an exception for them, because that would violate our objective concepts. So that's –

**Elizabeth Palena-Hall, RN, MIS, MBA – Office of the National Coordinator**

This is –

**Paul Egerman – Businessman/Software Entrepreneur**

– that's the basic challenge here, in terms of how you do things, and although I'm not sure that we can necessarily solve that right now. Because I think a goal here is just to get through this presentation and understand – it's a valuable discussion, our goal should be to understand how the certification process works and then to help use that knowledge to form a good recommendation as it relates to behavioral health and LTPAC.

**Elizabeth Palena-Hall, RN, MIS, MBA – Office of the National Coordinator**

So this is Liz from ONC. I'm just doing a time check here because we're about 5 minutes before 12 and so I was wondering if –

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Thank you, I'm jumping in there.

**Elizabeth Palena-Hall, RN, MIS, MBA – Office of the National Coordinator for Health Information Technology**

Okay, great.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

So, this is Larry. My suggestion would be that we see if we can wrap up the presentation on certification and then rather than trying to cram the whole rest of this into the remaining 25 minutes, that we look at starting down the road and then we'll finish it on our next call on the 17<sup>th</sup>. So let's – Scott, you've got the floor, and to Judy and some of your earlier comments about need for more input, I think you've seen demonstration of that.

**Judy Murphy RN, FACMI, FHIMSS, FAAN - Deputy National Coordinator for Programs & Policy – Office of the National Coordinator for Health Information Technology**

Got it, thank you.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Okay, thank you.

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

Great. Next slide. So this slide lists the six testing laboratories and four certification bodies. So as you can see, there are four test labs, which are also certification bodies. Those are CCHIT, Drummond Group, ICSA Laboratories and then InfoGard. Two other organizations that are just test labs, which are SLI Global and Wyle Laboratories. Wyle was just added to the testing program a few months ago. These organizations, like I said, provide the testing and certification oversight to the program that we directly detailed in the program overview earlier. And just wanted to kind of indicate who they were – who they were currently in the program as it sits now. Next slide.

So just wanted to show how the certification bodies receive their marching orders, as it were, and approval. So this basically explains that prior to being authorized by ONC, the certification bodies must be accredited by ANSI, which is the ONC Approved Accreditor. Accreditation is granted to a certification body based on the assessment of the body's competence in accordance with ONC and ANSI requirements, including the various standards that are listed below. So the ANSI provides that – provided oversight to the certification bodies in a number of ways. Certainly we have – so we operated through one last fall and are having another one this spring where the testing labs and certification bodies come to ONC for workshops to ensure that they are doing everything in the correct way, in the way that we've designed the program. And as we add additional pieces to the certification program as a whole, so for example, with the 2014 edition we did that review last fall, for some upcoming changes to the program, which include some inclusion of testing scenarios or linked unit tests that we're designing. The testing labs and certification bodies will come to ONC for another series of workshops where ANSI and NVLAP will work through expanding their scope of approval and accreditation as well. Next slide.

This just continues and explains why we've opted to authorize through a third-party organization to support the conformance of our federally tested and approved certification criteria. Certainly other options are improving the test results that come through the testing labs, rendering decisions on certifications and providing that input to us for review. Keeping a directory of certified products so the certification bodies also have their own internal lists of the products that are submitted to us for review and publishing and then providing the official certificate of certification mark, which we talked about earlier.

That HIT certification piece that's provided to the testing – provided to the developers and vendors once they've passed through certification. And then working through post-market surveillance of certified products. The surveillance piece is actually one that is pretty significant in the program as we work through expanding the safety and surveillance part of our operations. Certainly it is not just our goal to ensure a product is meeting testing and certification from the very beginning, but that the product continues to meet those requirements as it moves forward. It's not just kind of getting through the door, but it's also operating in the right way once it's been installed and in operation and in use in the environment that we – in the public and in the best way it can be. So, safety and surveillance are huge parts of this program that the certification bodies provide support with us in operating the program as a whole. Next slide.

This is just a summary of what we've kind of talked about today and gives us some highlights on where things are. Again, the certification program officially launched on October 4, 2012, that was the change from the temporary certification program to the permanent certification program as we currently sit. The CHPL 3.0, which is currently in use, launched January, 2013 and includes three unique doors which folks are very familiar with, a 2011 door, the 2014 door, which is only – only contains products certified to the 2014 edition certification criteria and then a combination door that supports both during the calendar year 2013. The test method updates, which we talked about, between 2011 and 2014, those were approved and posted on December 12, excuse me, December 14, 2012 and the new certification program as it currently sits, began on January 2, 2013.

The last bullet is what we just talked about, including the scenario-based testing. The current developed testing scenarios are currently in draft review, so it's not just the first scenario, it should be the first group of scenarios to be included in the program during the Spring of 2014. So that ends my portion of the presentation. I know we want to kind of talk about some next steps, so I'll pause here for any questions or comments.

**Paul Egerman – Businessman/Software Entrepreneur**

This is Paul Egerman. This is a great presentation, thank you. It was very helpful.

**Scott Purnell-Saunders – Program Analyst – Office of the National Coordinator**

Thank you guys for allowing me to do it.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

So if there are no other questions at this time, maybe we'll move on to the next round of our work. Okay, so, take a breath, we're switching gears here from the structure of certification to what we heard at the hearings. So, let's continue on, next slide. So we had six panels, I won't go through all of them right now. Next slide. So, summary. I think interoperability came through as by and – across the board, this is where everybody felt the primary focus ought to be and that this doesn't need to be tied to meaningful use, but that the standards that are in place in meaningful use really need to be built on. And that there was also some work underway to address standards and information content that's specifically targeted to the LTPAC settings.

A bunch of concerns were raised as well about where we are today, and so it was clear from some of the comments we got on information exchange that many of the providers have implemented some kind of connectivity that predates the current standards. And so we were hearing a lot about yes, there's direct out there, but we're not using Direct, we have an existing HL7 feed that does this function, things like that. And that a lot of the transport today is still point-to-point and that Direct actually continues that as a point-to-point piece.

I think some other highlights about technology pipeline, maybe we need to tighten up what we're hearing about correct use of technology pipeline, but a sense that we shouldn't get ahead of where things are in the pipeline. But also to recognize that sometimes we need to get things into the pipeline if we want to have something useful out the tail end. And I think the S&I Framework activities around continuity of care that's involved a lot of the LTPAC providers and vendors and has resulted in some HL7 balloting, is a really good example of where industries come together to look to address specific needs. And that that pipeline in fact is on the verge of producing some HL7 balloted standards for additional CDA documents.

We did hear a mix of differences between vendors and providers about cautioning restraint in terms of what's actually doable, especially given budgetary constraints and providers expressing the need for robust systems. And that clearly is a longstanding push-pull between vendors and providers, I want really robust functionality, but it has to be easy for me to implement and it has to be inexpensive for me to purchase versus the reality of what it takes to build some of these things. And finally there was a broad concern about – on mandates. I don't know if this was specifically just about interoperability, but I wanted to make sure that it came forward in our discussion because there isn't a HITECH Program that's paying for this, this is coming out of ordinary payment cash flow and capital needs of the organizations. And I think a pretty consistent emphasis on the importance of this being voluntary and that there was value in having certification as a roadmap, because it clarifies a lot of questions, particularly around standards, and gets people clarity about what the target is.

So, any other high level – any high level thoughts from folks about interoperability and some of the concerns before we move on to some of the beha – some of the setting-specific issues and then the particulars of the different criteria.

**Paul Egerman – Businessman/Software Entrepreneur**

This is Paul, I have a couple of comments. One is, maybe just a minor comment, the word interoperability means different things to different people. In earlier times of the Policy Committee, we were careful to talk about information exchange and to be clear that information exchange involved transmitting or exchanging information between healthcare entities as opposed to getting systems to work well internally, it was really from one entity to another. And I don't know what is meant by the word interoperable in this context. I suspect they mean the same thing as information exchange.

The other comment I have is was that there was, during the hearing, an interesting discussion about the relative value of ePrescribing in an LTPAC environment where it was said that medications monitoring is more important from a patient safety standpoint than the actual prescribing. That was different from an ambulatory standpoint in that manner, although there were some people who felt that ePrescribing still had value. And I do think the bullets on this slide, the last two are particularly good, where you talked about the dichotomy between the vendor and provider comments. I mean the vendors were definitely cautioning restraint. If I remember correctly, there was one vendor who was basically saying no, so that was – there was resistance there. And the providers, it's interesting the way you wrote this, providers noted need for more robust systems, but the question in my mind is, well is certification going to create more robust systems? Or is this just going to help the systems try to talk to each other? And so this is – there's – I think there's an interesting issue there.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

So I guess I'm hearing a couple of things that we should probably clean up our language here. I think, to your point about interoperable and the ability of systems to do something with the information gets picked up and sort of the concerns about message content and coding, message standards and codes and things like that. Whereas I agree with you, the primary emphasis, I think, is really on information exchange and that would be good to clean that up in here. And probably we should go back to the specific comments about information exchange for that next to last bullet on dichotomy or maybe to actually think about those – the last two bullets really are broader than just information exchange, I think they are.

**Paul Egerman – Businessman/Software Entrepreneur**

Yeah, I think you're right.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Okay. Useful feedback, thanks. Any oth –

**Jennie Harvell PhD – Senior Policy Analyst – Office of Disability Aging & Long-Term Care Policy**

Larry, this is Jennie Harvell. I just wanted to follow up on, I think it was on Paul's comment about what was heard during the hearing regarding the relative value of ePrescribing and there was an extensive discussion about that. And in the materials, some of the materials that were sent for today's meeting, there was a spreadsheet that's called the LTPAC Cert/CA Workgroup Summary and Detailed Slides. And if you look – I think it's starting on slide 55 through 59, you'll see some quotes, pretty solid reflection of the testimony that was heard during the last meeting on ePrescribing and medication monitoring in long-term post-acute care.

And I think Steve Handler's testimony on this point, there was one bullet that's pulled out in those slides, and he said, I don't want to dissuade or discourage the use or development of prescribing decision support, but in the nursing home it's important to remember to focus on monitoring as well. So I think there was pretty much a pretty robust and balanced description about the importance of prescribing and monitoring in long-term post-acute care.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

And – this is Larry, so Jennie, you're also pointing out that the discussion wasn't about the relative merits of ePrescribing, but the use of decision support as part of ePrescribing.

**Jennie Harvell PhD – Senior Policy Analyst – Department of Health & Human Services/ Office of Disability Aging & Long-Term Care Policy**

That's correct.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

In addition to pointing out that you need to get the prescription right, but that there also seem to be problems in monitoring use of meds and picking up problems early.

**Jennie Harvell PhD – Senior Policy Analyst – Department of Health & Human Services/ Office of Disability Aging & Long-Term Care Policy**

Right.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Okay. Thank you. Any other comments before we move on to some LTPAC-specific issues? Let's go on to the next slide. So we heard about some setting-specific issues, about really focusing on what the regulatory minimum is, as we look at the setting-specific requirements, and also pointing out that there are – each setting comes with its own set of requirements, and that might be further reason to try to limit how we address differences among the care settings. As well as that there are differences in the workflow distinct from EPs and EHs and its interesting that meds seems to be the hot topic for today about variations on getting prescriptions. So hospitals often tend to have captive pharmacies where HL7 has been the traditional messaging standard and ambulatory docs typically don't have an on-site pharmacy and they're using retail pharmacies and they're using NCPDP Script as their communication technology.

And typically the nursing centers have a dedicated relationship with a specific pharmacy that they've created various electronic and manual processes to manage the flow of information. The physicians tend to be off-site, although less so these days, in terms of writing prescriptions. So the whole workflow is very different, including that there's a requirement for clinical pharmacists to review meds of long-stay patients, to make sure that their med regimen is reasonable. So, there are lots of workflow issues as we dive into the specifics of these settings in a detailed to the earlier discussions about certification driving workflow, to be very sensitive to that as we look at the specifics.

And finally, increased clarity and consistency regarding standards. There was sort of a joke in the early days of Policy Committee about there are so many standards you can pick and choose whichever ones you want, but unless we narrow that list, it's not very helpful for exchanging information and actually heading towards interoperability. And I think that we have some examples in this space as well of where there are a variety of standards in play and actually harmonizing those standards would be a really good thing going forward. Any other comments about the setting-specific criteria in general, before we go on to details?

**Donald W. Rucker, MD, MS, MBA – Associate Dean for Innovation, CEO IDEA Studio, OSU Wexner Medical Center – Ohio State University College of Medicine**

Comment by Don Rucker. I think I'm also curious, and I don't know if this came out in the testimony on the variability of IT resources in these settings, to implement the systems. Because I'm like you and I think sort of hospitals that have sort of a maybe somewhat standard IT operation, I think a lot of these folks have very, very thin resources in terms of just configuring whatever is being asked of them. So I think the varying IT resources should be incorporated as well.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

I think that's a really good point. There was some discussion about the larger organizations having some depth of resources, but that there are many, many small providers in this space that don't have a lot of resources. I guess in some ways it's analogous to the physician world, there are some large groups that have large resources and there are groups that are affiliated with hospitals that have access to large resource pools. But the free-standing physician groups generally are pretty limited in the resources they have, and that would certainly apply to many of the providers in this setting.

**Paul Egerman – Businessman/Software Entrepreneur**

I mean, there's also hospitals that are small –

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Small hospitals –

**Paul Egerman – Businessman/Software Entrepreneur**

(Indiscernible) – some small community hospitals are like that, too.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

So that is a real point Don, and we've seen, I think, in some of the recent presentations to the Policy Committee about the continuing struggles to get the very small providers onboard. Good point as we look at things in this setting. So what I'm thinking, given that we've only got a few minutes left is, we'll continue through these overview slides and next time we'll pick up the details. So let's go on to the next slide.

Okay, continue. Next slide please. So we have some general principles here about looking at transitions of care as a high value area, looking at privacy and security as a fundamental requirement and I need to think through – we should look at whether interoperability is appropriate here or if it's really information exchange, and we started using shorthand. Leveraging existing capabilities of the systems and of the certification process and LTPAC-specific efforts, and you'll see the subsequent slides try to address these. Let's go on.

**Joseph M. Heyman, MD – Whittier IPA**

Can I just ask what you mean by that very last bullet?

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Sure, let's back up to the slide.

**Joseph M. Heyman, MD – Whittier IPA**

This is Joe.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

So, there are setting-specific maybe requirements is better than efforts. So, there are mandated patient assessments –

**Joseph M. Heyman, MD – Whittier IPA**

I see.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

– in several of the care settings. There's a very detailed survey process in the care settings and there's facility certification, not IT certification.

**Joseph M. Heyman, MD – Whittier IPA**

I see, okay. I guess my concern here would just be that we not ruin the workflow by making requirements for the way those things have to be accomplished.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Good point. We'd gotten a dose of that earlier today, but I think we should remember that as we go forward. So, next slide. This is a recap of what we've done or what ONC has done. So there was Information Exchange RFI. We had the hearing and there were submitted letters. There was some work that ASPEs done that was presented early December, late November, to us. And there's some ongoing work that's happening with HL7. Okay, next slide.

So broadly, the subsequent slides are broken out to have a slide or a set of slides for each of these bullet points. So there is discussion about privacy and security, about various aspects of, I think we'll switch our language to information exchange. There's some input on advanced care planning, patient demographics, clinical health information which is used as a broad bucket for the general communication of patient status, patient condition, some med things. Public health reporting, specifically looking at immunizations as opposed to some other functions that probably don't apply in this space. The federally required patient assessments for each of the care settings and survey and certification requirements; so the last two are addressing setting-specific requirements and the ones above are really building on the existing criteria.

**Joseph M. Heyman, MD – Whittier IPA**

This is Joe again.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Um hmm.

**Joseph M. Heyman, MD – Whittier IPA**

I sent in a written comment, but it – this is another opportunity to make it, so I'll just say it. Where you've got clinical decision support, I think there are some important areas in which EMRs can help with clinical decision support. As far as clinical quality measures are concerned, I'm concerned about how this all stifles innovation. For example, they'll be many robust HIEs in the very near future where it's possible for third parties to develop applications that can take the data in these HIEs and develop more efficient ways to achieve quality and efficiency measurement. And also better reporting mechanisms. Why bother with such innovation when there's a certification program requiring everything to be done with a particular process, rather than looking for a particular outcome? My personal belief has always been that EMRs should function predominantly as physicians and other clinicians need for record-keeping in their workflows, and there should be a third-party software or application that does the measuring required by so many different programs. And that way the clinicians would pay for what they need and the measurers could pay for the applications that are accomplishing the measurement. Instead we put the entire burden on the clinicians, or in this case, we'll be putting it on the long-term care people or the behavioral health people. And I really think it's a mistake to require the measurement part to be included in the EMR. I'm just putting that on the table.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Okay. So thank you for bringing that up as part of this overview piece. I think – so, I'm hearing your concern is much broader than just LTPAC and behavioral health –

**Joseph M. Heyman, MD – Whittier IPA**

That's true, but I'm thinking we can learn from some of the problems we've had with our own, so as not to put this burden on them as well.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Exactly. Good to learn from that. And also I think that there's an opportunity to maybe tease apart the two sides of – so the quality measure piece, which is your comments of, use the EHR to provide the care and presumably we're collecting the patient-specific information as part of that, and then having a good way to feed that information to supply the quality measures.

**Joseph M. Heyman, MD – Whittier IPA**

Right, that doesn't interfere with the workflow, which is what happens now. Right now, in order to do the measurement, all of our workflows have to change, and it makes it much less efficient, and we end up paying for the burden.

**Paul Egerman – Businessman/Software Entrepreneur**

Is this though –

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

So – go ahead Paul.

**Paul Egerman – Businessman/Software Entrepreneur**

This is Paul. I'm looking at this slide and up until now it seems like most of what we've been talking about has been like background and summary of the hearing, but now I look at this slide and it says recommendations, says ONC should consider the following. This seems like we're pivoting and saying something very important on this slide, this is a fairly specific and broad recommendation. And I would just have to say, if that's the case, I would be opposed to what's on this slide with the reason saying it's too much stuff – doesn't mean that sound really particularly clear. But for a program that is supposed to be where there's no financial incentive, where there's a huge amount of vendor resistance, I think we could do much better if we focused on a few particular areas, like transitions of care as opposed to trying to do so much stuff with – all at one time.

**Elise Anthony – Senior Policy Advisor for Meaningful Use – Office of the National Coordinator**

Hi, this is Elise here from ONC, I'm sorry, I just wanted to provide, I thought, just a little bit of background that I think might be helpful in terms of the thought of how to walk through this in terms of when we were developing this with Larry. This slide provides a capture, this is a list of all that's to be discussed and the goal would be to walk through each of these categories and to receive the feedback from the workgroup on what the proposed recommendation would be. And then that would lead to a final list, so this is just kind of a catch-all slide. And I definitely agree with your point that just kind of smacking this in here as a recommendation wouldn't be the right approach, but it provides more of a list to guide the conversation as you go through the subsequent slides where you'll see one issue discussed per slide. Sorry Larry, if that was what you were going to say.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

And I was –

**Paul Egerman – Businessman/Software Entrepreneur**

So I was just confused by the title where it said recommendation. It really should say like possible recommendations or something like that.

**Joseph M. Heyman, MD – Whittier IPA**

Considerations.

**Paul Egerman – Businessman/Software Entrepreneur**

An inventory of possible recommendations.

**Elise Anthony – Senior Policy Advisor for Meaningful Use – Office of the National Coordinator for Health Information Technology**

We can make that change.

**Joseph M. Heyman, MD – Whittier IPA**

I think it would be better if it just said considerations –

**Stella Mandl, RN (Stace) – Technical Advisor/Nurse – Centers for Medicare & Medicaid Services**

This is Stace from CMS, I agree.

**Joseph M. Heyman, MD – Whittier IPA**

– because some of these are not going to be recommendations.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Okay, let's do it, just considerations. I agree, that's really where we are and that's what this should say. So let's get through the next couple of slides as context and then when we're on on the 17<sup>th</sup>, we'll pick up the details. So, next slide. So this is a grid that takes that list and lays it against where the MU Program is with respect to each of those and whether it's in the base – MU2 base criteria, or if it's specifically in the interoperability and we should check our words, whether it actually should be information exchange criteria. So, this is meant to be a framework, we're not going to go through it today, but I offer this as a baseline reference. And the next slide continues that for the rest of the specific bullet items, including the last two that are blank because they're not in MU because they're part of the additional stuff we're doing for LTPAC.

So let's go one more slide, I think, okay. So this is not for discussion, this is just to indicate format. So the rest of the deck is organized in these three columns. So it talks about prior work that's been done, what happened at the hearing, so a bunch of quotes from the hearing and then where this aligns to certification. So the column that says recommended areas for certification is sort of looking at the broad heading of privacy and security, and these would be the specific bullets that would then be addressed. So this is the format of the rest of the slides. Okay, so all that clear as a format and as a set of things for us to consider when we pick this up again –

**Joseph M. Heyman, MD – Whittier IPA**

So this is sort of a breakdown of the previous slide that was for consideration –

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Yes, yes.

**Joseph M. Heyman, MD – Whittier IPA**

– because this one also says recommendation on it.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

We will flip them all to consideration for next time.

**Joseph M. Heyman, MD – Whittier IPA**

Okay.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Okay, so I'm going to jump – there is a slide towards the end that talks about next steps, but we don't need to go there, I'll just mention. So we have an upcoming call on January 17 and we will pick up here and make our way through these specifics and then, if I remember the schedule right, we switch to behavioral health. And we have a similar process for behavioral health and then we have a final couple of sessions to regroup, having taken a deep dive on what we actually want to bring forward. So is that all pretty clear and understood by folks? Any other questions about what we're doing? Great, first time this group's been silent. So let's go on. Let's open up for public comment.

**Public Comment**

**Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**

Operator, can you please open the line?

**Rebecca Armendariz – 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 do have a comment from Matt Reid.

**Matt Reid, MSMI – Senior Health Care IT Consultant - American Medical Association**

Yes, this is Matt Reid with the American Medical Association. I would like to make two quick points. One, regarding the certification process, the AMA is concerned with the lack of accepted paneling testing in the current certification process. We believe that it is the lack of this critical component that is partly to blame for certified EHRs not performing as expected in the real world environment. The second point I would like to make is that the AMA is interested in working with the ONC, the EHRA and other stakeholders to provide input in the EHR certification process. In a recent report from a RAND study regarding physician satisfaction in their medical practice, two significant contributors to physician dissatisfaction bubbled to the top. One of those was EHR usability. We believe that it the current EHR process and its requirements do little to address usability and from what we've heard here today on the call, can negatively affect usability and EHR performance in the field. Thank you.

**Rebecca Armendariz – Altarum Institute**

We have no further comment at this time.

**Larry Wolf – Health IT Strategist – Kindred Healthcare**

Well, I'd like to thank the workgroup for all of the discussion today, pretty broad ranging and it's good to get our context straight before we dive in to considering what we heard at the hearing in specific. So that will keep us busy on the 17<sup>th</sup>. And thanks again to ONC and all the support folks who did all the work to put this very rich slide deck together. We'll continue our conversation in a few days. I think that wraps up.

**Public Comment Received During the Meeting**

1. The problem list has both standards (SNOMED-CT) and defined test data, i.e. problems to enter, edit and review.

2. Vendor supplied data is used for Advance Directives and Image Results, both of which do not have standards specified.
3. All vendor systems must certify processes that customers do not want or use. this is the requirement to be a Complete EHR which is desirable to be competitive in the marketplace.
4. There is waste of programming at every vendor, not just the self-developed software like Intermountain or Beth Israel!
5. So as not to interrupt, I am concerned about how all of this stifles innovation. Soon there will be many robust HIEs. It will be possible for third parties to develop applications that can take the data in these HIEs and develop more efficient ways to achieve quality and efficiency measurement, reporting mechanisms and other things that now are required for certification. Why bother with such innovation when there is a certification program requiring everything to be done with a particular process rather than looking for a particular outcome? I have long believed that EMRs should function predominantly as physicians and other clinicians need for record keeping in their workflows. There should be a third party software or application that does the measuring required by so many programs. The clinicians should pay for the EMRs, and the measurers should pay for the applications accomplishing the measurement.