

**HIT Standards Committee
Transcript
October 17, 2012**

Attendance

The following Committee members were in attendance at this meeting:

Jonathan Perlin

John Halamka

Dixie Baker

Anne Castro

Tim Cromwell

John Derr

Lorraine Doo

Floyd Eisenberg

Jamie Ferguson

Leslie Kelly Hall

C. Martin Harris

Stanley Huff

Elizabeth Johnson

Rebecca Kush

David McCallie

Nancy Orvis

J. Marc Overhage

Kamie Roberts (alternate for Charles Romine)

Cristopher Ross

Wes Rishel

Walter Suarez

James Walker

The following Committee members did not attend this meeting:

Christopher Chute

Kevin Hutchinson

Arien Malec

Sharon Terry

Presentation

Operator

All lines are bridged Ms. MacKenzie.

MacKenzie Robertson – Office of the National Coordinator

Thank you, good morning everyone, this is MacKenzie Robertson in the Office of the National Coordinator, this is the 41st meeting of the Health IT Standards Committee. This is a public virtual meeting and there will be time for public comment in the agenda and the meeting is also being transcribed so please make sure you do identify yourself before speaking. I'll now take the roll call. Jonathan Perlin?

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Good morning.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Jonathan. John Halamka I know will be joining shortly. Dixie Baker?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

I'm here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Dixie. Anne Castro?

Anne Castro – BlueCross BlueShield of South Carolina – Chief Design Architect

I'm here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Anne. Christopher Chute? Tim Cromwell?

Tim Cromwell – Veterans Health Administration – Director Standards & Interoperability

I'm here.

MacKenzie Robertson – Office of the National Coordinator

John Derr? Oh, Tim was that you?

Tim Cromwell – Veterans Health Administration – Director Standards & Interoperability

That was me, yes.

MacKenzie Robertson – Office of the National Coordinator

Great, thanks. John Derr?

John Derr – Golden Living, LLC

I'm here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, John. Lorraine Doo?

Lorraine Doo – Senior Advisor - Centers for Medicare & Medicaid Services

I'm here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Lorraine. Floyd Eisenberg?

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Present.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Floyd. Jamie Ferguson?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Jamie. Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Leslie. Martin Harris?

C. Martin Harris - Cleveland Clinic Foundation

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Martin. Stan Huff?

Stanley M. Huff - Intermountain Healthcare

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Stan. Kevin Hutchinson? Liz Johnson?

Elizabeth Johnson, MS, FHIMMS, CPHIMS, RN-C – Tenet Healthcare – Vice President Applied Clinical Informatics

I'm here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Liz. Rebecca Kush?

Rebecca Kush – Clinical Data Interchange Standards Consortium (CDISC)

Good morning.

MacKenzie Robertson – Office of the National Coordinator

Thanks. Arien Malec? David McCallie?

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Good morning.

MacKenzie Robertson – Office of the National Coordinator

Thanks, David. Nancy Orvis? Marc Overhage?

Marc Overhage – Siemens Healthcare

Present.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Marc. Wes Rishel?

Wes Rishel – Gartner, Incorporated

Here.

Nancy Orvis – Director Health Standards Participation – Department of Defense

Nancy Orvis is here, okay?

MacKenzie Robertson – Office of the National Coordinator

Who was that I'm sorry?

Nancy Orvis – Director Health Standards Participation – Department of Defense

Nancy Orvis is here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Nancy. Charles Romine?

Kamie Roberts – Associate Director - National Institute of Standards and Technology

This is Kamie Roberts for Chuck.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Kamie.

MacKenzie Robertson – Office of the National Coordinator

Cris Ross? Walter Suarez?

Walter Suarez – Kaiser Permanente

I'm here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Walter. Sharon Terry? And Jim Walker?

James M. Walker, MD, FACP – Chief Information Officer – Geisinger Health System

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Jim. Okay with that I'll turn it back over to you Jon.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Good morning everybody and many thanks, actually I'll come to my introductory comments and review the agenda, but first let me turn to and thank Dr. Mostashari for being here for his hard work, my goodness the road warrior extraordinaire, but appreciate your really carrying the torch to advance healthcare and health informatics and appreciate your opening comments this morning.

Farzad Mostashari, MD, ScM – Health and Human Services – Office of the National Coordinator for Health Information Technology

Thank you; I will be brief and apologies for the background airport noise and announcements. We continue to make really good progress and week after week despite what may be some misperceptions about the state of interoperability and the progress on interoperability, the fact on the ground, whether it's in Massachusetts where John Halamka participated in the driving of the golden spike yesterday with Governor Patrick kicking off the Massachusetts eHealth Exchange, the transmission using national standards of health information across the state from unaffiliated providers whether it's with New York and the consortia of states that are collaborating together using an ONC accredited certification body with the national standards that we've used, the state health information exchange branch exerting leadership on bringing people together and pushing ahead the icebreaker to push ahead on filling out the additional standards that are going to be needed and linking them back to the national standards development process, whether it's with the announcement of the maturation of the eHealth Exchange that is now onboarding more organizations than ever before, whether it's with the vendors who have announced millions of dollars in investments in networks that will use national standards and will enable not just within vendor communication but across vendor communication.

I have never been more hopeful that though the path is hard there's no question that there are...the more progress we make the more problems that need to be surmounted that's just the nature of progress. But there is no question that progress is being made as never before on interoperability and the actual exchange of information. We are on the right path and we just need to push forward.

I saw recently some marvelous results from pilots to link Prescription Drug Monitoring Programs, obviously opioid overdose is a huge public health problem in this country and yet those Prescription Drug Monitoring Programs are underutilized and not checked very often, and many states have turned to mandating using legal requirements to force doctors to check the PDMP, but it's hard to check it and these pilots integrated that automated those checks within the using, leveraging, building on the eHealth infrastructure, the EHR infrastructure, the ePrescribing infrastructure in a variety of different ways and they showed tenfold increases in the access and utilization of the Prescription Drug Monitoring Program. These are the kinds of on the ground results that we need to celebrate, we need to talk about, we need to document, and we need to learn from and push ahead.

So thank you for your work it seems like just as Stage 2 is...now we're still working with the Implementation Workgroup on the test scripts and on finalizing the Stage 2 progress, we are already into Stage 3, well into Stage 3 with the recommendations from the Policy Committee, the Request for Comments from them coming out shortly and the standards piece obviously a hugely important companion to that. So, I just want to thank you, thank you, thank you, and let's keep going.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Well, thank you so much, Farzad, your leadership and your team has just been extraordinary and indeed it's inspiring to hear the progress, so much of this work is coming to fruition. I think the metaphor of the golden spike linking previously incompatible or non-interoperable data sources and allowing the appropriate flow of health information really inspires us to keep moving our work forward as we support Stage 3 and all that we hope to realize.

I want to thank all of the members of the committee and all who participate virtually. I want to thank you for two things, one of course is your hard work and intellect, the other is your dedication and flexibility. I know that we shifted to a virtual meeting this time, I hope ultimately that is satisfactory to you and relieved you of some travel, but at the same time, really as per your help virtual meetings I think are actually harder, they require more intense concentration and more self-discipline from distractions. So, appreciate your engagement. At the same time I hope that everyone is comfortable either in their offices or at home, we'll try to not picture our West Coast colleagues in their bathrobes or otherwise, but we know it's very early there and do appreciate your joining.

As we look at today's agenda, I think it's notable to really contemplate the sort of real world utility of the work we're doing not just in the broad sense of better health and care, and higher performance and value, but in terms of really the challenges that confront those that both operate in some way as health professionals or as supportive health professionals and all of us who are patients.

And, what I'm moving toward is that as we look to the comments of the FDA Notice of Proposed Rulemaking and unique device identification, I really look forward to that because I think we have an opportunity to really understand devices in a way that we can for most pharmaceuticals.

As our nation is gripped by the concern about the meningitis outbreak, you know, one of the challenges is of course the identification of discrete items and, you know, this is an issue where there are specific identifiers for most medications, this falls into the area that is somewhat of an exception and that challenge is a challenge that has existed in the device space towards really understanding the performance of devices, being able to quickly identify patients who are exposed to a particular device, think about the utility of this work going forward, it's so important and I just want to thank not only the standing members of the committee, but all who have worked on this topic from the Clinical Operations Workgroup and Vocabulary Taskforce, your work just couldn't be more timely.

I look forward, as well, to all that will join us and really introduce Healthyway and evolution of eHealth Exchange, we have a number of guests, and more introduction as we approach that, and just always appreciate Doug Fridsma's leadership and really helping us align to make sure that our work is not just timely but supports and leads in intersection with S&I Framework and all of the work of ONC. So, many thanks to each of you.

Let me come to the first...I'm sorry, let me just mention two other things and I'm sorry I should've mentioned this at the beginning. We really take our responsibility for public input seriously and in addition to the public comment period today, as always, we welcome input and comments on Twitter and remember that our hashtag is [hastaghitstandards](#) hashtag to use for tweeting during the meeting. So, please feel free to exert your right to input and we look forward and value that input a great deal.

I want to come to one other issue and during the course of the meeting we may discuss this a little bit more, but, I hope that everyone is aware, and I appreciate as always Dixie and Walter, and Steve Posnack, and Joy Pritts leadership, but the Privacy and Security Workgroup really has a new charge from ONC which resulted from our September meeting and as you may recall at our September Standards Committee meeting there was concern over not explicating that there be certain privacy and security requirements as a matter or a condition of certification, and so Steve and Joy and the ONC Team took this back, conjugated and indeed identified that certifying electronic healthcare modules against some set of minimal of privacy and security standards and certification criteria would be a reasonable approach.

I would note that ONC reports receiving several public comments that the 2011 approach required for EHR module presenters to implementation would not be the kind that would be used in actual operations or to generate documents that would be of utility outside of the certification process. With that background in mind ONC is asking, charging, the Privacy and Security Workgroup to provide recommendations that are targeted for the 2016 edition of EHR certification and what they're specifically asking of us is to identify a minimal set of privacy and security, and standards, and certification criteria for certifying electronic health record modules.

So, our recommendation, our Standards Committee recommendations should anticipate not only that, but broad adaption of the NSTIC-based authentication and be compatible with that NSTIC approach for those new to this acronym, National Strategy for Trusted Identities in Cyberspace, NIST supported approach to authentication. And so the Privacy and Security Workgroup will present its recommendations to the Standards Committee in the future and we hope to have good recommendations that we can transmit to Dr. Mostashari and to ONC.

Let me do two things. Let me just come to the first standing order of business, which is approval of the minutes. And, I know already an electronic card went up yesterday or as soon as the minutes were distributed and I believe there is one amendment from Dixie Baker and so I would invite her both to offer her comments on the minutes, as well as, if you like, any comments on the additional Privacy and Security Workgroup charge. Dixie?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Sure, thank you Jon. I'm very grateful to both the committee and to ONC for actually giving the Privacy and Security Workgroup an opportunity to address the certification of EHR modules. We think it's extremely important, not necessarily that these modules provide additional privacy and security capability, and certainly not capabilities that would never be used in actual use, but especially we want to make sure that those modules are at least capable of using any security functionality provided by the base EHR. So, I'm looking forward to really addressing this with the committee.

The main comment I had about the minutes had to do with the conversation with the issue that Jim Walker brought up about the problems that he has observed and that Geisinger has actually studied regarding when you cancel...the cancellation of a prescription when a patient leaves the hospital and the inability of a lot of pharmacies to actually accept those cancellations. I found this whole issue really interesting and I wanted to make sure I totally understood it, and I didn't think the minutes accurately reflected what I actually heard when I went back and listened to the transcript.

In particular, the issue was that the 10.6 version of NCPDP not Surescripts as now reflected in the draft minutes, enables the receipt of translation, but that not all pharmacies have upgraded to that version and the fact that pharmacies are not included in the Meaningful Use Program, so they're not compelled to upgrade to 10.6 and at the end of that, you'll remember this was an extended conversation, and at the end Farzad took an action to follow-up with Surescripts to ask about the capabilities of pharmacies to receive cancellations. So, I just wanted to bring this to everybody's attention, because it's not accurately reflected in the minutes.

Farzad Mostashari, MD, ScM – Health and Human Services – Office of the National Coordinator for Health Information Technology

Yeah, just to recap that, we also discussed how the changes to the Part B Regulations, which do affect pharmacies, do have an upgrade to the 10.6 standards as well, that should also be reflected. So, these are not the...Meaningful Use is not the only lever we have and I did speak with folks at Surescripts and we got on the same page in terms of the need to work intensively with pharmacies over the next 12 months to make it possible to increase the likelihood of pharmacies not only being technically able to receive those transactions, but also to have the training needed to do it effectively. I don't think in summary, I think it's the right policy and we have to make...for the next 12 months we have to work hard with our partners in the pharmacy space to make it happen.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

So, I guess Jon, I would suggest that we update the...still update the minutes to reflect that that was there.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

I think that reasonable and MacKenzie if we can incorporate both sets of comments there and we'll amend the minutes toward that. Any other corrections or implications on the minutes? Okay, is there any objection then pending that correction that reflects the discussion that we just heard. Let me assume consensus unless there are any objections.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Well, I also sent MacKenzie some, you know, less...some other corrections to the minutes that were really not worth talking through but they were more editorial corrections and I'd like those reflected as well.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Okay, no objection here and I saw those, they were really a number of grammatical things that just enhance the intended clarity. Any other amendments or modifications to the minutes? Okay, hearing none we will look forward to the corrections to the minutes and Dixie, appreciate your very thoughtful review and we'll move forward with our agenda. I do know that John Halamka was giving a keynote this morning at OSEHRA the virtual world lets me know that he is actually doing Q&A right now. I don't know, John, we'll test if you've joined? Not quite, but he'll be with us momentarily.

Let us then dive right into the first order of business and I want to thank both the Clinical Operations and Vocabulary Taskforce, Clinical Operations Workgroup and Vocabulary Taskforce for your work on the NPRM from FDA on unique device identification. And, Jamie, let me turn to you please.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great, thank you. If I could just have, I think the title slide for now. What I realized in reviewing the slides actually last night is that we are in this section of the meeting we're reviewing the comments that were discussed in Clinical Operations Workgroup and Vocabulary Taskforce, but we haven't actually done a review of the unique device identifier rule itself for the full committee. So, I'm going to take just a minute and summarize some of the key points of the UDI proposed rule.

And, so first the identifier itself, the unique device identifier, UDI is based on ISO-15459, which is essentially GS1 and it includes two major components, the identifier itself as a static device identifier or a static device ID that includes the manufacturer, the make and model. And then it also has a production identification section that's dynamic that includes the serial number, lot number, expiration date, and manufacturing date and so that's the identifier itself.

And then the proposed regulation has a number of different sections. The rule specifies very extensive labeling requirements, but the rule also has a number of exceptions, for example all Class I devices UDI maybe on the package not on the device itself, it includes exceptions for over-the-counter devices, and a number of other exceptions, and it also says that the manufacturer may change the UDI for almost any reason. A major section of the rule has to do with the global UDI database, which will include a number of different data elements related to the UDI, including for example, the G10 identifier, the GMDN identifier, labeler information and other data elements, a large number of other data elements.

This is a database system to be maintained by the FDA that will be available to the public with I think a couple of data element exceptions such as the FDA listing number. The rule is intended to be implemented in stages based on risk and so Class III devices would essentially be implemented immediately starting in May of 2013 and ending in May of 2014 all Class III devices would be input and updated and maintained in the UDI database, Class II devices by May of 2016 and then Class I devices by May of 2018. And, so that's just a very high level summary of the rule itself and now I'll go through our comments.

I think it might be most useful if I go through the comments first and then hold discussion until I've gone through all the comments. So, if we could get the slide on the first comment please? So, this comment essentially says that we really like this rule, that the UDI has been a long time coming, it's we think going to be very useful that the proposed database is really going to be extremely useful for many different purposes, so this really should enable the industry and providers, and manufacturers, and users, as well as patients to understand many different aspects of the devices, and the rule I think will have many benefits ranging from patient safety to supply chain integration and efficiency, so, many different benefits. Second comment, please.

Now, this is the first thing that we don't like about the rule, which is the proposed exemptions for retail devices or the over-the-counter devices we felt were problematic from a couple of different angles and so we would like to propose, and remember all of these comments are comments to ONC for ONC's comments to the FDA. And so we would recommend that all measurement devices that produce information that is used in the care process should be required to be labeled by UDIs whether they are retail or not. Now, in terms of things that are classified by the FDA as treatment devices, this includes a wide range of different types of items and so we would recommend that the FDA should consider defining guidelines that would specify which treatment devices would require labeling by UDI.

But, one of the areas that we thought was especially problematic is that many devices that could be over-the-counter may also be prescribed devices that could be the subject of a professional prescription order that could also then flow through to payment through public or private insurance and for which it would be especially useful to have UDI included as a requirement for all the prescribed devices and specifically all frequently prescribed devices, OTC devices we felt should be required to be labeled with UDI. Next comment, please.

And, so the third comment has to do with the specific way that primary and alternate UDIs are represented in the global UDI database. And so, because manufacturers can change the UDI for almost any reason and because the, for example the static portion of the UDI would change based on corporate ownership of the device manufacturer even if absolutely nothing changes about the device or its manufacturing and serialization is the same from a manufacturing and production stand-point, so we wanted to ensure that, if for example in the case of a recall if you need to search the database for all devices of a certain kind, that that should be made easy and so we wanted to have the UDI database provide essentially a history of UDIs for any particular device. Next comment please.

So, comment four has to do again with the database and so this is a number of specific data element recommendations for the database. One is that many devices may currently be identified for example by an NDC code and so we would recommend that the NDC code would be discontinued when the UDI codes are issued for the device, but that the previous NDC identifier and other identifiers would be included in the UDI database for cross-referencing purposes. At the same time, the GMDN code section of the UDI also is correlated or mapped to SNOMED CT identifiers and so we felt that there should be a place in the database for those SNOMED identifiers for the devices.

And then finally, many of the measurement devices or test kits produce results that can be identified by LOINC codes for the identification of the test and so we wanted all of the LOINC codes for the tests that are performed by the devices to be able to be added to the database. Next comment please.

The comment five has to do with timely maintenance and so we're urging here for the FDA to provide guidelines as to what defines timely maintenance and one of the particular issues that was raised has to do with timely maintenance of the database when a device is withdrawn from the market, that, that should be known in the database essentially immediately and so that timely updates, as to the marketing status, should be the subject of FDA guidance. And then onto the final comment, please.

And this is really a comment that is not intended, so all the other comments are intended for ONC to consider its comments to FDA; this particular comment really is just for ONC in the context of Meaningful Use. And so actually, I'll start at the bottom of the slide and it was raised by members of Consumer Empowerment Workgroups that patients should be able to know the information about devices that are implanted in them, for example when they see a discharge summary they should be able to know by the UDI what the device, what the implant is, but not everything is...not all implants are done in inpatient settings, so it's not always going to be in a discharge summary, it may be in an outpatient procedure and so that was the origin of this comment, but then as we discussed it in the Workgroup

for purposes of quality measure developers and others, it would be extremely useful, particularly starting with implants, for the appropriate CDA templates within the paradigm of transitions of care and other health summaries, for there to be a place for the UDI as applicable and so that's the final comment and now I'd now love to get discussion on this.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Well, thank you very much, Jamie, very thoughtful overview and let's open for discussion. I would remind people, given our telephone format please identify yourself as you raise your virtual card.

Wes Rishel – Gartner, Incorporated

Hi, this is Wes.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Hey, Wes, please go ahead.

Wes Rishel – Gartner, Incorporated

Jamie, I'm not sure I followed your quick summary as completely as I should have, but there's been an ongoing problem with NDC codes in that there is no isolation of any indication of the therapeutic characteristic of a medicine, is that problem duplicated in these codes as well?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, I think the analogy there would be, Wes, for those devices that are measurement devices to have the LOINC codes for the test that they perform included in the UDI database. So, that's I think an analogy.

Wes Rishel – Gartner, Incorporated

So, it's like if NDC had been originally implemented with the database then we wouldn't be having this problem is that correct?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, I mean, of course, yeah if the database had all the right elements and was extensible and so forth the way the...which is what's proposed for the UDI.

Wes Rishel – Gartner, Incorporated

Okay. I guess that's the best we can do.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Now, I'll also say to extend this part of the discussion, we did have some input that requested further extensibility of the UDI database for linking additional information provided on whether it's an adverse effect or other issues, or comments in the database. We decided not to add that as a comment, but some individuals will put that probably in their individual comments.

Wes Rishel – Gartner, Incorporated

Yeah, my view is they can link the other way. So, the FDA doesn't have to get involved in sort of curating all of those comments and issues. But, I am a little concerned that they can change the UDI. Does that mean they can change the instance code of a device, the instance information of a device, does that mean they can simply change the labeler information?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, it means for example they can change the labeler information, they can change the model number and things of that nature and so when those kinds of changes occur then what we are requesting in our comments is for that history of exactly similar devices to all be linked together in basically a single record.

Wes Rishel – Gartner, Incorporated

Okay, thanks.

John Halamka, MD, MS – Harvard Medical School

And, this is John Halamka, I've just joined.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Good morning, John. Do you have any comments that you want to offer on this topic?

John Halamka, MD, MS – Harvard Medical School

Just that Jamie and Betsy have had an extraordinary discussion and the summary of the PowerPoint I thought was quite salient and reasonable, but nothing specific to add to the work they've already presented.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Well, thanks, thanks.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

John, I have a question, this is Dixie Baker.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Please, go ahead.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Jamie, on your comment number two, and first of all these are great comments and we really appreciate representing the committee in responding to this. The comment number two had to do with UDI requirements for retail devices. In thinking about where we envision health care to go, where it's almost going from a very location specific delivery, to more ubiquitous care and continuity of care across care settings including the home I think it's going to become more and more difficult to make a clear differentiation between what can be prescribed and what is truly a consumer device, and perhaps even the reason, you know, any kind of justification for making that differentiation may go away. Did your team discussed that when they discussed this comment?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Yes we did and in fact, really the sense of the team overall, the sense of the Workgroups together overall, was we felt that essentially all devices should have UDI's period.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yes.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

But then in terms, if you see the section on treatment devices, so things that are classified as treatment devices could be for example cotton swabs and so there may be a limit of what should be labeled with a UDI and that's what we're urging FDA to develop guidance on.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

I see. So this recommendation is really FDA develop your rules for deciding, regardless of the setting, whether it should have UDI code or not.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Exactly, but anything that produces a measurement that can be used to inform care, regardless of the setting, anything that could be prescribed regardless of the setting should be labeled with a UDI and in the database.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

So, Jamie, this is Jon, as I contemplate healthcare of the future, I just want to extend Dixie's question a little bit and get a little bit more of the sense of your deliberations. Certainly, you know, the smart phone is already serving as a sensor device, you know, a heart failure patient might be tracked as well by a Fitbit, I don't mean to mention a particular brand name, but just it's becoming so ubiquitous as a digital scale on. What was the sense of your contemplation of that trajectory?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, again, so we looked at classifying things essentially by measurement devices versus treatment devices, which I think are generally well understood concepts and so I'm not sure how the rule would apply to software as a device, which obviously is not going to be labeled with a physical barcode or QR code label, but we did want to ensure that anything that really can be used as a device to inform care should be labeled.

And, then the other thing I'll add, not really about the software, is in terms of prescription the comment, the bullet point here for the prescribed devices, we really wanted to ensure that device identification could be linked from the point of manufacturing through the treatment record over into the payment record and that really by having anything that can be prescribed, labeled with the UDI, we thought that we would better enable that linkage.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

And it could be self prescribed as well, but, I think that...I think this problem gets much harder when you think about the consumer really getting engaged in their care and really using a PHR for example and I think that there clearly, you know, cotton swabs don't need a UDI label, but it seems to me just about everything that can be used in measurement, treatment, you know, sensing everything that can be used to really monitor and care for an individual should have a UDI code.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

This is David; I have a question on that.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Please, David, go ahead.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Jamie, that was a great summary and I apologize that I don't know this space better than I should or I don't know it as well as I should, but I'm concerned about the cost to retail and consumer facing devices of complying with the recommendations that you put forward in terms of what it would take to obtain and track the UDIs on consumer facing devices. Let's say some piece of hardware that works with a smart phone that might otherwise be really low-cost, you know, maybe under \$20.00 even for some of the sensors that I've seen emerging. Do you have any estimate of what the cost would be and will this suppress that market, where I think a lot of innovations are poised to occur?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, I think the essence of it, David, is that all of those things have bar codes on them now and what this says is the barcode that's on it should be the UDI in essence and that that should be updated into the FDA database. So we did not consider the cost of those database updates, no.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

And is obtaining the number, I'm not sure what the process is if you have a new device and you want to get that UDI number and put it on your barcode, is that a cumbersome process? Does that require regulatory review of any kind or is it just...?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, again, so that's based on the existing FDA approval processes, so nothing changes about that and so, I mean we thought it was not unduly onerous for the labelers to have to update this database when they have a new device.

Wes Rishel – Gartner, Incorporated

Jamie, this is Wes. I'm wondering, when I think about David's question and Jonathan mentioned heart sensors, ECG sensors, you know, there are glucometer add-ons to iPhones, there's pedometers, you know, is there anywhere in that sort of scatter of different things you think UDIs should or shouldn't be required? I mean, I'm specifically thinking about items that may well be used in treatment but are often used simply by patients who are interested in their own health and aren't part of any monitored program.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Right.

Wes Rishel – Gartner, Incorporated

And pedometer is the one that comes to mind.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Yeah, no those are great examples Wes, thank you. So, the sense of the Workgroup was that everything that you mentioned should be labeled with a UDI and, you know, let's think about a use case of a glucometer or a home blood pressure device, or something else that's going to produce a measurement that may go into the patient's PHR then in sharing that information with their professional care team having the UDI would enable the provider to understand the precision or other characteristics about the measurement device and so we think that that would be very useful for promoting the integration of these different care settings and of self-care with professional care.

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

This is Floyd. Jamie, I want to just reiterate what you just mentioned, and I think going back to Dixie and other comments, that was the feeling of the group during the discussion. The concern is where does one separate what might be tracked and what might not be. So, the example of cotton swabs and dressings versus a lower extremity compression device as a treatment entity and then it's something that might be tracked, presumably anything might be tracked, and for the patient to understand the value of this data, the precision it's important to know where it came from.

Bob Perry

This is Bob Perry, I agree wholeheartedly. We had...a couple of years ago we had a recall on alcohol wipes, something as small and minor, but it created serious problems because they were in kits and there were millions and millions of them and so it turned into a larger situation something as minor as an alcohol wipe.

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

This is Leslie. I have a comment.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Go ahead.

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

So, first of all thank you for including the consumer needs in here. We did hear loud and clear in several different opportunities that the patient's wanted to know what was inside of them and along that line, if you have an opportunity for harmonization a companion guide to the consolidated CDA for Meaningful Use 2 came out in the last two weeks for comment and within that structure the UDI was largely silent and although there was opportunity under the op note structure for a model number there was not a requirement that there needed to be a UDI or that an op note should include an implantable device occurs that level of detail within the op note, that could be also harmonized further for that particular section within the consolidated CDA to have that information available for transitions of care either to the home to or another area of care. So, I think there's good opportunity for harmonization in the companion guide requirements and the requirement for UDI and it's very timely to do so now.

Wes Rishel – Gartner, Incorporated

This is Wes. I just want to throw a monkey wrench in the works here. Is including, particularly for implantable devices, does including that in the record make the data that surrounds it identifiable, does it preclude the use of that data in situations that would normally be thought of as de-identified or a limited data set?

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Well, Leslie I don't know if you might be wanting to comment on that, but that's I think a great question, Wes.

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

Did you direct that to me or who did you direct that to?

Wes Rishel – Gartner, Incorporated

No, I just asked the group, I wasn't...

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

Oh.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

I think that's a great question. So, if I understand the question, Wes, is does the inclusion of a specific identifier de facto identify the individual even in de-identified data?

Wes Rishel – Gartner, Incorporated

Well, I'm just, you know, I have this tremendous amount of expertise in forensics that comes from watching television and I know that implantable device serial numbers is the way they identify dead bodies according to my expertise. I'm just wondering, you know, less sarcastic manner, does that constitute an identifier for the individual once it has been established really?

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

This is Leslie, Wes, you'd still have to have what that device ID went back to if you were taking that information out for research purposes, but I think this is an instance where the benefit outweighs the risk, because if that implantable device is recalled or a battery needs to be modified or there are some known changes that take place the benefit to the patient is greater than the risk of exposure and I think we have to be mindful of that as we go forward.

Wes Rishel – Gartner, Incorporated

That's how I would take it too, however, what I would hate to see is those that spend more of their attention on what can go wrong with shared data would say that an entire data set containing that identifier is de facto identified.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Wes, this is Dixie, can I just interject here?

Wes Rishel – Gartner, Incorporated

Sure.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

A device identifier is one of the 18 elements in HIPAA that makes data identifiable. So, I don't see that this makes any difference at all.

Wes Rishel – Gartner, Incorporated

Okay, thanks.

Walter Suarez – Kaiser Permanente

This is Walter, I just wanted to interject. It might be helpful to distinguish the global universal vice identifier database that the FDA is intending to create does not have any identification back to the patient; it's all about the device itself without any connection to the patient. The connection to the patient of course happens in the EHR where the record contains of course the patient information along with in the future the device identifier itself. If there is that requirement of course because the FDA rule does not require providers to include in the EHR the UDI, the rule requires manufacturers and imposes requirements on manufacturers to obtain the UDI and use it, but it does not...the FDA in my understanding does not...so it's important to distinguish the two databases.

Wes Rishel – Gartner, Incorporated

And, I wasn't implying that patient identities went into the global identifier. I just think that there are various legal and business requirements that cause that identifier to be tied to patients down line, but as Dixie has pointed out this has already been addressed at the level of HIPAA so I'm satisfied we're not creating a new area of investigation that it's already been addressed.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

So, this is David. We could be radically expanding the number of devices that have these identifiers and therefore are tracked and linked through the EHR. So, I think it may change the balance of identifiable data somewhat even though it's not new regulatory space.

Wes Rishel – Gartner, Incorporated

Yeah, that's true. Does the FDA regulation require that devices that transmit data transmit their UDI?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

No.

Wes Rishel – Gartner, Incorporated

Should it?

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

That's a good point.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yeah, because...

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

Yes.

Elizabeth Johnson, MS, FHIMMS, CPHIMS, RN-C – Tenet Healthcare – Vice President Applied Clinical Informatics

That is a good point.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Well, I'm not sure.

Elizabeth Johnson, MS, FHIMMS, CPHIMS, RN-C – Tenet Healthcare – Vice President Applied Clinical Informatics

Well how would you know then, this is Liz, how would you know then where the data was coming from? How could you assure yourself that you're responding to the correct data associated with a particular patient?

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

This is David; I think that the fact that the device is well understood doesn't mean that you trust the signal from that device and I'm thinking mostly now in the consumer space not implantable devices, but in the consumer space, you know, someone may possess the device it's properly registered and attached to them but they've mounted it to their dog instead of to themselves, I mean providers have to be cautious about interpreting the data not as a function of whether the device has been properly registered in the UDI database with certain known precisions and so forth, nothing has changed from the onus being on the provider to be careful about interpreting data that he didn't capture himself, so I worry about overly regulating a nascent market where we're seeing an explosion of fascinating new, powerful sensor devices. If we slow that down we may do more harm than good.

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

This is Leslie; however, I think with the implantable devices that is a different question and we've heard from patients already the difficulty of getting access to their own data coming from their own body. So, where there is an implantable device we should have that kind of structure. I would encourage us to do so and then back to the point of the EHR as a separate database from the FDA, my suggestion on harmonization is that in the EHR, in the consolidated CDA we do have opportunity to and fields identified in the same manner for unique device identity within that structure.

Elizabeth Johnson, MS, FHIMMS, CPHIMS, RN-C – Tenet Healthcare – Vice President Applied Clinical Informatics

So, Leslie, this is Liz, are you suggesting that that would go as part of the consolidated summary?

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

Yes, I am. And today in the op not we'll often find this, but it's still kind of random and unstructured, in the new implementation guide or companion guide they do include op notes, there are fields somewhat but not at the detail level of what's been put forward in this recommendation and it's great timeliness to harmonize those efforts for when the devices are included there is enough detail so that at a future date if there is recall or change we can get to the actual patient and will also lay an infrastructure for future when devices communicating can also communicate back to a patient or a patient's system.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Okay, we've had a broad ranging discussion and, you know, Jamie I want to make sure that we provided you and more importantly we're providing ONC the sort of synthesis. So, we hear the tension between regulation and a nascent market. We hear sort of a challenge with defining the margin between consumer devices that might qualify as health-related devices and those that do not. In my earlier question Jamie, you know, I was thinking actually of the accelerometer and the iPhone as an example and I realize that's been powered by software, but, you know, if I were tracking a heart failure patient that may be the most practical way to do that in the future and David McCallie makes a good point in the discussion of not only the verification of the device, but that the verification of the use of the data. I know my pedometer does a lot better when my dog wears it for me. These are real and living issues that I don't think we're going to solve. But, let me just ask for one last sort of round, if there are any sort of summary...

Wes Rishel – Gartner, Incorporated

Jonathan, this is Wes.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Wes, go ahead.

Wes Rishel – Gartner, Incorporated

In addition to the things you summarized, I think it would be good to call out at that summary level the issue of whether a device that has a UDI and transmits data should be required to transmit the UDI.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

That's a good question.

Wes Rishel – Gartner, Incorporated

I'm saying, suggesting that the committee take the position that that should be a requirement in the FDA regulation.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Let's just then, before we put that through a more formal question, let's just hear other comments on that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

This is Jamie. Jonathan back to your summary, one thing that I wanted to mention is that the UDI rule does not extend to the medical device data systems or MDDS and, you know, I think everybody is aware that, although FDA regulatory authority for devices does include electronic health record systems, aside from the MDDS they're not currently regulating that space and so I think that a lot of these questions about software labeling with UDIs will have to wait for further rulemaking activity in that whole space.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Okay. Then in terms of Wes's comment, you think that opining now is premature?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, yes, I mean personally I do, just, you know, not speaking for the Workgroup but just for myself and I would echo, I think David McCallie's comments on that point.

Wes Rishel – Gartner, Incorporated

Jonathan, let me make my comment clear. I said if a device has a UDDI.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Okay.

Wes Rishel – Gartner, Incorporated

And transmits data then it should be required to transmit the UDDI and I might modify that to say it should be required at least to transmit all of the typing information about the UDI, whether it goes to the individual unit or not is an issue that has more privacy concerns and is worth adjusting, but fundamentally it seems like I'm asking very little for a pretty good benefit.

Bob Perry

Yeah, this is Bob Perry, I really agree it's just like on this phone call where we identify ourselves before we say something a piece of equipment needs to identify itself and say this is where the information is coming from.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

The question, my clarifying question, I hope clarifying question, really wasn't about the utility it was about the apropos of Jamie's comments making sure that we didn't proceed necessarily regulation to be able to, you know, provide a recommendation that found context, but I think it's pretty...you make a pretty compelling point. So, let me just ask for sense of the group are there any objections or concerns about this recommendation?

John Halamka, MD, MS – Harvard Medical School

And this is John Halamka. So, if in fact as Wes has stated, that we have a UDI embedded in the device, that is this is not talking about devices that don't yet have one I certainly think the notion of metadata coming from the device that describes what it is that is doing the sending is would of great utility and I can imagine a variety of applications that would depend upon knowing the provenance of data and UDI certainly seems like, as was said in an analogy, if you know who is speaking on a phone then you'll be able to access the value of what they say. Well...so I like this notion of if it is present including it in metadata certainly seems reasonable. It is premature, it is early but it's certainly a very good idea.

Walter Suarez – Kaiser Permanente

This is Walter, independent of the merits of the proposal from Wes, I'm not sure that this particular rule is the right vehicle. This particular rule defines really the enumeration process and the requirements about the UDI, but it does not really intend to regulate the actual device in the way that other rules within the FDA do, particularly those for example that regulate devices that transmit data. So, it might be a comment to be made. I'm not sure, again, that this particular rule would be the vehicle that FDA would be able to use to make such a requirement of a device that transmits data, transmits the UDI.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Okay, you've made some very good points. So maybe unless I hear differently from the sense of the group that we do make this recommendation, that device provide transmitted identification under the circumstances that Wes described, why don't...if there are no objections we recommend that to ONC, but leave it to them to determine the best vehicle, whether it's with respect to comment on the NPRM or other ways for it and this as a recommendation.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yes.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Agreed.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Okay, terrific then...

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

And then Jonathan, I don't want to get lost the harmonization efforts between these requirements and the consolidated CDA.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

I'm sorry, who was that you broke up?

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

Leslie, I just want to make sure we get the harmonization comments in.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Oh, thank you so much.

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

So, Leslie, this is Jamie, so I think that that's really included in our comment number six as it stands, which would require that the UDI be a coded entry in applicable health summaries.

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

I agree, it's just that the timeliness is that that vote was finalized on Monday. So, a little bit more urgency, that's all.

Walter Suarez – Kaiser Permanente

But, again this is Walter here again, and Jamie you can correct me if I'm wrong, but this FDA rule would not be the vehicle for that either, this would be a requirement that ONC would have to look into as part of the EHR requirements is that correct?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

No, that's exactly right and that's why comment number six is essentially labeled for ONC only not for the FDA rule.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Okay, Jamie, I think you have a way of parsing the different comments back and I think to the extent that they are appropriate and can be attached to the NPRM that's great and I think the other set is to ONC. Do you have a sense of the next iteration of that?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, I mean, I think, that the comments that we've presented here, it seems to me from the discussion, are ready to ask for approval on the committee with the addition of the comment to ONC that Wes proposed and so we can come back and provide the final wording on that comment in a transmittal letter, but I'm not sure...can we...

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Great, why don't we take that as of motion or recommendation and let me just ask if there is any discussion on Jamie's summary of that? Okay, hearing no objection then Jamie that will go forth then as a recommendation.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Great, thank you.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Well, I thank you very much for your leadership and I want to welcome Dr. John Halamka who gave the keynote this morning at OSEHRA and it's amazing the individual who can be in many places simultaneously, because as you spoke the tweets flew and welcome John. Let me turn to you both for any broad introductory comments as well perhaps as a segue to the eHealth Exchange discussion.

John Halamka, MD, MS – Harvard Medical School

Oh, great, well thanks so much and so two brief comments. So, the OSEHRA conference is all about open source goodness and how is it that we can ensure that we create a community of developers sharing intellectual property for the benefit of all, so about 350 folks over here at the Gaylord National. So, of course I flew to Washington today with the notion, that as you say, Jon, I could do multiple things in Washington and then we made the meeting virtual, alas, the best laid and plans.

So, one other comment, yesterday in Massachusetts we went live with a Direct Project framework across the entire Commonwealth and Deval Patrick, the Governor of our State, clicked on the mouse and launched the transmission of his entire medical record from the Massachusetts General Hospital over the Direct Project framework to a community hospital in the western part of the state and immediately following that transaction a series of other transactions connecting patients and providers, and payers happened illustrating that we could have an ecosystem based on the Direct Project that would create novel uses of data as long as there was a trust fabric.

So, I just want to highlight, this is really a thank you to the Standards Committee and to ONC who made all this possible, because in effect all we did was create open source software and appliances running the Direct protocol that now are, as of today, connecting about 5000 doctors and over the course of the next year will connect some 20,000 providers in the Commonwealth. It works, it's real, it's open for business, and it was really all of you who laid the foundation for that.

Now, importantly, I think the rest of the agenda, Jon, for today is looking at how we're going to do things like Direct going forward and sustain that effort. Do we do it in a public context like ONC or do we do it in a public/private context in a way that is somewhat neutral to the outcome of elections. I mean, all of us probably watched the debate last night and asked ourselves, gee, what will the next several years bring and how will standards making change based on the outcome of the performance in such a debate?

Hopefully, we can create plans and organizations that insulate us in a standards making world from the outcome of elections and debates and so I look forward to the presentations on the Healthway and further discussions from Doug Fridsma on how the S&I Framework and it's componentry may be moved into public/private partnerships that insulate it from the vagaries of election-year politics. So, Jon, if you'd like I would be happy to oversee the comments for Mariann and the group.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

That would be terrific. I appreciate your metaphor about the election; Candy Crowley's next question was going to be on standards to the candidates I'm sure.

John Halamka, MD, MS – Harvard Medical School

Perfect. I think both candidates were consolidated CDA compliant, how about that? They just simply had different metadata headers. So, with that let us move onto the Healthway presentation, and as I said, its how do we create a sustainable model for carrying forward the NwHIN, S&I Framework and, you know, further substantiations of the standards that we have developed together in a way that will persist beyond any particular party or election. So, Mariann take it away.

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Oh, John, thank you so much and thank you so much to the committee for inviting us here today to brief you. It's such an exciting time for HIE and the country and I think John, your announcement is just great news. I think this is showing dramatic progress. So, what we wanted to talk about today, if you go to the next slide, is to share a little bit about the eHealth Exchange transition, this has actually been an effort that's been underway for quite some time in terms of planning, we'll introduce you to Healthway and we also wanted to use some of the time together to talk about our recent collaborative effort in working with that EHR, HIE Interoperability Workgroup and leaving some time naturally for discussion.

So, as a matter of introduction I'm Mariann Yeager. I actually wear two hats, so I actually am still a contractor to ONC, and I've been working for the past last year and a half or so in helping to map out and coordinate and facilitate the transition of the Nationwide Health Information Network Exchange to operate and sustain as a public/private endeavor and then the other hat I wear is that as Interim Executive Director of Healthway which is the nonprofit which has assumed support for the exchange.

So, with me today I actually have Michael Matthews, who is the Healthway Board Chair and President, as well as Kitt Winter from the Social Security Administration, and Kitt is actually the Chair of the eHealth Exchange Coordinating Committee. So, before we jump into the update, I don't know if we have Michael or Kitt online if you all would like to maybe say a word or two to the Standards Committee.

Michael Matthews – CEO - MedVA

Thank you, Mariann, this is Michael Matthews, I'm the CEO of MedVirginia, also I am a contractor with the Virginia Department of Health to build out our statewide HIE called Connect Virginia, as well as having the honor and privilege of serving as past Chair of the Nationwide Health Information Network Exchange Coordinating Committee, and now the President of the Healthway Board of Directors. I tell you all of that as background, to say I have both regional and state, and national perspectives of what an important time this is for the HIE industry.

As Mariann said while there has been a lot of rapid announcements and news breaks over the past few weeks this is the culmination of over a year and a half of very thoughtful engaged planning by the stakeholders and the NwHIN Exchange now known as eHealth Exchange and that was one of the components was a re-branding of the NwHIN Exchange to eHealth Exchange.

We all recognize, I'm sure everyone on this call, that we have to move to a point where HIE is viewed as a standard of care, if it's not a standard of care and it's truly arbitrary and up to the provider then that doesn't bode well for the future of health information exchange as a critical component of our healthcare transformation moving forward. We've gone through the pilot phase. The pilot phase, when there were these lone voices crying out in the wilderness to the believers to just come on board. We've moved past looking at HIE as a science fair project where all we were trying to do was dazzle with technology.

We all knew that we would get to a point where the proof, the evidence is in the data on ROI and the value proposition is there and we would then need to move into a scalable and sustainable operation of exchange. That's the excitement of where we are today is building on the solid foundation of all the production participants and ONC, and the Standards Committee, all of the heavy lifting that went into all of that, moving forward now how can we use that foundation so that we can truly embrace all those who want to participate in meaningful exchange.

So, Dr. Halamka's comment about having a public/private context I think is spot on and as you'll hear from the remarks today I believe that's exactly what we've created and we're very bullish on the future of our activities. Thanks so much for the time in the committee to have us be able to update you on all of this activity.

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Thank you, Michael and do we have Kitt Winter with us? I know she might have a little laryngitis, but Kitt are you able to speak.

Kitt Winter – eHealth Exchange Coordinating Committee Chair – Social Security Administration

Yes, thanks, Mariann, that's the dangers of having a child in elementary school. So, I do appreciate the committee in allowing us to speak today, I think that it's critical for the scalability moving forward. We've accomplished a lot over the exchange over that past several years and SSA with all its partnerships including MedVirginia and the other contractors that we have brought on we've definitely seen an image that it can bring to the federal agencies and the federal community as well as the public sector and well as the patients being able to access their records and access their disability benefits and be much more effective in a faster manner.

I think moving forward I'm looking forward to seeing where the exchange can move and I definitely appreciate the work that we've done with the Office of the National Coordinator and the Federal Health Architecture Board, I know that Tim Cromwell sits on this committee and working together with both VA and VLER, and the IPO, and DoD, and CMS have really benefited bringing all of that insight in trying to collaborate with the national standards. So, sorry again for my voice, but thank you.

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Thanks, Kitt. So, if we want to move to the next slide. As a matter to orient for those who may not have been tracking this work as closely, the eHealth Exchange, which was formally referred to as the Nationwide Health Information Network Exchange, is the community of exchange partners who share information today in production under a common trust agreement called the Data Use and Reciprocal Support Agreement or affectionately known as the DURSA and they share information based upon a shared set of technical requirements, policies and they rely on a common testing process as well. The standards are based upon national standards; this does include those which are Nationwide Health Information Network standards as well as others.

As you all know this started as an NwHIN Program initiative with production efforts starting back in 2009, but it really was the genesis of this work was really part of the trial implementations back in 2007. And so the idea is that this should be transitioned to a public/private partnership, which again is operated by Healthway and at that point was rebranded as the eHealth Exchange.

And at some point we'd like to talk a little bit more about lessons learned and the national return on investment, which has been realized through efficiencies and savings by having a shared trust agreement and testing processes it's minimized the need for point-to-point arrangements and there is actually a real ROI with that which we started calculating. And also, it lessens the burden of having to test each and every time you want to exchange with a new partner the idea and principles upon which the exchange was built is that you should have the ability to test once and rely on the trust agreement and the trust framework and have the ability to share information securely with all other partners in the network and so with that it provides the ability to expand coverage and connectivity throughout the US, which today reaches hundreds of hospitals and thousands of providers and millions of patients.

So, Healthway is the nonprofit organization which was chartered to support the eHealth Exchange and also recognizing that the issues we need to solve for the exchange also are quite applicable to industry and so we believe that it's important that Healthway also focused on cross industry collaboration to advance implementation around HIE and the effort we talk about later with respect to the EHR HIE Interoperability Workgroup is the first of many.

So, on the next slide, I think Michael talked about that we have been following a strategic roadmap for the eHealth Exchange, early efforts started in the NHIN trial implementation back in 2007 with the production really starting in 2009 with an early set of pilots really over the past several years. ONC has led by supporting and helping to incubate this growing community of exchange partners and when we took a look at where we were, really about a year ago, we realized that with 22 participants and hundreds of hospital providers and millions of patients connected that it really was growing beyond a pilot, and that in order to continue to scale and grow that it was important to allow this initiative to move from a federal program initiative and to operate as a public/private endeavor.

And so really the goal this year and next year is really focused on maturing and scaling, and growing so that we are ready for a full-scale rollout really within the next 6 to 9 months. The longer-term aim is to continue to move towards sustainability. I will mention that there was a pretty thoughtful and rigorous transition planning process that started more than a year ago and that resulted in both an operational plan as well as a business and sustainability plan and by having, you know, ONC and the federal partners, and the private sector at the table, as well as the technology partners who have been supporting this, we think we have a very solid vision and mission for the future.

So, if you go to the next slide the vision of the eHealth Exchange is to really serve as one of the critical elements of the Nationwide Health Information infrastructure and so we recognize that it's one of many networks that may exist and our sister network, the Care Connectivity Consortium, is a wonderful example of how multiple networks can really prosper and that by working together and collaborating it just strengthens HIE and strengthens the whole goal here which is to improve the health and welfare of people in our country. And so to really realize that vision it's important for the exchange to really lower the barriers to HIE, expand and extend HIE across connectivity, across geographies, organizational boundaries, interconnecting states, communities and other networks. And so the idea is to provide the services and the framework that allows HIE to expand beyond the current domains.

If you go to the next slide, we're very happy to let you know that there are now 34 organizations in production today, there are another six who have completed testing and are in various stages of the activation phase. So, we will have close to 40 in production by the end of this year. Our pipeline is growing dramatically, more than two dozen organizations. We've received probably 10 applications last week alone, it's largely we're seeing interest in the private sector and so we do expect to double participation easily within the next year.

And, so the initial interest was primarily to share information with federal agencies in support of federal programs. We're seeing a really dramatic shift that that interest is definitely still there, but we're also seeing organizations coming forward as a way to support private to private exchange, state to state exchange etcetera. And so, I think it's definitely an important shift in the evolution.

If you go to the next slide it lists the technology partners who support the exchange today, and again, this is a group that's growing dramatically, there is a very diverse range of technology ranging from EHR systems, HIE systems, gateways, integrators, and even some self-develop systems. And so, here again when the exchange first went into production, the earliest implementations were largely supported by CONNECT which is a software that was developed in a cross agency settings facilitated by the Federal Health Architecture Group and that really helped stimulate implementation, we're seeing that there's a dramatic growth in again different types of systems which now support the exchange partners. We believe that increasingly there will be more HIE and EHR systems that come forward, particularly in conjunction with our joint work with the multi-state initiative which we'll discuss later.

If you go to the next slide, the goals with the transition were actually pretty straightforward and so as we mapped out the transition strategy and the plan we wanted to make sure it was really grounded in the underlying goals and objectives. So, it's very clear that we really had to remain and wanted to remain aligned with the national strategy. I mean, the last thing we needed to do, as this moved from a federal program initiative to a public/private partnership, is to verge from the national strategy and to fracture and fragment our industry, rather we seek to unify and remain very closely aligned with the national strategy.

It was also important to make sure that we could insure the continuity of the operations and support. This is in fact a production network, it's not a proof of concept, it's not a pilot but information is shared every day to support the treatment of patients and veterans across the country, and to make sure that the disabled get their benefits more quickly, and so it's important that we not have interruption in operations. So, I think that was a little different, it was more than just packaging up a bundle of documents, but it was making sure we were very thoughtful and insuring continuity for this production effort.

It was also important that we take measures to scale the growth. We see the trajectory of growth and that's really without any marketing or proactive efforts to promote the exchange, but simply the demand that exists and so it was important that in addition to having that handoff that we set up a program that could really scale and through that we realized it was important to leverage the lessons that we have learned and to implement the improvements and there is one particular area that we'll emphasize later on around testing and that was probably signally one of the most important areas where we spent quite a bit of time with studying lessons learned, developing a strategy and implementing the new program.

And so the idea was that it's important to handoff and sustain operation, but also develop a gross strategy that would lead to sustainability. And again, this has been a very collaborative effort ONC is a tremendous partner. ONC and federal partner leadership have been actively engaged every step of the way through the process and so we think we've found a good way for this to work for again the benefit of not only the participants but also in support of the national strategy.

So, if you look at the next slide, it's helpful to highlight what has changed and what actually has not changed. So, as I mentioned that formally when this effort was supported by ONC as the Nationwide Health Information Network Program Initiative it was called the NwHIN Exchange and now that it's operating as a public/private initiative it's been rebranded as the eHealth Exchange. There are two important elements of this that have not changed at all and that's the coordinating committee, which is the group which oversees the exchange and they have their duties specified in the Data Use and Reciprocal Support Agreement or the DURSA, which also has remained unchanged. So, the day-to-day function of the exchange, the governance of it, the trust framework is exactly the same as it was before.

What has changed is that the on-boarding and testing process, which has been facilitated by ONC over the past several years, is now being handled by Healthway. In addition, the operation support that has been provided and funded by ONC is now provided and funded by Healthway and so the services which have been provided to participants for free over the past several years did have a cost associated and so there will actually be service fees that apply in the future and that's one part of the sustainability strategy which we'll discuss.

So, where are we in the transition? If you go to the next slide, Healthway assumed responsibility for eHealth Exchange operations effective October 1, 2012 and naturally there was a gradual handoff over time so it did not happen all at once, and this included the on-boarding process which is the mechanism for receiving and processing applications, for the participation testing which is now going to be facilitated by CCHIT as the testing body, which we'll talk about a little later. We assumed support for managing digital certificates, the service registries, supporting the coordinating committee and its work as well as maintaining the legal agreement and the operating policies and procedures. And again ongoing support promotion for the eHealth Exchange is now the responsibility of Healthway.

One item which was not specifically called out on the slide but it requires an important mention is the specifications work and so for the past several years ONC had supported work for the NwHIN Exchange through what's called a specification factory. We're actually working with IHE USA to assume responsibility for ongoing maintenance of the implementation specifications, largely because the work that has been implemented in the eHealth Exchange is based upon IHE profiles.

So, in lieu of having a separate specification development endeavor we are working with IHE USA to establish a very nimble implementation level specification process that can be responsive to the needs of this production community and others, but also to really work in support of a broader ecosystem where the testing actually informs the evolution of the specification. So, it's really what we're setting up is more of a lifecycle of the implementation specifications are implemented and tested through the testing program which then informs the refinement of those implementation specifications. Go to the next slide.

Again, just to reinforce, it's so important, because we do get a lot of questions about this. The trust framework used to support the exchange is unchanged. The DURSA remains in full force and effect. The coordinating committee continues to retain all its authorities that the participants grant to it as specified in the legal agreement. And the Healthway Board is a Corporate Board it serves as fiduciary capacity; it does not have any oversight with respect to the exchange, but will operate through an agreement with the coordinating committee. So, essentially the coordinating committee is the governing body for the exchange, it has selected Healthway to support the operations and the business of the exchange, and the coordinating committee retains oversight of that group.

If you go to the next slide, this is where we really talk about what we changed around the testing program. We, about a year ago, did a formal assessment of what was the previous on-boarding and testing process and realized that the process that was initially set up was great in getting us set up with an initial set of participants, but as we look forward it's important to really try to leverage lessons that we learned and to really establish a program that was going to help bring the exchange into the next wave of its evolution. And so, at that point it was clear that there was a desire to move the testing from being an internal function of the eHealth Exchange to working with an accredited test lab, which again also aligns and is consistent with the national strategy.

It was also important to raise the bar while the level of testing was sufficient for the early stages as the network grew we realized that it was important and there was an opportunity to raise the bar significantly with a significant focus on interoperability testing. There were also ways to streamline and make the process efficient and scalable, essentially making the program about 1/10 of the cost to maintain and with about 10 times the throughput.

So, in effect the program that we were implementing with CCHIT has very little cost implications to the eHealth Exchange itself, but really puts the emphasis on one making sure that the products both conform and interoperate and that there is effective testing for those who wish to join the exchange. And just to reemphasize the testing program that we are setting up with CCHIT does require participant testing as a condition of joining the eHealth Exchange. We do have more information that is posted on a public wiki that describes both the strategy and the artifacts.

If we go to the next slide, as a matter of introduction to Healthway, Healthway's mission is really twofold, one is to support the exchange, providing the infrastructure, resources, staffing to make sure that the eHealth Exchange and it's participants can accomplish their respective missions, but in addition, Healthway also has an opportunity to really help address the broader needs of HIE implementation and what we realized is that in many of the issues that we're trying to help address and solve for the eHealth Exchange have much broader applicability and rather than trying to focus very narrowly on trying to address things that work with the eHealth Exchange that Healthway has an opportunity through collaborating with other initiatives to really find ways to benefit industry and focusing on HIE implementation efforts.

So, the first initiative that we embarked on with this was around testing and we collaborated with the EHR HIE Interoperability Workgroup. We think that the end program that we have launched is actually much better for it and we think there are other opportunities as well.

If you go to the next slide, we wanted to just illustrate the interactions between the eHealth Exchange Coordinating Committee which again is the governing body which oversees the eHealth Exchange and the relationship with the Healthway Board, both of these having representation and leadership from both the private sector and the public sector.

So, the eHealth Exchange Coordinating Committee actually has appointed three individuals to serve on the Healthway Board of Directors, and those individuals are Michael Matthews, Jan Root from Utah Health Information Network and then Paul Matthews from OCHIN. In addition, the Healthway Board includes up to nine elected members. So, Healthway in addition to supporting the eHealth Exchange is also a membership organization where anyone in industry can essentially join Healthway as a corporate member and one of the benefits is having the ability to be eligible for representation on the corporate board. And so we're in the process right now of collecting and working with organizations who are joining Healthway as corporate members and then we'll hold board elections and fully constitute our Board of Directors.

There are also federal agencies and other agencies can actually serve as liaisons to the corporate board of directors. There are limitations on what a federal agency can do in terms of being a member of a corporate board, there are limits on what they're permitted to do, so there are currently four governmental liaisons two from ONC, Doug Fridsma and Jodi Daniel as well as Julie Crouse from CMS and Kitt Winter from the Social Security Administration. So, again, the role of the corporate board is really around making sure that the company is sustainable, helping to set the strategic direction on the programs and making sure that we're properly supporting the eHealth Exchange as a customer.

If we go to the next slide, I think this is where we'll move to talk about the testing program. I'll ask Jon Perlin; do we want to hold questions until the end?

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Why don't we go ahead with the rest of the presentation and hold questions, I think that's a good idea given the phone format.

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Okay, Jon.

John Halamka, MD, MS – Harvard Medical School

In fact, Jon, I was looking at the contents of this entire presentation, I think it all hangs together pretty well, so let us do questions at the end of everything.

Leslie Kelly Hall – Senior Vice President for Policy for Healthwise

John, could I ask her to speak up or increase her volume please?

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Absolutely, I'll project more, sorry about that. So, we want to move to the next slide, this is where we're talking about the joint effort with the EHR HIE Interoperability Workgroup and so I have several individuals who have joined me today who can also speak to this work. Representing the EHR/HIE Interoperability Workgroup we have Anuj Desai from the New York eHealth Collaborative. Again, we've already introduced Kitt Winter and Michael Matthews and then we also have John Donnelly who is the State Representative who is one of the Co-Chairs of the Joint Testing Task Group but has also been instrumental in this work. If you go to the next slide.

As a strategic context and why we embarked on this joint work, again the eHealth Exchange had a real operational need to have a testing program that would verify as a condition of participating in the network that a system both conformed and was interoperable and that other participants could rely on the fact that if somebody had gone through that testing program that it would work and they could rely on the fact they would not have to do one off development or tweaking, or subsequent testing, but they could truly rely on that testing as being sufficient and agreeing to share data.

And so, in addition, the states also had a similar desire in just recognizing and I think everyone on this call probably appreciates more than anyone that there are barriers to HIE adoption. There are disparate implementations and interpretations of standards, interfaces today are costly and a lot of times require custom development and we've see too often that there are ad hoc negotiations and point-to-point arrangements both around technical requirements as well as policies and so that lack of uniformity and that lack of having a credible benchmark to verify that a system is indeed not only conforming but can actually interoperate in production out of the box is just a gap.

So, it was clear that, and as the exchanges had implementation level specifications for some time, that there was a need to have tightly specified implementation level requirements that could be verified through automation as much is possible to really verify interoperability, to verify that a system once implemented actually has the ability to work with many other systems regardless of the vendor, regardless of the platform or the organization.

And so, we realized that the way for this to be accomplished is to work with other groups through cross industry collaboration, build on the foundation of national standards and the foundation of the national level certification program and to work together. And so, probably about six to nine months ago when we were looking at the eHealth Exchange transition and setting up the new testing program we realized that a multi-state initiative led by New York called the EHR HIE Interoperability Workgroup had a similar need and so rather than developing two separate programs we realized there was a significant crossover in the technical specifications and the objectives, and the vision, and we realized that we had a duty really to collaborate and work together to come up with a single program that would satisfy both needs.

And so, we felt that this not only reinforced and strengthened the vision, but would provide cohesiveness which is so needed right now and also, because Healthway is a mission driven organization and as is the EHR HIE Interoperability Workgroup that it was important that this effort be led by mission driven organizations. And, because it supports both the state HIE program it would enable the future growth of eHealth Exchange and it would again include the representation and voice of federal agencies and leaderships. It really gelled in terms of the spirit of public/private partnership.

And, so now I would now like to turn it over to Anuj Desai, I'm not sure how familiar the Standards Committee is with the work of the EHR HIE Interoperability Workgroup and we wanted to give you an opportunity to hear directly from them. So, Anuj?

Anuj Desai – Director of Business Development - New York eHealth Collaborative

Thanks, Mariann. Good morning everyone. Thank you for the opportunity to present to this group. We can go to the next slide, please. I also want to introduce Nick VanDuyne who is our Chief Technology Officer at the New York eHealth Collaborative, who is in my office with me.

Nick VanDuyne – Chief Technology Officer – New York eHealth Collaborative

Good morning everyone.

Anuj Desai – Director of Business Development - New York eHealth Collaborative

So, I just want to provide a little background on the Workgroup and you may have seen some of these slides in different contexts or different forms, but to kind of set the record straight about who we are and what our mission is. So, the Interoperability Workgroup was formed about 18 months ago I guess by HIMSS 2 years ago by New York, because in New York what we saw was one of the barriers towards adoption of HIE was the differences between the technical implementations. So, the connections between EHRs to HIE was a custom interface every time and there are standards that already existed in the industry but they weren't implemented the same and consistently.

So, what that drove to was eventually to the state HIE Programs and to the providers a very high cost of developing these interfaces. So, we thought there had to be a way to reduce the cost and try to drive the industry towards a single way of doing things. So, we formed this Interoperability Workgroup and the way we've looked at it is really the win/win/win for all the parties involved.

For the vendors, particularly the EMR vendors it's an opportunity to differentiate their product in a highly fragmented market. They build an interface once; it can be used across multiple HIEs in multiple states. For the State HIE Programs, you know, it's an opportunity for us to get adoption in the market much quicker and reduce the overall cost. And for providers it's really increased the value problem of their individual EMR. They should understand that when they buy an EMR it has the capabilities necessary to connect to HIEs and really drive toward more fulfilled exchange. The next slide, please.

So, the Workgroup strategy I guess it's a two phased strategy that we've employed in the last 18 months. Phase one was really where we formed the Workgroup and developed a series of implementation guides, you know, we realized we couldn't do this alone and we had to get other states engaged and really get the states and vendors working together. So, we formed a group and I'll talk about who the members are in a minute. We've developed a functional, technical, and test specifications for 3 specifications around Direct, patient record lookup and the contents of that.

And what we found really there was the patient record lookup and content specifications were directly aligned with the work that Healthway was doing moving forward with the eHealth Exchange. We worked with each state's policy group, so the state-wide entity represented their state on the Workgroup and they worked internally within their organizations or within their own states to insure that whatever work was being done here would also work across the regional HIEs within their state. And then we truly appreciate the support with ONC throughout this project and we've done a lot to maintain alignment or specifications with ONC.

Phase two is where we are now. One other thing that is unique about this program is we're working with the Regional Extension Centers within states, Direct Programs in states to ensure that the specifications that are held up by this Workgroup are in the contracts, you know, in the preferred vendor contracts for the EMR and HIE vendors in their state that we've included the language to ensure that the vendors are including the compliance e-specifications in their products. We developed the test specifications and today we're announcing the compliance strategy. Next slide, please.

So, here's a list of the members in the Workgroup. We started with seven states and now we're up to 15 states. These states are really our cross-section of the country. In total they represent about 50% of the population if you look at that measure and there are 37 HIT vendors engaged. So, about half of them are EMR vendors and about half of them are HIE vendors. Pretty much all the big players are engaged in the Workgroup and many of the smaller players are also engaged.

We worked very collaboratively with the group over the last 18 months, so we really looked at what was implementable within the next year, you know, we didn't start with the whiteboard, we started more with saying look let's look at the capabilities of all the products, let's look at what the needs are of states, how we can get to a single roadmap for the vendor community in a short period of time.

And what holds the Workgroup together is that every state and every vendor on the Workgroup has signed an MOU, just that lays out the terms of participation and essentially what it says is that the vendors have complied to within 1-2 product releases to include conformance specifications that have been released. The specifications were released back in November and over the past year many of the vendors have committed product timelines in terms of when their products will meet these specifications.

And the state programs have also committed through the MOU to ensure that the provider community is aware of these specifications and are demanding from their vendors that they comply with these specifications, either through the regional extension center program, through policy or through other means. Next slide, please.

So, as Mariann alluded to earlier, you know, there really was an opportunity for the Interoperability Workgroup to work with another partner to develop a compliance testing program, you know, we feel that working together really achieves a larger marketing impact and provides the industry with a single roadmap. It reduces fragmentation and, you know, we really have a shared vision. And Mariann, I don't know if you want to add a few other points to this in particular in our relationship and our partnership?

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Well, I think, the synergies were just so clear and it's interesting you never really know what to expect when you first start going down a path of collaborating, but if anything it just became more evident over time how intertwined the work is and so I would say not just in a conceptual level, we knew in principle, we knew theoretically, we knew the outcome we wanted, but I think we were able to accomplish so much more and we have a much, much, much better program for both vendors and participants, because of the close collaboration and truly working jointly.

I think the biggest lesson learned here is we had to be very equitable in having joint leadership in the groups and the joint work every step of the way and it's just worked phenomenally. So, do we want to talk a little bit about the specific ways in which we've collaborated and move to the next slide?

So, there are really three primary ways that we've been working together, again jointly and one is on the joint Workgroup which is a testing task group so there were some testing artifacts which have been used in the eHealth production efforts for some time as well as the artifacts that have been used and developed for the multi-state initiative and so we've been working together over the past several months to harmonize the test requirements. The task group is actually co-chaired with a representative from the states as well as a representative from Healthway. It is open, there is a wiki anyone can join it. There is a collective review of the artifacts, consensus on what to bring forward for testing. We then go through a collective review with the testing body and then go from there.

So, we will, while there has been some previous work which is leading up to the pilots which we're kicking off with CCHIT in the next several weeks, there also will be ongoing engagement to review work products in support of both the state efforts and the eHealth Exchange.

The second area where we had collaborated is in the selection engagement of the compliance testing body and this is a really important decision because it essentially serves as a huge foundation for the eHealth Exchange growth and also for the states. And, so, I think Anuj can talk a little bit more about the process we went through, but we did collectively work on a Request for Proposals, there was a joint selection committee and then we jointly defined the statement of work, terms and pricing that would work both for eHealth Exchange as well as the state program.

And then we're continuing to work very closely together as we implement rollout and support the testing program going forward and so while it wasn't one of those one-time things where we wanted to just sort of select a testing body and move on, but I think see this really as a long-term strategy.

So, if we go to the next slide, the overall goals of the program were to really address the barriers to HIE and so that is to really establish a benchmark for interoperability while minimizing the cost and complexity of having to do custom developed interfaces, and so again to try to accomplish the ability the test wants and have the ability to exchange with many others. So, there are two facets of the program one is focused on testing products and that is again to provide market assurance and clarity that if a product has that seal that it truly is not only compliant but it also provides assurances to providers and to HIEs that that product is in fact interoperable and that it's been validated, that it interoperates with systems developed by different vendors and different platforms.

The second part of the program is really tailored to the testing that's needed for participation in eHealth Exchange and this is where the testing body will verify that the implementation of those successfully certified systems are compliant and that they also assure interoperability among participants in the eHealth Exchange. So, Anuj, can I turn it over to you? Do you want to talk a little bit about the process we went through to select the testing body?

Anuj Desai – Director of Business Development - New York eHealth Collaborative

Sure, thank you. I'm sorry, next slide, please. So, in terms of selecting the testing body it was really a joint process between Healthway and the Interoperability Workgroup. It was truly a very rigorous RFP. We issued a joint RFP between the Interoperability Workgroup and Healthway to select an ONC authorized testing body to carry out the testing program. The selection committee really was made up of equal representation of both Healthway and the Workgroup. So, it was four states, you know, from the Workgroup, Interoperability Workgroup, a cross-section of states, and then four representatives in the eHealth Exchange and these were primarily federal agencies, and then we had a third-party facilitator to help make sure all the processes were fair and that the process was completely rigorous.

We decided to pick a single testing body initially and that was really...the goal was to form a true collaborative partnership with the testing body, you know, and really work closely with them to develop the testing program. There was some thought given about taking multiple testing bodies and we still reserve the right to do that in the future, but initially for the first period we'll be using one testing body. And we've worked very hard in terms of negotiating with the testing body to ensure that the prices that they are putting forth for testing are fair and the process that they're going through is extremely rigorous since that was...we spent a good three to four months on this RFP process. So, next slide, please.

So, just to share a little bit about the criteria we used on selecting the testing body. The testing body had to be an authorized testing body from ONC so it was a very limited pool we were looking at. We really looked very closely at conflicts of interest and we wanted to make sure they were not owned by a vendor or had any like vendor representation in a big way in their testing process. We wanted to be sure that the technical capabilities were up to par, that they know the industry, that they know the partners here, they know the specifications extremely well, that they're very collaborative and, you know, they've done a lot of internal and external audits, their quality is high, and that they're financially stable. So, you know, we think the testing program is very rigorous and then we'll talk about that in a minute, but we wanted to ensure that the vendor we picked also met them at the high level of interoperability quality that we were looking for. So, next slide.

So, we have picked CCHIT to be that testing body and as everyone here is aware they are an ONC authorized certification body, they have proven experience of HIT at the national level, I think they've certified the most products out there out of any testing body. As, Alisa mentioned earlier we were looking for a nonprofit, mission driven organization that believes in our vision of driving true exchange. And they had an ability to ramp up quickly and provide a price that was really fair for the industry. So, Alisa, are you on the call? I'll turn it over to you.

Alisa Ray – Executive Director - Certification Council for Health Information Technology

I am, Anuj. I am on. Can you hear me?

Anuj Desai – Director of Business Development - New York eHealth Collaborative

Yes.

Alisa Ray – Executive Director - Certification Council for Health Information Technology

Okay. So, let's move onto the next slide and I'll just take a moment to introduce myself. I'm Alisa Ray and I serve as CCHIT's Executive Director and on behalf of the whole organization we're just completely delighted to play a supporting role in making this work because it's so consistent with our mission that hasn't changed since we were founded in 2005 and that's simply to facilitate or accelerate the adoption of Health IT and that we think an efficient, credible and rigorous testing, and certification process can really do that.

So, maybe I'll spend...I know we don't have much time, but I think just to...I'd like to highlight our experience and qualifications, but maybe I'll do that in the context of how the role of testing and certification has evolved over time. As, I mentioned we were founded in 2005 largely in reaction to the founding of ONC and the first strategic plan for Health IT then. We had a contract to design certification criteria and a testing process that hadn't been done before. So, this was sort of pioneering work that I think we've built off of and evolved, and learned how to advance, and do better with over time.

Most importantly, we showed that you could test software number one and number two that you could do it virtually and quite efficiently. So, that was a very important part of our work there. Another thing that you all might, some of you anyway might recall is that we created, we had an early endeavor into open-source tools for facilitating interoperability collaboration and testing it's called Project LAIKA. We worked with the MITRE Corporation on that. We learned a lot from it, I think we would all agree that seems like a long time ago if you think about interoperability years, but that really helped up position and be ready to take this on now.

We quickly evolved as the environment evolved with the HITECH Act and other testers and certifiers came on and we embraced the work, we became a testing body and certification body under the temporary program and provided a lot of support and leadership there, went on to do the hard work to become accredited by ANSI and NVLAP and also authorized by ONC as an ACB we're ready for the permit program and the 2014 addition criteria when those come on, that's very important to us too.

We also did some work in that time working with self developed systems, helping providers who either had self developed or customized systems in the ONC program. Testing implementations and participants as we call it is important here so we think that experience will serve us very well as we look forward to creating this new program in conjunction with Healthway and the Interoperability Workgroup.

So, let me, just one more slide, the next slide, talk a little bit about the testing approach. I'm not going to delve on this here, because I know we're short for time, but Mariann really talked about the premise of this work is that you test once and you can rely upon it for the future, but that only stays hinged together if you have a rigorous testing process that allows for that trust. So, there are really two components, the product testing that she mentioned and then, again the participant testing. We have a similar approach to that. Our experience shows you can use testing guides; some automated testing tools, other sorts of support to help the vendors prepare their development process. Now, rest assured the product has to actually be locked down with a commercially available version before they come to have that verified, that conformance verified by our CCHIT testing team and that's overseen in this automated environment.

The participant program works in a similar way, they're a slightly different set of test cases and qualifications there, we can talk about that a little bit more, but in the interest of time I think we should move on other than just to say that there is a similar process for preparation and then actual validation and testing process. Next slide.

This shows the compliance testing process, but as it fits within the larger on-boarding eHealth Exchange process. Mariann talked about the DURSA and other things that they do in their application process. Mariann, I would turn this over to you, but maybe we should move on where I think we're short for time.

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Sure, that sounds good.

Alisa Ray – Executive Director - Certification Council for Health Information Technology

Okay, anything you'd like to add?

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Just that it just illustrates the two-pronged process for both the product piece and then the bottom rows illustrates how the process works for on-boarding, but I think it's self-explanatory.

Alisa Ray – Executive Director - Certification Council for Health Information Technology

Sure and then moving onto slide 30, that's my last slide, just to give you a little bit of information on the compliance testing environment itself and my colleague Dennis Wilson who is our technical testing director is actually on the phone too. If we have more questions Dennis will be responsible for standing this up, but we're partnering with Aegis, I think that's an organization that many of you have heard of before, the premise is that we're developing an open source environment, we'll maintain that, within that there will be some highly automated testing tools really again with the idea that vendors and participants can go out there and practice prepare bang against this reference implementation to really pre-validate and make sure that they have their products all ready to go before they actually come to us with a lock down again, confirmed locked down ready for production version to confirm that they're ready for testing.

The whole thing builds on our experience of designing programs that are easy to use and efficient for folks to get through, yet still have the right balance between the rigor and efficiency that's needed to assure everyone's goals. Mariann, I think I might stop here at this point and turn it back to you to see how we'd like to use the rest of the time.

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Sure, absolutely, so I think we want to just offer it up for committee discussion and questions.

John Halamka, MD, MS – Harvard Medical School

Great, well thanks very much and so let me start off with a question which is, recognizing the scope of your presentation today covered exchange and I wonder, and this is a question probably for the group and Doug, as we think about Direct and of course test platforms for Direct are going to be required as part of Meaningful Use Stage 2 and the ability to do cross vendor or to CMS directed exchange, does any of the scope of this new public/private initiative cover Direct or is it really about spitting out exchange and certification testing and development of exchange?

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Well, this is Mariann; I can...Anuj do you want to address that one?

Anuj Desai – Director of Business Development - New York eHealth Collaborative

Sure, yeah, so, John thanks a lot for that question, it does include Direct as well. So, where the overlap is between Healthway and the Interoperability Workgroup is really on exchange and the content specs but Direct is also part of the testing program and that's specifically for the state HIE program.

John Halamka, MD, MS – Harvard Medical School

Great. Are there other questions for other folks? Wes, please go ahead.

Wes Rishel – Gartner, Incorporated

Yeah.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

This is David.

Nancy Orvis – Director Health Standards Participation – Department of Defense

Yes, Nancy Orvis has a question too.

John Halamka, MD, MS – Harvard Medical School

Okay, so we've got Wes, we've got David, we've got Nancy.

Wes Rishel – Gartner, Incorporated

So, I have a comment and a question. The comment is that the hypothesis that a number of different systems testing with a central certifier and then working interoperability as opposed to a triangular testing model has only ever been proven in relatively restricted environments like weapon systems and things like that. It tends to work better at the non-application layers of the protocol so you can do things like after, you know, five years experience they've almost got Bluetooth testing to where Bluetooth devices interoperate pretty well, but in the first few years all they could make sure was that they plugged and sent signals back and forth.

That's not any way demeaning the work that's being represented here, it's just a suggestion that the forthcoming challenge will be to deal with interoperability issues that are discovered post certification and providing some measure of community support for resolving those issues, this is a very similar comment to a comment I've made with regards to the regulatory standards that I believe there needs to be kind of a well supported informal channel for discussion of these issues and coming up with tentative solutions that can operate more quickly than the SDOs do in formal process, but is supported by those SDOs. And that the momentum that you have developed here doesn't stall but you somehow end up carrying the ball all the way to implementation as opposed to stopping at certification.

The two questions I have are, one, what's your annual budget and how is that reflected on the members? And two, do you have the ability to measure what's being done? You have a very long list of participants, a very impressive list and you talk about there being in production, but it's different to exchange a CCD as a document or a lab result than it is to exchange a CCD and be able to shred the data into a structured database. I'm just wondering where are you along what is clearly a multiyear path towards fully interoperability?

Nick VanDuyne – Chief Technology Officer – New York eHealth Collaborative

Hi, this is Nick VanDuyne from New York eHealth Collaborative, if you don't mind I'll take a stab at your questions. So, the first one, what's our budget, on the Interoperability Workgroup side it's been an all volunteer effort. New York has...we funded the...and we'll continue to do that, but the collaboration has been from the vendors in the states in an effort where they know it's needed and it's important work and they volunteered their time and energy.

As for your second question, you know, you're correct; everything is an iterative cycle, right? I mean, if you were to look at this in the grand scheme of things, it's kind of like that first step and we feel that the Interoperability Workgroup is going to continue to function in that way and our vision on this has been look we got vendors to admittedly tell us in confidential terms that, hey we're really lacking in even the collection of certain data elements, we can't really do a lot of this today and we can't really make any of it happen. So, they're committing to refining their platforms to actually get the data elements. They're committed to refining their platforms so that they can actually send the data elements.

And when we looked at, you know, the C32, you know, great first step, right? Nobody is going to deny the work that HITSP did was awesome, but it left a lot of lateral freedom because people just weren't there. So, we've tightened that up and our vision is like, you know, the consolidated CDA and HL7 V3 and the green CDA are all sort of things that are coming down the road and we need to be marching to that, but at the same time, as a group, we all know technology morphs, right?

So, we need to keep our eye on hData, are we going to start doing things in a RESTful way and I think the idea here is that we have a group of committed states and committed vendors that are saying, you know what interoperability is good for us as a state, it's good for our populations and we have vendors that say interoperability is good for our business model and we've created a cohort that's agile enough to continue moving down this road.

I mean, I feel pretty strongly when you look at what we've done with the information that was given to us, we have moved relatively quickly and I think we still have that agility. Now, granted, a lot of this work is based on work from other groups, okay? So the HIE Group gave us all the standards that we have today and HL7 might do hData but the industry is going to move and we need to move with it in the direction that the federal government wants us to go.

Wes Rishel – Gartner, Incorporated

Thanks, I'd like to get the question answered by Mariann about the Healthway budget.

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Sure, Wes. What we realized is that the cost to support the eHealth Exchange are fairly fixed and so to support the infrastructure and staffing everything is about 1.5 million a year and the incremental costs of adding a new participant is fairly small and so our sustainability model is essentially once we reach a critical mass of participants that they're very achievable per participant annual service fees that they would pay ranging anywhere from \$4,700.00 a year for the smaller participants based on the annual revenue up to \$19,000.00 a year for the larger organizations and they were naturally involved in helping us develop the pricing.

Regarding the second question and the ability to measure connectivity and what's actually being exchanged and how people are actually using the connectivity, I mean, I don't have any data today. We know that in the early implementations they're getting connected and they're sharing data with the idea of sharing the CCD and using it and displaying it for both clinical decision-making as well as for Social Security Administration, they definitely take it in and Kitt can speak to that. But, I think we need to do more study, I mean, we frankly have this national level beacon community and I think it's ripe for study.

Wes Rishel – Gartner, Incorporated

Well, I would just like to make a suggestion that you build that notion of study in as close to the base as possible, you know, in your operating agreements and so forth, because it's really hard to go back and study afterwards.

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Yeah, okay.

Wes Rishel – Gartner, Incorporated

I have another question, but I'm going to defer to other people on the panel and see if I get a chance later.

John Halamka, MD, MS – Harvard Medical School

Well, thanks. David McCallie?

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

Yes, hi, thanks and awful lot of material on the presentation. I suspect we could debate every slide for quite a while, but, you know, two broad questions, one is about the certification whether the focus is on content or transport or both and I think I know the answer, but I would appreciate clarification on that.

And then the second one maybe more important is, as Mariann mentioned, there will inevitably be multiple of these networks that emerge, I think you used term sister networks and I'm wondering if it's possible to have any benefits of the certification to be decoupled from network membership? From a vendor point-of-view joining lots and lots of networks may be counterproductive when the main goal is to be certified if the certification turns out to be, you know, useful and valuable as per Wes's question, to be certified without, you know, kind of pre-committing to all these networks and letting our clients drive that as they wish to join the network. So, can the certification be decoupled from membership is I guess my real question?

Anuj Desai – Director of Business Development - New York eHealth Collaborative

I can take that Mariann. So, to answer your first question it is both, it's content and transport, it's definitely both. From the Interoperability Workgroup side we look at product level testing. So, it's, you know, the certification is down to the product level and, you know, it's not for any particular network. The second part of that testing is for the eHealth Exchange. So, the first phase is product level testing so they can join any HIE and that certification would be an instrument for that, but the second level is the eHealth Exchange testing. Mariann do you want to add to that?

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Sure, just one addition to the question regarding the scope of certification, it covers transport, content, as well as the transactions themselves. So, lookup and retrieval of records, document submission, administrative distributive and others, so I think it's pretty comprehensive. And Anuj is correct that the product certification is indeed available publicly for any technology that wishes to seek it and it's not linked to the network. There is additional testing that is required once that system is implemented to verify that the implementation is in fact interoperable and that's different. We think it's something we'll have to evaluate over time. And we definitely just want to collaborate and explore on how to make this work for the industry.

John Donnelly – IWG – State of New Jersey

Yeah, hi, this is John Donnelly from IWG, just wanted to add one small comment to that. At the product level testing I think one of the things, and I think to the question, the intention here is that the vendor does stand up then a production ready version of their test and they could do that certification once with that version so the added value here that we want to have in this testing program is that there some level of version control over what got tested for the product and then the subsequent piece is the utilization of that particular version or a version by participants. So, we do see it as a one certification at the product level opportunity for a vendor.

David McCallie, Jr. – Cerner Corporation – Vice President of Medical Informatics

This is David, just to continue on my question. Thanks for that clarification and that sounds like the right direction. I would respond though to the prior comment from one of the IWG members, I didn't catch the name where you listed a number of forthcoming potential things like green CDA and I think you mentioned, oh, hData, I mean we should be careful, I'm again speaking for the vendor point-of-view of a laundry list of potential standards, some of which aren't even standards yet as being swept into the notion of what you are your certifying. I think these need to be very specific and not open-ended like that.

I mean the vendors are not going to...I suspect most vendors would not make an open-ended commitment to whatever emerges from your certification pipeline that they will meet that standard. I think these will have to be driven by market adoption, by use case needs, and so forth. So, be specific and you'll get more cooperation I think from the vendors.

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Thanks, Dave.

John Donnelly – IWG – State of New Jersey

And, I think there is the example of what we did in the rigor, this is John Donnelly again, I'm sorry, of the first pass of specifications and it was very specific as to what the deliverable requirements were in collaboration with vendor readiness and I think we're going to maintain that level of dialogue with them for any of these newer use cases or initiatives that have emanated either from S&I or other places. So, it is a matter of constant interaction similar to what we've done up to now.

John Halamka, MD, MS – Harvard Medical School

I know we're running short on time and we need to give Doug Fridsma a chance to give us his updates. So, the last two comments, Nancy Orvis and then Dixie Baker.

Nancy Orvis – Director Health Standards Participation – Department of Defense

Right, I'm familiar with the CCHIT certified products and I just want you to clarify for me whether you're doing a separate kind of certification for these consortia of exchanges? Is it one and the same or is it different? It's like a certification of exchange stuff versus the products?

Mariann Yeager – Interim Executive Director – Healthway, Inc.

It is a separate program. Alisa, do you want to characterize this?

Alisa Ray – Executive Director - Certification Council for Health Information Technology

Yeah, just to be clear, the joint Interoperability Workgroup is what we call the scheme owner, right? They are the ones that actually, you know, create the test specifications, the test cases, detail the standards, the levels of optionality, etcetera. So, that happens within that stakeholder community and then they turn it over to us to bring to our automated testing environment and we really just confirm the compliance with those specifications. So, it is very separate from the CCHIT Programs that we also operate.

Nancy Orvis – Director Health Standards Participation – Department of Defense

I can't see right now what your 35 vendors are, but there are a lot of small products that have real difficulty going into a EHR, you know, whether like an anesthesia record or this and that and the other, are any of those kind of vendors in or are they all vendors that were previously in the CCHIT world?

Alisa Ray – Executive Director - Certification Council for Health Information Technology

I'm going to defer back to Mariann and Anuj, but this is a totally separate world.

Nancy Orvis – Director Health Standards Participation – Department of Defense

Okay, fine, thanks.

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Yeah, Nancy, they're largely HIE vendors and EHR vendors. I don't know how much interest there is in the specialty side. Anuj, can you speak to that?

Anuj Desai – Director of Business Development - New York eHealth Collaborative

No, I mean, I think, they're all just a large, I mean they're all EHR and HIE vendors.

Nancy Orvis – Director Health Standards Participation – Department of Defense

Thank you.

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Sure.

John Halamka, MD, MS – Harvard Medical School

Okay, Dixie Baker, last word.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Okay, this is really impressive work so thank you and it was a really good presentation as well. My question relates to the specifications that you are certifying against. As you may know, you know, a team of our Standards Committee looked at the exchange specifications so that relates to this question. You said you're taking responsibility for the exchange specifications from IHE USA and then one of your slides said you were developing your own technical specifications and implementation guide.

So, my questions are first, do you plan to take all 12 of the original exchange specifications forward as part of eHealth Exchange? And, second, do you plan to take the modular transport and security spec that's part of the 2014 addition; do you plan to adopt that as part of your specification?

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Sure. So, the original...the 12 specifications which were supported in production will move forward. I mean, they're supporting real world patient care and disability determination today so that's just a byproduct of what provides value to the network participants and what's working in production. So, there has been a specification factory which was run by ONC for the past several years which had maintained those specifications, that is the work we are handing off to IHE to maintain going forward which naturally would include the modular spec work.

I can tell you that the modular specifications work was actually the foundation for the test requirements that were harmonized with the IWG work and that are being incorporated into the program. So, we know we have a little bit more work there to do to completely harmonize, but I think we're on the right track in terms of what's being tested. Does that help?

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Yeah, but I thought you said that you guys are taking over maintenance of the specifications from IHE?

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Oh, no I might have...I misspoke then, we are taking over...we assumed responsibility for ongoing specification maintenance from ONC and ONC specification factory.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Oh, okay.

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Then instead of...the exchange doesn't want to be in the business of spec development, we think that's better served by SDOs and spec development groups and so we're working collaboratively with IHE so IHE assumes that work.

Dixie Baker – Science Applications International Corporation – CTO, Health & Life Sciences

Got it, thank you that's very useful. Thanks.

Mariann Yeager – Interim Executive Director – Healthway, Inc.

Okay, thanks, Dixie.

John Halamka, MD, MS – Harvard Medical School

Okay, well, hey Jon Perlin, I think we're ready to move onto Doug Fridsma's summary, which I think will hopefully continue some of this theme of how it is we will ensure sustainability across all the various ONC activities, especially the S&I Framework.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Absolutely, right and I think it may even hit on Wes's implementation question. So, thanks, John and Doug to you.

John Halamka, MD, MS – Harvard Medical School

Yes.

Doug Fridsma, MD, PhD, FACP, FACMI – Director of Standards & Interoperability - Office of the National Coordinator

Great, so if we could go to the next slide. I'm going to try to get us back on track, I don't have a whole lot of slides to present and it's just really a wrap up on a follow-up to a lot of the good discussion that has happened before.

The first thing I want to say is I just want to congratulate the team that was working on the transition from the production pilot as we've called them when they were part of the ONC portfolio and all of the hard work that's gone into the transition now into a public/private partnership. It's an area that we've been working on relentlessly really over the course of the last nearly 18 months or so trying to streamline the on-boarding process, making sure that we've got the right artifacts together, simplifying some of the specifications and I think it's a testament to the dedication of the membership on the coordinating committee, the federal partners that were participating as well for us to see sort of the success of moving something that started in the incubator that was ONC and now has become something that is going to be out there in the private sector in a public/private partnership and I think providing tremendous value to those that will be participating in information exchange. So, if we can go to the next slide.

I think one of the things that I wanted to do is give you two brief updates. The first is to talk a little bit about the standards in the interoperability framework and some of the lessons learned as part of the standards and interoperability work and how we anticipate going into sort of this next phase of the S&I Framework activities, how we're trying to address challenges that we identified through the process and how we want to kind of support this next phase of standards, acceleration, and sort of consensus building within the standards and interoperability framework.

So, as just by way of reminder, this is a diagram that has a lot of boxes that are fairly familiar but the standards and interoperability framework has a series of contracts that are sort of organized into different tasks, so there is the use case development, there is harmonization of core concepts, we have support and engagement with the SDOs as part of the standard development support, we develop implementation specifications based on those standards and then we try to pilot them, develop reference implementations and ultimately lead to certification testing.

I think one of the things that we realized is that testing of the standard occurs for the first time during the pilot demonstration and that's pretty late in the process and so to Wes's point one of the things that we did in sort of this first stage of the standards acceleration activities is to just get the portfolio constructed and get some standards out there that people could start to use.

What you'd really like to do in a mature industry is that as people come against interoperability challenges or they have business requirements to create standards that will accelerate the exchange of information and the like, you'd like to have those pilots and those use cases drive the standards development process. So, in fact, you identify that you have a need to do a particular kind of information exchange, you realized that the portfolio of standards that you have is not adequate and so then you begin to engage the SDOs to fill that gap based on the business needs that you have, and so, what we found is, is that we're actually doing the testing fairly late in the process they way it works.

I think the other thing that's important is that when you come into a problem, in the sense that to two people have implemented a particular standard and it isn't achieving your objectives of getting to interoperability, there are kind of three places in which there could be a problem. It could be that the testing specifications or the way in which we do our testing is inadequately specified and so we're not being rigorous enough in our testing framework to achieve the goals of interoperability.

It could also happen in our implementation guide in which we aren't particularly constrained in the options that we have or we don't have all of the clarity in the way in which the implementation specifications define how that standard gets used and so two different organizations might do it differently or it could be that the standard itself lacks an attribute or doesn't have the value set that it needs or there is something fundamental to the standard that we need.

And so, as we were taking a look at sort of our standards and interoperability framework we realized that in fact things like the pilot demonstration, the development of reference implementation and sort of getting us to an early assessment of testing is going to be an important part of our ability to both learn from the real world experience and feed it back into our standards and implementation guides and to our testing platforms, as well as making sure that we in some sense reverse the process or we begin to kind of pivot in the sense that we can begin supporting implementations identifying where there are needs for interoperability and then using those needs to drive where we make our investments and where we develop new standards and implementation guides.

So, if you go to the next slide. So, one of the things that we are working on right now is that we have put into our budget for 2013 the development of what we're calling an implementation and pre-certification testing framework in much the same way that the standards and interoperability framework is there to accelerate the standard development process, one of the things that we're trying to do is create a framework, if you will, or a platform that people who are trying to solve real implementation challenges have a place where they can share best practices, that they can do some testing and we can provide some tools and resources that they can bump up against and that we then can use all of that information to refine our standards, improve our implementation guides, and sort of set the stage for better testing and sort of pre-certification environments.

It isn't to say that those testing environments necessarily will be the ones that the ATCBs might use. We think that there's another step that needs to happen in terms of getting consistency and hardening those standards, but one of the things that I think is impairing our ability to accelerate both innovation and standard's adoption is support for implementation, feeding that back into our standards infrastructure and making sure that we've got testing infrastructure that will allow people to kind of come ready to the table in terms of how they're able to do things.

And, so, over the course of the next couple of months I'll report back to this group about the implementation and pre-certification testing environment and this is really, I think, directly to the point of Wes's initial comment which was we need to try to support implementation and, you know, as organizations like eHealth Exchange and others are out there in the communities and they're developing the specifications and they're testing them out, we then can use this platform to provide some national consistency to get feedback and to flow that into the regulatory work and the standards that we identify as part of Meaningful Use and national interoperability.

Can we go to the last slide? The big picture, and this is something that I think we will evolve over time is if you think about it, back in, gosh when was it, Mariann would know, it's like back in the pre-aura days, when we were beginning the work on developing the NwHIN exchange pilots where we funded a host of different organizations to help identify how to exchange information based on those specifications working through the governance pieces and all of those efforts, the work of ONC spanned all the way from use case development, and this was the query response use case that is so fundamental to the eHealth Exchange paradigm, all the way through to developing, identifying the standards, developing the implementation guides, operationalizing data and software like CONNECT and then creating the infrastructure that would allow production exchange to occur.

The thing that I think is important to recognize is that ONC still is there to support the kinds of organizations like eHealth Exchange in terms of understanding what their specifications and problems are, percolating up from the various organizations those set of national standards that conform to the work that the NwHIN Power Team looked at, looking at the standards that are ready for adoption and engaging organizations like eHealth Exchange in the use case development, the work of standards acceleration and harmonization and getting feedback from the implementation and pre-certification testing environments.

And, so in large part the work that has gone on with ONC that predates much of the Meaningful Use activities, the work of developing standards, executing in pilots, doing testing and certification, and then operationalizing those in networks like the Nationwide Health Information Network Exchange and now the eHealth Exchange, that work continues, it's just that we have changed the landscape a bit in the sense that ONC still is working towards national interoperability standards and developing use cases, and standards, and harmonization, supporting and learning from the kinds of exchanges that are occurring out there.

So, Direct trust and the eHealth Exchange activities are going to be helpful in us being able to identify what works and what doesn't, supporting those implementations, identifying ways that we can do pre-certification testing and people can see how to implement their technology and then we hope to have a whole host of various ecosystems and various different networks like eHealth Exchange that will support national interoperability.

So, I just want to again sort of congratulate all of the folks that have worked on this transition from the Nationwide Health Information Network Exchange into this eHealth Exchange activity. We've been working shoulder to shoulder with Mariann and our federal partners in trying to do the transition and supporting the activities over the course of the next year, over the course of the past year and actually continuing now in the next couple of months as well and we continue to hope that, we, ONC can serve as that convener of authority that helps us identify the right use cases, accelerate the right standards, harmonize things on a national level, and then support implementation and precertification testing so that we can learn from all of the experience that folks will have with information exchange. So, with that, I'm going to close out, open up for any particular questions that people might have about that.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Well, thank you, Doug. I really appreciated your very thoughtful perspective and what a counterpoint to the eHealth Exchange transition discussion that really is an object lesson in what you've described. So, we're running a little bit behind. So let's open for brief comments.

MacKenzie Robertson – Office of the National Coordinator

Sorry, this is MacKenzie; I would just ask if any members aren't actively speaking if they can please remember to mute their lines because we are getting some background interference on a consistent basis, thank you.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Thanks, MacKenzie.

John Halamka, MD, MS – Harvard Medical School

So, Doug, real quick question on testing the certification scripts. I received some e-mails from members who are reviewing some of the waves that have come out and one of those is the implementation of the InfoButton standard, which of course the Standards Committee said was a very bad standard to require because it didn't seem appropriate for use nor mature, nor well adapted, but it did make it into the final rule and now reading the testing script there is a lot of strange ambiguity as to what it actually should do and so I think we want to just be sure, based on your slides and what you've outlined, that there are real world testing that goes through these waves, especially around things that the Standards Committee said weren't a good idea to make sure that the testing and certification criteria are doable.

Doug Fridsma, MD, PhD, FACP, FACMI – Director of Standards & Interoperability – Office of the National Coordinator

Yeah and I think, John, to that point, part of the reason why we want to provide this implementation and sort of pre-certification testing environment is that, you know, when we go into sort of regulatory mode we can't do a lot of public work on our testing infrastructure, because it will then sort of provide...you know, it will essentially message as to where we're going with some of our regulations and we're restricted from, you know, providing that kind of competitive advantage, if you will, out there in the industry.

Part of what we can do with this implementation and pre-certification testing is that we can work with the industry to find the best ways to test the interoperability specifications, refine those specifications that maybe are ambiguous and that are difficult to test. We've been in discussions with NIST and with others, you know, there is the electrical industry actually regulates and tests over 500,000 different products but they have very few regulations and they use the underwriter's laboratory to make sure that circuit breakers and conduit boxes, and wire specifications all meet the standards that are out there for safety and the like.

And, so part of what we want to do is we want to engage the industry in identifying the best ways to test, the best ways to implement and the right standards to use, and it's going to be hard for us to get this all up and running in time for Meaningful Use Stage 2. Obviously, the waves and things are coming out rapid fire, but our hope is that over the course of the next year we'll set the stage for what we hope will be a best practice going into Meaningful Use Stage 3 and as we learn the best approaches to do this hopefully we'll be able to use it as an ongoing basis to refine our testing methods and make sure that we're feeding back into the implementation guides and the standards that are adopted.

John Halamka, MD, MS – Harvard Medical School

Again, of course, I've always volunteered, Beth Israel Deaconess as an institution with its self-built systems to try to exercise some of these scripts to give you feedback as to where there might be ambiguity.

Doug Fridsma, MD, PhD, FACP, FACMI – Director of Standards & Interoperability – Office of the National Coordinator

And you will now have a place and a platform in which you can offer that approach to the country and that people then can take advantage of that.

John Halamka, MD, MS – Harvard Medical School

Okay, thanks. Wes Rishel, I believe that you have a comment?

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

A Tweet.

John Halamka, MD, MS – Harvard Medical School

Indeed.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Wes, if you will read the Tweet please?

Wes Rishel – Gartner, Incorporated

Yes, so I just, as we have been offering Twitter as a way to have a side discussion, going back to an earlier discussion about UDI, a gentlemen named Kirsten Forsberg said, please an HTTP-based URI as UDI so linked data principles can be used. Again, being aware of the limits of the regulation that was under discussion I'm not sure that that represents a comment to go to FDA or not, but I think the notion, you know, getting behind the notion of the Internet of things by examining the issue of extending URI to include UDIs seems like an important issue to take up perhaps as a recommendation to ONC.

John Halamka, MD, MS – Harvard Medical School

Very good. Well, I know we're running short on time, but Jon Perlin, I guess any last questions or comments?

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Not on this end and I think, Doug, that was a terrific presentation and perhaps we can really return to that as we initiate, hard to believe, the 42nd Standards Committee meeting next month. Let me just thank again all of our presenters, particularly everybody who assembled for the eHealth Exchange transition discussion, just a terrific tour de force and really a testament to the effectiveness of the entire process and a substantiation of many aspirations and a lot of work of members of this committee. So, thank you all members for that and as well for the continuing public input and Wes thanks for bringing that comment forward and that makes sense and lets handle that more formally in our continuing deliberations, but certainly our colleagues at ONC are aware of that concept and let Jamie and team incorporate as might be appropriate to what we've already authorized this morning. Let me turn to MacKenzie to please invite any public comments.

Public Comments

MacKenzie Robertson – Office of the National Coordinator

Sure, thank you, operator can you please open the lines for any public comments and just to make note that public comments will be limited to three minutes. Operator, can you please open the lines for public comment?

Caitlin Collins – Altarum Institute

If you are on the phone and would like to make a public comment please press *1 at this time. If you are listening via your computer speakers you may dial 1-877-705-6006 and press *1 to be placed in the comment queue. We do have a comment from Carol Bickford; please proceed with your question.

Carol Bickford – American Nurses Association

Hi, this is Carol Bickford from the American Nurses Association. I want to provide significant accolades to the Workgroup and Taskforce that helped us appreciate the importance of responding to the UDI proposal from FDA, your slides were very helpful in framing and thinking for helping us move forward on providing our comments to that document.

And I also, thank very much the presentation on Healthway and the eHealth Exchange, it really affirms that all the work is not in vain, but has brought together a product that will help us move forward in the public/private space. Thank you very much for both presentations.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Thank you. MacKenzie, any other calls on line?

MacKenzie Robertson – Office of the National Coordinator

Sorry, I was on mute. Operator, are there any other public comments?

Operator

Yes, we have one from Gary Dickinson; please proceed with your question.

MacKenzie Robertson – Office of the National Coordinator

Gary are you there?

Operator

Gary your line is live.

Gary Dickinson – Centri Health

Oh, sorry, I was muted. This is Gary Dickinson representing Centri Health. I guess our concern again is around the use of the term interoperability and interoperability between EHR systems when in fact we're talking about some very basic interoperability structures that represent data sets not full interoperability of electronic health records between systems. I think it's very important that we make the distinction when we talk about interoperability that we're not talking about full EHR record interoperability instead just some very limited subsets of data or data sets that are in fact proposed as interoperable in these cases.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Thank you, Gary, as always for your insight.

MacKenzie Robertson – Office of the National Coordinator

Operator, are there any more public comments?

Operator

No more public comments.

MacKenzie Robertson – Office of the National Coordinator

Thank you.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Thank you, operator and MacKenzie could you just review the logistics for the next meeting. I want to make sure that both committee members and members of the public are fully apprised of logistics for the next meeting.

MacKenzie Robertson – Office of the National Coordinator

So, let me make sure I'm not on mute, so as it stands now, the November Standards Committee meeting is going to be on November 13th. It is going to be held at the DuPont Circle Hotel which is in Washington DC. If anything does change, we will try to get the word out as soon as possible, but especially for members of the public please always refer to the ONC website for any last minute changes of either location or having them virtual.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Thank you very much for that. Dr. Fridsma, any final comments on your end? He may be muted there, but let me just in the interim thank ONC for their hard work and leadership, MacKenzie and all the staff. Dr. Halamka any comments on your end?

Doug Fridsma, MD, PhD, FACP, FACMI – Director of Standards & Interoperability – Office of the National Coordinator

I was on mute.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Oh, sorry Doug, go ahead.

Doug Fridsma, MD, PhD, FACP, FACMI – Director of Standards & Interoperability – Office of the National Coordinator

No, that's okay; I just want to thank the work again of the eHealth Exchange and to thank all of the participants in the standards and interoperability framework, those of you who have worked to develop those specifications and all of the hard work of the committee. It's always very humbling when we actually take a look at what's been accomplished and see how far we've come even in the short period of a few years.

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Well said, thank you for your leadership.

John Halamka, MD, MS – Harvard Medical School

I just want to make sure that everyone on the Standards Committee appreciates the impact they're having, whenever you see these weird articles that come out or strange letters that are written because of election-year politics that say, oh, there are no standards, we have no interoperability, I think all of us in our various either vendor lives or in our public participation in state HIEs actually know the data is beginning to flow at scale, so the work is important and the work is successful and the naysayers can be ignored or at least educated how about that?

Jonathan Perlin, MD, PhD, MSHA, FACP, FACMI – Hospital Corporation of America

Well, John, I think that sense of optimism is a great point to end on and indeed I think the opportunities that have been created are really beginning to become manifest in so many different ways and I think I appreciate the very robust discussion. I think this was a particularly good call, very thoughtful and engaged comments and appreciate everyone's attention despite the virtual nature and even more thank you all for all of the hard work. Thanks to ONC for all your effort and we stand adjourned.

John Halamka, MD, MS – Harvard Medical School

Thank you, very much.

MacKenzie Robertson – Office of the National Coordinator

Thank you.

Wes Rishel – Gartner, Incorporated

Thank you.

M

Thank you.

M

Good bye.

M

Thank you.

M

Thank you.

M

Yeah, thanks.