HIT Standards Committee
Implementation, Certification and Testing Workgroup
Final Transcript
December 4, 2014

Presentation

Operator
All lines are bridged.

Michelle Consolazio, MPA – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology
Thank you. Good morning 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 and also as a reminder, if you are not speaking, if you could please mute your line, it would be greatly appreciated. I'll now take roll. Liz Johnson?

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Liz. Cris Ross?

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. Andrey Ostrovsky?

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand
I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Good morning. 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? I know David's here. John Travis?

John Travis, FHFMA, CPA - Vice President & Regulatory Solution Strategist – Cerner Corporation
Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, John. 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
Hi, Kyle. Rick Moore?

Rick Moore, MS, FACHE, FHIMSS, CPHIMS, PMP, CISM – Chief Information Officer – National Committee for Quality Assurance
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? 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
Good morning. And Zabrina Gonzaga?

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
I think she was going to be here…yeah, I think she was going to be a few minutes late.

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Brett. Alicia Morton?

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
Yup.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Scott Purnell-Saunders?

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

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
And anyone else from ONC that I missed? Okay, with that I'll turn it back to you, Liz and Cris.

Elizabeth Johnson, MS, FHIMS, CPHIMS, RN-BC – Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Okay, I'll start and then Cris can add. This morning we're going to spend some time really getting an update on the Certification Program, what's to be included, what the methods used in the pilot was and then I want to spend a little bit of time talking about…excuse me, our next steps and actually leave the workgroup with assignments, kind of like we talked about last time. So I think Brett has his team here and Cris, please, additional comments.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Well, I'd just like to say I'm glad we're all meeting together as a group. I'm sorry that I was not able to be at our last meeting, which was essentially a kick-off of this workgroup with its new membership. It's exciting to see all the new folks who are engaged in this work, as well as some people who have been engaged in the past. And I'm looking forward to this meeting for the purpose of, I think, it's useful for all of us to get kind of a level set on how does the Certification Program and the Open Test Method Pilot Program work, to get this feedback around what have we heard in terms of feedback around the certification process.

I know everyone on this call has been engaged in these activities in some form or fashion, either as a provider or a vendor or some other participant and I think what we're attempting to get with this meeting is a level set that will help us then have context for the important work we've got ahead. This workgroup has been a hard working workgroup and I expect that through 2015, we'll have plenty to work on and having us all be on the same page is great. I know we're in kind of a listening mode today, which is good, but I do hope that we'll have a good chance for dialogue amongst the workgroup

members. So, I think we should…Liz, unless you have anything else to add in terms of context that I think we should just get on with the overview material.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
I agree. Let's go. Brett?

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology
All right, so Alicia, do you want to start to walk us…excuse me; I believe Scott was going to walk us through the certification overview.

Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services
Yeah, thank you, Brett.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
Yes, this is Alicia Morton. So I'm the fairly recent new Director of the ONC Health IT Certification Program and Scott Purnell-Saunders of which most of you are probably more familiar with, has been with the program for quite some time, is a Senior Advisor and technical expert in the office and he'll walk you through the overview today and then I'll join in for a very brief update on the Open Test Method Development Pilot Project, which actually ended about a month ago. And then we'll both tackle your questions.

Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services
Thank you Alicia; good morning everyone, this is Scott Purnell-Saunders and we'll kick off the presentation. Next slide, please. So I'll defer this slide to Alicia in explaining part of it from my perspective. She included this slide as an overview to talk about the importance of certification. Her preference would happen to be the nice new Corvette on the right hand side; my preference might be the car on the left, given that I have a new baby and need to put him in the back seat, so I need a back seat to carry him around in.

But there are significant differences in the cars even though they both meet baseline safety standards, functional components testing, vehicle emission testing and others. But those baseline standards are not the significant differentiator in between both of those cars. So, each individual person or organization may have preferences on what they would like or not and how this relates to certification. Our Certification Program is based on standards that are met across the board. I mean, we certainly understand that there are certain preferences that certain applications have and certain users prefer over others but that are not included in our Certification Program. Next slide.

So this slide goes into explaining how the ONC Certification Program works. First off we start with regulation. So regulation is issued by ONC, I mean, sometimes ONC and CMS release joint regulation documents to kind of talk about Certification Program from both areas of perspective and those regulations include the certification criteria and associated standards for health IT products and corresponding Certification Program requirements.

Developers then create health IT products that meet those standards and certification criteria adopted by the HHS regulation process. Between step 1 and 2, is the creation of the certification criteria test method documents that we actually create at ONC. They go into the step-by-step details surrounding how testing is to be conducted, sample test data that's to be included and used in the testing program and the applicable testing tools that will be used in testing the certification.

Going to step 3, the ONC ATLs or the Authorized Test Labs, test the health IT products based on the standards and certification criteria that are adopted by HHS and that are included in the developed and published test method. Following that, the ONC ACBs or the Authorized Certification Bodies, are then tasked with issuing certification based on the testing records that are received from the ONC ATLs.

They also conduct surveillance that we'll go in to a little bit further, but that includes the follow up on products that may not necessarily meet all the particular pieces of certification or follow up processes that we've included in the program. Once they finish issuing that certification record, they then submit that to us at ONC for viewing and posting on the CHPL, the Certified Health IT Product List. The ONC CHPL is the single source of all certified health IT products that were certified and included in our program and that's readily available, and we'll go into that in a little more detail later in the presentation.

And finally, providers and hospitals are given permission to access that products that are certified and are listed on the CHPL meet specific certification criteria and associated standards. The CHPL then serves as a place where they can review those products and look at details surrounding what was tested, what particular standards were used and then they can also leverage the information on the ONC CHPL for inclusion in the CMS and Medicare and Medicaid EHR Incentive Program, or as some people call it, Meaningful Use. The providers and hospitals are able to create a CMS needs or certification ID on the CHPL and then submit that with their attestation records to be included in the EHR Incentive Program and receive payment based on that. Next slide.

This is the overall structure and organizational process with all the various stakeholders we just reviewed in a graphical format to try to really explain how data flows and how the process works start to finish. At the very top you'll see that ONC approves using ISO standard 17011 NIST NVLAP, which is the National Voluntary Laboratory Accreditation Program who then accredits the ATLs or the Accredited Testing Laboratory that I mentioned before. On the right-hand side of the document, you'll see that the ONC AA which happens to be ANSI at this time, the AA stands for Approved Accreditor, accredits the ONC ACBs which are the Authorized Certification Bodies.

Between the ATL and ACB is a wall of fire, essentially a firewall that prevents information from being passed from one organization to the other. Ideally that was designed to prevent…while there are certain organizations who are both attesting labs and certification bodies, they are completely separate entities, so we developed the program this way so that our product can be tested by one particular testing laboratory and then certified by a different one, or if it goes back for recertification it can go to any one of the certifying bodies to be reprocessed and re-updated, if need be. And the ONC authorizes the ONC ACB through ISO standard 17065, which was recently updated in the program year 2014.

At the bottom of the diagram you'll see that the developer goes through testing with an ATL and once the product is successfully tested, it is passed to the ONC ACB which then successfully certifies that particular product. And then it's passed to ONC for review and posting in the CHPL, as we talked about before. Next slide.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Scott…

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

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
You might pause occasionally just in case anybody off the workgroup has a question related to these slides.

Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services
Okay, I'll do that.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Thank you. So, I know we've gone through a lot already, anybody off the workgroup, are we all together on that Scott presented or do we have questions? We can stop for just a moment. Okay, keep going. Thank you.

Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services
Thanks Liz, and I'll make sure to pause moving forward.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Okay.

Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services
So, this slide goes into detail surrounding the certification changes and testing categories that are included in the 2014 edition. So you'll see a major list of 7 different domains or categories including clinical, care coordination, clinical quality measures or CQM, privacy & security, patient engagement, public health and then utilization. The certification criteria that are listed in green meet or are included in the base EHR definition.

The idea with the organization of the 2014 program was to develop a base EHR that would surmise the minimum amount of functionality and inclusion in the program that would meet general program needs. While it doesn't satisfy all the needs that a particular provider or hospital would need, it gives a good basis to start from. And this base EHR is leveraged in the Meaningful Use Program as a starting point, so there are certainly specifics related to core and menu measures that are related to the clinical quality measures and other certification criteria that must be included for a fully functional EHR to be certified and accepted in the Meaningful Use Program. But it was also designed this way to allow for flexibility for members of the program that weren't necessarily acceptable as of yet; so for example, behavioral

health and long-term post-acute care organizations that could also leverage some of these certification criteria in reviewing their certified electronic health records technology. I'll pause here for a second for any questions. Great, next slide, please.

So this is our getting to know you slide, this will help for clarifying terminology. There are a lot of different terms and acronyms that are used in our program, so we'll go through a couple of those right now. CEHRT or Certified EHR Technology is specific to the MU Program, that's an acronym and a term that we use to really describe pieces of technology that have been certified through the Health IT Certification Program.

The base EHR definition which we just went through surmises the qualified EHR, while it doesn't, like I said, does not include all the particular aspects that a provider/hospital would need, it just starts to be a good baseline to start from and can be added on with additional modules or complete products as need be. And then the complete EHR definition, which is actually going away in the 2014 Release 2 Final Rule, which was released earlier this year, has no effect on the 2014, has no effect on Certification for 2014 Edition, but was inclusive of programs or products that met not on the base EHR definition but a significant amount over that.

And it was decided to be removed moving forward after the 2014 edition just because at times it was a misnomer, some people understood or thought that complete EHR met every particular need that they would have. And in some cases it did, but in many cases it did not, so additional certification criteria need to be met or additional functionality had to be included for some particular care settings. I'll pause here for a second. Great, next slide.

Okay, so this goes into the ONC Health IT Certification and CMS Meaningful Use relationship. When we talk about this, essentially ONC and CMS are inexplicably tied together on relating our Certification Program with Meaningful Use. So if you were to go through this diagram looking at the top, ONC first adopts certification criteria that specify technical capabilities for EHR technology. CMS then sets specific provider performance measures and metrics related to the use of those certified capabilities and then eligible provider reports their performance on each particular MU metric to CMS in order to receive an incentive payment and to avoid a particular payment penalty.

So for example, any particular piece of certified capability in EHR added to the MU measure and that demonstration of Meaningful Use is what actually gets providers a particular incentive payment, or in some cases, the avoidance of a payment penalty. And there are some examples that are listed here as well; for example the EHR technology required to be able to record records in SNOMED is listed included in our rule and the EP must record problems into a standardized data format for more than 80% of those patients. And then that particular provider attests to 93% of that and that would be a demonstration of Meaningful Use. So I'll pause here for any questions at this point. Great, next slide, please.

So this slide goes into the details surrounding the Certified Health IT Product List. So as we talked about before, the CHPL, or Certified Health IT Product List is available at healthit.gov/chpl and it is the entire listing of any product tested and certified through the ONC HIT Certification Program. One thing that was added back in the fall of 2013 was this ability of a test result summary document to be displayed and included in the CHPL. So that document actually goes into specific details surrounding how products are tested and certified to particular measures so for example, safety enhanced design quality management systems and specifics surrounding what particular standards were included in testing that were in addition to some of the details that were provided on the details products page of the CHPL.

Those reports are currently available in PDF format, so the screen shot that's included here just shows a sample product and the highlighted yellow box in the document on the left-hand side includes a link to where that PDF can be accessed. Certainly that report is not in a…format currently for folks to be able to gather a lot of data out of it, but we're certainly succinctly working on plans moving forward to improve some of the transparency and flexibility of this process moving forward. I'll pause here for any questions. Great, next slide, please.

So the Certified Health IT Surveillance Program, as we mentioned before, is conducted by the ONC ACBs and in this slide we're going to talk about some of those processes and steps. So first, the ONC AA performs surveillance and technical assessment on the ONC ACBs. According to our program requirements and standards, the AA then is responsible for the ONC ACBs process and performance. The ONC ACBs perform performance on certified Health IT products, so there's a proactive process and a reactive process.

On the proactive process, ONC priority areas of exchange, safety, security, population management and quality measurement are then viewed and looked in the public or products that are certified through the public program by the ACBs. And on the reactive side, when complaints are submitted to ONC the ACB then kicks off surveillance on that particular product and it starts investigations to kind of determine whether or not those particular complaints were valid or not and then takes appropriate action.

The surveillance on priority areas are listed below. So for the first, in the calendar year 2014, there's a link to that. The report from that first year surveillance is to be due out in late February 2015. We have been discussing possibly presenting some of the information on some of these workgroup calls, but that's yet to be determined. And then the second calendar year, 2015, just kicked off and we received the initial plans from the ACBs and we'll be moving forward to get those operationalized.

NIST NVLAP, who is actually the lab accreditation partner in the program performs surveillance on the ONC ACLs, but for our intent in the program, our Health IT surveillance program focuses a lot of time and effort on the ONC ACBs and the activity surrounding product validation and certification. I'll pause here for a second.

Rick Moore, MS, FACHE, FHIMSS, CPHIMS, PMP, CISM – Chief Information Officer – National Committee for Quality Assurance
This is Rick, I have a question. Why is there reticence to post the surveillance activities, because I think there's a lot of value in learning from whatever it is your findings are? I'm just curious to understand.

Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services
Well because this is the first time we're actually doing it, we want to make sure that all the information included there is the best it can be. So for certain information, some of the information that could be included there is maybe proprietary, so we want to ensure that we are valuing our stakeholder's privacy and security as best we can while getting as much information shared about this, about the process used as we can…in the public's eye. So we're still determining that process as this is the first year that we've completed this.

Rick Moore, MS, FACHE, FHIMSS, CPHIMS, PMP, CISM – Chief Information Officer – National Committee for Quality Assurance
Right, I appreciate that. I appreciate the sensitivity of anonymity, I'm just curious just to know the actual…I guess from my perspective that we'd want to know the lesson learned, because I think there's a lot of value in that in terms of whatever it is that was corrected, modified or otherwise improved upon.

Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services
Yeah and that definitely at a minimum will be shared, but it's more trying to ride that line between sharing all the information, totally forgoing any proprietary data and then ensuring that we keep our stakeholders engaged in our program effectively.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
This is Alicia Morton. Also, yeah, so we're due these reports from the ACBs in February and like Scott mentioned, that's the first time ONC will have received the official report of their surveillance activities, although in our surveillance guidance and I believe also in our numerous certification rulemaking efforts, there's always been encouragement for the ACBs themselves to not only post their surveillance results, but also their surveillance plan.

So, I, in full disclosure, in the 2 months I've been doing this job, have not gone yet to the ACB sites to see if they've posted any of their surveillance plans for the calendar year 2014 nor any preliminary surveillance results. But if they don't, ONC is exploring what we will and can share after we go through all of the data that we receive in February.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems
This is Sarah, I'm not sure about the other certifying bodies, but I know ours has just started their proactive surveillance and is going to be retesting in January on those priority ONC areas, at least they're going to be retesting us on those priority ONC areas in January. So, it may be that like other…that other certifying bodies may be on this same timeline as well as just starting their proactive surveillance.

John Travis, FHFMA, CPA - Vice President & Regulatory Solution Strategist – Cerner Corporation
I get that…this is John…Sarah, I'll echo that, we very much similarly got a recent notice to prepare to go through some retesting activities with our ONC ACB, it may be the same one; so the timing of it was relatively late in the year, but that's our expectation as well as to timing.

Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services
Great. Thanks everybody for those comments; any additional questions? Okay, next slide, please. So now what you know is we've gotten to this point in the slide deck, we can open up the, I guess if that's possible, for any additional questions that were presented on the slides that weren't covered earlier. Our actual link to our website is www.healthit.gov/certification where you can find specific program details and links to released or currently released test method and archive test methods. And the link to the ONC CHPL is the www.healthit.gov/chpl. And any additional questions that you have can be sent to our mailbox, if you didn't want to necessarily discuss here, and that address is ONC.Certification@hhs.gov. It is monitored and you actually do get a quick response back as best we can.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
And then Scott, you know kind of in reference to the earlier question from Rick about seeing the results, are we going to talk about that either from Alicia or…when are we going to see that? Or is…

Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services
So the report is actually not coming out until February, so we had actually as a team internally discussed how we start displaying some of that, and certainly engaging this workgroup will be a part of that process. But we haven't determined all the details surrounding that yet, since we haven't gotten reports.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
So will we have an NPRM before that, do we think?

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
We can't answer that question.

John Travis, FHFMA, CPA - Vice President & Regulatory Solution Strategist – Cerner Corporation
Sneaky way to ask, Liz.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Okay, I'm always trying to break through that cone of silence, I get it…trying to figure out how the…I understand, but I'm trying to figure out how the group takes advantage of learnings is all, I think all of us are there, trying to make sure that we support what we've learned as we go. And I know you guys are on the same page.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
Yes.

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.
This is Kyle; obviously I'm involved with this, being that we're doing this. And at least from Drummond's side, we're wrapping up our what we call surveillance testing in samples, like a certain percentage of our products we certified for the year, we make sure we sample those and retest them on these specific areas. We're wrapping that up this month. We've done some throughout the year, but a lot of them were back-ended toward the fourth quarter.

So we're doing that and we've also got our…we've sent out…we've contacted customers of the certified vendors, sent out kind of an anonymous survey for them to fill in to identify kind of how things worked, if you will. So that's getting collected this month, I think we'll probably allow them to go all the way through the end of the year, basically, to get the chance to do it. So I would expect then in January, after the surveillance is wrapped up, after we've gotten feedback from end-users that we have to kind of compile this information in a way to present it to the ONC. I think…if you're asking as far as timelines, I'm thinking that ONC is not really going to get that from us until some kind of toward the end of January

or so. And then they have to put it together and I guess however they're going to present that out. So, I mean if you're looking from the ACB, ATL kind of timeframe, it's probably not going to be until mid-January until we can get out…and I think, what was the date on that, Scott?

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
Deadline for you guys to get those to us is late February.

Kyle Meadors – Director of HER Testing – Drummond Group, Inc.
Late February, so, I mean we're targeting like January 31, just to get that…I mean we'll put that as our target date to get that compiled. This is kind of the first go around really to do this type of activity to this level with ONC. So, I mean if you're asking for the NPRM and that kind of timing, I know they can't comment, but I can't…I don't expect…to even…to gets it to ONC would not be until mid-February or whatever for the ATLs, ACBs and then they would compile it, I guess and share that. So, anyway, this is just kind of feedback.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Yeah, that helps. Alicia, I'm not sure if it's you or Scott that when you all talk about on slide 9 usability, is that usability of the certification process or usability of the actual product?

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
So it's the user-centered design requirement as part of the safety-enhanced design certification criteria. So it's not…there are no requirements, so in our 2014 rule, there were no requirements to employ any specific type of UCD process, but…

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Right.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
…just to tell us what you're doing. So this is the first go around of that and if you pay attention or heard about the Safety Usability Workgroup on the Policy Committee side, they had a workgroup meeting recently in which a researcher actually kind of went through that and eliminated the findings of what is presently posted on the CHPL for those developers that reported out what their processes were around UCD and it was a pretty little bar and no one's too excited. But that was the first…

M
Well isn't it more of a process standard and self-attestation that vendor…CCD or is there objective measure…

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
It is tell us what you're doing, what, if any, UCD principles are you using, please let us know. So that everyone…so there is some transparency for researchers, end users, everyone. Who seems to have a

very thoughtful process and who said they don't have one or they have a homegrown one or…so that was the first step. It was just a get a window into that, have some transparency so that we could be informed to make future decisions about do we need to…where's the bar at now and how do we set it higher and how do we ensure that everybody moves towards a better UCD.

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.
This is Kyle again, just to kind contribute from what we see at the test lab is that…there are kind of two parts; it's the attestation of what UCD standard you've employed or methods or guidelines. And then the second part is actually to self-test your system by bringing users in, run through a series of tests on the criteria that's selected, document findings and report on that using the NIST template there, and that's submitted and that's part of the test report. I think one of the findings in the meeting that Alicia was referring to was the NIST template is probably a little more high level, a little more technical than a lot of people…it's not made…the simplest thing to read through and really get findings on it.

I would say, too, just again from kind of the ground, and our check is basically they have just filled out the template, put in the all the sections, they've identified participants and so on. I do think one of the values I've seen is just frankly just users, especially maybe on a more smaller scale, not…who don't have the same size that some larger vendors who can…who have probably been thinking about usability and have teams on that, is just for them to really think of it as an objective measure and kind of go through that process. And I think it's good for them just kind of…and then they'll share like we're surprised that people have these problems or have these concerns.

And so I think it's been a good just first step of it, just again from my objective seeing that. But if you look at the reports, I mean you can go through at the end, you can scroll through and find them, but they are a little tedious to read, frankly, if you're not into that stuff all the time.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
And…complete, let me tell you.

Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services
And this is Scott and on that same token, I mean certainly we understand that there have been some significant requests for additional insights into the program and how products are tested. And the test result summary was just the first kind of crack at that, to provide additional detail. We are working on, like I said, more ways to make data that was submitted through the program more available, more transparent and we'll have additional details on our process with that moving forward, some additional details on Open CHPL Development for 2015.

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand
And this is Andrey. I have a quick question, I apologize if this has already been addressed, but I remember from the last meetings documentation community input in terms of testing methods is something that is going to be prioritized closer to Q3. And I'm just wondering, as a physician and as a software vendor that works with EMRs, I think usability is probably the biggest challenge in terms of EMRs and I'm wondering is there an opportunity or is an opportunity to involve community contribution to shaping testing methods to influence this very topic around usability and maybe making that a higher priority and expediting how that is reviewed and evolving that?

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
So, this is Alicia. So I'm going to, when we finish this discussion, give you an update on what I think you're asking about, which was the pilot project to develop test…community-driven test procedures.

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand
Thank you.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
So, I don't think, and this was a lengthy discussion on the other workgroup I mentioned, I don't think any of us here think that we can solve usability challenges or set best practices across the board on usability through the type of certification program we have right now, which is really conformance to the standards and to the criteria.

The Certification Program really is a minimum bar set and so do I think that we will, in the future through our learning, continue to add some requirements that enhance usability and user-centered design? Sure, but are we going to get it to the place where it needs to be for end users to feel like their systems are satisfying and useful and usable? I don't think that that can happen through product certification, which was kind of the point of that example of the two cars, both of which would pass, which are not anything alike, and somebody would probably be really happy with the Corvette, but not so happy with the other thing, which I think is the Cheverly, I don't remember, I just grabbed an old blue car.

W
Well I think…

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
So, I think there are…

M
I had a question…

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
…plenty of places to continue to have those discussions about how to help end users really understand design principles and advocate for what their needs are and understand the tension between the functionality and usability and some of that effort might be something like the SAFER Guides that were done or the SHARP-C Grant, which really focused on usability and put out a lot of information about UCD principles and a continued transparency into the good practices through some of the devel…smaller developers that may not have even thought in that way and they could learn from the more advanced developers as well. But as far as certification addressing the lion's share of the needs in UCD, I don't think that that's appropriate or possible.

Rick Moore, MS, FACHE, FHIMSS, CPHIMS, PMP, CISM – Chief Information Officer – National Committee for Quality Assurance
Alicia, this is Rick, I…

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems
…Sarah…this is Sarah. Well, I think that you're right that conformance testing is not going to get usability where physicians and other caregivers would like, but we should certainly take a look at where certification introduces decreased usability…

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
Absolutely.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems
…because we've certainly seen that with the need for automated calculation of numerators and denominators that additional steps have been required and some of the quality measures requiring exclusions that would not normally be documented as part of care. So I do think that we have a role in assisting that the certification process does not introduce additional usability problems for the products.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
Absolutely, I agree. I agree and I think what we've found, and actually I've been surprised by, is that some of the test methods or test procedures that have been developed as a method of testing of course conformance to the criteria, some developers have thought that that was kind of the high bar not the low bar. And we've been kind of shocked by some of the things that we've heard about where someone read a test procedure and kind of constructed their whole product around that very narrow test procedure, which in the live environment, turned out to be not the best solution.

So, we welcome and look forward to continuing to have folks like yourselves on the call review our test procedures when they're out for public comment, highlight for us areas where you think we've stepped too far or we're not in line with the intent of the rule. Or we've introduced some step into the test procedure that's inefficient, not aligned with good UCD principles, and could be misinterpreted by industry.

M
Thank you guys for those comments, appreciate it.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Okay, if we've got…Alicia, do you want to move on to pilot results?

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
Sure, it'll be quick. So, predates me, so Scott, if I forget something, chime in. The way the program has been structured actually anyone, anyone from…anyone can present to ONC for consideration test data, test procedures and testing tools. That's not yet happened to date, and so there was an attempt to try to kind of bring in the stakeholders into the community of helping us develop test procedures to kind of address some of the issues that Sarah mentioned and that I just said that we really do need expert industry feedback on to ensure that the test procedures are at the right level of rigor and aligned with the intent of the rule and aren't too arduous to complete.

So, there was a pilot that was launched in the summer and went on for four months in which there was a call out for people to participate in developing test procedures to the 2014 criteria, so at this point there were already finalized test procedures and folks had been working through those test procedures as they got their product certified. So, there was familiarity with the current test procedure. And the workgroup launched and they determined that they would focus on two criterion, CDS and e-Prescribing.

And the first kick-off meeting had about 100 participants. And so the findings from this short, although 4 months for some people might not be that short, pilot in which there were these two workgroups that would focus on both CDS and e-Prescribing. They met once a week and like I said, this ended in early November, was to…the first order of business for them to like select the criteria and how did they want to document this or what would be the template for developing this. And the new "template" did not differ significantly at all from the original.

And the findings from this, in addition to the 100 participants quickly waning to just a handful, up to 20, was that not only did the template not really differ; folks did not contribute original test procedure information. And so after some stalling there, it was requested that they were provided something to react to. And so they kind of reacted to what was already in existence and did do some modifications, but they turned out to be fairly minimal.

And for ONC this was kind of…it was eliminating because we had a lot of people interested at first, it waned pretty quickly, we did do a small like post-workgroup analysis to find out what the challenges were. Time was a challenge for people and competing priorities, of course, and we've been good at ONC for doing that to industry for several years now. And that the variety of the participants wasn't conducive, at times, to ensuring that like all stakeholder opinions and expertise were contributed to the effort.

So where we're at right now is, and anybody can go to the link, to the open test method development pilot project link Wiki and see that there are two documents there with two draft test procedures that were developed by these two workgroups. And like I mentioned, the delta is not significantly different so at this point, for us here at ONC, I mean, it was a heavier lift for us and our contractors to staff these workgroups for four months and kind of drive the process. So going forward, we definitely won't do something like this that way going forward.

Of course anyone can submit one to…a test method, a test data or a tool if they desire, for our consideration for leveraging in the program. Our intention now with these two drafts, which like I said, are publically posted, is to have a discussion with the testing labs and the certification bodies to see what they're thoughts are about these end products and if they find value in finalizing these and offering developers the opportunity to test to the 2014 certification criterion using these test procedures. And I'm truly going to leave it up to them at this point because they don't differ significantly and we're kind of well into the 2014 certification cycle, if they find value in authoring this, then we'll finalize them. And if they don't, it's a lesson learned.

So quickly, the details about the changes on e-Prescribing, they changed the test data to allow the vendor to provide the pharmacy information rather than having it assigned. It was apparently a burden to the vendors as they were testing to create dummy pharmacies within their current, often proprietary interfaces. And so that was one of the changes to the e-Prescribing test procedure. And on the CDS test procedure, it was about streamlining that testing process just to make it more efficient and to combine

maybe demonstrating things like the interventions and the diagnostic reference information together, rather than doing that separately and also removing the requirement to log in and out multiple times to demonstrate the various role and user based access with regard to specific CDS intervention.

The participants did appreciate the experience and the transparency into the development process and the discussions about aligning to the rule. The also requested that in the future when test procedures are developed, there's more transparency around the public comment process and what ONC does with the public comments on the test procedures and to have some closure for them and to extend the test procedure comment period longer than has previously been done. And they did indicate that they prefer to react to a proposed test procedure rather than create some whole…at this point, given the time constraint.

So, I don't know if anybody on the call participated, Kyle, I think maybe you did, but I'm not sure, because this predates me. So, if anybody else participated…

Scott Purnell-Saunders, MSIS – Senior Advisor, Health IT Certification Program – US Department of Health and Human Services
Yeah Kyle…Alicia, this is Scott. Kyle definitely did.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
I'd love to hear anybody else's thoughts and feedback on this.

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.
Well, I can certainly talk, so, I don't want to…I'll throw it in then. I did get involved with…for the decision support one and I…first of all, I thought the ONC test procedures were fine to begin with. I mean, there are things I think to maybe make it less wordy in some areas…

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
Yeah.

Kyle Meadors – Director of EHR Testing – Drummond Group, Inc.
…but overall, I really am good with what we had, so I wasn't contributing from any…like we've got to change this, but just it was an opportunity to be involved. So, one thing I would say, I don't really recall, I wasn't at every meeting, so could have surely missed some of this, I guess I don't…one thing I would differ a little bit in terms of my recollection is, I didn't really recall an encouragement or really kind of a direction to just to think out of the box for the test procedure layout, in terms of it really was more like we kind of presented the…we started with the original one and then kind of…so by then, you're already kind of naturally biased to kind of stay with it, it's hard to just to kind of wipe the slate.

And I can't recall if we just thought that might be easier just to kind of start off initially doing that, I don't know, but in terms of just the…you're right, it looks pretty much the same, but I don't really recall just this major effort to, let's just reimagine this, what should this look like? And I'm not saying that's what we should have done either, but I don't really recall that being really a point of emphasis. And then as a result, obviously it looks pretty much the same so, like you said, I mean I thought you guys as far as handling it, did fine. I mean, it was made open, it was made available; people who were leading it were very responsive to comment. My only kind of point, and again, I'm not saying we need to change

because I'm happy with the test procedure by and large, I didn't really see an idea of let's just…how should this look differently? This some degree, start with a blank slate.

And again, I'm not saying we should do that, but that really wasn't quite what I heard and my general comment for the test procedures is, it's just kind of dense at times with all the wording. If we can just kind of simplify things, I think they're good, at the same time, it's what an APL should do, I mean there supposed to help the vendor say, hey, this is really what core things we're looking for. And so that's kind of our role as well.

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
Yeah.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems
This is…

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
Well no, I appreciate that, thank you. I wasn't involved in the beginning either, so I'm going on the report that was provided. So, I mean, it sounded like from the report that initially there was this kind of, what do you want to do and how do you want to do it? And we've all been on those workgroups where no one raises their hand and so I think after some silence for a while, it was okay, to get this going we need to give people stuff to react to.

But yeah, I mean, out of the box would be great and two-page test procedures over 80-page test procedures would also be wonderful. It's striking that balance, which I hope that this workgroup and the next rulemaking phase, when you look at the criterion, you can think through, how would that be tested? Is it something that has to be tested or can we attest to it? Is it something that, you know, if you did this one by proxy, you would have completed these other four and you'd make those connections and help us really…I mean, the end goal for all of this is to make this as less cumbersome as possible, but with the rigor required to give the assurances to the payers, to the end users, to the certification bodies that have to certify these that they do meet the criteria required and we expect them to perform as such in the live environment.

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems
This is Sarah, I did not participate. I think that one of the issues was that vendors are so busy trying to improve their products that the last thing that they wanted to do was devote development effort onto creating new testing tools. But certainly the…what you mentioned, the need to remove the repetitive steps, which are just painful in the testing process and I'm dreading when we have to retest on the generating reports where you have to do it like 200 times to show how you can filter this way and filter that way and the logging off and logging on that just increases the cost because you're billed by time and it just it is painful for the person…the organization being tested and I know it has to be painful for the person that's watching it, because it so repetitive.

I think that that doesn't require a lot of stakeholders to say, we need to reduce the repetition and certainly as we discussed at our last meeting, deeming by certification that if a vendor is already certified by Surescripts for e-Prescribing, why do we need to retest it again? And so we should look for deeming where there are already industry standards that show that you're doing what our goal is, which

is our goal is to make sure people can have the functionality necessary to e-Prescribe and leave it out completely.

John Travis, FHFMA, CPA - Vice President & Regulatory Solution Strategist – Cerner Corporation
This is…

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
Yeah, I agree.

John Travis, FHFMA, CPA - Vice President & Regulatory Solution Strategist – Cerner Corporation
…oh, I'm sorry. This is John Travis. Some of it is very similar to what Sarah said and I'm looking for a way to phrase it, and this goes particularly toward the surveillance retesting. My understanding is we are held to the current version of the test procedure to do that, from what we're hearing and Sarah that may be consistent with what you're hearing.

In some cases, some of the subject matter what's being retested might have been certified a very long time ago and quite honestly, there are some test procedures where the guidance has made for a material change in the way the test procedure may be applied. And so you get into a situation where you have to prepare for it, you still have to do all the diligence to prepare for it as if it were new, I think. And I think where Sarah highlighted the measure algorithms, there have probably been places where the specifications and the FAQs and the guidance have changed to a fair degree so I think…I don't know exactly what I'm saying other than to observe that when we go through surveillance retest, the bar may be different than, you know, the conformance testing tools have changed. If we are retesting, I know CQMs is one of the areas we know the specs have changed.

I think we need clarity in that about what is it that the vendors should be prepared for and I'm not saying we wouldn't be prepared for it, but I think the challenge goes towards change happens and what is the expectation of the surveillance retesting process towards that. And that goes towards this as well, for the maintenance of the test procedures over time, if they're going to inform and be the bar by which the retest is to occur, based on the current iteration of that. Does that make sense?

Alicia Morton, DNP, RN-BC – Director, Health IT Certification Program – Office of the National Coordinator for Health Information Technology
Umm, yeah.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
I'm going to interrupt for just a second here, guys. This is Liz. I…all the comments that are being made tell, I know Cris and I and Brett and Michelle that we've got exactly the right people on the workgroup now, when we get this NPRM. I think rather than continue to discuss the…our concerns in the pilot and so on, we need to move on and get the hearing results, because I want to be sure that we have a good foundation as we make work assignments. So I'm going to ask to hold discussion for just a few minutes. Brett, I'm not sure who's going to do hearing results for us?

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology
I can walk through them.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
That would be great. Thank you.

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology
Yeah, I know Alicia and Scott have to jump off in a few minutes here, so, I'll handle covering the hearing results and Cris, Liz, if there's anything that you want to jump in, I know that you were both involved in that hearing as well. So, if there are additional comments or feedback you'd like to share as I'm walking through, feel free to stop me and interrupt.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Okay.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Thanks Brett.

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology
All right. So on May 7, 2014, the Health IT Policy Committee, I believe, was the committee that held a certification hearing to better understand some of the issues that the…what's working and where there are challenges, as well as to identify opportunities to improve the program based on lessons learned in Stage 1 and 2.

So here on the screen you can see some of the FACA members that were in attendance at that hearing. Actually there were four different hearings or four different panels here on the next slide, that covered providers, vendors, the ACBs as well as the ATLs, I believe and then there were also a panel of private sector representatives. So as we move through each of the different panels, I will give you an overview, if we move on to the next slide, I can give you an example.

We will see the different folks that were on providing their testimony as well as some questions that are not unlike, in many cases, the questions that we have posed for this workgroup and that we walked through on our previous slides on the last meeting. So, from providers we really wanted to find out, assuming designing an ideal program, what's the benefit of having the program overall from the perspective of their organizations? How does the program help? What are providers looking for…look forward and find out kind of the current certification and the capabilities that exist in an EHR? And would certification ever indicate a level of quality of those, whether or not it's just kind of pass or fail or certain qualities? Challenges experienced and kind of ideal design of the program that achieves benefits while minimizing the burden to those participating.

So, moving on to the next slide, some of the key points that we found from the providers participating that, and a lot of this may not be news, but it's good to hear from the testimony and get it all in one place. So, the functions that are implemented may disrupt the workflow, so while products might meet the letter of the criteria, they may not meet the intent. And some examples that were given were clinical summaries, patient education and some functions may be implemented kind of as checking the

box. So it's easy for the vendor to create and certify that their product does it, but as a provider, it may not be super useful or may not be helpful for patient care.

We also heard that providers feel constrained to use a product that's certified and there may be some inefficient workflows again. And some certified products frankly just don't work or don't work the same as they do in every state. So we have one more slide with findings from providers, and then I can pause for any questions that folks have.

Another thing that we heard from providers was that certification doesn't adequately cover interoperability so that the products that they're using and other providers they may be trying to work with those products may not interoperate well. The Certification Program should be less prescriptive and focus on the what and less on the how products work after they're certified; looking for more flexibility and time for implementation as they are preparing to work on Meaningful Use and other programs. And then we heard also that an ideal Certification Program would provide product comparisons in terms of their functionality overall. So, before we move on to what we heard from our panel of vendors, any questions about the provider comments that we heard?

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
One of the things I was gonna mention here, Brett, is that and I know Cris will be talking about it in just a few minutes, we are going to give the workgroup an opportunity as their homework for the meeting to bring back what we're not covering here. And like I said, we've heard some great ideas already. So, you don't need to feel compelled to add to this, but I suspect based on enormous knowledge in the group that we will see additional things come back to us next time, Brett and Cris.

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology
Yeah, we are certainly hoping that we can find additional feedback from the workgroup members that may not be represented here, so we can get a good overall picture of the program and some of the issues that we may not have heard from our limited group of folks that we had comment.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Yeah, this is Cris. I think that that's a great point. I guess I might also emphasize, these workgroup meetings are a really good opportunity to take public hearing comments and go deeper. So these areas may have sketched out the landscape, but our chance is to flesh this out and get behind some of these issues in more depth.

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology
Great, so let's move on to the second panel which was vendors. We had representation from a number of different vendors that you see on the screen here as well as the EHRA group overall. And we were really looking to see, from the vendor perspective, assuming we could design kind of that perfect program, what's the benefit of the program overall from the vendor side of things? What are challenges experienced with the current Certification Program? And how to design a program again that gets to those benefits while minimizing burden?

So on the vendor side, we found that…if we move on to the next slide, here…there we go. So the complete set of requirements is not provided with adequate time for development. So again, just time

needed to implement those products and get them certified and requirements can change from what was originally defined in the Certification Rule at the time when they are trying to achieve certification so that can impact quality and usability as the vendors are designing and developing those products.

In terms of MU objectives, reports that measure the objectives and the CQMs are not necessarily aligned with each other and are not necessarily aligned with clinical practice. So that was one area, and I know that ONC and CMS have been working to make improvements, especially in terms of aligning each of the program requirements already.

The testing tools and the data may not be properly tested before they're rolled out for use in the vendor community and can change from time-to-time, so that can create a burden. There was a recommendation that the complexity of the program be reduced and that a Kaizen process be used to support an effective review of the Certification Program at large. And we'll go into that a bit further as we get farther in the slides. And that certification should focus on the few critical elements, not kind of everything. So from the vendor community, that's it. Any additional comments from Cris or Liz or questions from the workgroup before we move on to the certification and accreditation bodies?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
I don't think so; I think we need to stay on course to get to assignments at 11:15, so thanks Brett.

Brett Andriesen – Project Officer, Office of Standards & Technology – Office of the National Coordinator for Health Information Technology
All right, we will move on then. So we had a good representation across the board from all the ACBs, Kyle who's on our workgroup was a participant, so he may be able to add additional comments if we need to, again trying to answer some of the same questions that we have been through all the different parties.

So, moving on to the key findings from the certification bodies, they want to pilot new test procedures and test tools prior to publication, so that they are working stronger. Improving consistency between the testing labs, they should be a venue for all the ATLs and ACBs to observe testing and understand the results; learn how the test tools operate and provide feedback to ONC. We heard that testing tools need to be more automated to be more efficient in handling test cases, reusing test data sets, employing more robust types of testing methodologies including testing of security. Need to be more focus on the certification criteria related to interoperability and security testing and as well as how EHRs handle various functionality and heard that that should be left to developers to allow for innovation.

We'll move on now to the next panel, which was folks from across the private sector, a variety of different groups commented here, Healtheway, CommonWell, IHE, DirectTrust and again answering some of the same questions and hearing some common themes here from those that we've heard from some of the others, but the need for additional upfront testing and for quality assurance. If we can move on to the next slide; we've heard from them about the need for upfront testing; that mid-cycle revisions to testing and for certification criteria can be disruptive to the overall program at large. Needing some subject matter expertise for program development; again hearing to focus on a critical few criteria and enhanced collaboration between public-private sectors could help improve the process overall.

So, on the next slide here, overall summary of the several hours of findings was, there was no disagreement about the intent of MU objectives, everyone kind of was on the same page as it relates to

improving quality, reducing cost, etcetera, but again, not enough time for product development and testing to be done well. Specific concerns about the program, you can see them all here, we kind of went through them across the board through the variety of different panels.

Moving on to the next slide, one of the final recommendations from this group back to ONC was that ONC hold a Kaizen to really create a well-coordinated, integrated certification process and minimizing burden. So ONC is working on developing a day-long Kaizen-like process and program; so we are working on holding one of those and we'll get information about that as it becomes available.

And then the final recommendation 2 was again to focus on a limited number of certification criteria that are critical to the industry and to folks at large. We are looking into this, but I know Alicia is trying to balance this recommendation as well as the need to create certification components that are well aligned with Meaningful Use and other programs that are using the certified technology. So, we are continuing to work with this group to do the best we can in focusing and implementing these recommendations. So, I believe that is the last of these slides. Cris, Liz, any other comments or discussion you'd like to have with the group?

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
I don't think so, I think, Cris, if you want to take it, we've…I think we've laid the foundation and we need to talk about next…where do we go from here and how…do we want to make assignments in conjunction with specific expertise or just generally open? I'll leave it to you.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Yeah, thanks Liz. This is Cris. I think what we had anticipated that as homework what we wanted to do was to ask workgroup members to review the materials from these hearings and get your recommendations about…for the next call, either other additional issues you've encountered from your perspective; that would be number one, sort of additional issues.

The second would be ideas that the workgroup ought to consider recommending to ONC to enhance the certification process. We heard some of that in the earlier conversation, but I think if we could get them in…compile them in some sort of written form. So if you have a few moments to write up the thoughts you might have.

And then I think the third would be, if you think amongst those two areas that is, other issues and additional recommendations, the third area would also be of the things that were listed in this summary of the hearings, are there areas that you would prioritize for additional focus. So again the homework would be walk through these materials supplied to the ONC team so that we can compile them any additional issues, any additional recommendations to ONC to enhance the certification process and then the third would be if you have notions about prioritization of things we should look at, that would be great, too.

Liz, do you want to improve that? Brett, Michelle do you want to comment on that?

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation

No. I think those are exactly the right categories, I'm just thinking that in order to orchestrate an organized response, we ought to potentially make assignments or have people say, this is the part of that I'd like to respond to, I'd like to respond to all of it. You described it very well.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Yeah, right, exactly. So if you list that stuff you can say, here's an area that I think is important, but not necessarily volunteer to be on it. Obviously if you think an area is important, we'll take that as an indication that you're a good person to be voluntold, you're going to have to work on this work. Maybe let's get some comments back from the workgroup, does that sound like a reasonable assignment? Do people understand it, have questions, comments?

Rick Moore, MS, FACHE, FHIMSS, CPHIMS, PMP, CISM – Chief Information Officer – National Committee for Quality Assurance
This is Rick, it makes sense to me.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
This was a pretty talkative group earlier, have we all gone silent or are we on the same pa…are we doing okay?

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Yeah, I was going to say…

Sarah Corley, MD, FACP – Chief Medical Officer – NextGen Healthcare Systems
Well, I certainly know having been someone that testified and was limited to only 5 minutes; I can certainly expand upon the recommendations greatly. There will be no problems.

John Travis, FHFMA, CPA - Vice President & Regulatory Solution Strategist – Cerner Corporation
Yeah, this is John, I would agree. I think we're, Sarah and I are going to agree on a lot of stuff. I echo particularly some of the stuff that I saw as feedback out of panel 4, which was kind of what I was mentioning earlier that the changes in interpretation that go on over time and so forth, but I don't think we'll have any problems coming up with things. We're even doing a retrospective on Stage 2 ourselves and 2014 certification over the next few weeks, so we may be developing some good feedback out of that.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
So Cris, do you want to divide the group up into specific report back issues where they can give it to us in writing in advance so that we can all be…have reviewed comments, create questions and so on? What do you think?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Well, either divide or self-select; I'd kind of go with self-select, Liz, what do you think?

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation

I'm fine with that as long as the team is, but what I want to make sure is that we determine before we leave the meeting who's going to do which part so that if we end up with an area that we don't have coverage before the next meeting, it would be really great to go through the four areas as identified by the hearing.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

So that's fine. So I think we said the three things that are up here on the homework slide, the opportunities for improvement, recommendations and then talked about prioritization. I would say anyone should comment on any prioritization, that's open game. But maybe we could just do a little bit of verbal show of hands about folks who want to talk about opportunities for improvement as opposed to recommendations, is that what you have in mind, Liz?

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation

That's perfect.

M

I would propose even that you might consider since there was feedback out of the four areas that maybe we could do it that way, but that's just one idea, so that we cover the ones that already came out. Because this seems to be this homework as it is now is more broad, it's like review everything and come back with recommendations.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Yeah, fair point. So, why don't we go back to the slides with the four points and see if you wouldn't mind, Brett, if we can just backtrack to panel 1, 2, 3 and 4. Maybe we can get again sort of verbal show of hands of who wants to respond to each of these areas. So, yeah, maybe that one right here; so the provider group, are there folks who are interested in speaking and dealing with the provider feedback? I know that I will, this is Cris again, so from a Mayo perspective I'll provide some feedback. I imagine Liz; you might as well, too.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation

Yes, I will.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Are there other folks who want to comment on that panel?

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

This is Danny Rosenthal; I'll take providers as well.

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

I mean, this is Sarah, I can cover providers and vendors but probably with the amount of work, I should limit myself to vendors.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Well you can always sign up for more, that's always good, two is okay…
John Travis, FHFMA, CPA - Vice President & Regulatory Solution Strategist – Cerner Corporation
I'll sign up for vendors as well. This is John.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
John, yeah, thanks.

Udayan Mandavia – President and Chief Executive Officer – iPatientCare
This is Udayan and I would also like to contribute towards vendor spot.

Andrey Ostrovsky, MD – Chief Executive Officer – Care at Hand
And this is Andrey, I could contribute to providers and I think private sector representatives; that would be fine.

Zabrina Gonzaga, MSN, RN, cPNP – Senior Nurse Informaticist – Lantana Consulting Group
This is Zabrina Gonzaga; I'd like to contribute to providers.

Kyle Meadors – Director of HER Testing – Drummond Group, Inc.
This is Kyle, obviously I'll take the certification accreditation bodies and I can follow up on that.

Rick Moore, MS, FACHE, FHIMSS, CPHIMS, PMP, CISM – Chief Information Officer – National Committee for Quality Assurance
This is Rick; I'll go with Kyle on that, on certification body.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
And Brett or Scott, we assume you guys are getting this, right? We've got great volunteering going on here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Yeah, we'll follow up to confirm what we heard. Anyone else want to volunteer for the private sector, I only heard one there?

Kyle Meadors – Director of HER Testing – Drummond Group, Inc.
This is Kyle, let me just say, there are some things that I'll probably do on the certification side that kind of bleeds over a little bit to the private sector representatives, since some of those were speaking about certification programs outside of ONC, which I'm involved with as well. So I guess you can put me down as that, it may be more focused though on panel 3, but…

Rick Moore, MS, FACHE, FHIMSS, CPHIMS, PMP, CISM – Chief Information Officer – National Committee for Quality Assurance
Yeah, I'll join Kyle; this is Rick, as I think he's right, there is some bleed over there.

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

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
All right, well I think we've dispensed with our homework assignments. Unless there's any additional closing comments or questions, either from the workgroup members or from the ONC staff, maybe we can go to public comment. So first, any comments or concerns or recommendations from the workgroup?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Cris, this is Michelle. There are just a couple of members who aren't on so I'm going to designate them where I think they belong and I'll summarize that in an email that I send out.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Well, you're the best at that, thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Okay. If there aren't any other comments, we'll go to public comment.

Kyle Meadors – Director of HER Testing – Drummond Group, Inc.
This is Kyle, real quick. Since I think I have our next meeting down as January 6, I think as far as our kind of feedback on this to send it…I guess summarize it and send it out, about what time do you need that?

Rick Moore, MS, FACHE, FHIMSS, CPHIMS, PMP, CISM – Chief Information Officer – National Committee for Quality Assurance
And on that note, could we summarize it…on that note, thank you, building on that, do we do that as the designated together as a group and send it as one or do we do it individually? Like to our respective panels, like Kyle and I are on a panel together? Go ahead.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
It's up to you all, but we can certainly take it and summarize it for each panel, to make it easier on all of you. I mean if you want to collaborate, obviously that would be wonderful, but we can certainly take that information; so when I send out the summary email with who's on what panel, we'll also identify a date for when materials will be due and how…to make sure that we have time to summarize that in preparation for the meeting on January 6.

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics –Tenet Healthcare Corporation
Great.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
That would be great.

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

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thank you all. So I think we're ready for public comment. Operator, can you please open the lines?

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 phone and would like to make a public comment, please press *1 at this time.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
We have no public comment. So thank you all for a wonderful discussion today. As was just said, the next meeting is January 6, which means that we won't be talking before the holidays, so happy holidays to everyone. As we just discussed, we'll follow up with an email describing who's been assigned to what panel and detailing the homework and when assignments will be due.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Michelle, Brett and Scott and others, thanks so much for your guidance for the workgroup today. We really appreciate it, this is a good session and it's going to kick off our work into January. Thank you so much and thanks to all the workgroup members.

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