



**HIT Standards Committee  
Implementation, Certification and Testing Workgroup  
Final Transcript  
March 23, 2015**

**Presentation**

**Operator**

Thank you. All lines are now bridged.

**Michelle Consolazio, MPA – FACA Lead/Policy Analyst – 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, Certification and Testing 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. Cris Ross?

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

I'm here.

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

Hi, Cris. Liz Johnson? Andrey Ostrovsky? Danny Rosenthal?

**Danny Rosenthal, MD, MSc, MPH – Director of Healthcare Intelligence – INOVA Health System**

Here.

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

Hi, Danny. David Kates?

**David Kates – Director of Interoperability – The Advisory Board Company**

Here.

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

Hi, David. John Travis? Kevin Brady? Kyle Meadors?

**Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.**

Here.

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

Rick Moore? Hi, Kyle. Rick Moore?

**Rick Moore, MS, PhD, FACHE, FHIMSS, CPHIMS, PMP, CISM – Chief Information Officer – National Committee for Quality Assurance**

Rick Moore here. Here.

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

Hi, Rick. Sarah Corley?

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

Here.

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

Hi, Sarah. Steve Waldren?

**Steven E. Waldren, MD, MS – Healthcare IT Strategist & Physician Informaticist – American Academy of Family Physicians**

Here.

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

Hi, Steve. Udayan Mandavia?

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

Here.

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

Hello. And Zabrina Gonzaga? And from ONC, do we have Brett Andriesen?

**Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology**

This is Brett.

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

Hi, Brett. Scott Purnell-Saunders?

**Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services**

This is Scott.

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

Hi, Scott. Is anyone else from ONC on the line? Okay, with that I'll turn it over to you, Cris.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Thanks very much. As some of you may have heard just a minute ago, Liz Johnson's not able to make the call here today, so I'll be leading us through this. Just as opening remarks I would offer only two; one was we had a nice report out to the Health IT Standards Committee last Wednesday, based on your good strong work and if you...I'm sure you saw the materials that encapsulated our comments on I1 around...mainly around testing improvement and then also included the attachment around C-CDA consolidation.

The work that was done on C-CDA consolidation was really first rate. We got a couple of good comments from committee members of the Standards Committee as a whole who wanted to weigh in on some other notions related to C-CDA, and we'll receive those and pass them along to this workgroup for our consideration as well, because they were well-informed opinions. And I'm sure we'll be glad to take a look at what people had to add.

So the main comment is, it was a little bit of rapid fire updates from workgroups at the Standards Committee, for those of you who follow such things, and they went really well. A couple of the presentations from some other workgroups were very helpful and very substantive and I think we're moving forward. So that's just sort of comment one. And let's look forward to doing our comments on I2.

The second comment, I guess speaks for itself, the MU3 rules are out for all of our consideration. And I imagine it might be a little...even a little bit difficult to talk about interoperability roadmap recommendations at this point without thinking at least somewhat around the NPRM for both CMS and ONC; just to simply acknowledge the fact that there's a gorilla or a polar bear or some other kind of thing in the room here with us as we're talking about interoperability roadmap.

I don't have anything else to add, in terms of opening remarks except to say that I'm hoping that in our time today, and we've got a good hour, we can plow our way through I2. Our work on I1 took a while; if you look ahead, I guess I2 looks like it's a similar amount of work, so I'm hoping that we can plow our way through it. So, Michelle, unless I've left something out that you think I ought to mention, I think we want to turn things over to Brett to walk us through section I2. Michelle, is there anything you want to add?

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

I just want to add, as you mentioned, the certification rule; so, I just wanted to give everyone a heads up and say a thank you for all the hard work. We know that it's been a lot and unfortunately it will continue until you all present your recommendations on the cert rule through May. And what we will be doing offline is we've assigned, just like we did for the roadmap, we've assigned different sections to each workgroup.

And so we're going to work with the Chairs first to kind of walk through with them what we think will be appropriate with the meetings we have on the calendar. And then during our next meeting, hopefully talk about process and how we divide and conquer the work. So, it's coming, so if there's anything we

can share prior to the next meeting, so you know where to focus your reading, we will certainly do that as well. So, stay tuned.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Well Michelle, in that category that's a little bit like meetings will continue until morale improves. Can we go to the next slide in the presentation here like we'll say that gives the deadlines? Thank you. So just for everyone's reference, this is the schedule for the work ahead of us through Q2 and into part of Q3. And I think this aligns against Michelle's comments, so, we'll be charged with responding to NPRM soon. We're going to want to be able to provi...finish our feedback on interoperability roadmap comments, as you can see the second line from the bottom in the April meeting of the Standards Committee. So we've got some time to work forward ahead on that, but as Michelle notes, there's other work ahead of us.

So with that in mind, I think we want to turn it over to Brett to lead us through comments on Stage...I'm sorry, on I2. Brett do you want to...

**Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology**

Yeah, sure, happy to. If we can advance the slides down to exactly that slide right there, just a quick overview for folks on I2 here, mainly about certification programs and here kind of is a summary of the components that we were charged with commenting on. And if we move on to the next slide, we will jump right into the first portion here.

There's this slide as well as one further here, and I think just in the interest of time and because we're looking to try to get through as much of I2 as we can in our meeting today, I will forgo kind of recapping what's on the slide; I know that you all have had a chance to look through the roadmap in detail and we shortened a little bit the comments that you had made and tried to summarize them as best as possible. But I think if we jump right into the workgroup discussion that might be a better use of time than reading those summaries.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

So Brett, you were looking to try and absorb 1 here?

**Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology**

Yeah, I think is we spend maybe the next 20 minutes or so is what I had allocated for this slide and the next slide, which is the 2015-2017 short term goals, number 1 here that we see on the screen; I think that will keep us on track.

**David Kates – Director of Interoperability – The Advisory Board Company**

Okay, so this is Dave Kates, just a brief comment. I mean, I think the comments here might also reference the C-CDA constraint stuff, because I think that also provides some additional recommendations around some of the bullet points listed here as comments, profiles and the like. So largely agree with the discussion that's referenced here stands on its own, but that might be an additional cross-reference to tie it together with other material we've presented.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Dave, that's...this is Cris, that's a good comment. The other dimension of this is in the extension of scope, right, to long-term and post-acute care, home and community based services in non-institutional settings and in behavioral health settings. So, I think we want to make sure we're looking at that as well when we're looking at this particular section.

**David Kates – Director of Interoperability – The Advisory Board Company**

Than...good point. Yeah.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

I note that just because I think our workgroup didn't comment on that directly, and that's something that I wanted to raise. So David, we should focus on what you said, but I also want to make sure we address the scope issues.

**David Kates – Director of Interoperability – The Advisory Board Company**

Yeah. So, brief comment. We should just look at the comments and maybe Brett or somebody can highlight whether we did touch...address that specifically. I know on the C-CDA constraint side, there was broad allusion to use cases including some of these things that had not been originally part of the scope, but making sure that profiles or whatever are...and again, I'm just talking about interoperability and care coordination aspects of it. There are probably other dimensions of certification related to those settings that similarly need to be addressed, which I am not commenting on, so I'll leave that to others.

**Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology**

Yeah, I think if we move on to the next slide here, and not to say we won't jump back and forth between these two, but some comments about scope were listed here on...thank you for advancing that. There was a comment recommending some caution in adding additional certification requirements for other healthcare sectors, but another one, or another few that really liked that idea.

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

Well, I think there are a couple of things; one, what...this is Sarah Corley; what got mentioned in the question was long-term care, those types of settings where I for one, recommended caution because you want to make sure that there is a business need for certification to drive adoption. We know that adoption was increased because of the Meaningful Use Program, right now long-term care facilities, behavioral health settings are not, for the most part, eligible for Meaningful Use dollars; therefore they don't have a financial incentive to adopt electronic health records unless it meets their business need.

And then you would say, does...do the requirements of the certified electronic health record meet the business needs of these care settings and I would propose that they do not. We actually in the past there was certification for long-term care under CCHIT that was developed specifically to meet the needs of long-term care facilities and I don't know that even that more specific and developed by people in that sector certification process increased adoption. So, I would not like to see a lot of effort and money put into developing certification requirements for sectors where we aren't sure that the business drivers are in place currently to leverage the time that is spent.

Now in some...in the comments by some of the workgroup members where you see expanding it to entities such as labs, immunization registries and HIEs, there there certainly is a need that would reduce

the cost and barriers to interoperability that we're currently seeing because of the variability in adherence to the same standards that EHR vendors are certified to.

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

This is John. I joined a little bit late. If you can go back to the previous slide real quick, I want to kind of tie what Sarah said to the first bullet there and both offer a support for that idea, but also a caution about what kind of policy levers might drive that very first bullet here. I absolutely agree on there needs to be a clear business requirement. I do want to kind of offer perspective on the levers that have been there.

So there's no Meaningful Use, per se...there is no Meaningful Use equivalent that exists in say long-term care or home health, behavioral health so the policy levers that they do have, at least at present, are pretty much either payment policy, so kind of the stuff we're seeing from PAMA around diagnostic imaging or with chronic care management for physician fee schedule. Or conditions of participation, kind of a little bit the sabre rattling that happened with home health in last year's Home Health Rulemaking.

I'd like to suggest we take great caution and be careful what you wish for in the latter case if conditions of participation become the linkage, because that to me, in a manner of speaking, is a nuclear option. Because that now is not just for your ability to bill for a given service or to be subject to a variable amount of payment related to quality measurement or to payment adjustment over the overall fee schedule. That's your ability to participate in the program at all.

So I think we need to really be careful about when we say something like this first statement here, also have an opinion maybe about what kind of policy lever it would link to be that business driver, because we could...I don't think condition of participation linkage is your first tactic. I think that's going for the jugular in that it is black and white, you know, then you are actually requiring use of CEHRT as a requirement to participate in Medicare Program and the Medicaid Program. I don't think we want...we're in any way, shape or form ready for that kind of leap.

So maybe we want to elaborate on the kinds of policy levers that would make sense. Maybe that's out of scope here, maybe that's something for the Policy Committee, probably is; but, I want to make sure we're aware of be careful what you ask for because going for too profound a linkage could be a huge leap over a program that doesn't have any such concept of a linkage right now.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

This is Cris. Sarah and John, I appreciate your cautions on this. Let me ask a devil's advocate question, which is from a provider perspective, we want to be able to share information and integrate with the care settings that are listed here, and maybe others. So what's your proposal abo...sort of from the vendor to the provider perspective? If there wasn't a certification program, what ought we do? And it's intended to be an exploratory question.

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

Yeah, I'll offer one concept, and I think it's not that there's no certification program, I think it's defining what it means to have one that's linked to something. And I actually think on that score, they didn't quite refine the model because it didn't establish...but they got partway down the path, CMS did, with what they did for chronic care management. They called out a limited scope of certification criteria that actually were already present in the EP certification criteria set for the 2014 edition.

But what they did, they called out about half a dozen of them and then they specifically stated where the certified system needed to be used in support of delivery of the chronic care management service. I think that's your kind of model. So you could include in that whatever criteria are of high, high value to the care venue and they might even be new ones, you know, I'll confess, I was out last week and dealing with a lot of other stuff and I'm beginning to make my way through the present we got Friday and we'll see what's in there.

But it seems to me that would be the sensible model, go for what is of high value, limited in number, somewhat limited in scope that way, where there still is a policy linkage, in that case to a payment policy, for being able to bill the Medicare Program for that benefit. That takes it at a more probably consumable level than linking it to your overall ability to participate in Medicare, to me that's extreme. So is not having any...going on a purely, if you build it, they will come sort of model, because I think what Sarah was saying is that they did build it, they didn't come, so I'm not sure you would face any better luck trying to build a voluntary program that has no teeth in it, no use requirement and no linkage to anything that the provider is then compelled to have to do to adopt.

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

This is Sarah. So we wouldn't...we're only talking about certification, we're not talking about policy. So we cannot recommend anything that has to do with expanding the Meaningful Use Program or terms of participation, we're talking about the value of setting up a certification process for these other domains. And I think what you were asking us is, how would you make sure that someone that was purchasing software in that domain got the tools necessary to exchange data with an ambulatory or a hospital EHR, if there was no certification process.

I think that you would simply, if you were in that domain, you say, you shall meet the same requirements for data exchange via C-CDA and the ability to import discrete...the discrete data elements required under Meaningful Use. You would simply reference those and not require that it's...that there's a separate certification process because they can certify, particularly under modular certification, they could certify right now to those areas that would allow for interoperability without calling out something specific to them.

My point was that when you're developing a brand new certification program with requirements specific to that domain, you need to make sure that the return on your investment is there in that you think that someone will actually accelerate their adoption of EHRs because of it. And my point was that without expanding any type of requirement, such as we have for ambulatory and inpatient, to these domains, it's not going to be worth the time and effort to develop a certification process because that is not the driver of adoption right now is something being certified and that it could be handled through the RFP process.

**Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.**

This is Kyle, Drummond Group, and I guess one thing I would add, I mean obviously those are good points about the incentive, there are though, I'd say...reference, I mean we do have behavioral health systems that come and get certified, we've had some long-term care systems that have come, obviously it's not as significant in terms of numbers as just general care. But I think one thing we could maybe consider at least is that we have these criteria out there that are general, like a problem list for example, but like we could, if we're looking at these settings, for people who are coming forward, let's just again

assuming these different industries are coming to be certified, is to make sure that the test procedure or at least test data corresponds to that.

Like for example, behavioral health; we have a problem list on our test, but for them they have these different axes, Axis I, Axis II...Axis I is for clinical disorders, Axis II is these more behavioral health type of disorder/problems. And could we have test data sheets at least that kind of address those different settings? So maybe one of the things to consider at least is for those who are coming in these other areas outside the maybe "typical clinical care situation," can we take out current situa...our current criteria and make sure we tailor our test data or test procedures to take into account the needs of those interested, meaning that they do use the same criteria but they frankly apply it in a different way.

And just so...I mean, I guess that's the one...I could see in terms of if people are coming, I think behavioral health especially, they come, we have a lot of behavioral health that are certified, but all the test data is really just very clinical, it's recording hypertension and what not. And I know those do play a part in behavioral health too, but there are many other things that we can make it that are more tailored maybe to a certain industry vertical.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Other comments? Well, let me ask another sort of framing question. So, is the concern in draft this is an incorrect question and if so, reframe it. Is the concern here about having entities, the EPHs...EHs and EPs that are currently...I'm sorry, vendors that are currently being certified on behalf of the existing EPs and EHs, having that cohort, the pre...the current cohort certified to expand their scope to include other clinical domains? Is that the principle concern or is the principle concern certifying entities that are today outside Meaningful Use who could be added? Are they both of equal concern or does the concern lie in one of those versus the other?

**Rick Moore, MS, PhD, FACHE, FHIMSS, CPHIMS, PMP, CISM – Chief Information Officer – National Committee for Quality Assurance**

This is Rick, I was going to chime in on that concept. I thought it was about where there are such Meaningful Use objectives that touch on the other domains, we should figure out how those other entities play into the system and whether they require certification. I believe that was part of the gist of those comments. Because right now to have those Meaningful Use objectives that include those other domains and no certification, there's a gap.

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

Yeah, this is John. I was...I guess I took it, and it may be a bit of an amalgamation of the problem statement and I respect what Sarah said. I definitely was on more a policy point, but speaking as a vendor, we did certify behavioral health ourselves. I think you can certainly do those things with the criteria set at hand and I think adapt into test data set is a good step, but it does...it is a question of are you really developing a program that is appropriate to those other domains, and I would go beyond behavioral health to consider the long-term and home health domains as well.

Or are you trying to adapt what you have to reflect the fact that you have...you're not really after creating an institutional participation by those other provider types, but you're trying to enable the professionals who practice there to be able to include those as a site of service; but we've already got that. Now I think if that's your objective, it's probably mainly looking at things that are really hindering their participation considering those sites, which to me comes down to a couple of things. One is, do they have viable EHR options for those sites that aren't strains of credibility to be implemented there?

Do they have the types of criteria that reflect use and enable participation in quality measure submission in particular? I mean, you don't want to create any more square peg and round hole situations. And are you trying to enable institutional participation in the adoption and use of EHRs? Because quite honestly, most of those entities are the buyers, not the EPs, but the institutions themselves; so I do think it gets at trying to enable the...whether you want to say incent, I'd say enable the purchase of EHRs that serve those purposes that are usable in those venues. And I'm not sure the program we've got, it kind of enables a limping participation by EPs practicing in those venues, it's certainly possible but we all have seen a lot of the complaints about feeling a bit disenfranchised by that, speaking of those EPs.

**David Kates – Director of Interoperability – The Advisory Board Company**

So this is Dave Kates. So, I mean, it sounds like this may just be summarizing some of what's already been stated, but like John and others, Sarah have said like if we were trying to create certification requirements for purposes of either spurring adoption or making...protecting those organizations as they're making selections about the types of technology, it may be overkill. But I think the root of this is that the coordination of care as patients move from one care setting to another often times into those facilities that currently don't have explicit requirements for how they might...not the automation within the four walls of those long-term care and other types of step-down units, but at a minimum.

So as patients move in and out, back and forth from long-term care to hospital and back to home and back to their primary care physician, to Sarah's point, they may already exist, but maybe if there is a minimalist approach to the systems as good citizens, as part of the healthcare system that information can be conveyed in and out of those care settings that a program focused on that might be useful, but all the prior comments notwithstanding in terms of how it aligns with funding and policy and the like.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

David, this is Cris, piggybacking on that point. Given the fact that the policy direction, if you will, is a desire to...by ONC to expand the scope of certification, are you suggesting that, and I don't want to put words in your mouth, but are you suggesting that we focus just on the joint set of requirements that represent the current scope that could be applied to other venues of care as opposed to adding additional criteria or requirements?

**David Kates – Director of Interoperability – The Advisory Board Company**

Ahh, largely I think that's right, but I think what...probably saying it slightly differently, what I'm focused on is the interoperability or the sharing of information as it relates to patients being received into those care settings and patients being sent from those care settings back into the settings where we do have certification requirements today. So not necessarily a logical subset of the existing requirements, but focused more on the transition of care and less on functionality within those four walls.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Yeah. So maybe, Sarah, John or someone else, Sarah...to a previous CCHIT certification, maybe Kyle might know from the certification...what were the kinds of things that were included in the previous certification that are not in MU2? Not to put you on the spot, but I'm curious.

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

So, gosh, I've got them all on my computer, somewhere, so let me just...I think that they did have more support for care plans, which are in Meaningful Use. So, pull it up here thanks to the wonder of...CCHIT is gone, I guess it's off of their website. But, the way that CCHIT worked is that they had a core set that

were appropriate to every care setting. So you didn't see, for example, growth charts as a requirement in the core certification because you only need those in a pediatric setting. So there was an add-on certification for child health.

So this long-term care certification that CCHIT had was designed to support home health agencies, skilled nursing facilities, hospice, inpatient rehab and long-term care facilities. And so it would have had the specifics that were not part of the core requirements, and a lot of those would have been care plans as...so...I can't...that list of all of the criteria that were on them, although I'm sure I can get...

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

John...Cris, this is John; John Derr would know, he was big...

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

Yes, the commissioner...

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

...advocate for that and I think that he even presented on it to one of the work...well, I don't remember which workgroup, but when that was actually...I think it was one of the Policy Committee workgroups, maybe their certification workgroup, looked into that I want to say about two years ago, in pretty good detail, looking at what would be a criteria set to adopt specific for a long-term care type certification. And that's available on the ONC site, I'll be, if Michelle or others recall what I'm speaking of. There was actually a transmittal letter on it.

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

Yes, I'm blanking on the old name and it's sad to say that, but Larry Wolf and he Co-Chaired it, Certification & Adoption Workgroup.

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

Yeah.

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

They did a lot of work on voluntary certification or that's probably not what we want to call it, but related to long-term care and behavioral health.

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

And John was the CCHIT Commissioner.

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

Yeah, so they came up with a criteria set that actually I don't know that it was exactly correlated with what CCHIT may have had in theirs, but, it's kind of what...and I remember they started from the premise of looking at what CCHIT did have and then kind of...John advocated a particular criteria set out of that, I would imagine it probably works to be a subset of it.

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

Yeah, so they leveraged that work and they did some listening sessions.

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

And it did...very significant on transition of care and things of that nature.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

So registering this caution of those who have spoken up so far, which I understand the reasons for it, we're at a little bit of a challenge here. Since ONC has indicated again a policy desire to expand the scope of certification, many know that John Derr, for instance, has been a steady and polite advocate for don't leave out LTPAC and so on. So caution understood, what's a constructive roadmap by which we could make steps in this direction or is the consensus of this group that the policy is unachievable? I want to sort of call a question on that.

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

So this is Sarah, I would say that the immediate steps would be to review what the certification criteria were in the past for long-term care and see where the gaps might be and from that standpoint, then you would need to do a current environmental scan to see whether the products that are currently servicing that market lack the functionality to support the needs of that care setting. And if they do, you know, and the gaps that are not part of the existing certification process right now, then you could make your decision based on that.

**Rick Moore, MS, PhD, FACHE, FHIMSS, CPHIMS, PMP, CISM – Chief Information Officer – National Committee for Quality Assurance**

This is Rick; I would add to Sarah's comment that the focus, if there's a need to refine scope of focus that the gap analysis be just on those that affect Meaningful Use objectives. I think it might be a stretch too far to say, again, just putting it out there for discussion, that we're...that there should be a program that certifies whether long-term care electronic health records meet the business need of that domain. That might be much further out of scope.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Yeah, good comment. Who else?

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

Yeah Cris, this is John. I think, and I appreciate the need not to get into policy here, but I think that the utility of the program, may I just simply say there's a way to see if that's something to be referred to the Policy Committee to consider, because again, getting into the situation, I think we accept our assignment certainly to go evaluate that, I do have concern putting other hats on of creating a program that has no linkage to anything. So John had an advocacy and it certainly did include enabling participation for Meaningful Use. I don't recall if he was advocating institutional participation versus EP, but whatever that is, that may be something to just hand...say that came up, so it's not an academic instruction of a program. Maybe there's a policy interest to be revisited. And I'll drop it there.

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

And also...this is Sarah. I would also say that as part of the analysis you should speak with the testing and certification bodies to see about the resources and cost that might be likely with a very limited number of people coming for testing and the need to develop and support the testing programs, whether that would be an unreasonable cost for vendors seeking this separate certification.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

So given that we've gone about 10 minutes over the time we'd allocated for this number 1, Brett and Michelle, I wonder if we could come back to this with a couple of pieces of material. And team, please correct me if I didn't summarize this right. Number 1 would be to go back and mine the CCHIT work around additional areas for certification that may need to be added above and beyond what's currently in place. Number 2 was to look at the work that I think it was Larry Wolf did with the Policy Committee around, Michelle, I think you referred to it somewhat grudgingly as voluntary certification, there may be some guidance for us there.

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

Yes.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

And then the third would be, I wonder if we could turn to Kyle on behalf of the certifying bodies, to answer Sarah's question around popularity of this program and expense and so on. It feels like our conversation would be more constructive if it was more data driven; not that it hasn't been so far and you all know a lot of things, but it feels like if we had a little bit of that data in front of us, we could come up with a good recommendation. And I'm hearing John say that when we come back to this next time, that we ought to figure out well what would be a path forward that was in the constraints of the current policy and where it gets to the edges of current policy, to make some comment that we think the policy maybe should be evaluated in some areas. Does that sound like a summary of where we've been and a go forward idea?

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

Yes.

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

Sounds good, Cris. Thank you.

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

I think so.

**Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.**

This is Kyle, I'll send back some comments to the group just about kind of what I would say would be the impact from a testing certification side of things on that. I'll send that later this week.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

That would be great because I think we've got at least one more meeting, don't we Michelle, between now and when we need to put materials together for the meeting on April 2? I'm looking it up...

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

Yeah, so the Standards Committee meeting is on April 22 and we do have another meeting, but I'm hoping that we can shift to the NPRM. So maybe we can do some quick wrap-up at the beginning of that call and then move on.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

So there's our challenge ladies and gentlemen, we're together on April 9, if we can fly through the remaining items 2-6, perhaps we can leave lots of time for NPRM. So with that, Brett, can you take us to number 2?

**Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology**

All right, so number 2, and I think again in the interest of time, we'll try to limit here the recap of the recap that you all have already submitted in your comments here and just let the workgroup have a discussion here about other kind of existing industry certification programs that could continue to complement ONC's Certification Program to ensure that a different aspects of health IT conform to technical standards necessary for interoperability. And I think for both sections 2 and 3 here on this slide, I'd allocated about 15 minutes for us.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Okay. So who would like to comment on 2 or 3?

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

Well this is John, I, to my own detriment, probably always open my mouth too much, but on number 2 I think the first bullet there really is the anecdote for recognizing Surescripts certification for ePrescribing. We know that the implementation specifications are distinct, but it kind of says, find a way to overcome that barrier ONC and NCPDP and Surescripts so that what we do as the predominant production transacting all of you will point to. And it isn't the job of the vendor seeking certification to go harmonize that.

We all kind of felt like we were, Sarah said this very plainly and I...and we had the same experience, we had to do work to work around the mainstay production manner of doing ePrescribing. That kind of stuff just shouldn't happen. We do understand there are differences, but in the adoption of the implementation specs referenced by certification, that's the place to overcome those or deem how other things that do those things in large scale production can be recognized. So...

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

This is Sarah. So separate from Surescripts, which has a formal certification process, I think that one of the other things that might save time and energy would also be to deem certification for existing interfaces in production that...where the trading partners, the exchange partners meet the requirements of, you know, HL7 2.5.1 whether we're speaking of labs, immunizations, syndromic surveillance; if there is an existing partner that already accepts that and you have an active interface that is working in production, it seems that it would be...because often the testing are a generic variant of it and that generic variant can't actually be sold to anyone.

It is more meaningful to those purchasing the software to know where you actually have a functioning interface with that trading partner and identify who that trading partner is rather than saying you are certified to syndromic surveillance, but because your state doesn't follow the same standard or has other optionality, your vendor has not created an interface for that state and you don't know that until after the fact. It would be, I think, more informative to those purchasing software to provide a list of those and you can perhaps as part of the certification process, verify that they are functioning appropriately. But rather than having vendors build some new interface that's vanilla that will not serve any other purpose but certification, to deem to those.

**John Travis, FHFMA, CPA – Vice President & Regulatory solution Strategist – Cerner Corporation**

I...this is John again; I like that and if that sounds like something that would be hard for ONC to necessarily accept, I'll point you out that that is exactly the kind of model that is permitted to live under HIPAA EDI and the operating rules. So the operating rules when it comes to things like what defines their safe harbors, you must comport to the operating rules exactly. But they are not intended to drive out a use the production trading partner means of exchange that already exists that conduct that very transaction.

Now they start from being compliant with HIPAA EDI, but they're the things that are the subject matter of companion guides and service level agreements and things like that that are part of a lot of the localization that has to happen anyway; so if those things are already occurring and occurring successfully, it's the tolerance of not driving out of use things that are useful interoperability on the trading partner level. And when that is purpose served, don't go break or disrupt that, and maybe we'll look for opportunities for comment that way when we get into the review of the 2015 edition.

But Sarah I'd like to offer a friendly amendment; that is very much the behavior under the CAQH core operating rules that have been adopted by regulation. So it's not as if the HHS has never seen something like that before.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Nice, other comments? Well I think on number 2 we had made the point in our previous remarks around the value of deeming as an approach to certification and accreditation. I think these comments are really, really helpful. If we could capture Sarah's comment as amended by John, does that reflect the views of this group? If so, maybe we can...I'm sorry?

**Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.**

This is Kyle, my only comment back on that is, and I'm certainly not...I think the Surescripts example is a great example of a lot of...I totally get, because we saw a lot of frustration from vendors having to do things that then they turn around and have to undo completely. So I guess there is still though the part that, I mean, as far as deeming, acceptance of other programs, it's not...it shouldn't be just a blanket activity. Obviously there has to be some kind of framework to kind of process that because obviously the ONC has their initiatives on things; so I recognize that.

So I think that's something certainly to explore with the caveat of, we still have to have a framework to validate, just because it's being done currently doesn't mean the ONC still doesn't want to push to another, hopefully it's industry wide to move into another area. I think part of the challenge though is there's limi...you know, the vendor gets the rock and the hard place where they're required to do this but there are entities maybe that they're working with, labs or whatnot, aren't required to do this. So they're kind of...or state agencies, they're kind of doing their own thing sometimes and now the vendors kind of stuck with that.

So I do think we should find a way to work with the vendors so they're not having to duplicate work with, like again with the caveat, that ONC still has to have some kind of framework. Putting this in place is not just a simple thing, you have to have some kind of accreditation, so to speak then to validate that this program that you're using right now is compliant, and going back with the Surescripts thing, one thing that happened in the beginning was the RxNorm, the ONC was wanting to move to RxNorm and that was not used in Surescripts and so you kind of had a kind of conflict there and I don't really think it

was ONCs fault or Surescripts fault, but that was just a recognition of kind of government policy kind of colliding with certain industry situation.

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

But as John mentioned, this is a process already accepted.

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

Yeah and I can go find some more information to share Cris, if it's worthwhile, but what is the operating rules under HIPAA describe as safe harbor that trading partners have to abide by but if they already have existing exchange relationships that are not per se following those operating rules, but working for the purpose of that relationship, then there is a provision not to drive those out of use, just for the sake of it...the trading partners determine that, in that case, for themselves.

Now that may not be a real manageable model for certification of EHRs, but the metaphor is, if it...but if it works, you know, don't break it in an effort to homogenize it. I respect what was said though that you need to have a process for how that deeming occurs and there may be are different levels of what that needs to be when you recognize something that is capable of meeting the intent of the objective from a use perspective and I would say is, in fact, being considered as counting for Meaningful Use credit anyway.

We certainly are counting ePrescribing production use with the Surescripts version of ePrescribing because that we have to for that to transact. So, we kind of are already there and it's really a matter of how do you codify a process of recognizing production use that may not exactly be by the certification standard, but nonetheless is in use and in effect. And then perhaps also the differential tier would be if you're actually recognizing a different body's process.

So I think that we have two camps of what we're talking about with deeming; one is as Sarah has highlighted; the production use of something that serves purpose that we don't want to drive out of use, mine mostly. And then we have how do you recognize other organizations that do their own certification. I realize there you get into the ASTM and the ISO...I'm sorry the ANSI and the ISO concerns that have been adopted as part of EHR certification for ONC ACBs and ATs. And it would...I do respect you have to be careful not creating an un-level playing field there, but...

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

John, doesn't a lot of that fall under the category that ONC must...that doesn't...is not obligated to recognize every single deeming opportunity possible?

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

No, no, it's not. I mean, they're going to...we're not talking about dictating to them which ones, but...

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Right.

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

...I think that would be their policy purview to determine, but we're suggesting that where there's one that's quite common, and especially one that substantially is a de rigor requirement anyway...

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Yup.

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

...should be focused on.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Yeah. So deeming makes sense, ONC must judge emphasis on those that are most commonly used, either universally or on some axis between...typ...represent some particular attribute of trading or interoperability or exchange currently.

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

Yeah.

**Rick Moore, MS, PhD, FACHE, FHIMSS, CPHIMS, PMP, CISM – Chief Information Officer – National Committee for Quality Assurance**

This is Rick. I wanted to chime in on this particular issue because...

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Yes.

**Rick Moore, MS, PhD, FACHE, FHIMSS, CPHIMS, PMP, CISM – Chief Information Officer – National Committee for Quality Assurance**

...I understand the intent is to not otherwise...what's already working, I think is part of the issue here while...and the other part is to not make people go through needless additional certifications just because it wasn't done by a particular body. I think they're possibly two different things but very related...while Surescripts may have been in use as the dominant force at the time, agreed we shouldn't have tried to forward it needlessly or mindlessly, we should have figured out a transition stage or period by which we would accept it.

But I can see by where a dominant market force would say, well they're current methodology is the standard because they have the majority of it therefore everyone must conform to them. So that's one of the slippery slope issues I have with that particular concept. So, not to say that's what we're intending, but I can see where than might go.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Sure. All right, good comments; I think we can reflect those in our feedback. Should we...unless anyone has a last word on number 2, we'll talk about number 3. And we may have actually spoken about number 3 a little bit.

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

This is Sarah, while I would certainly say that I would encourage ONC to only use mature standards where they have been deployed and one understands the necessary infrastructure as well as potential unintended consequences or co-dependencies for success on that. As an example I would use Direct and the failure to foresee the need for a centralized directory of addresses.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Yes.

**Rick Moore, MS, PhD, FACHE, FHIMSS, CPHIMS, PMP, CISM – Chief Information Officer – National Committee for Quality Assurance**

Yeah, that's a good example.

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

Yeah.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Any other comments on number 3? If not, maybe we can pick up some time here and move to number 4. Brett, can you help us there?

**Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology**

Of course; so looking into more medium term here, 2018 to 2020 timeframe on this slide here looking at health IT developers, certification bodies, testing labs, other stakeholders continuing to provide feedback to ONC regarding certification criteria that could be added to the certification program in order to increase its impact on interoperability. And I think for this slide here, I allocated about 10 minutes or so for us to discuss this here.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Any comments? Maybe the person, not to put you on the spot, but whoever made the comment about the Kaizen type meeting, that's an interesting idea. I wonder if you want to elaborate on that at all. Or if you didn't write it and you think it's a good idea, speak up.

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

(Indiscernible)

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

Well, this is John and, nah, go ahead. Sarah and I are probably jumping in with...

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

(Indiscernible)

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

I was just going to suggest we still are kind of in the middle of determining if the Kaizen that we saw in February that Sarah and I both were at can be considered a full success. We're just now into the phase of kind of the execution on the actions identified there. It certainly has a potential to be very good. I think I would ask, in terms of the improvement opportunity, what status of rule are we speaking of as to the launch of the new rule? Would that be, by timing after a final rule or...I take it it would be.

**Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services**

This is Scott and I just wanted to comment. So we are following on the mini-Kaizen process with about 6 months of review so we'll have more details kind of what success and what it looked like after that point and then we can try to figure out what kind of happens next. But I think in reference to what John just asked, it's probably best, especially if we're looking at it trying to make program like reviews or improvements, that it happen after...you know, kind of at this particular point in time, once a rule has

been out. Because during the opening comment period is when things can be shifted or adjusted as opposed to once something goes final.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Okay, any other comments? So do we want to lean on this Kaizen type approach or do we want to make any other recommendations around means to get feedback from the groups listed.

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

This is Sarah, I think the Kaizen process, at least in terms of opening up stakeholder's eyes as to the complexity of the process was very useful. As has been mentioned, we have yet to see whether the certification Kaizen will bear fruits that will make the stakeholders that attended happier with the process. But I think that it was certainly useful for educating all that attended and we know that in the past the Kaizen's around the CQMs, the quality measures have resulted in positive change. So I would advocate for continuing the Kaizen process, even though we don't yet have the results from this last certification one.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Well having not attended, I know that one of our previous methods was to do a variety of feedback and hearing kinds of activities sponsored by the Implementation Workgroup and now the Implementation, Certification and Testing Workgroup. Some of you had participated in those before; I think they were of good value, but in some ways it feels like a very much more hands on, somewhat informal, more problem solving setting, may be even more valuable. Again, not having...

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

Well in a hearing you're limited to time and participation...

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Right.

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

...and in a Kaizen, you're allowed the time to go through the entire process and identify all of the steps in the process and root causes and you just don't have that sort of time and luxury in a hearing. So it's beneficial to have hearings, certainly the public can participate and keep up with what people are thinking about, but in terms of the level of detail of work that needs to be done to assess really how to make the process better, it requires much more time.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Yeah. Any other comments on this item? If not Brett, it looks like we can catch up some time and maybe stay on schedule if we can move to number 5.

**Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology**

All right, let's do it. Moving on to number 5; again, medium term here, this one is regarding ONC and other industry certification programs focusing on including more stringent testing, such as scenario-based testing as well as post-implementation testing to ensure interoperability of the certified health IT; and a number of comments here that we can see on the screen.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

So, let's take these in the two parts, scenario-based testing and post-implementation testing and maybe we can talk about others. Some of you are veterans of this group and we've worked through a whole bunch of clinical scenario-based testing, which was well intended but I think had limited to no impact. And I don't know if that had to do with timing from when we were doing our work relative to the requirement for certification around Stage 2 or other things. I guess I've given a little bit of an editorial view on scenario-based testing. What do others think about that? I see the written comments, I think they're all good. Does anyone want to amplify this?

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

This is Sarah, I would certainly say that I think that scenario-based testing is easier for the end users purchasing the products to understand and it also allows, if done appropriately, for the vendor to have a smooth workflow for the testing to go through that in a logical process. And I know, not to beat a dead horse, but in the CCHIT certification process, they did use scenario-based testing that was developed by stakeholders, physicians, to be clinically relevant. And a good bit of time, volunteer time, was taken to get that right.

It's my understanding that there was not that same level of volunteer participation in the creation of these testing scenarios. And in addition, because these were designed to stand alone for each requirement, because you could certify individually rather than everything, that there was still...there was not a smooth flow and there was a lot of redundant data entry. That was one of the things that came up in the Kaizen to have more realistic scenarios to reuse data from one requirement to another and to reuse data from one testing year to another so that you are not entering over and over again historical data to try and...you can simply add new data but still have your historical data in terms of testing.

So I think that scenario-based testing is the right thing to do, but it has to be done with the right stakeholders so that it is clinically accurate and reflects actual clinical scenarios.

**Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.**

This is Kyle and it's...so, as someone who...I participated in the ONCs previous scenario-based testing...from the pilots that they did of it and I do think, kind of...what Sarah said, I mean it was a challenge what we'd done previously was that really we just took the existing work and just kind of rearranged it...scenario. And I really think we've got to kind of start with the end user kind of feedback in developing things that really...when I say scenario, it really should be more of almost, how do you saw workflow, I know we kind of are careful to develop on workflows, but this is how it flows for us; here are the inputs that we're bringing in, here are kind of the steps that we go through in this process and really kind of start from that side of what either they're using now or how they'd like to see it be used and then develop...if you think of the criteria that we have now as kind of the building blocks, arranging those in a way that then best simulates or prepares products for this end user situation.

Obviously there are some challenges about making it too specific to any sort of industry, but I do think that...I will say in my experience, what we've done previously with the scenario testing in the last 5 years or so, I guess 2-3 years ago we started doing it with ONC and then some earlier...or late last year is that it...we really didn't get enough of the end user feedback on this. It was just kind of vendors and ONC kind of rethinking things, we really need to get...if we're going to do scenario-based testing, we really have got to get feedback from the providers, hospitals and not just...and to some degree some detail on it, how they want it. I think we can always test something if we just know kind of what clearly is the goal

here, what are the...you know, what are the elements that we're working with and what's the goal to produce.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

So I know at least John Travis and if I'm forgetting someone else, forgive me, was a member of this workgroup when we went through clinical scenarios and it was aimed at exactly what you all are talking about which was, realistic scenarios that were driven by providers. We had a larger group of providers on the group at that time than perhaps we have today, and it was to get to the data reuse that was sought at Kaizen. So, we may want to just ask Scott Purnell-Saunders just to speak up here about this a little bit, you were providing some primary support for us from ONC as we were doing that work. Do you think that the work we did before, given the comments here, was just the wrong kind of work, that we didn't do a good enough job? Was the timing off? Kind of, what would you view as the debrief? And Michelle, you may want to comment as well, or others.

**Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services**

Yeah, Cris, thanks. I mean I think we...back with the ONC and we discussed it internally...we got kind feedback and what happened, even at the...our hearing last year. We understand that there's an interest in scenario testing...scenario-based testing and workflow testing as Kyle described it, from a lot of different folks in our environment, so the stakeholders that participate with it and those who are impacting affected by our work. But we realized that the group that we had together on the FACA committee at that time to do it, engaged as best they could, but it involved...it's a broader stakeholder engagement process that we need to do.

And we had a process in the fall where we pilot tested another test procedure where we were working through an open development process with that as well and didn't get a lot of feedback either. So we as the kind of originated a lot of this content, need that external support and we realize as much as we kind of come to the table and ask you guys for your support and help, often times timing is of the essence and when there's too much to do, everybody doesn't have the cycles to be able to do it in the timing in which we would need it.

So, I don't think scenario-based testing as a long-term option is out of the question, but I do think that if it's something we want to do and target, we need to really have good buy in from everybody, from some folks who are in the hospitals and providers doing the work, dealing with patients and providing care up to the developers and everybody kind of in the middle, even folks from possibly CMS and other folks ONC, because it's going to kind of take that concerted effort to do it effectively. And what we did the last time, at times we were in a vacuum as much because we were kind of familiar with it already and we kept iterating on the same ideas.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

John, do you want to comment on this at all or...

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

You know, I think Scott hit the nail on the head; the rubber meets the road moment is getting people to help you test drive those and it is hard to spare cycle time to go and do it. And early on, some of the iterations were improved versions, but still very unit-test oriented with...and I think that's where ONC was looking for a lot of help of okay, if we do consolidate these into scenarios, how would we go and do it?

Sarah's idea, and she's iterated it a number of times is that what made CCHIT's work effort fairly successful was the convening of really expert panels that did involve clinician volunteers to serve as the development panel for the scenarios that they use. The major lesson perhaps to be learned there is that CCHIT did rely on expert volunteer panels to develop their criteria and their scenarios that were... they're overall script scenario-based testing and that kind of echoes Scott's point, you really are probably going to have to find that kind of participation and expertise to make it work.

That's a little bit distinct from the advisory committee structure that we have; that's actually kind of taking the place of outsourcing that script development, perhaps instead of it being...it could be done under NIST sponsorship, it could be done under a convening NIST would oversee, but it would involve that kind of advisory group of the experts being involved in the ground floor development, making sure it met the criteria requirements.

But, CCHIT had a criteria set and then they had their script and so it was not a foreign concept of mapping script into scenario; that's exactly what they did, but both of those were developed largely under the auspices of their volunteer participation from industry and from other cross-industry, vendor, provider, standards developer; very focused to task and they took ownership of that. And Sarah, I may not be remembering it entirely right, I know you were involved with that; I was involved with it a lot as a vendor making public comment, doing the review of those things.

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

Yeah, that's correct. We had a lot of providers that were on the volunteer panels that vetted the...that developed the use cases and then they were vetted by the other workgroups and publically because it was released for public comment and every comment was addressed by the workgroup, the same way that they did for the criteria. So it had widespread review.

And then there were pilot tests as well, which is something that has been lacking in the current certification process, where they pilot tested generally with at least 3 vendors to make sure that the...and that often sorted out if you had an invalid code or a medication that had been discontinued that somehow slipped through the clinical review.

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

Yeah and I'm trying to remember, there was an...I don't remember the secret sauce, if you will, but Alisa Ray would probably know as to what incited those volunteer participants, but it did work. And as to the pilot testing, I think that they had two phases; they had kind of a desk check pilot where they...and they did that with us, for example, and you probably did that as well, Sarah, where they came and visited you and they...you took your teams through it with them to review the propriety and the efficacy of the criteria in the script. And then they also had a stage of actual live testing using it where I think the incentive for the vendor was you got at least recognition as that pilot partner, you might have even gotten a certified status out of it; I may not be remembering that right, but there was fairly strong incentive.

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

No, you did not get certified status, what you got was advanced practice basically.

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

Yeah, yeah, which was of value; we didn't go to that step, I don't believe, we did go through the earlier flavor that I mentioned. Now granted, we had less competition for our attention span back then, but if the proc...if that is the process, it might help incent and now that quite hon...if we have a little longer runway, again I haven't read all the details of the rule, but it sounds like we might, to get ready, then maybe that kind of participation can be revisited.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

All right, well unless other people have comments, I guess I would suggest that we ask Brett and staff who are going to do work on this to take these comments and I think strengthen them and make them more pointed. Because you could read these comments as written, which are very constructive and polite, but I guess we tried this, as John said, through a FACA environment and it didn't work. I...we had weekly calls and we had smart people on the phone, we had volunteers like Wes Rishel, picked up some pieces of the work and took them home and came back after hours and hours of work.

So it wasn't for lack of quality people working hard at it, and yet it didn't work. And I'm hearing that in another setting it did. So it feels to me as though we need to make this feedback pretty strong to say you need significant amount of stakeholder involvement in a setting that's more intensive and more involved than what the FACA process can allow and so on. You know normally I just want to kind of convene these meetings, but I guess I've got a pretty strong opinion about this that we don't want to really go through that again, it was...I mean, we met weekly for months and couldn't crack this nut and I would hate to see us go down this road again in the same kind of way.

So unless anybody has comments about scenario-based testing, maybe we could talk about post-implementation testing. And I know we talked a little bit about post-implementation testing in our comments on I1, so perhaps we can be a little bit more parsimonious if you will. Do people have comments on post-implementation testing to ensure interoperability?

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

Well, this is Sarah. The...I would ask to what purpose if we are not seeing complaints? It would seem that this would be resource intensive on the part of the certifying bodies, testing bodies and the vendors without benefit. I think it is certainly reasonable to do if there have been complaints about a lack of functionality.

Again, you are going to see as we...over and over again the fact that the current process of certifying to a vanilla standard when the partners in data exchange do not follow that same standard, you may certainly see that a user will buy a system that is certified to an immunization registry. For example, but they're state has variations on that or uses a flat file instead of HL7 and therefore the immunization registry is not available to the person who purchased the system or is...or they have to wait for it to be developed.

In the case of syndromic surveillance, that's quite typical because the states are not following the CDC implementation guide. So, I think that it would be important to have that tool available in cases where it was reported that certified functionality is failing to perform as expected, as long as you understand that you can't require that they certify to every variation that is out there.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

So I think the intent here was more or less voluntary post-implementation activities as opposed to ongoing certification and recertification. If this were the case of essentially voluntary efforts to maintain connectivity, would you have a...sorry, interoperability, would you have a different view, Sarah?

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

Again, I'm not certain why you would be using resources to voluntarily be doing something that should already be working.

**David Kates – Director of Interoperability – The Advisory Board Company**

And Cris and Sarah; it's Dave. I mean, I think the original comment around inspection or post-implementation testing was based on real or anecdotal discussions, maybe it was related to immunization registry and I think Sarah's points are dead on in that regard, but it was also specifically around the C-CDA and again both anecdotes and I can speak firsthand, we've run into situations where products that were certified products, certified versions of products that were generating C-CDAs that were non-compliant with the spec and not parsable XML, things like that. And whether that was version control issues or whatever, I think that's different in kind though than...because of the broader discussion around C-CDA and the whole other path around constraining that so that it can be more certified. So I think that's the genesis of what prompted having some sort of inspection process, because of the comments in the industry regarding lack of consistency about certified products than what's actually in the wild around generating those types of documents.

**Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.**

This is Kyle and we're...I know we're not on the NPRM but those who looked through part of it at least, I mean the randomized surveillance aspect has been introduced and its really significant, not just talking about complaint-driven, like I've got a problem, please look at this but actually a more proactive ACB initiated survey of implementations. And I think too, I guess kind of where this is at is, I mean, I think points were well made about what are we defining here because obviously doing the more proactive, initiated surveillance is a significant resource.

I think going back to what was just mentioned, what David mentioned that if there are still complaints about things, there needs to be an inspection process for that and obviously to verify, but that's really more about certification compliance, to make sure systems actually are working as they were certified to. Sarah mentioned too you've got to kind of differentiate between more of how specific is that niche, maybe what a user needs. But if we're talking about just purely going out afterwards and somebody doing some kind of follow up testing, I guess, I mean as part of certification, just to make sure things are still working, I mean there's a lot to be said there.

We've got to be very careful about that again for a lot of reasons. I'm not quite sure exactly where this kind of I guess comes in with us, because this is kind of to me a little more...I mean, I guess we are the certification group as well, but this is getting into surveillance as well. I don't know if that's quite what the questions are asking for or not.

**David Kates – Director of Interoperability – The Advisory Board Company**

Yeah I mean, I think...I'm going to circle back to Sara...the spirit of Sarah's comments like even whether it's C-CDA, whether it's immunization registries that I would propose that the workgroup offer as recommendation that there be an escalation process or some sort of reporting process whereby if there

are issues or concerns, there's a mechanism to do that, but to spend resources on an area post-implementation surveillance, that just seems onerous; it just seems like a sledgehammer for an ant.

**Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.**

Well I agree with that, so please comment on the NPRM for that, since that's actually proposed currently.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

All right. So not a whole lot of love for post-implementation testing on the workgroup today; I guess I want to ask the question about in other settings there has been more enthusiasm for voluntary efforts to try to maintain tests against open frameworks to assure that as there are version changes for data and so on, that there are means to make sure that your compliant. The example given previously was under HIPAA the X-12 transaction set was...there continued to be a validation frame that ran at all times, more or less, against which participants could test their X-12 transactions. And it was seen as highly useful in that setting. Why is it that we believe that that would not add similar utility against Meaningful Use?

(Multiple speakers)

**David Kates – Director of Interoperability – The Advisory Board Company**

I'll jump in; this is Dave again. I think framed the way you just did, Cris, that that does resonate and I'll let others speak, but I do recall us as a group talking about it and I would endorse that in terms of having a mechanism by which there are test fixtures and the like that as an individual vendors upgrading their product of fixing a bug that they can go and regression test against a known set of interoperability standards.

So voluntary in that context, like you just want to ensure that a patch release or a new version or whatever is certified, that that as a resource made available seems valuable. When you said voluntary testing it sounded like something that people would use to credential themselves and things like that and I don't think that's got much merit. But as a resource made available, a la your X-12 example, that seems awfully sound.

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

Yeah, Cris, this is John; I'll echo that. I think I was one of the ones who made the comment that you cited, especially the X-12 model that you have the opportunity for trading partners to use those as validation with each other. You can...certainly the valid case of we update our system, we want to make sure we're still in compliance, even absent any surveillance purpose or spot check testing purpose done by an ATL. I think vendors and implementers should have that opportunity to use it for whatever purpose they wish that they find use for.

That would be a more positive regime of use than necessarily...I'm not arguing necessarily against the other, I think that its reality, there's got to be a surveillance element that includes doing some manner of assurance, but the greater use could be on the implementer and the vendor because our...the thing we keep kind of leaving out is that our...while the provider community may assert complaint, the provider community also wants something that will continue to work. And the biggest point of surveillance in all this is going to be ongoing use. So despite what the certifying bodies and the ATLs might do, the clients are going to do...the providers are going to do what they will do to make sure they

can have a system that supports ongoing use. And they'll take that matter up with the vendor each and every time, so...

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

So, we're running out of time and need to go to public comment. Can we...do we have some consensus that we want to make remarks about wanting to avoid unnecessary kind of mandatory testing post-implementation, but note the value of ongoing voluntary, I don't know if you ca...conformance or ongoing interoperability testing a la the X-12 experience where groups could voluntarily test their products against the test frame. Does that seem like a consensus?

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

Yes.

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

Yeah.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Hearing none, I'm going to take Co-Chair's privilege to say, let's see if we can include those comments. So Brett and Michelle, we're not going to get to 6 and we need to look back to number 1 and we have just a few moments. Unless anyone wants to make some closing comments, I think we should go to public comment. So, any last comments?

**Public Comment**

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

All right, hearing none, operator, can you please open the line?

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Thank you, Michelle.

**Lonnie Moore – Meetings Coordinator – Altarum Institute**

If you are listening via your computer speakers, you may dial 1-877-705-2976 and press \*1 to be placed in the comment queue. If you are on the telephone and would like to make a public comment, please press \*1 at this time. Thank you.

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

So while we wait for public comment, we'll wrap this up during the next call and then move on to the NPRM, hopefully. It looks like we have no public comment.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

So we're back together again on April 9, correct? Michelle, is that the next date that we meet? I see a meeting on April 9, I don't think there's one before then is there?

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

Yes, that's the next meeting. Sorry, I had to look.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

All right, so April 9 is our next date, we're going to come back to item number 1 and Michelle, I saw you were Johnny-on-the-Spot and already sent out some of the materials that we had talked about. I think if we could distribute that to the whole workgroup that would be great. I think Kyle offered to give some other comments to support that...our comments on number 1. We'll go to number 6, but hopefully begin to really dig into NPRM the next time we're together.

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

Thanks Cris. I think the whole workgroup did receive that, we just sent it to the chairs and everybody else.

**Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.**

I received it.

**David Kates – Director of Interoperability – The Advisory Board Company**

Yeah, I got it.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

Perfect. See, you're ahead of me again. That's awesome. All right, thanks everybody, have a great remainder of the week.

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

Thanks all.

**John Travis, FHFMA, CPA – Vice President & Regulatory Solution Strategist – Cerner Corporation**

Thank you.

**Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems**

Bye everyone.

**Cris Ross, MBA – Chief Information Officer – Mayo Clinic**

See you all. Bye.