



**HIT Policy Committee
Implementation, Usability & Safety Workgroup
Final Transcript
May 1, 2015**

Presentation

Operator

All lines bridged with the public.

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

Thank you, good afternoon everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Implementation, Usability and Safety 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. Also, if you are logged into the webinar and you've used the public comment feature please make sure or be aware that we may share your public comment during the public comment period at the end of today's meeting. And with that I'll now take roll. David Bates?

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Here.

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

Hi, David. Larry Wolf? Joan Ash?

Joan Ash, PhD, MLS, MS, MBA, FACMI – Professor & Vice Chair, Department of Medical Informatics & Clinical Epidemiology – School of Medicine – Oregon Health & Science University

I'm here.

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

Hi, Joan. Janey Barnes?

Janey Barnes, PhD – Principal & Human Factors Specialist – User-View, Inc.

I'm here.

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

Hi, Janey. John Berneike? Bernadette Capili? Michelle Dougherty?

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Here.

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

Hi, Michelle. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Here.

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

Hi, Paul. Terry Fairbanks? Tejal Gandhi? George Hernandez?

George Hernandez – Chief of Applications and Development – ICLOPS

George Hernandez is here.

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

Hi, George. Robert Jarrin? Mike Lardieri?

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

I'm here.

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

Hi, Mike. Bennett Lauber?

Bennett Lauber, MA – Chief Experience Officer – The Usability People, LLC

Present and accounted for.

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

Hi, Bennett. Mickey McGlynn?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

I'm here.

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

Hi, Mickey.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation
Hi.

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

Alisa Ray? Steven Stack is not here. Betty Mims Johnson? Ed Lomotan?

Edwin A. Lomotan, MD, FAAP – Pediatrician & Informatician – Health Resource Services Administration

I'm here.

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

Hi, Ed. Lana Lowry?

Lana Lowry, PhD – Project Lead Usability and Human Factors for Health Information Technology – National Institute of Standards & Technology

Here.

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

Hi, Lana.

Lana Lowry, PhD – Project Lead Usability and Human Factors for Health Information Technology – National Institute of Standards & Technology

Hi.

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

Megan Sawchuk? Jeanie Scott?

Jeanie Scott, MT, ASCP – Director, Informatics Patient Safety, VHA Office of Informatics and Analytics/Health Informatics - U.S. Department of Veterans Affairs

I'm here.

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

Hi, Jeanie. And from ONC do we have Ellen Makar?

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

Yes you do.

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

Hi, Ellen, anyone else from ONC on the line? Okay, with that I'll turn it to you David.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners

Great, so our plan today is...we have an action packed meeting, basically we’re going to have a...if we have him with us we’re going to have a recap of the certification NPRM presentation to the Health IT Standards Committee from Mike Lipinski who is from ONC.

And then we’re going to have the group three report out and discussion about that, and then we’ll have for you some of the overarching comments about certification we want to just go through those and have some group discussion about them. So, that’s the overall plan. Does that sound reasonable to everyone?

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Yes.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Yes.

Bennett Lauber, MA – Chief Experience Officer – The Usability People, LLC

Sounds great.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners

All right. Is Mike with us?

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

Mike said he’ll be able to join us at approximately 2:45.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners

Okay, so perhaps we should start with the group three report out if that’s okay and then we’ll basically come back to that when he’s able to come in. Mike is very busy and we’re just lucky to be able to get a small amount of his time today. All right, so who is going to drive on the group three report out?

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

This is Michelle, I believe I am.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners

That’s what I thought, but okay, so over to you.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

All righty. So, the first e-mail you received today had our...wasn’t our final draft comments you received an update and I believe that’s what will be displaying on the screen as well. I think it’s going to be displayed on the screen.

So, if you want to...if you have access to your e-mails you'll also be able to follow along with the report out document. The first page just lists the group three members and we met a handful of times to go through our section.

We had about nine sections to review and discuss and we compiled comments, because we had a little more time than some of other Workgroups we were able to hold one more meeting to pull together not just our discussion but our...draw enough conclusions based on the sections. So, the documents that you have don't necessarily reflect all of the various discussion but it reflects the kind of final or summarized comments that we have per section that we reviewed.

Our section focused on two main areas and one was, again the best way to summarize it is a broadening of the scope of the certification program beyond the EHR Incentive Program. So, it was addressing changing in terminology in the rule, eliminating certain statutes in the rule, making modifications and gathering additional input related to different care and practice settings and then there were some specific certification program elements that we tackled as well, you know, around removing a measure, the base EHR definition.

We also had the pharmacogenomics data request and were very interesting in getting the full group's opinion.

And we had assigned to us some of the new sections in the certification around design and performance. And because we didn't have any specific concerns, but there certainly was a lot of discussion on the last call, we thought this would be a great opportunity to revisit and maybe get additional full Workgroup input as well.

So, on the next page we then had a chance to think about what were the overarching themes and I think you'll see when we go through the document and different sections there certainly were themes to the comments and so we pulled those together in one section.

And, you know, the first overarching comment that we had as a group was that the approach outlined in the NPRM creates a program, certification program that does have significant broader scope and applicability across the healthcare ecosystem to be much more inclusive of those stakeholders, all of the stakeholders or any of the stakeholders that are sending and receiving electronic information.

And we recognize that, you know, the last iterations were focused on the EHR Incentive Program but when you take it in the context of the goals of healthcare reform and the Affordable Care Act it requires that there is this broadening of the healthcare community that can use and exchange information to reduce fragmentation and improve coordination.

So, we saw potential for the modular approach in the certification NPRM to engage a much broader set of stakeholders and set these foundational interoperability requirements for sending and receiving electronic health information.

Our second overarching comment was that we saw that the redesign of the program into this more modular approach, we felt like it provided the needed flexibility, you know, in a way to increase its applicability to various stakeholders as well as technologies that need to interoperate but we also recognize that there is an inherent risk to that flexibility and that the program was going to become more complex particularly we felt for those stakeholders who had to address multiple modules and certification requirements from various agencies, regulators, payers and we encourage that ONC in the role as coordinator to facilitate that alignment between these various program requirements and the related Health IT modules to try to mitigate some of the complexity and cost.

So, ultimately we saw this as the next kind of evolutionary step for certification and that it will include new challenges and potentially repercussions, and so we summarized that, you know, with a more complex program when that significantly increases the scope of the stakeholders that it may be applied to that it likely will drive up costs particularly for those who certify to multiple modules that are considered with single large systems, so perhaps it might have been more economical for them in the past so that's something to consider.

And that there are challenges to keeping the modules and the requirements as foundational, kind of these building blocks, and not begin to expand its scope unnecessarily, and that as other parties identify these certification paths or requirements, and we'll be talking about those in some of the modules we reviewed, we were concerned about kind of opening the door that erodes these foundations or building blocks and have other bodies begin to modify or have add ons that will create even more complexity or challenges for those who have to implement. So, you know, we just recognized that it will be...with the significant expansion that it will be more complex and, you know, the challenge of how to keep it as simple as possible.

So, those are our overarching comments and happy to take some thoughts, feedback on that. It may not make a lot of sense until we get into the different sections themselves.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

So, questions now for Michelle? And we are going to take a break in a minute assuming Mike is able to turn up.

Paul Egerman – Businessman/Software Entrepreneur

Yes, this is Paul Egerman; my question is, in terms of this expansion from EHR to HIT, where in the legislation does it say that?

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

So, I...you know, if you...hold on one minute...we can...the very first section there is some part that we reviewed and you'll see the different sections and the pages, and you'll have a chance to read through that text as well and it does talk about the authority, because I know that was a discussion that came up on our last call, you know, is there authority to do this and so in the rule it talks about a few places where it gave both the intent that the program would not...would begin with ambulatory and inpatient, and then the voluntary certification statute talked about its authority to be able to expand.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

I was going to just jump in right now, this is Mike Lipinski, I'm on the call, I've been on for a few minutes, so just, you know...

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Great, thank you, Mike. Other quick comments now about the overarching things before we hand things over to Mike? Okay, well so, why don't we go over to Mike for a bit and then Michelle we will come back to you.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Okay, so hi everyone, this is Mike Lipinski, I'm the Director of the Division of Federal Policy and Regulatory Affairs within the Office of Policy ONC. So, I was just recruited today to talk to you about the NRPM. I'm not sure if there are slides for this, but...or what's your focus, I mean, I'd rather just if there are questions about the NRPM I can...if you guys have had an opportunity to look at it I can answer those or, you know, because I'm not sure we have a slide deck available as far as I know.

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

Mike, your presentation to the Standards Committee is available.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Right.

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

We just added that as informational to the group.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Okay.

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

So, if there were particular slides that you wanted to call on that we could look at them.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Sure, I mean, so this group focuses on implementation and then usability as well, right?

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Yes.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

So do you want me to focus on the whole proposal as related to the program or particular criteria? I can do either or both. I know it's a limited amount of time. So, I don't know if that's...

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

Yeah, I think the criteria would be most helpful.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

So, all the criteria or the ones focused mostly like on, you know, usability like the safety-enhanced design or...

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

Yes, yes safety-enhanced design.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Okay. All right, so I guess let's level set by going to, I think it's maybe like...can we try to get to like slide 30 I think. Okay, that one, that one is good, perfect, was that slide 30?

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

Yes.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

That's crazy. Okay, thanks, Michelle, I've been giving this too many times already.

So, this is I think a good slide, we worked on putting this together after the rule came out that kind of hits on every single criterion proposed in the rule. So, it also lies out like essentially what...and where they all fall. So, I guess, you know, there are certain certification program requirements which are the ones on the first two columns and just as a reminder, you know, with our rulemaking last year we said that we would no longer permit certification for complete EHRs with any future editions so this would be the first future edition. So, going forward there will only be certification for Health IT modules.

And for a module to get certified it's at the developer's discretion as to what they get certified. So, a Health IT module just to remind you is the same definition as the EHR module definition that we had before which was essentially certification to one criterion any software, service, product that would certify to one criterion would be labeled as a module and in this case based on a proposal Health IT module.

So, let's for example pick that you were going to get certified to one of the public health ones, that's my favorite example, so like ability to transmit to...create or transmit to immunization registries. So, a developer chooses to do that. Well these first two columns highlight what else they would have to do no matter what and so once they've chosen what they want to get certified to they then have to get certified...every module that comes through no matter what that first decision by the developer is, is going to have to get certified to a quality management system and then there is also, as proposed, the accessibility centered design which is patterned after the QMS criterion.

And then from there it depends on, you know...so in this instance with the example I've given there are certain privacy and security requirements that this module would have to meet and that particular example I've given with immunization it would be like authentication, access that's like (d)(1), it would have to be able to do the auditable events so that's like (d)(2), audit reports which is (d)(3) and also meet the encryption criterion which is (d)(7).

So, after that, you know, the selection was in this case the example I gave you immunization, which falls in that middle column which are all criteria that support the EHR Incentive Program Stage 3 as proposed. So, that's where the selection comes in and then that far column is also criteria and functions that include functionality that a developer can choose to get certified to but they're not associated with the EHR Incentive Program.

In many cases we worked closely with colleagues in HHS, the example I always like to use is the CQM filtering one where we worked with CMS and the functionality included in that criterion supports group practice reporting for CQMs as well as ACO reporting for CQMs.

I think the key is self-explanatory but I guess the one that's maybe not self-explanatory, if you're not familiar with our program or even if you are, has been minimally revised, so those three criterion highlighted in blue all that is changing there is the SNOMED code, the version of it we're proposing the most recent version so that's the 2015 version versus a 2012 version which you find in the 2014 edition.

So, I just wanted to give that framing right there. Before I go and talk about more criteria, particular criteria, are there any overarching, you know, questions about this structured proposal we have in our rule? Because I can spend some time, I know we have slides in here that talk about how you would support the EHR Incentive Program what you would need to meet the EHR Incentive Program, so we can focus on that, we can talk about, you know, any of the ones on the far column or we can dive right into like the ones, you know, QMS and safety-enhanced design.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Mike, its Larry Wolf, quick question.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Sure.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

The placement of the privacy and security things has shifted in this?

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Yes.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Could you explain a little bit...

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Yes.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

How that works?

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Sure, so I'll take you all the way back to the 2011 edition. So, back in the 2011 edition every complete, well complete EHR had to meet all the privacy and security criteria to make it a complete EHR but for a module they were essentially subject to that same requirement but they could show what functionality was inapplicable or infeasible to the module based on, you know, how that module was developed and presented for certification.

So, we took feedback we got on that approach and then in the 2014 edition we changed our approach, we said, all right, we'll just include all the privacy and security...

W

Who is speaking now Mike Lardieri?

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

We'll include all the privacy and security requirements in the base EHR definition so that's a definition that's included within the certified EHR technology definition. So, by that fact all providers had to meet the base EHR definition and so it then became the responsibility of the provider to ensure they had all the appropriate privacy and security capabilities that being a certified technology to those privacy and security capabilities, and the rationale behind that is that this gave flexibility particularly in a hospital setting that they didn't necessarily have to buy technology that had built in functionality because we heard from developers the certification process in terms of the inapplicable and feasible they would sometimes just have duplicates...they would just build in the functionality to get through certification and then the provider had duplicative functionality on their end then.

So, based on additional feedback on how this has all been working, and feedback including from our Federal Advisory Committees, we proposed a new approach now which takes that privacy and security capability out of the base EHR definition and makes it part of certification and the way it does that is, not to get in too detail, but we've essentially assigned by categories and maybe we can jump to the next slide so I can show you those categories.

All right so this is a good, I don't want to call it a cheat sheet for developers, but really just a tool to explain the policy in some respects. So, on that first column you see the buckets that we've always had how we bucket our criteria the ones that we think fall under clinical, ones that fall under care coordination. So, the column next to that starts to talk about, again, those privacy and security criteria. So, we've identified, so if you had any module presented for certification that, you know, was going to get certified to...let's just go with CPOE the first on the list, right?

And then we said, well, we think these are the capabilities that this module should also have related to privacy and security and we've identified them there which is essentially practically all of them except for (d)(8) which is integrity and then (d)(9) which is accounting for disclosures is always and optional criterion. And then that meant you had to do it.

So, you either showed you had interfaces to...or at least you would have to I should say, based on the proposal, you would either have to show that that's built into your EHR module or excuse me your Health IT module or that you could have...that there would be a way to connect through interfaces to that functionality for certification.

So, this way as discussed in the rule we believe that developers know exactly what they have to do to get through certification, providers don't have to worry about whether or not they've purchased a module that has the appropriate privacy and security capabilities that will all be done through the certification process.

And then, you know, as I said we identified, so there is no more inapplicable or infeasible, we've essentially said this is what should apply, but, you know, obviously this is a proposed rule so if you don't think those are the right, as a stakeholder, the right functionalities for, you know, each of these buckets of other functionalities like care coordination and so forth then, you know, we're looking for that feedback to influence the final, you know, approach and final decisions made through the final rule.

So, does that all help in terms of how the privacy and security works now? At least based on the proposal?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Yeah, I still have questions but at least I feel like I know where to dive in. Thanks.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Sure.

Paul Egerman – Businessman/Software Entrepreneur

So, Mike, this is Paul Egerman, I have a question on both this slide and the previous slide about...

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Sure.

Paul Egerman – Businessman/Software Entrepreneur

Self-developed software and open source software so if a physician self-develops some module...

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Right.

Paul Egerman – Businessman/Software Entrepreneur

That he or she wants certified but for their own use why do they have to go through safety-enhanced design and quality management, and similarly if you want to use open source software, you don't want to use the Vista system maybe you don't know what the quality management system was or the safety-enhanced design approach was but you know it's in use in a lot of different places and it's working well. How do you deal with that those situations?

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Well, this is...and I haven't gotten that many of them but this is one of those questions, comments that I have to ask you to submit that through the rulemaking process. So, good, you know, question/comment as to how these particular products would be impacted by the proposals. So I'd suggest you submit that as a comment on the rule...

Paul Egerman – Businessman/Software Entrepreneur

Well, and let me just say it seems to me that the approach is entirely a vendor approach that these systems are not installed entirely as vendor approaches, there are self-developed systems, there are open source and then there is interesting hybrids where people will use combinations of that or will buy a vendor supported software and then will customize it with paying an extra fee to a vendor to get it to work the way they want it to work in their own workflow.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Right.

Paul Egerman – Businessman/Software Entrepreneur

And it seems like a lot of this is based on the concepts that these are like products almost like devices that are the same everywhere provided by vendors but I don't think that's a clear description of the entire landscape of how the software is available to providers.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

I mean, I appreciate the thoughts but that's not one...I have some...responses for you for at least on the safety-enhanced design one, but it's an open comment period on a proposal so I would appreciate if you can submit that on the rulemaking, you know, through the process and then we can take that under consideration in finalizing, you know, any final...how this would apply as a potential final regulation.

So, I do...and I guess I should have said that from the beginning with an open rulemaking I can't clarify anything or add any additional rationale that is not already in the rule itself. So, what I can do is try to...you know like we've done with these slides try to put some of our proposals in a different format that may resonate more clearly with folks as to what we are proposing because we do understand there is a lot of reading and complex technical reading.

So, we've tried to, you know, use the slide deck to provide...present that in a different way, but again if it's anything related to clarifying something that may seem ambiguous or how it would apply, or, you know, that you felt that there wasn't enough rationale or something in the rule that I have to just ask you to submit as a comment which we can address through the final rulemaking process.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

This is Mike Lardieri, I have a question.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Sure.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

And I was concerned that, you know, with the module approach and we spoke about it in our group that if any module is going to send information out that it needs to conform with the Consolidated CDA. So, I see that in your third column but it's not in every row and have you folks decided that where it's not in the third column that this module would not be sending information out?

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Right, well it wouldn't be...that module wouldn't be being tested to any criterion that had the Consolidated CDA in it. So, where is an example where it doesn't apply...

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Well like in clinical quality measures.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Yeah, so clinical quality measures is using the QRDA not the Consolidated CDA so we don't test that one to the ability to create the appropriate Consolidated CDA and then you know (d) is obviously the privacy and security criteria, public health again they have their own content standards there and then the (g) ones are like the...kind of that we call them I think like, I can't remember, like design certification maintenance and design, so those are like your automated measure calculation criteria, your safety-enhanced design is in there. So, I mean where the Consolidated CDA is referenced in a criterion then you would have the creation performance requirement on that module.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Okay and does it go both ways? Does it go...does it require the ability to send out and also accept data back in from a CDA or just sending out?

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Just sending out, I don't...I mean, I think only with the care coordination one (b)(1) is the only one where we actually test the ability to receive a Consolidated CDA off the top of my head.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Okay, thanks.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

I think that's right. So, I think you guys are probably well versed in the framework of how we're...the proposed, you know, just structural changes to the program and how we're making the program more agnostic but I'm welcome to...I'm open to talking some more about that or we could shift right now...I can either talk through some more of the criteria about how they support the EHR Incentive Program, I know we have some slides on that or we can just, like I said, delve into safety-enhanced design or QMS.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

I would say let's go to safety-enhanced design if that's okay?

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Sure, I mean, again, we put a lot in the rule on it so...and I can't talk beyond that, but maybe there are questions I can answer on it. So, who is working the slide deck? Can we go...I think we need to go back the other way until we get to like maybe the patient...well, this is the Health IT Standards Committee deck. I still don't think we have a specific on safety-enhanced design, but if you can go back to the patient safety slide it's called I think Health IT Safety or something proposal.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

How about slide 20?

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Okay, yeah, I don't have...I can't see the pages in front of me so I'm just kind of going...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

It might be 21, patient safety proposal it starts with patient matching...

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Yeah.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

It has a sub-bullet for safety-enhanced design and a sub-bullet for QMS.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Exactly, exactly. Okay, so the safety-enhanced design, it is pretty much the same in most respects as to the 2014 edition safety-enhanced design criterion if you're familiar with that and that was the first time we had proposed and finalized the criterion, what you called safety-enhanced design, which is about user centered design, which is then essentially about, you know, usability. So, what we did in this criterion and have you guys had an opportunity to talk about it yet or no?

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners

We have.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Okay, so you’re probably somewhat familiar then with the proposals related to this but we are proposing to expand the application of this criterion to more...other functionality and thus other criteria, so for instance demographics I believe was one of them, there are five I think that are new if I can find it somewhere, so demographics, the new proposed vital sign criterion, the implantable device list, the two decision support criteria that we proposed, I believe that is all the...maybe there is...I think there might have been two more, I think there might have been seven, oh, yeah labs and, do I have the other one somewhere here...I can’t remember what the other one is. Well, I apologize for that, I’m not seeing...

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

Demographics, demographics...

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Yeah, maybe demographics, one, two, three, one two... in any event it’s in the...it should be in the preamble of the proposed rule actually it’s page 16857 of the proposed rule but there might have been like a highlighting issue because I’m looking at it now...oh, problem list I think is the other one that’s the one I forgot to mention.

And then obviously it’s still the same NIST standard 7742. What we found though through testing and certification is I guess our intent was not clear with the 2014 edition as to what information needed to be provided by the developers in terms of the test results that they submitted and then what would actually make its way to the certified Health IT products list. So, we provide more clarity through the actual criterion itself in terms of what information needs to be provided now.

Another specific area worth mentioning is the amount of what the testing group would be, how many representatives they should be and the makeup of that group, you know, the cohort we’ll refer to it as or the users, where we’re requesting comment on whether or not that should be specified as a requirement or if it should just be guidance based on the NIST guidance provided in that regard.

So, right now...so that’s something that you will find within the preamble not necessarily in the Reg text but, you know, based on comments that we get it could end up as part of the final rules, certification criterion.

And then we provide some guidance within the rule about like how you can meet user centered design. Is there any...I mean, I can try to answer some questions, but again, I have to be true to what we said in the proposed rule. And that was conditional application as I said, I think there’s a total of 17 criterion which if a module was being certified to one of those it would also have to be certified to safety-enhanced design.

Hearing no questions I can move onto quality management system. Okay, so again, this criterion was first proposed in the 2014 edition and as you recall our rationale behind that and the discussion both in the proposed rule and the final rule we talked about it being as a first step related to the certification of Health IT to quality management systems and it might be worth mentioning here, while not in the rule and not a justification for the proposal itself, we do reference both the safety-enhanced design and the quality management system criteria as part of our...the initial FDASIA draft report which was issued last April and how that focused on health management Health IT and how that related to FDA's regulation over that type of Health IT.

And if you remember the 2014 edition, just to give you a little more background, we talked about creating, in the proposed rule, a QMS just specific to essentially EHR technology or, you know, health management Health IT. When we got to the final rule that had not happened, the development of that standard died. So, it was abandoned in that final rule and again here you don't find that proposed either.

What we've said is we've identified some QMS standards to which you could, as a developer, meet for both implementation maintenance, development of your product and then identify that. So, it's still essentially an attestation way of meeting the criterion so versus say demonstration or a conformance tool, in this case it still remains, based on the proposal, developers can attest to what standards the developer meets, QMS standards that is, identified, you know, SDO ones or federal government ones, or the other option is, which is again the same option within the 2014 edition, is to show how their QMS that they've developed for their products maps to identified SDO standards or federal government standards.

And so what is different, the big difference, is we no longer propose to allow a developer to attest that they do not use a QMS system, so that is permitted currently under the 2014 edition and as you recall the rationale behind that was that this was a first step to testing and certifying Health IT to quality management. And so with this new rule or proposed rule we're proposing to abandon that option for meeting this criterion.

I could talk to the accessibility centered design one if you want as well. It's essentially completely patterned after the QMS one from the 2014 edition so everything I just said is how it's set up for the accessibility center design you can meet that criterion without...you can meet that criterion by stating that you do not use accessibility centered designed or do not use...or you've not developed your product to meet any standard for accessibility I guess is the best way to put that.

The one, you know, point to make about that is, oh, with the fact that we're converting the certified Health IT products list to an open data file that information should be more easily and readily available to stakeholders and that is for all data including the safety-enhanced design data test results that will be provided through certification will be more readily and easily available to stakeholders to download, analyze, you know, whatever, aggregate, compute and reformat and make that available in another way on another site to their interested stakeholders.

So, you know, associations that are interested in accessibility and whether Health IT is meeting, you know, requirements, whether it's 508 or otherwise they can do that type of analysis and let the market decide, you know, consumers what they think about the products that have been certified and how they meet or don't meet accessibility centered design standards.

So, those are like the big three and I've talked about privacy and security, so those are kind of like all the criteria and we actually even touched on the Consolidated CDA one. So, we've actually touched on all the functionality and requirements that are really just strictly part of the certification program as proposed. So, again, any questions on those?

Paul Egerman – Businessman/Software Entrepreneur

So, Mike, its Paul Egerman.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Sure.

Paul Egerman – Businessman/Software Entrepreneur

On the QMS system...

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Yes.

Paul Egerman – Businessman/Software Entrepreneur

You have to be compliant with or map to one of the QMS established by the government. Does the NPRM list all the QMS systems that are established by the government? Is there...

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

It does not, I don't believe...I mean, we used just a preamble as an example so we have not I guess, you know...so I guess we've not identified potentially all QMS systems. I mean, we worked closely with FDA in identifying which standards we did in our rulemaking and the prior rulemaking, but I personally cannot say that we've caught every, you know, potential standard that would be justifiable in terms of meeting for the QMS process.

Paul Egerman – Businessman/Software Entrepreneur

And is that a static or a dynamic list, in other words, if the rule is issued in like...

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Right.

Paul Egerman – Businessman/Software Entrepreneur

Six months or a year after the rule is issued the government establishes a new QMS system does that new encounter...or do you need a new rule for that? In other words does it just relate to the one that's established...

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

We wouldn't need a new rule because the rule would not...

Paul Egerman – Businessman/Software Entrepreneur

At the time the rule was made?

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Yeah, so, there wouldn't be a need for a new rule because, again, it's any recognized federal standard or SDO for QMS so really I guess the issue would be, from your perspective, you know, what constitutes a QMS standard, I think that would be readily known based on the SDO's work and/or the federal government's identification of it.

You know at this point I'm not going to like...you know, could somebody argue that doesn't apply to Health IT or so forth, you know, that's to be determined later on, but we don't say it's got to be one of these groupings of a recognized standard we just say that it has to be a recognized standard or mapped to one of them is what has to be shown.

So, I know I've actually gone maybe even a little longer than initially we intended. So, I don't want to get you guys off topic. I can join again later I do have to go for another call but I can join later if you have additional questions or if you feel I've given you the overview you need then I guess won't need to come back.

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

Thanks, Mike, why don't you just pop in at the end if you could, we appreciate you coming on...

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Okay.

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

And spending time with us.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

All right, so if anything else pops up during the rest of your discussion I should try to be back on about quarter after four, right, you're going to 4:30? Is that a good time for you guys if I come back on?

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

Yes.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Yeah that would be a good time.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

All right, thank you so much, appreciate it.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners

Thank you.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Okay, bye-bye.

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

Bye. Thank you.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners

Well, I find all of this complicated, but maybe others do not. Let’s go back to Michelle to take us back through the rest of the group three comments.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Okay, it sounds good. So, now we’ll move into the actual sections of the NPRM that were assigned to us. On the next page is the first section and it is pretty clear this one basically is a fairly concise section that says that they’re going to...they’re proposing to replace the term HIT with Health IT and also replacing the term ONC HIT Certification Program with ONC Health IT Certification Program and then removing the statute related to certification of health information technology other than complete EHRs and EHR modules. So, we reviewed that and in the end we did not have any concerns with those three changes. Let’s stop there and see if others have any discussion to add or comments to add?

Paul Egerman – Businessman/Software Entrepreneur

Well, this is Paul Egerman, and I’ll try my best to be brief, but I disagree with switching from EHR to HIT. I’ve made this statement before I think the certification process should be focused on privacy, security and interoperability and not a lot of functionality for lots of different areas.

I do see one advantage from switching from the HIT to EHR which is in my word processor every time I put in EHR it changes it to HER and now I won’t have that problem.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Thank you, I’ve got it. All right, so the...you’ll see the theme again this will come up in a few different ways on these next modules, so the next one is the ONC Health IT Certification Program, in this one, in a nutshell this section that was on page 12 of the NPRM replaces prior rulemaking and how they use the term EHR and EHR technology with Health IT so with the abbreviation.

And then it talks about the intention or the rationale for this change and this is where they talked about the intention originally was the certification rule that would on inpatient mandatory settings and the rule would permit other types of technologies to receive attribution that aren’t necessarily EHRs and it also allows certification to be referenced by other care settings.

This section also asked for comments about decertification for blocking of the sharing of information and so the Workgroup pulled together...so we discussed this and had a number of comments related to it.

So, if you scroll to the next page I believe, okay, so we...as a whole we agreed with the term changes as we said before and you'll see that consistently stated, that we see that potential to engage a broader set of stakeholders that need to interoperate and those that need to interoperate with those ambulatory care and inpatient settings that don't have a mechanism because of the design right now to be interoperable.

And we agreed that the approach allows other programs like other health and human service agencies, other public programs, private entities and associations to reference certification and you'll see later on that that's already happening now and referencing the certified Health IT but this is where our first discussions began around the complexity of the program in driving up costs as there are so many multiple different certifications as you cobble them together have to go through each test that it could be more costly for certain types of systems.

The NPRM listed specific examples of those systems or technologies, or providers that could be served or included in this approach to certification and included health information exchange organizations, the HISPs, lab information systems, LTPAC providers, behavioral health providers and so in our discussion, you know, along that line we also identified others that are in a similar type of a role where they're exchanging information, electronic information and certification may be applicable to them, and they may not be...may not have thought of it as applicable to them and we just give examples of different types of services like pharmacies.

We see work being done in the long-term services and supports in the S&I Framework and some of that work with other providers not eligible like ambulance and blood banks that have information for certain specific purposes who's systems they provide services and their systems have to exchange with different providers that may find the modular approach applicable.

And then we just gave other examples of providers beyond LTPAC and behavioral health, some of the areas around devices and device makers and telehealth and monitoring maybe applicable as well as health and wellness.

So, in terms of the decertification this group had a different approach, I think the last meeting we talked...there was discussion around decertification, and we had already had the conversation, we revisited the conversation and we didn't have the same like, no there should never be a decertification process for bad behaviors, and so that's what we basically state here is we think ONC may suggest...should explore levers and authorities that are available to them that discourage bad behaviors that would prohibit interoperability and blocking of information sharing may be one of those.

And that we thought that one of the potential actions to discourage these bad behaviors could be decertification. We also recognize that decertification may happen all the time because we had talked about the challenges and tension, and apprehension it can create in the industry that need to be addressed...in the case where there is an entity that's purchasing an Apple Kit system that's certified and assumes it will stay certified, but we also recognize that choices are made not to maintain certification to not to maintain certification of a certain version or application and so there are processes that have to be in place, but we felt like there should be some transparency about what those bad behaviors are that discourage the sharing of information.

And we recognized that decertification would be...in this case would be handled...likely handled through ONC, ACBs with the testing process and not that we necessarily were advocating for a whole separate extensive reporting process but we did note that the blocking of information may not necessarily reside with just the system that's certified that this behavior can happen by any entity.

So, for example a provider could chose to turn off functionality or features and implement processes or practices that would limit sharing and so...and then also that there could be very legitimate practices or reasons or factors for that and I think we talked about that a while as well.

So, we recognize that this is a complex issue but one that ONC should use its various authorities and levers as well as HHS to explore. So, comments on that?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

This is Mickey, I have a comment on the first part of the discussion when we were talking about the other programs leveraging it, leveraging the HIT. Did your group talk about...I guess in my mind the initial premise of certification was that certification would ensure providers that if they bought a product or owned a product that this product would be capable of helping them...of letting them achieve Meaningful Use, right, and that was, as best I recall, kind of “the primary” purpose of the program.

So, now with this...there seems to be a fundamental shift where now there is a lot of certification and capability and then various programs can, if they choose, leverage to say “well, if you want to participate in this program then you need to have this version” or “you need to be...the products need to be certified of this module.” But it's not inclusive and it's just kind of a set. So, that premise seems to have gone away that certification would enable providers to be sure to meet a program. Did you discuss that at all on the Workgroup?

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

So, we...and I might have other people on the Workgroup certainly jump in as well, so we discussed a variety of things because the decoupling from the Meaningful Use Program and specifically how it's going to be done is on another section that we reviewed, so we knew what was coming in the sequence and somewhat reordered it.

So, I think we were particularly focused on the fact that other...well, two things, that the certification program is an evolution there was a certification program or process prior to the Meaningful Use Program it was voluntary obviously...so it's not the first time with the EHR Incentive Program, this isn't the first time certification has come.

So, to some respects we saw this as the natural evolution because the Health IT Policy Committee has...a year ago, more than a year ago prior to 2014 had the testimony about those who are looking for certification paths who have requirements that are seeking that the technology they use be certified and yet the way the program is designed it prohibits them to do so because it's so tied into the Meaningful Use Program. So, you know, our discussions were more around there, the limitations and challenges because of these various factors that were coming in.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

And this is Mike Lardieri, I'll just add onto Michelle, so a number of programs on the behavioral health side that SAMHSA runs they require certain components of, you know, two years ago it was a certified EHR but you didn't have to use everything, but you had to be able to send a Consolidated CDA or a CCD back then, you had to do ePrescribing and you had to have one clinical decision support implementation or implemented. So, that's happening now so that's why we thought this would be good because this way it allows states or programs to say, you just need these three modules in order to meet the terms of these programs and we'd have some assurance that if providers use those modules they'd be able to share information back and forth would be the most important thing.

Paul Egerman – Businessman/Software Entrepreneur

So, this is Paul, I just want to follow-up on what you just said Mike. You mentioned an important comment that certification is not just for Meaningful Use it's going to be used by other jurisdictions and other agencies for other purposes.

So, the problem with that though is you put in some certification criteria in this NPRM and it's voluntary in the NPRM and so a vendor or a provider doesn't pay any attention to it because it doesn't seem to apply to them but then some state government says, oh, you've got to...your running a long-term post-acute care setting you've got to do these three things that are in the federal standards and now all of a sudden something applies to you and you didn't even know possibly that they existed and never had any chance to comment on it.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

You know and we do...

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

...

Paul Egerman – Businessman/Software Entrepreneur

I'm just saying, how is that fair to put something forward here in certification that it's not clear where it's going to be used in the future...

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Well...

Paul Egerman – Businessman/Software Entrepreneur

But it will be used possibly by somebody, right?

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Yeah.

Paul Egerman – Businessman/Software Entrepreneur

Why can't you wait until somebody decides they want to use something and then go through a normal regulatory process. It just seems like the regulatory process here is potentially unfair.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Well, I...in my view Paul, this is Mike again, in my view I mean that's already happened even under the Meaningful Use...it was Meaningful Use, behavioral health wasn't included then some programs came through and they said, okay, you'll get money from the federal government SAMHSA or in some states they had certain programs, but you have to have these functionalities.

They didn't...I don't know it now what's going happen two years ago or two years from now I would not want to wait for a whole certification process before I could jump in, I'd want to build on what's available now. I mean, that's the reality of what's happened already.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

This is Mickey just one other comment to add to Paul's that we have been thinking about a lot is, so let's just say you're a given vendor and you say, okay, based on my customer base or, you know, I think I need to get my product certified on these modules and then, you know, you go through the process you get certified and then, you know, a program opts to refer to modules that you didn't get certified and then that... you might need a whole other round of development in there that that's really...there is no kind of timeframe or leeway time when a program can say, all right I'm going to require these modules then all of a sudden none of the products or only a handful of the products are certified towards that...

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

I think that...

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Because any program can kind of designate at any time.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

So, that was I think something we discussed as a risk and it's going to come up in one of these sections, but I generally think that's something that should be in our comments because the recommendation is it's going to be coupling from what does the program require and like I said you'll see...and the rule gives examples, we give additional examples, it's happening already.

But with all these different modules how do you manage the various different parties or entities or authorities that could be requiring compliance with certain modules. So, I think that's a really good thing that we should definitely highlight.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, it's Larry, I want to jump in on this notion of other programs referencing the certification criteria. Those regulations go through a regulatory process so just like we're seeing proposed rules and final rules, and comment periods the other regulatory agencies have similar intervals to publicize that they're rules are coming into play in time for public response. So, I don't think we...

Paul Egerman – Businessman/Software Entrepreneur

Only if it's a federal agency Larry. Isn't that only for federal agencies? I mean, a state government...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Well, states...

Paul Egerman – Businessman/Software Entrepreneur

...they don't have to do that.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Well, you know, states can choose to do all kinds of things Paul and it doesn't matter if there is a federal program or not.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

The other thing is those rules...it's true in a lot of cases that there is a regulatory process but it doesn't take into consideration like the ONC's rules do that software development needs to happen in those timeframes. They're typically on a much faster timeline than say the certification rule.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, plus if there is a regulatory process there won't be an opportunity to suggest a change to an existing standard that was already part of...where there is already a regulation. So, that...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Yeah that's for sure but hopefully there's also existing code out there that supports the need and can demonstrate the supportable use. I think this argument cuts both ways.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Yeah and this is Mike again, one of the comments we made is that ONC as the coordinator, I guess that was in our overarching comments, we'd like to see ONC coordinate with the rest of the Feds and also with CMS to encourage the states to use the modules that are approved already and not to add different modules so that they should just use one of the modules two, three whatever number they need for their program of the modules that are already approved so developers don't have to go do something for a specific state it would have already been one of the 20 modules or whatever, total number there are that were already developed. Maybe that vendor decided not to develop a specific module at a specific time, well that's just like a business decision they didn't do it at the right time.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

All right...

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

All right.

Paul Egerman – Businessman/Software Entrepreneur

Can I just make a comment also about the data blocking aspect of this?

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Sure, yes.

Paul Egerman – Businessman/Software Entrepreneur

I don't think you need to necessarily repeat the last discussion, I'm pleased that you did make reference to the idea that data blocking could come as a result of a provider's business practices as opposed to a vendor's business practices although the way the NPRM is written if a provider decides to block data the remedy is to decertify the, you know, the product which means it effects not only that provider it effects every other provider who may not have blocked any data. So, it seems like an odd remedy.

I also want to point out that this expansion to HIT creates another problem for interoperability and data blocking in that you now are talking about interoperability with entities that are possibly not covered entities and possibly you do not have a business associate agreement with so that could include vendors who provide software for mobile devices who could use the data for selling data, it could include organizations that providers might not like maybe it's faith healers for example, it could include alternative medicine providers, acupuncture people and as currently written, the way I understand this, a provider has to provide information to all of those and it seems like that's really a major change in the privacy and security environment.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

So, just my read or take was that they could...those who have systems that support those areas or create systems could choose the certification option. So, I'm just trying to understand, just to get it down for our comments...

Paul Egerman – Businessman/Software Entrepreneur

My issue there is an issue about data blocking...

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

...okay.

Paul Egerman – Businessman/Software Entrepreneur

There are good reasons why a provider might want to block data and the...so there's two comments one is there are good reasons to block data. Secondly, the provider might be causing the data blocking as opposed to the vendor and third, just expansion beyond EHRs means you're expanding to organizations where HIPAA is no longer applicable...

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Yes.

Paul Egerman – Businessman/Software Entrepreneur

And have we considered the privacy and security aspects of that.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

I think those are really important comments because there are so many nuances to this and I think we just continue to bring out more and more around it that it's not a simple solution with decertification.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

This is Mickey, I would just add to that, I mean, I think it's very difficult to say you would decertify...so there is certification requirements then if a product isn't meeting those certification requirements that's fairly...it's gray, but, you know, black and white and you'd say, okay, well, I'm going to decertify them.

Now we're talking about all these other things that could potentially come into it. One, there is no criteria of which they were evaluated against in the first place and as, I think it was Paul pointed out earlier, certification only applies to the vendors and, you know, I think it's clear from this data blocking discussion that's happening across the industry there are hundreds of reasons that could be considered data blocking and I think we're at the research and study phase as opposed to the decertification phase.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Yeah that's a great point. All right.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Yeah, I think, this is Mike, in part of our discussion we identify that in the reporting, the reporting should be able to accommodate whether it's the provider who is doing the blocking versus the vendor because like Paul said, you don't want a vendor decertified for all their customers just because a provider is doing the blocking.

Paul Egerman – Businessman/Software Entrepreneur

Well, it also to me doesn't make sense that the vendor would be blocking because the vendor passed certification.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Right.

Paul Egerman – Businessman/Software Entrepreneur

You know to me it's more equivalent to the idea of saying, well gee if you had a CPOE system and a physician ignores all of the advice that they get from the CPOE system therefore you're going to decertify the vendor now the vendor has no control over what really happens there and if the vendor passed the CPOE certification criteria they're sort of like done as long as it still passes. The same would be true of all the interoperability stuff, if it still passes it's really up to the provider to decide what they're going to do with it.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Good discussion I think I'm going to keep us going if that's okay.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Yes.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Yes, go ahead.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

All right, the next section really overall on the next page, the modifications again to ONC Health IT Certification Program, this is on page 251, so in some aspects there are different parts of the rule kind of maybe honed in on certain things.

So, this is the section that reiterated language from, I believe it was in the 2014 voluntary edition, proposed rule, they cited their authority for being able to expand the program so Paul I think this maybe the section you want to read.

And then it goes through a discussion that many have asked for that expansion of the program and that the outlined approach was meant to be more open and accessible to those who have been closed out from or prevented from participating in the certification program and so the Workgroup's comments were that we agreed with this approach beyond the EHR Incentive Program expanding beyond EHR technology only would begin to address that.

And we did have concerns, although in listening to our discussion earlier by Michael, about whether those modules could interoperate, we had some discussions there and we didn't see a practical way for that to be incorporated into certification. So, again, we've talked about this a bit already so I want to see if there are any additional comments?

Okay, the next section is on the certification of EHR technology definition and basically this section is proposing the removal of the statute around the certified EHR technology definition and that the definition would reside within the EHR Incentive Program regulation and so...the next section actually talks about some of the references to these other rules and what's happening today and I know we've talked about this a bit already so this is just kind of that segue into that discussion that the intent is to move that definition into the EHR Program, EHR Incentive Program regulation...

Paul Egerman – Businessman/Software Entrepreneur

Well...

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

And we agreed with that in context.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul Egerman, my comment is, this is just really another way of saying that the certification program wants to grow so that it's much bigger than just the EHR Incentive Program.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Right.

Paul Egerman – Businessman/Software Entrepreneur

And that's obviously something I object to, but I would appear to be almost alone in that.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Well...

Paul Egerman – Businessman/Software Entrepreneur

That this program is increasing pretty dramatically in size and scope.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

This approach certainly gives it the...and our Workgroup discussed this, the possibility of significant growth and applicability.

Paul Egerman – Businessman/Software Entrepreneur

Sure.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Broader scope definitely, yeah, and in these sections then the discussion was around the requests. There have been different testimonies and things like that from those entities asking for these changes and so this was the approach to address it. All right any other comments before I move to the next section?

All right on the next page, on the next section this is referencing ONC Health IT Certification Program on page 256. This is the section that actually gives examples of where the existing law or regulation statutes are currently referencing the certification rule and, you know, how it could further permit this approach then further permits this referencing and the use of certified Health IT.

And so we gave other examples some of which we've already talked about and so beyond...for example, I think one of the examples they provided was the reference to Stark and the Anti-Kickback Rule had, you know, prior to the EHR Incentive Program had a reference to certified technology and then there were others that were listed and so we also added on, we've seen states who have required the use of certified technology for all of their providers without...where the program was designed not a way for all of those providers to get certified through this process and Mike talked about SAMHSA and some of the requirements for their grantees for certain modules.

We're seeing other examples, for example health homes in New York I believe they have some requirements around EHR technology or certification technology for those who interoperate in their health homes. So, we had some additional examples to provide as well.

Our concern was, you know, where we see advantages to allowing the certification process to be just a certification process and not the, you know, who must do what, when, you know, what's required in pushing that to those authorities that may already have established expectations or rules around how technology is used or managed, what may be contained in electronic records for example so that they would identify which modules would be applicable but that we were concerned about the scope of how many organizations or programs could set their own rules, how they might conflict with requirements of the base certification and asked for consideration of, you know, how can ONC help with alignment and consistency and use some of the authorities with HHS to encourage for example state Medicaid Programs to align with the base, you know, how do we prevent let's say that base from being eroded or that chaos from occurring when entities, you know, with authority could be expanding, modifying, tweaking, adding on, you know, and so then it becomes chaos.

And these are messages we've heard from other providers who have tried to connect we'll say with various different HIEs and different processes and how difficult it is because everyone has their own methodology for doing it and so it kind of reminded me of that process where different entities could be requiring their own unique approaches to...and twists on the certification module and that's a comment there. So, I'll open it up to other comments or thoughts? I know we talked about this earlier and had a bit of discussion, so last call before we move onto the next section.

Okay, the next section is around types of care and practice settings, this is on page 254 of the rule. And this section specifically called out that they wanted to focus on two care settings that were left out of the EHR Incentive Program that regularly routinely need to be interoperable with both acute and ambulatory care settings and, you know, issues and challenges have come up with the ability to send information back and forth.

So, basically it talks about...this section talks about the need to make the program agnostic to care and practice setting and so why we moved the Meaningful Use, and they are proposing a new data segmentation certification criteria and asked for comments on additional needs by these sectors as well as commenting on an assessment and so, you know, we reiterated our agreement with the expansion to allow additional care and practice settings be included.

We also agreed with the establishment of the data segmentation certification criteria but recognized that some of the work done so far is specific to a certain case and a fairly narrow application and encouraged that increased functionality continue...increase work in standards development continue so that it can move beyond what we have...what's currently in place for data segmentation.

Related to additional needs and these sectors, you know, some of the areas that were important in, you know, identity matching we've talked about but bidirectional exchange is also very, very important to these sectors, advance directives, telehealth and monitoring, and assessments are specific areas that we called out.

And then talked about the...with respect to the assessment topic, the group comments were specific around aligning with other requirements that are emerging in this space in both the LTPAC and behavioral health area, so for example the IMPACT Act was legislation that congress passed in the fall of 2014 that required standardization of post-acute care assessments and so we would want to see...this is a significant area in which the data is used for multiple different purposes. This is an opportunity for certification and an opportunity for coordination across entities and then also gave examples of behavioral health assessments that would apply as well where the current processes require a lot of rekeying and duplication of efforts and standardization would help create some efficiency in reporting and reuse. So any comments on that section?

Paul Egerman – Businessman/Software Entrepreneur

Yes, Paul Egerman, my comment is you're sort of looking at behavioral health and long-term post-acute care as outside the scope of the incentive program but there is a part of the behavioral health process that is inside the scope which is the psychiatrist and psychiatrists actually have a fairly low level of adoption compared to other specialties and compared to primary care.

And what would make sense since they are part of the system would be if we're really going to focus on behavioral health would be to try to understand what special needs psychiatrists must need, must have and then find a way to get a higher level of adoption by psychiatrists.

I mean, I look at behavioral health and long-term post-acute care together and the thing that they have in common is something simple is they don't have any money and the absence of money makes it hard for them to buy these systems.

And in one case where there is incentive money available it seems to me ONC should be trying to see if there's something creative that they can do so that the psychiatrists, more psychiatrists are able to qualify.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

You know Paul this is Mike, so I look at it a little differently, you know, psychiatrists, yeah we want more psychiatrists to qualify but the professionals who deal with the more seriously and persistently ill, and the ones that are the higher costs for healthcare are not the people who are going to individual psychiatrists they're the ones who are going to clinics and safety-net providers in the clinics where you probably have one psychiatrist that supports 10 or 12 social workers, psychologists, counselors and they do the medication management but all these other folks are doing the actual treatment and that's where all the care coordination has to happen in those settings more than just with an individual psychiatrist setting.

I mean, I want psychiatrists to get more money as well, but if you're in these other settings you need to be able to...that's where the care coordination is paramount not so much with the individual psychiatrist because it hits all those really high cost people.

Paul Egerman – Businessman/Software Entrepreneur

The point that I'm trying to make and maybe you have a better idea as to how to do it, if we want to help behavioral health we should try and see if there is a way that more of the existing incentive money can go towards them...

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Oh, yeah, oh, yeah.

Paul Egerman – Businessman/Software Entrepreneur

Which means physicians and social workers don't count according to the current process, but if there is a way to do that that's something that ONC should be exploring and that would also...that money would be used to buy the appropriate computer systems...

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Yeah.

Paul Egerman – Businessman/Software Entrepreneur

Otherwise we're creating standards for people who can't afford to buy the systems.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

But I...

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Well...

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

I just want to add in because I think you've definitely hit on an important challenge but I think we also have to recognize what's happening because with the EHR Incentive Program and the need to exchange with providers that their care, you know, they're care partners with that these entities are being asked to sure up systems, upgrade systems or, you know, interface in order to participate in new models and so there isn't an efficient way and because there's not necessarily one way that fits and so this could potentially be a lower hanging fruit approach by, you know, focusing in on a handful of standards that will allow that care coordination or communication to happen versus having to adopt to every...and pay for all the various interfaces to connect.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Right.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

So, just another way of looking at it and I don't disagree with the incentive funding discussion.

Paul Egerman – Businessman/Software Entrepreneur

Right.

Joan Ash, PhD, MLS, MS, MBA, FACMI – Professor & Vice Chair, Department of Medical Informatics & Clinical Epidemiology – School of Medicine – Oregon Health & Science University

And this is Joan, and I'd like to also point out that the behavioral health folks when they talked to our prior Workgroup were very encouraging for us to take this direction but also the long-term care people who talked to us were beyond encouraging they were really crying out for this sort of thing and that's what really struck me was that they really need help and this is a way of helping them.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Okay, any other comments? All right hearing none.

Multiple voices

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Then moving onto the next section. Okay, this was on the removal of the Meaningful Use measurement certification requirement, it was on page 253 and basically the NPRM provides their intent to remove the statute related to automated numerator recording and automated measure calculation.

So, we certainly understand in the spirit of what the rule is saying and changing that we'd move that...you need to move that out, although we were at the same time concerned that if there was a regulatory component that still required that capability to calculate the measurement and/or report it that this could create frustration as well for those program providers that they still need a mechanism to have this done and, you know, now there isn't an assurance, we'll say, that their system can do that for them. So, want to open that up to comments as well.

All right, not hearing any...

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

This is Mike...

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Oh, okay, Mike?

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

I guess my comment on that would be if that calculation requirement goes away and the modules do not have to do it, they don't have to do it, but they might do it, so I think it's important on the CHPL that the CHPL identify that a certain module does do the calculation because if I'm a small provider I'm going to buy something and looking at something that does the calculations already that if I still have to report on them that's going to be important to me than having to buy that and then buy something else that's going to do the calculations. So, it should just be transparent whether a module does or doesn't do it if those measurement calculations are still going to be required.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

All right. Anything else, any other comments? Okay, hearing none, then moving to the next section, this was on a base EHR definition and certified EHR technology definition. And basically this referred to the fact that there still is a designation for base EHR definition specific to 2015 and why that would be done and they requested comments about where there were differences.

And so our main comment was around some of the things that were included in that base EHR definition that may not be applicable to all the various let's say care providers or service providers that it would still apply to and does there need to a process that separates data creation from how that information is received or handled. So, that was our only comment about does it apply in all cases with this expanded list of providers. So any comments on that?

Okay, moving to the next section, this was on pharmacogenomics data and the request for comment around that Health IT systems should be able to capture this information to increase patient safety and enhance patient outcomes and we certainly saw the value and also the fact that this work, and the standards work related to it, is still in its early stages and so we encouraged a process that highlights priorities, future priorities like this but stopped short of requiring certification particularly where there is a lack of foundational standards that are mature enough for the certification program but it sends a signal that an early prioritization allows the industry and/or ONC to address those gaps in the standards prior to being fully integrated into the program at a future date.

W

...

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

So any comments on that? Any thoughts on this kind of a stepping stone approach or early prioritization?

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners

I mean that sounds reasonable to me, this is David Bates, just there aren’t that many use cases for which you really need the information today and the standards work, as noted, you know, has a little bit of a ways to go.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Yeah, well, I mean, we talked about the...

Joan Ash, PhD, MLS, MS, MBA, FACMI – Professor & Vice Chair, Department of Medical Informatics & Clinical Epidemiology – School of Medicine – Oregon Health & Science University

This is Joan...

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Frustration...

Joan Ash, PhD, MLS, MS, MBA, FACMI – Professor & Vice Chair, Department of Medical Informatics & Clinical Epidemiology – School of Medicine – Oregon Health & Science University

I completely agree with that because this is just a little bit ahead of the game and there are so many other patient safety priorities that to put this on the back burner for a while I don’t think would be a problem.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Yeah and it allows...if it stays as a priority...if there is a way to identify a priority it allows the industry and those stakeholders who are most knowledgeable to rally around whether it’s standards development or inclusion so it isn’t a frustrating process at a point that it may be fully integrated into certification.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

This is Mickey, just a point kind of tangential to this is there are many standards in the rule that are not ready to be implemented across the United States in multiple areas so I think if we agree that this maybe goes in the general comments, but, you know, a couple of people just made that point on this one area, there are many that aren’t...

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Yeah, good point.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

In stage.

Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

Yeah or they may be applicable in some settings and not others because of how they’re designed. So, I think that’s a great consideration for overarching comments.

Paul Egerman – Businessman/Software Entrepreneur

Yes, this is Paul, I agree with what was just said. So, I'm wondering if we could broaden this comment to say that. That the certification process should not be used to, you know, create standards where there is really no existing standards in common usage already in place. There is actually a huge amount of that in the NPRM on all kinds of interesting things.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

I think we can flag that for later on.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

Got it, all right, anything...any other comments before we move to the last one? Okay, hearing none the last was around the design and performance, it basically was around the modules for safety-enhanced design, Consolidated CDA, creation performance, quality system management, accessibility centered design and so we recognized that maybe a lot of the experts in those areas were in a different Workgroup, had to wonder if maybe we weren't supposed to have this one somebody else should have.

So, we didn't have any specific comments but also thought like a discussion from the broader group would be warranted to capture comments that we should consider around this. For example, so I jotted down two that I heard earlier, I think Paul you mentioned how do self-developed and open source Health IT, you know, software how do they address the safety-enhanced design quality system management module and what I heard Mike say is that it's not known and that would be a good thing that we would need to submit in comment so that could be one addressed here.

And also the discussion around what constitutes a quality management standard, do we readily know what it is, it was kind of a fairly open definition or pretty broad definition and there isn't necessarily one designated list and maybe that's good. So, just wanted to start there and see if there are other comments in this section. And perhaps another section that or another group has already addressed this and it's a matter of consolidating comments over other groups.

Paul Egerman – Businessman/Software Entrepreneur

This is Paul the only other comment I might add would be to say through all these design and performance concepts certification is certifying a process but it's not certifying an outcome and we have had a lot of focus simply on process and that's not the same as having a focus on outcomes.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

All right, thank you, anyone else?

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

I mean, I guess just a question, what...I mean what was...talk about the certify that they were doing it. I mean, is the skill level there in the ACBs to do that or just to validate the attestation?

I mean, there is...you know, auditors that make a business, that have businesses on auditing these processes that many of these companies, many of the vendor companies pay, you know, a lot of money to, to validate these processes, but now are we saying we want the ACBs to do that?

Janey Barnes, PhD – Principal & Human Factors Specialist – User-View, Inc.

Well, this is Janey Barnes, I mean, we're already doing that with the safety-enhanced design requirements now and we see that it wasn't consistently certified at the same level of what an expert human factors person would certify or not certify safety-enhanced design or user centered design process at.

Paul Egerman – Businessman/Software Entrepreneur

So, I don't understand what you just said, what they currently do in safety-enhanced design, are they simply accepting the attestation or are they actually somehow checking the attestation and determining whether or not it's valid and...

Janey Barnes, PhD – Principal & Human Factors Specialist – User-View, Inc.

Yeah...

Paul Egerman – Businessman/Software Entrepreneur

And...

Janey Barnes, PhD – Principal & Human Factors Specialist – User-View, Inc.

Right, so in Stage 2 what folks have to do is they have to attest that they apply the user centered design process and so they have to attest, but then they also have to in turn they have to submit their summative usability test report and when you read the summative usability test report then there are aspects of what gets reported that give insight into your process and that when you read those reports from a human factors usability specialist perspective that you can see that there were instances where people did not follow sound user centered design process as evidenced through things that they...details that they report in their summative test report.

Paul Egerman – Businessman/Software Entrepreneur

Yeah but my question is, what is the ACB's role in all of this? Do they simply act administratively and take the attestation check it off the list and file it away or are they...

Janey Barnes, PhD – Principal & Human Factors Specialist – User-View, Inc.

Well they have to...

Paul Egerman – Businessman/Software Entrepreneur

Supposed to like judge it and made some determination as to whether or not it's adequate?

Janey Barnes, PhD – Principal & Human Factors Specialist – User-View, Inc.

Yeah, well, so for the summative test report they actually review it and give feedback back and either pass or fail certification based off of certain characteristics and from what we can tell and from our reviews of reports on the CHPL site is that they're mostly failing people because of not following the format that the summative test is supposed to be in but they are not looking into the quality of what is reported and that they're again, letting instances where there...based off of what the report says that you can see that they're not following the user centered design process but they still got certified. So as an example...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Is the current...

Janey Barnes, PhD – Principal & Human Factors Specialist – User-View, Inc.

Like just a concrete example that Terry Fairbanks and Raj Ratwani pointed out one of the proofs of a user centered design process is that you use the intended user and then they talked about the example of a report from a vendor that got certified that used the CIO, the CMIO and the lead developer as the participants in their summative usability test and from a human factors expertise I would not say that those are the three representative end users of a product.

Rollin (Terry) Fairbanks, MD, MS – Director, Emergency Room Physician, Associate Professor of Emergency Medicine – National Center for Human Factors in Healthcare, MedStar Health Washington Hospital Center, Georgetown University

Right, this is Terry Fairbanks...

Paul Egerman – Businessman/Software Entrepreneur

But the key issue...the key question I'm trying to understand and ask is, what role do we want the ACB to play are they simply...I mean, what I always thought they did was simply objectively does something pass a test, is something submitted according to the rules like are the margins and the font size correct in terms of the format or are they actually going to be making subjective determinations as to whether or not some submission is adequate for certification? If you go to...

Rollin (Terry) Fairbanks, MD, MS – Director, Emergency Room Physician, Associate Professor of Emergency Medicine – National Center for Human Factors in Healthcare, MedStar Health Washington Hospital Center, Georgetown University

Well, this is Terry Fairbanks, if I can address that. First I want to clarify, you're answering...I mean you and Janey are talking about similar but somewhat different, you were initially asking about the attestation which...and you were asking if they evaluated the attestation itself and the only evaluation of the attestation is whether or not there is a presence of an attestation.

Paul Egerman – Businessman/Software Entrepreneur

Okay.

Rollin (Terry) Fairbanks, MD, MS – Director, Emergency Room Physician, Associate Professor of Emergency Medicine – National Center for Human Factors in Healthcare, MedStar Health Washington Hospital Center, Georgetown University

They don't objectively or subjectively evaluate that, but what Janey was talking about I completely agree with, there is an evaluation about whether the user centered design or safety-enhanced design is adequate and I think what you're asking actually is where the answer is.

If we expect it to be subjective it's going to be very hard to do and it's also very hard for the vendors to know what the expectations are and I think one of the challenges in the past has been that there have not been enough published criteria, and this is what we are hearing the vendors say as well, not enough published criteria to help the ACB be objective about it.

And what ended up happening is that they were...that there are several certified pieces that even when you look objectively probably don't meet criteria for very basic user centered design but that's what the experts say and there is nothing published about the objective criteria that's detailed enough for them to be able to do it well.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, let me suggest that we can clarify the discussion a little bit. The current rules only require that the vendors provide the information. There is no assessment of whether this is in fact user centered design by anybody and the discussion we're now having could be appropriate comments back to ONC about that they should do more than just ask vendors to report on what they've done, which is what was in the existing rule.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, I'm not suggesting that, Larry, I'm not suggesting that they do more. I think that the certification process has to be objective. It has to be...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

And like right now...

Paul Egerman – Businessman/Software Entrepreneur

It has to be...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Right and right now it's...

Paul Egerman – Businessman/Software Entrepreneur

You have...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

It's a null case of objective, the only requirement is that you submit documentation on what you're doing.

Paul Egerman – Businessman/Software Entrepreneur

Yeah and...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

And it doesn't...

Paul Egerman – Businessman/Software Entrepreneur

That's still objective, right, you submitted it yes or no...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Yeah.

Paul Egerman – Businessman/Software Entrepreneur

And you're done.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Exactly.

Paul Egerman – Businessman/Software Entrepreneur

I mean, you...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

And the discussion I'm hearing though is saying that right now the rule doesn't require...doesn't set a standard for what is or isn't...what would or wouldn't make something actually be safety-enhanced design or user centered design only that the developer document what they did.

And we, as a Workgroup, heard many presentations earlier this year and last year about what various experts say would be a good user centered design and I think there's an opportunity here if we want to provide some of that guidance for the future, but today it's not in the scope of what ONC is proposing.

Bennett Lauber, MA – Chief Experience Officer – The Usability People, LLC

So, hi, this is Bennett Lauber, I just wanted to comment again about the different certification bodies that there is a lot of variability between the studies that they certify depending upon who the body is. Some of the bodies took it upon themselves to create minimum standards and some of them did not and I would recommend to ONC that they do provide what those minimum standards for the study should be so that everyone can be judged on the same criteria.

Rollin (Terry) Fairbanks, MD, MS – Director, Emergency Room Physician, Associate Professor of Emergency Medicine – National Center for Human Factors in Healthcare, MedStar Health Washington Hospital Center, Georgetown University

Yes, this is Terry Fairbanks I completely second that. I think that we heard from many different angles there was a need for that.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation

So that may be our comment, a specific comment that we include here.

Bennett Lauber, MA – Chief Experience Officer – The Usability People, LLC

That would be great if you guys included it there.

Joan Ash, PhD, MLS, MS, MBA, FACMI – Professor & Vice Chair, Department of Medical Informatics & Clinical Epidemiology – School of Medicine – Oregon Health & Science University

This is Joan and I certainly agree.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

So, just...I think...just so I'm sure I understand, because this having a standard is key to the discussion. We're saying that ONC as part of the certification criteria should define a minimum set of standards that would say, unless you meet these standards you're not achieving...even though...you're not achieving the user centered design process.

Rollin (Terry) Fairbanks, MD, MS – Director, Emergency Room Physician, Associate Professor of Emergency Medicine – National Center for Human Factors in Healthcare, MedStar Health Washington Hospital Center, Georgetown University

Yes and I think that relevant...this is Terry Fairbanks, at the very beginning of this Workgroup I gave a presentation on our findings from visiting 11 vendors and the bottom line was that we found that all the vendors felt they were following a user centered design but on our analysis there was a range from doing it very well to the middle range to people that weren't doing it at all and so in order to move the needle we need to have standards because the vendors also felt like they didn't know what the expectation was and that was frustrating to them.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

I'm very familiar with that study and fully understand it and I'm all for, you know, the company I work for has an extensive process, but even where my company that has a very extensive, you know, I would say for sure be in that top tier of the three tiers, if I would say to them "okay, can you go over to the filing cabinet and pull out the set of standards that you would say should be industry standards" they would say "well, no, that really doesn't exist."

You know there isn't one that if Cerner went over to it and MEDITECH went over to it, and EPIC we wouldn't all pull the same standard. So, I guess I question the timing. I do agree that some set of guidelines makes sense, I just...it seems like that would be a valuable effort, I'm not sure...just like a minute ago we said "these rules can include anything that's not a well-defined standard" and we're acknowledging there isn't one.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Okay, so this is Dave Bates we're getting close to time and I just want to take us through what the plan is. We'll come up with some language around this that would be a draft recommendation and then we can beat that up in our next call. So, we have one more call before we have to report to the Policy Committee, that's May 11th 11:30 to 1:30, and our plan for that call is to go through our overall set of comments and we'll include a set of overarching comments as well as some of the specific comments.

We do have an hour with the Policy Committee, which is really great and we'll have to see how much of that time we devote to our comments versus letting them react because they'll need some time to react.

We did put together some overarching comments which have been included verbatim so they're relatively long but I just want to flag these for you, one related to the utility of CHPL and people noted that the CHPL is hard to use.

The second is really Paul's comment about not all HIT being provided by vendors.

A third one relates to what many on the group feel is an inappropriate expansion of use of certification.

Another one related to a shift from functional requirements to interoperability and privacy and security, and, you know, we think that does relate to feedback but there is still some criteria that focus on functional capabilities only which shouldn't be included.

M

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David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Another is if adopted the scope goes past the proposed timeline for a reasonable completion.

Another is that many stakeholders both in the industry and in our group felt like the previous iterations of certification were too complex and that this proposal wasn't really responsive to this feedback and it's still pretty complex.

Another was that many of the proposed standards and implementation guides aren't sufficiently mature to be promulgated through regulations, again, that's something we've just talked about.

And then one other is that ONC is proposing significant certification requirements on some segments of the market but not all and again that came up today.

And then there is also a set of comments about the user centered design process.

So, again, you know, the plan is to go through our final comments. All the three Workgroups have done really an enormous amount of work over a short period of time and really appreciate everybody's thoughts and input.

I think the final NPRM will be better as a result of the suggestions that we make. Larry, other things that you'd like to comment on before we...maybe final comments and then go to public comment?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

I want to support your thanks to the Workgroup for the discussion and for all the effort that's gone into the material so far. I think the overarching comments is going to be a really good thing that David you and I are going to have to crunch down and get back to the group as part of our discussion on May 11th.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Yes.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

I'm very encouraged with the intensity of everybody's discussions this has really been terrific.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Great.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Larry, I just want to mention, this is Mike Lipinski I'm back on.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

Okay, so and Michael I think we will not need you, we've had a very stimulating discussion.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Good.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women's Hospital & Partners

And we just need to figure out how to get from here to the finish line, but thank you so much...

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Hey...

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners

For being with us.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Yeah, no problem, I did happen to hear some of your feedback and obviously we appreciate all the feedback and look forward to receiving it through the formal process. There was one point though that I guess I would encourage you to clarify when you think functional is not appropriate and when you think there should be standards there.

So, to give an example, in the discussion that happened in the Health IT Standards Committee, you know, we received feedback from some of those members at the time about like for instance API they were happy that it was more focused on just functional requirements, meeting certain functional requirements versus actually specifying all the standards that should be applied to it and the same point was made about the decision support that, you know, there are standards associated there, Health eDecision, with the proposal but we received feedback where maybe it might be appropriate that you could continue to keep this criterion but that it would be...that maybe it should be functional.

So, on your point that you made we would just...I think it would be helpful if you could potentially go into more detail in terms of your analysis there.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners

Yeah, that’s very useful and we can be more specific and those are I think good examples of situations in which functional specifications are better and I think there are times when that’s the case.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Okay, thank you, but, yeah, again look forward to getting those comments and I appreciate your time. So, I’ll jump back off then.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners

Thanks so much.

Mike L. Lipinski, Esq. – Division Director, Federal Policy & Regulatory Affairs – Office of the National Coordinator for Health Information Technology

Okay, bye-bye.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners

Other comments from the group or thoughts from the group? Okay, well, really good discussion today and, you know, we will get the draft final comments out to you as soon as we can so you can look at those. And Michelle could you take us to the public comment?

Public Comment

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

Caitlin can you please open the lines?

Caitlin Chastain – Junior Project Manager – 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.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners

Okay, Michelle, I just want to thank you again, it seemed like you had a great deal to go through.

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

Thanks.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners

Yes, really good discussion today, thank you all we’ll look forward to speaking on May 11th and Larry and I will be doing some work between now and then. Thanks again.

Mickey (Michele) McGlynn – Senior Director, Strategy & Operations – Cerner Corporation

Thanks, have a good weekend.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Bye.

Ellen V. Makar, MSN, RN-BC, CPHIMS, CCM, CENP – Senior Policy Advisor, Office of Clinical Quality & Safety – Office of the National Coordinator for Health Information Technology

Thanks, all.

Michael Lardieri, LCSW, MSW – Assistant Vice President Strategic Program Development – North Shore-LIJ Health System

Bye-bye everybody.

Michelle L. Dougherty, MA, RHIA, CHP – Director of Research & Development – AHIMA Foundation
Goodbye.

David W. Bates, MD, MSc, FACMI – Senior Vice President for Quality & Safety and Quality Officer – Brigham & Women’s Hospital & Partners
Bye.

Bennett Lauber, MA – Chief Experience Officer – The Usability People, LLC
Everybody have a great weekend.