



HIT Standards Committee Final Transcript July 16, 2014

Attendance (See Below)

Presentation

Operator

All lines are bridged with the public.

Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology

Thank you. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee; it is the 59th meeting of the Standards Committee. This is a public call and there will be time for public comment at the end of the meeting. As reminder, please state your name before speaking as this meeting is being transcribed and recorded. For those of you following us on Twitter, the Twitter handle for today's meeting is #HITSC. And I will now take roll. Jacob Reider?

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

Here.

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

Hi, Jacob. John Halamka?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Here.

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

Hi, John. Andy Wiesenthal?

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)

Here.

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

Hi, Andy. Anne Castro? Anne LeMaistre?

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health

Present.

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

Hi, Anne. Arien Malec?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

I'm here.

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

Hi, Arien. Marty Harris?

C. Martin Harris, MD, MBA – Chief Information Officer – Cleveland Clinic Foundation

I'm here.

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

Hi, Marty. Charles Romine?

Kamie Roberts – National Institute of Standards and Technology – IT Lab Grant Program Manager

This is Kamie Roberts for Charles.

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

Thank you. Cris Ross? David McCallie?

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

Here.

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

Hi, David. Dixie Baker?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

I'm here.

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

Liz Johnson?

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

I'm here.

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

Hi, Liz. Eric Rose?

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

I'm here.

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

Hi, Eric. Floyd Eisenberg?

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Here.

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

Hi, Floyd. Jamie Ferguson?

Jamie Ferguson – Vice President, Health Information Technology Strategy and Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy

Here.

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

Jeremy Delinsky? John Derr?

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

Here.

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

Jon Perlin? Keith Figlioli? Kim Nolen?

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.

Hey Michelle, I'm here.

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

Hi, Kim. Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I'm here.

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

Hi, Leslie. Lisa Gallagher.

Lisa Gallagher, BSEE, CISM, CPHIMS - Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Here.

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

Hi, Lisa. Lorraine Doo? Nancy Orvis? Becky Kush?

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)

Here.

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

Hi, Becky. Sharon Terry? Stan Huff?

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

Here.

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

Hi, Stan. Steve Brown? And, Wes Rishel?

Wes Rishel – Independent Consultant

Here.

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

Hi, Wes. And with that, I will turn it to you Jacob.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

Michelle, this is Cris Ross joining late

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

Thanks Cris.

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

Thank you, Michelle and thank you everyone for coming and welcome to our 59th meeting. I feel like we need a 60th birthday next time, so maybe we'll get a cake and some candles, at the next meeting when we're in-person. So, I'm going to keep my comments very short with just a welcome to everybody on the committee and everybody on the phone. Looking at the agenda, it looks like we have a reasonably full

agenda today, hearing from a couple workgroups who are reporting back to us and also an update from ONC on a couple of topics.

One reminder for the group, and I'm going to say this every time for the next few until we all get it seared in our minds, because I think over the past couple years we've had a fairly distinct focus on standards and certification criteria as it relates to the Meaningful Use Incentive Program. And I want to remind the group that the scope of this group goes beyond standards and certification criteria with respect to just the Meaningful Use Incentive Program. This group's charge is to make recommendations to the National Coordinator, and then by extension, the Secretary of the Department of Health and Human Services for standards and certification criteria for EHR technology overall. And so we need to make sure that we don't just think about MU as the customer of the standards and certification criteria that we discuss. Because as we all know the information that is caught by various health information technology systems needs to be done so in as standardized a way as possible. Of course, finding the Goldilocks between a great user experience full narrative text and flowing prose that all clinicians would like to generate and standardized terms that are caught and understood by systems in a semantically distinct manner.

Then the information needs to be moved in a standard way both using standard transport and standard semantic syntax etc. representation. And then it needs to be received and when it's received, of course, it needs to be received in a way that's understood and parsable by a receiving system. As I think Wes has opined so eloquently, we need to be able to catch things in a manner that is tolerant of ambiguity and yet send things as specific a manner as we possibly can. So, with those kinds of reminders/thoughts, I'm going to move...hand the baton over to John for some opening remarks and a review of the agenda.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Great. Well thanks very much, Jacob. So of course, we're all waiting for summer vacations to arrive so that Meaningful Use, ICD-10, the HIPAA Omnibus Rule and ACA will give us luxurious relaxation time, but it has not happened. So as is the case of the Office of No Christmas, we continue to press forward and make good progress, today's agenda is no exception. We'll hear from ONC as to what is the current eligible professional and hospital attestation rate. As Jacob, before the call started, reminded us all that we should not judge the trajectory completely based on early performers, but I think there is some interesting data to review as to what vendor products are being used for early Stage 2 attestation. And probably should cause self-reflect on what is it about those products and their characteristics and functionality that might have been success factors, knowing that aspects of attestation like the transition of care summaries for 10%, the patient family engagement criteria and EMAR have certainly been challenging for many organizations.

The bulk of the agenda will be looking at our LTPAC and behavioral health certification recommendations and how that voluntary certification should proceed and what characteristics it should contain. And I think it's some very thoughtful work put together by quite a lot of people really asking how we can achieve quality, safety and efficiency through a voluntary certification program.

Data segmentation of for privacy of course is, of course, something we all care about as we try to exchange more data with more people for more reasons while keeping it private, per patient preference. And how do we start looking at more granular options for data exchange that would allow not just institutional opt in but actually maybe categorical or subject areas that a patient might want to restrict.

We'll hear from Dixie on the provider directory update. And I think, Michelle, you actually do want us to vote on the sort of next steps or directionality of that as we look at the maturity of existing standards in the marketplace to provide provider directory query response. But also ask, well what in the future might be possibilities to do this to scale, to make it implementation easier.

And we'll hear from Steve Posnack about what is the state of the S&I framework projects, which are going to be wrapped up, which will continue. And we are we going to see the phasing of the next couple of months to years working on a number of those important issues.

And then Jacob will review what might be some early assignments for our workgroups, looking at Co-Chairs of those and the slides were sent out I think I ahead of time showing you some nominees for Co-Chairs for our new workgroup organization. So other than that, I think we all continue pressing forward getting our EHR's used widely, getting health information exchanges implemented and increasing our volume, getting our patients and family engaged. So I think no one can argue that the trajectory we're all on is making very rapid progress. So, as always I look forward to today's meeting and continuing the progress and closing the gaps on the standards that remain.

So Michelle and Jacob, shall we take it away with the ONC data update? Oh actually, I know Michelle, you probably want the minutes approved. So we do have...

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

Please.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

We do have minutes that were circulated from the last meeting and if there are any objections or corrections to those minutes, please let us know. Well none being heard, Michelle we will consider by consensus those minutes approved and we can move on to the rest of the meeting.

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

Do we have Jennifer King on?

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

Good morning everyone. I'm here today to provide an update on some of the early data that we're seeing from attestation in 2014. So this is an update that we provided to the Policy Committee last week and thought would be great to provide to you all today as well. So, on the next slide here, just an overview of what we will be talking about.

We're going to be taking a look at the early data that we've gotten so far this year to look at the characteristics of professionals and hospitals that have attested to Meaningful Use thus far. We'll also take a look at how they've been performing on the Stage 2 core objectives and a little bit of information on the vendors that they've been using.

On the next slide, I included this, which is actually something that Elisabeth Meyer from CMS reported last week to the Policy Committee. But just to give you a snapshot of the latest overall numbers that have been reported, so this is through July 1 and this is the total number of professionals and hospitals that have attested in the 2014 reporting year so far. So just over 2800 eligible professionals, 972 of whom have attested to Stage 2 and 128 eligible hospitals have attested in the 2014 reporting year, 10 of whom have attested to Stage 2. So these are providers who have attested using their 2014 addition EHRs. And, just as a reminder, it's the group of providers who first attested to Stage 1 Meaningful Use in 2011 or 2013 who are those who are eligible to go to Stage 2 this year. So, these are the current numbers of those who have currently gone to Stage 2.

So, on the rest of the slides we'll be talking about the characteristics and performance of these providers and just wanted to note that some of the data that we used in the following slides are from a slightly earlier point in time, so we had time to do the analysis. So, some of the "n's" on those slides are a little bit lower than the "n's" you see here and that's why the differences, there are just some slightly different points in time.

But on the next slide, wanted to also sort of highlight here at the beginning, something that John mentioned earlier which is, that these are really are data on some of the folks who have gone through and attested quite early in the year. And as we've seen in previous years, so in all three of the years of Meaningful Use Program so far, the vast majority of providers who attest, do so in the later quarters of the year. So here, we're really looking at data from the first two quarters for eligible hospitals and the first quarter for eligible professionals. So these are the folks who have turned in their homework early, so important keep that in mind, but think it's also important to monitor as early as we can what we're seeing in these data. So, think some of the information that we're seeing on them can be useful going forward.

So on the next slide here, we will start digging in and see the eligible professional data. So, on the next slide we show the characteristics of the eligible professionals that have attested to Stage 2 as of June 2014. So, looking at how these professionals (these earlier attesters to Stage 2), compare to that whole group of professionals who are eligible to go to Stage 2. So those who first attested to Stage 1 in 2011 and 2012. So you can see that urban professionals are slightly overrepresented in that group of professionals who have gone to Stage 2 in the early quarter. Physicians are also a little bit more represented in that group, compared non-physician professionals. But among the physicians, we don't see many differences at all in terms of practice size. So we have some physicians in small practices and others in large practices sort of proportional to their makeup in those Stage 1 cohorts.

And the next slide takes a look at how these providers, who have attested to Stage 2 as of May 2014, were performing on these Stage 2 core objectives. And it looks like some of the labeling here is a little bit off, at least on my screen, so hopefully is not for everyone; but this slide here shows that the distribution of objective scores that were reported at attestation. So the green shading here represents the cells where a higher proportion of professionals landed in terms of the objective scores they reported and the yellow represents cells where fewer professionals reported those course.

So you can see here at the top, which are some of the CPOE objectives, the vast majority of professionals who attested to Stage 2 so far were reporting well beyond the thresholds, many in the over 95% range. When we get down towards the bottom of the slide, you can see sort of the reverse pattern and these are some of the objectives around patient engagement and transitions of care, so the patient reminders, view/download/transmit and electronically exchanging the summary of care records.

We see more professionals clustered near the thresholds than we do on these other objectives. So this is consistent with what we're hearing from the field in terms of the objectives that are most challenging for professionals.

And then on the next slide here we look that the number and types of vendors have been used by professionals who have attested so far. So as of May 2014, there had been 37 different vendors that had been used to attest the Stage 1 in 2014 and 8 different vendors that had been used to attest to Stage 2 in 2014. And the table on the right shows the breakdown of those who have attested to Stage 2 and the vendors they were using. So you can see the athenahealth and Practice Fusion are overrepresented in that group of the earlier attesters to Stage 2, relative to the share of all attesters to Stage 1 in 2011 to 2012, that those numbers accounted for.

So moving forward we're going to take a look at the same data for eligible hospitals. So here, we see the characteristics of hospitals that have attested as of June 2014. So the first bar here shows hospitals in terms of their size and urban/rural location. So that first bar is all hospitals that had attested to Stage 1 in the previous three years. The middle bar there shows hospitals that have attested to Stage 1 so far and 2014 and we see that the larger and medium-size hospitals are making up a larger share of that group than they did in the previous years of attestation. And among the small number of hospitals that had attested to Stage 2 as of June 2014, a couple were small rural hospitals but most were medium-sized hospitals.

So next, taking a look at how the hospitals were performing on these objective scores. Again, just want to highlight that this is based on a very small "n," so keep that in mind when interpreting these percentages. But we see a little bit more variation than we did on the professional side. There are some patterns in terms of the certain objectives where hospitals tended to score well above the thresholds, but on others, again some of the patient engagement and transitions of care measures, hospitals tend to be clustered closer to the thresholds there.

And finally on the next slide, taking a look at the vendors that the hospitals have used to attest in 2014 so far. We see that 13 vendors had been used to attest to Stage 1 as of May 2014 and five had been used to attest to Stage 2. And in terms of the specific vendors that had been used, we see some variation in terms of how that compares to their market share in Stage 1, but not to the same extent that we saw among the professionals.

And so that wraps up the data that I have here today. And again, just want to highlight that these are very early data so to some extent limited in how much we can generalize based on what we've seen so far. But still points to important sort of areas to monitor going forward to make sure that all kinds of professionals and hospitals are able to achieve attestation in 2014. And also provide some quantitative data that is consistent with the qualitative information we've been hearing on which objectives are most challenging for providers to meet. And with that, we can go to the last slide and happy to take questions.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And so of course as you try to interpret this data, one asks interesting questions such as, was a delay in the certification of software responsible for the fact that certain vendors may not be represented as richly in the attestations? Or was it implementation timeframes or training and education of physicians

that led to more adoption that is going to take a little more time? Any conclusions that folks at ONC are applying to these data at the moment?

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

I mean at this point, I would say it's still pretty early to be able to draw any conclusions along those lines. Obviously trying to understand from folks in the field what's happening to the extent that we can, but just keeping a close eye on the data as it comes in will help us understand that as well.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Certainly as we formulate the cycle of regulation and certification scripts and product releases and reporting and attestation, one hopes that we can say, hmm, it does appear from our best data gathering that that has to be a 3-year process from end-to-end, or such things. And so yes, I agree, it's going to be very interesting, as the data gets more rich, to try to help us inform our policy timelines. Other questions?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Well, John this is Dixie. Related to what you just asked, I thought it was interesting to see the vendor's lists. Have all the...or what percentage of the vendors who were on similar lists during Stage 1 have actually been certified against the 2014 criteria.

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

So, the latest figures I have on that are a couple months old right now. But on the hospital side, about...so in terms of the market share coverage of vendors, so about 95% of hospitals who had attested to Meaningful Use in previous years were using vendors that had a 2014 edition product certified. And on the professional side, that number was over 80%. So most of the vendors that are covering the majority of providers had a product certified to the 2014 edition.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Thank you. And this was really useful, thank you very much.

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

Great, thank you

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

Hey John, it's Liz, can I make a comment please?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Please.

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

One thing that's not showing up here, but I want to be fair about is, we have 21 hospitals ready to attest for Stage 2 now. There is a small hitch with the webpage or the portal we go in that we're working with the...folks at CMS. But I don't want to see the numbers out there and you guys not know that we actually have 21 additional hospitals that will come in and then 14 more for the next quarter. And right now, what we're working on so the numbers will remain not showing our numbers, is that they won't be ready to take those until October 1. So, not a huge deal but it does change the numbers somewhat.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Great.

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

Yeah, thank you very much for mentioning that and it really does highlight sort of the limitations of what we're getting so far in the data. We know there are other hospitals and providers out there who have successfully completed, or we suspect anyway, that have completed the reporting periods and just haven't gone in to file the attestation yet, so...

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

Right.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Ahhh, okay.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And I'm curious, this is probably more granular data necessary than you have, but of those hospitals that would like to attest to Stage 2, but can't because one criteria is hard to achieve. I of course hear from our hospitals that the transition of care 10% criteria is sometimes hard if there's no one to send the data to.

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

Yes.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And don't know if you're hearing such stuff.

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

I mean, we definitely are, and that's something that has come up in the listening sessions that the Policy Committee and others have done, so hearing sort of that those measures in particular are some of the most challenging. We also have some survey data from hospitals and professionals that...based on surveys that were conducted in 2013, so a little bit on the early side. But asked both hospitals and

physicians about adoption of the specific Meaningful Use functionalities at that point. And it also showed that especially on the hospital side, a really high percentage of hospitals could meet the majority or had functionality to meet the majority of Stage 2 objectives, but some of the lower ones were around the view download transmit and the transitions of care measures. So that was just about adoption of the functionality, didn't get into things like trading partners, but some additional information on what the specific objectives might be that are causing the most challenges for folks.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And Jacob I realize that it is unlikely that ONC will make public comment on this call. But of course as we reflect that some of the measures do require an ecosystem, an environment so that is, if you are going to have transitions of care, you need trading partners. If you are going to use view download transmit, you'd need to have patients families engaged and hopefully products and services that can be transmitted tom and so hence the notion of giving a little bit more time for that ecosystem to develop, as the NPRM had suggested, seems like a positive idea. And I imagine that again ONC will not comment on the progress on that NPRM or any future plans.

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

I'm sorry, just a reminder, if you aren't speaking, if you could please mute your lines we'd appreciate it. Thank you.

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

John, that's accurate because HHS is in rulemaking. We are receiving comments on the NPRM that CMS put out and therefore, until we've reviewed the comments and HHS has been a policy decision that policy decision won't be made public before the public is informed, all at once.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So I think what you can say is to be safe, continue on your trajectory, your pe...it's the pedal to the metal because there is no NPRM progress officially announced at this point and it is speculative as to whether or not a change will be made. Okay. Well, very good, other questions?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

I have one question this is Dixie.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Yes.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

What's the difference between provides summary of care record and electronically provides summary of care record?

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

So this is...the two parts of that summary of care record, the first is that providers need to provide the summary of care record in any format for...let me pull this up here...yeah. So you can see that the bar starts at 50% there, so they have to provide the summary of care record for at least 50% of transitions of care. But then that summary of care record needs to be provided elect...in a certain electronic format for at least 5% of transitions of care, or 10%, I'm sorry. So it's a two-part...there are two sort of measures to that objective.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

So the first one is actually to be able to generate it, I guess, huh? So how else can you provide it without its being electronic?

Jennifer King – Research & Evaluation Branch Chief – Office of the National Coordinator for Health Information Technology

So it would be providing the to the other provider in a manner, either electronic or otherwise. So generate and provide and so there's...feel free to jump in with...

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

Dixie, the way that you would do it is...this is Liz, you could print it, you could fax it, I mean there are other ways. You're correct that you would have to have the complete set of data, but there are other ways in which you could do it other than the greater than 5% for electronic transitions. Which I think we're trying to get to electronic transmission and I think John's earlier comment about the ability of an external partner to receive or to have an external partner becomes a challenge.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Yeah, that seems pretty core to what we're trying to do...

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

Yup.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

...so I'm surprised they're both not at the top end.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay, well thank you for those comments and thanks very much for the analytics. I mean clearly as we watch the trajectory, it will inform our future recommendations. So Jacob, should we move forward to LTPAC and behavioral health recommendations?

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

Yes please, on to Larry Wolf. Larry?

Larry Wolf – Health IT Strategist – Kindred Healthcare

Delightful to be with you folks virtually this morning, I don't see my slides up, is that my end or your end problem? Oh, there they are. So, the Certification and Adoption Workgroup has spent several months reviewing a charge from ONC to look at expanding the use of certification beyond Meaningful Use and specifically to look at it within long-term post-acute care and behavioral health.

We have a pretty big workgroup and we brought in a couple folks, John Derr and Stan Huff, to join us from the Standards Committee because it was felt that we wanted to ensure that that perspective was brought to the discussion. Because a lot of the issues to get certification criteria right depend on use of standards. So a big shout out of thanks to the workgroup members and also to Liz Palena-Hall who was relentless in keeping us on track as our ONC staff person, some of the other ONC staffers as well. It was really great to have support for this effort. So now let's talk about what we did and what we recommended to the Policy Committee and hopefully it makes sense to you guys. So, next slide please.

So, we had a two-part charge and we came back with two sets of recommendations. The first one was a framework for looking at doing certification programs outside of Meaningful Use, so we'll talk about the five factors in a minute. And the second one was things specifically related to criteria for a long-term post-acute care and behavioral health. And we really focused on transitions of care and privacy and security as key pieces to creating that ecosystem that you've been talking about this morning. That systems needs to use the standards to move information at transitions of care and when they receive information, they need to maintain it with appropriate levels of privacy and security.

It should be pointed out that in some ways these were seen as endpoint deliverables and if you were going to generate a document that met the transitions of care requirements, you would have to have in place many of the standards that are referenced in other areas as well as in those documents. So, if you're going to be reporting a problem list in your transition of care document, you would need to have functionality to maintain a problem list. If you're going to be reporting meds, reporting labs, you would similarly need functionality to manage that information. So it was felt like these would actually be drivers of the system capabilities within the setting, as well as available for transitions.

We then also looked at things that were specific to the care settings and we'll talk about that. And the lack of data, so tracking trends was a recommendation that we really need better information about what's in use today in order to assess where things are. And then some considerations for additional criteria. So we'll talk about those in more detail on the subsequent slides. Next slide, please.

So the charge was to do both a process look and some specific certification and...certification criteria and standards to move forward in this area. Let's go to next slide. And we reported back in two parts, so these were our check offs for what we wound up doing, and we'll into the details next. Next slide, please.

Okay. So there was a lot of discussion around how to extend beyond the Meaningful Use criteria. And we felt that certain criteria may be applicable to other settings and could be used to improve transfer and use of information across care settings and across systems and in many ways, in order to make this work, that we needed the same criteria, the same standards in all the settings. In some ways that sounds obvious, but if you look at the history of how these settings have been addressed, they've really been seen in silos. They are separate groups within all of the federal agencies that relate to these different care settings, they are separate legislative requirements, there are separate regulatory requirements and so historically, they've been treated very differently. And so have the information

needs placed on these organizations, placed on these healthcare providers, been treated very differently. So there's a general need to get better alignment across all the programs that would then address alignment across all these care settings.

We wanted to build on the modular approach that's built-in to the certification framework today. And that, while it doesn't say it in these slides, one of the real assumptions we had was that the certification criteria would be the same at the modular level. And that that might mean tweaking some of the modules a little bit so that specifics that related to hospitals or to eligible ambulatory providers might have to be shifted to other criteria if they were really specific to those settings in order to enable them to be truly universal certification criteria. So, it seemed like really important that we had building blocks that really could work as universal building blocks. So that's sort of the color commentary on the modular approach so that it could be used for providers who are both Meaningful Use eligible and those were not. And again, a continuing emphasis on interoperability and that this goes not just for the technology, but also applies to federal and state programs and how they use standards. Next slide, please. Next slide.

So here is our 5-factor framework and the question that the workgroup struggled with is how do we think about certification? And in the Meaningful Use context, it was very clear. The legislation says that you need to be meaningful user of certified electronic health technology. But what about other areas? And so we looked to that as a framework, as some initial guidance and said, well the first piece is that if you're going to put together some...a certification program, it really needs to advance a national priority or respond to a specific legislative mandate. So is there some compelling reason that we would have a certification program? And we cite things like the National Quality Strategy, which provides a priority list of, here are the things that the government...HHS has identified for action. And so that might support why this is an important area.

So we're basically saying, don't just grab the whim of the day, this should be aligned with a bigger federal initiative and further, it should tie in with existing federal and state programs. So, for example, there are a lot of regulations around all of the settings that we looked at, the long-term and post-acute care settings and behavioral health. So the work that's done on certification needs to be in support of those programs and may actually require some alignments of the technology and standards that may already be in use in those programs, either to modify what ONC is using as its standards or to modify those programs to use the standards that ONC is using. But not to be in a world of similar but conflicting standards requiring multiple data standards or multiple transmission standards, but to really create a roadmap that heads toward one set of standards and to align the programs.

We also heard a lot that the existing certification program may be pushing the technology pipeline and be asking vendors to do things that are not yet proven as viable technology or not widely used beyond some very tiny pilot use. So we wanted to be mindful of the level of how much was the certification process looking to push the environment or how much does it actually recognizing things that were in place and of proven viability and then endorsing those as the standards. And so not to make this sound like too high a bar, we weren't saying that something had to be so widely used that the certification process wouldn't actually be making some critical calls about what technology move forward on. But we wanted to go beyond use in one setting or in one site of care. So if there was an example of patient engagement then that was going to be picked up on as something that should be expanded, that there should be pretty widespread use of a tool demonstrated in a variety of pilot programs perhaps that it was of value.

Maybe a more relevant example to the transitions of care piece is, there's some pilot work happening under the...one of the ONC Challenge Grants in Massachusetts to create a more robust care summary so as patients move from setting to setting, the summary has in it the information that the receiving provider needs. So that's getting tested today and it's just beginning to actually hit operational use and so we felt like that was an example of the kind of pilot work that would demonstrate that a standard is actually ready. And that might be a necessary step before it wound up in the certification criteria.

Build on existing stakeholder support, so given that in many cases, these programs might be voluntary, to assess where the stakeholders were and whether this was something that they saw as helpful to better engaging with the rest of the ecosystem. Or furthering the work within their own care settings or whether they saw it as an out of the box burden.

And then finally, to appropriately balance cost and benefits of a certification program. We heard a fair amount of commentary in our hearings and again at the larger Policy Committee meetings about the cost to create the software for certification. And the process through the certification experience itself to get certified software and there was a general consensus that the costs in the proposed rules and the final rules that had been issued did not seem to reflect the experience of many of the vendors and had very little coverage of the actual cost to the clinical providers, to the healthcare providers to implement those systems. So it was felt like the cost side was under calculated and maybe should be better represented and should look at also some of the nonfinancial cost as well is also looking at the benefits. So, a more robust cost benefit analysis. So this was the framework that we put forward and wound up recommending to ONC as a way for it to structure other programs. Next slide.

Then we had some recommendations specific to these care settings. Next slide. So we broke up our recommendations into these three big buckets, the ones that we felt apply to all providers focusing on transitions of care, privacy and security. And what you see here is data segmentation and consent management. We initially gave it a broader heading of enhance privacy and security, but at the urgings of some of our sibling sub-workgroups, sibling workgroups, we identified this particular technology as an approach to look at, but the broader need is really to improve privacy and security, particularly in respect with the behavioral health.

So looking at the green box, we have some setting specific needs and we'll get into this a little bit in the subsequent slides. Patient assessments are mandated in the LTPAC settings. Long-term acute care hospitals, inpatient rehab facilities, skilled nursing facilities and home health agencies all have mandated assessments and they're all different. So one of the areas of support would be that the system supports these assessments, because they're required for you to have payment in these care settings. But the actual assessments themselves are different and the appearance of similar data across the care settings doesn't mean that they actually are similar in the details. So it's an area to improve alignment across federal programs. There are also needs, for survey and certification support in these care settings because there are pretty extensive requirements from the federal government implemented by the states to review the quality of care in these care settings.

Behavioral health had a different set of problems that there are many, many, many different assessments in place, but very little standardization. So that would be an area of more future work to be done to standardize the assessments. And finally because of the constraints around substance abuse and mental health treatment centers where there special federal regulations restricting not just the disclosure of information from one care provider to another but prohibiting the re-disclosure of that information. So, this is a case where a patient could give permission to send information to another care

provider, but that care provider would need to get permission again from the patient to send that information along. And that kind of restriction is generally not implemented in either EHRs or health information exchanges.

And then there was a broad set, what's in the blue bottom box, there's a broad set of criteria that look like it would apply to some behavioral health and long-term post-acute care providers. You should recognize that those terms cover a vast range of provider types. So some of them are dealing with very high acuity patients and others are dealing with very low acuity patients. And so the patient status might affect the kinds of services that would be useful in supporting certification criteria.

The other is the setting itself varies a lot from ones that are very heavily inpatient and look very much like a classic acute-care hospital and maybe even an intensive care unit of that hospital, down to assisted living where people are living more or less on their own with minimal support services. So a very broad range of the ways in which services are provided and the settings in which they're provided. And so based on that, we felt like there was...many of these certification criteria could apply to some of those settings, but we didn't have the time to really delve into which ones applied where. Next slide.

So, I've hit on almost all of these, some important things to understand is, and we've alluded to this a little bit earlier in your discussions today, we could only deal with what's already published. So we were using the ONC 2014 edition certification criteria as the basis for what we were recommending. I've talked about transitions of care, privacy and security and the LTPAC patient assessments. We believe that there really should be a push to create standardization of these assessments across care settings and that it would not only be valuable in terms of creating granular data that could be shared broadly, but it would actually allow reuse of these assessments as patients transition where there's mandated reporting. And you could actually get the prior assessment from the prior care setting and use it as a basis for going forward.

Behavioral health, I talked about the future work needed to actually identify standards to support these assessments and finally the need to track the use of the information systems in these care settings. There's been a fair amount of surveys done of the eligible professionals and eligible hospitals and the systems they have. There have been some surveys of these other care settings, but there have been inconsistencies in the definitions used and it's the in...simply put, the survey results are not compatible. It looks like we're seeing much higher levels of adoption in these care settings that we...which reflects actual systems in place, but they may not be comparable to the systems that are in place in the acute care setting, so development of appropriate survey tools and other reporting methods and then tracking that over time. Next slide, please.

Data segmentation we ask that Privacy and Security Tiger Team take a look at this and I think they're reporting back to guys next, on where they wound up on this. So, I'll let that come from them. We also talk to the Quality Measures Workgroup and they did not have a final recommendation other than to say, this is an area that would need to be delved into further. Next slide, please.

And so some of wrap-up comments about seeing this as voluntary and modular. So that there are building blocks and that, we already have seen some of the vendors in this space having their software certified either as modules or in a couple cases as complete EHRs. And we've also seen some of the larger EHR vendors beginning to expand their scope into this space, so there's beginning to be more vendor presence and more vendor alignment with the certification criteria. And we felt that encouraging this set of modular and voluntary level was appropriate.

Adjusting that we recognize that not all criteria apply to all settings, that the providers are different and some intelligence needs to be applied and that would be another reason to go into this lightly and then expand use as we saw how things were actually working.

A suggestion that where other federal programs reference these criteria that they be understood, as this is a minimum baseline and might not be everything you needed to provide good care in a setting. And finally, we had a lot of discussion about the value of certification in a vacuum that if you only had certification, was this a good thing or bad thing? And in some ways, it could be a good thing, identifying standards and giving people a roadmap to focus on. In other ways, where it was requiring systems do certain things that may or may not be of value in a particular care setting, it would be adding a burden to the development process and possibly to the provider process, depending on how things were implemented. Next slide.

So that wraps up the things that I want to walk through. There are some additional slides that we're not going to go over that provided some more detailed comments that we heard during our hearings and some more detailed thoughts from us about specific certification criteria. So, turn this back to the committee, if you have any questions for me.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So Jacob, I have one question. So I guess the question would be that as you have talked to the vendor community, do they see the voluntary certification program as providing extra cache, legitimacy, marketability to their product. So just sort of a this, here you've done an extraordinary body of work, which is clearly logical and do you think that there will be a significant uptake of voluntary certification because it will be either reputational or economically beneficial to the vendors?

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

Umm, so I will sidestep part of your question John in that all certification is voluntary and so we'd actually prefer not to describe what Larry was just going over as voluntary, because the whole program is voluntary. I think the question here is, certification that isn't tied to the Meaningful Use Incentive Program and would that be of value to the market? And are we hearing from various developers of information technology tools that market their products to folks that are outside of the scope of the current Meaningful Use Incentive Program? And the answer is a resounding yes.

The developers of these systems say to us, we think that it would be beneficial for our marketplace, for various reasons, and probably one of the primary ones that I hear is in the domain of standardization. Without explicit guidance on exactly how to do a certain thing, the developers of these tools are doing certain things in various ways because engineers come up with different ideas of how to do certain things. But especially in some of the domains, especially...such as the ones that Larry just discussed, they're actually looking for guidance and their expression of having a process by which their product would be certified would be favorable. And I can't say that that's every vendor, but we've heard from several companies that make products in these spaces that that would be favorable. Did I answer the question?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Yes, thanks very much.

Larry Wolf – Health IT Strategist – Kindred Healthcare

And...

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

This is John Derr. I work really closely with vendors and the providers in LTPAC, especially in SNFs and assisted-living. And I just came back from two days working with the vendors and providers in home and hospice care and they are all working with guidance from this on a voluntary...I think because they agreed with that because they need that in the transitions of care. So, there's an overwhelming...and they're different vendors than the hospital vendors. As you know, there are a couple of the hospital vendors that do market products in this space, but they're not, with due respect, the leaders in this setting. There's another set of vendors that...and most of the vendors now are working where they have the interconnectivity and interoperability between a SNF, assisted-living and home and hospice care.

And so this...on our side of the equation, we want to really be able to play in the game, that's why certification...I told John Halamka once that...he asked me why I thought voluntary certification was important, I said for two reasons. One is that the other sectors trust data that we send across and that we want to be a player in this whole thing, which I've been very encouraged with ONCs saying that they're going to handle everybody and not just the things in Meaningful Use.

And the big thing and one of the hindrances, which Larry didn't mention, because it doesn't come up much broadly but, a lot of reasons we have not been able to adopt things as fast is because the pay models are...have to be changed. Because they sometimes are against what we're trying to of interconnectivity and interoperability and sometimes, I've been told also that...and I mentioned this to Paul Tang one time, a lot of the Meaningful Use things are for sending information to us and not too many of them or any at all, are for receiving. So some of our people who are really ahead of the curve on transitions of care, can't get the receiving end to accept the information if we really have to send somebody back to a hospital for re-hospitalization. Which I've always felt that it's a problem that we would one day not send somebody back who really needs to be sent back because of the penalties that are in there.

And then the last point I wanted to make...I've tried to...we need to educate the hospitals. And one of the big things in the home and hospice meetings, there were about a number of panels and it was that the hospitals really don't understand our sector. And I tried to get HIMSS to put an interoperable...and I could seek any help from you guys, to put a section in the HIMSS meeting that had the providers and the vendors that we...because we're forming partnerships with them. And that they have to learn a big thing the home care agencies were having a problem with was the hospitals understanding our financial systems and understanding what an OASIS is and that...and in some cases even caring about understanding that. So, education of the acute care and professional sectors is very important.

And then the last point is, we realize that we are the ones that start longitudinal care from breaking away from the episodic. And that we really handle the chronic care and not just of a single disease. So, this is extremely important to us and both the vendors and providers in LTPAC. And I know maybe Mike's on the phone, but it also is important to behavioral health. So, I encourage everybody to support this. Thanks. Thanks Larry for doing a really great job.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Let me add a quick footnote, there are some of vendors that sell into the space who have already gotten certification to their products. And I think some of that applies to John Halamka's comments about not only does it give them consistency an entrée into the ecosystem, it's also way to demonstrate their products are sort of up to a certain level of performance. And that the providers using those products are on a par with the providers in the acute settings and can send information that is consistent with the information in those other care settings.

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

...a lot of vendors...this is John Derr again, can do CCDs and now they're working on the composite CDAs.

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

David McCallie, I have a comment. Are we open for comments?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So Jacob, do you want to moderate or should I?

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

Go for it, John.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay. David, please go ahead.

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

First, congratulations to Larry for such a clear presentation; that was really excellent. My comments are just basically editorializing. One is on the notion of certification, it's sort of just the usual be careful what you ask for, make sure you know what you're trying to gain from the certification process. You can lock-in to bad approaches, if you're not careful in what gets set as part of your certification criteria. I mean, I think we've learned the hard way on some of the Meaningful Use certification that it's easy to get it wrong. So just be careful what you ask for, that's number one. You know that already.

Number two is maybe a question, is the assessments...the patient assessments that you described as being non-standardized. My assumption is that the standardization of those assessment would be driven by clinical rather than just technical consideration. So, I'm hoping that there's widespread clinical agreement on what those assessments should look like before they get reduced to some kind of a CDA template.

And then the third comment, just to reiterate your point about the data segmentation for privacy and the downstream impact on the rest of the ecosystem when the restricted data is received. And the fact that the rest of the ecosystem really can't deal with that yet in a very workflow friendly way. So be careful pushing too hard on introducing restricted data that we just can't manage yet, until the rest of the world catches up to that. And I'll stop there.

Larry Wolf – Health IT Strategist – Kindred Healthcare

All good comments David.

Wes Rishel – Independent Consultant

Wes Rishel.

Larry Wolf – Health IT Strategist – Kindred Healthcare

I think the intent of the framework was to try to address trying to avoid some of the bad approaches, but thank you.

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

Good. Thanks.

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

This is Michelle. I just want to note that there are a number of people in the queue.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay Michelle, let us go through the queue.

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

Wes is first.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Please, Wes.

Wes Rishel – Independent Consultant

Thanks Larry. Just by the heterogeneity of the market here, you've clearly had to deal with a very broad view and appreciate the ability to boil it down the five factors. I need to make a comment. Used to be I would say I've been working on healthcare standards for 30 years. Some time I decided to switch and say I've been working on healthcare interoperability for 30 years and then I had to add, and I'm really hoping to see some soon.

The single issue that I find provides an absolute predictor of the success of interoperability is economic need on both sides. If you cannot call out with some authority the economic requirement, you can deal with lots of happy talk about standards and create standards that never really get implemented. Now I think I for one and many other people believe that changes in the payment system are leading towards those economic benefits that we are talking about. And we certainly have seen changes in the relationships between hospitals and a long-term care facilities in a fairly active basis based on the readmission rule and so forth. Nonetheless, I think it's important that in following my next suggestion, you put economics at the top of the stack.

The next suggestion is to go from where you are now to suggesting a specific sector and a specific use case in that sector that should be the basis of going forward, there's just so much to do. I think I understand that your general statement is that transitions of care is the most important use case. I just

would urge you, if I'm reading you properly, I would urge you to make sure you understand more specifics about where the greatest economic need is in that use case before pushing up for these kind of pilot programs that you recommend, that I agree with entirely, are necessary part of the process.

Finally, I...just out of curiosity, Larry, I have to ask, in talking about standards that have been produced absence proof of effectiveness through these pilot studies and so forth, what specific ones come to mind? What could we learn in our process based on your examination of that space? Thanks.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So maybe I'll go back. So Wes, thank you for the comments and you're right about the economic need. And what we're seeing is that the various aspects of healthcare reform, the various everything from readmission rules to bundle payment initiatives, ACOs are all pushing for better connectivity across the healthcare settings starting with simple things like ADT notification so you know someone's at a care setting. So much simpler than the transition of care documents but also seeing that transition of care documents are beginning to flow in the early stages of MU2, beginning to see interest in connectivity and creating the ecosystems and the various approaches to creating ecosystems, including vendor response in this care sector. Perhaps happening slower than some would like, but nonetheless happening. I don't think we should ignore that it's happening.

But in terms of whether actually getting proof of effectiveness, the Challenge Grant that went to the Impact Project in central Massachusetts is just now getting up and running. And they have extended the CDA document in line with the balloted changes from last year to almost triple the number of data elements in the transition of care document. And to see if that's useful. So they've created some technology to help post-acute providers who don't have full EHRs. And since they're extending the standard from what's in MU2 to provide ways to supplement the information being moved. Looking to try and get some...a real-life community experiment going and create the ecosystem in at least one community that involve dozens of providers to actually try this stuff out and see how well it works. And understand where it's complicated both as providers and technically. So maybe a bit of a long answer on one of your many points, but I think that's probably the most important one to talk about.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Good. Well, I know we're running a little short on time so Michelle, next person in the queue?

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

Leslie Kelly Hall.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Hi, thanks. Building upon those comments, I wonder Larry if as your group looks at certification criteria, if there are a minimal necessary data set from the existing certification that would inform both your group and all of us as we go forward with future efforts and standards, because we might have the ability to really learn from...

Larry Wolf – Health IT Strategist – Kindred Healthcare

Good point and I think that will have to be looked at as we move forward. Other than the work being done with the Impact Project, I don't know of folks working on a minimum necessary data set.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And as you say, Larry Garber and Terence O'Malley I think, from Massachusetts will report on the efficacy and utility of the expansions of the data elements and the ease at which they can get them out of existent EHRs. So, we'll learn more. Well, next person in queue?

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

Andy Wiesenthal?

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)

Yes, thanks. I'll have a...I'll be as brief as I can John. What I was looking for Larry, and maybe I just didn't hear it or read it is, if you look at the current certification standards available for ambulatory or inpatient. Is there a way of arraying what you have in mind for this sector against those standards so that we could say, this set of the existing standards can be reused as is. These standards can be reused with some editing or extension. These standards should not be used. Do you understand what I'm saying, so that we make this as efficient as possible for everyone concerned? So rather than having to pilot all sorts of things and come up with a brand-new set of criteria, that we look at the existing criteria as the starting point.

Larry Wolf – Health IT Strategist – Kindred Healthcare

So yes, that was our recommendation to work with the existing criteria as a starting point. We did not do the detailed analysis that you're suggesting, although I agree, it makes a lot of sense to do that. So, I'll leave the answer short at that.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)

Thanks

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

But...so Andy, Larry Garber has done some mapping so you can take existent C-CDA and say, oh, it has 133 data elements. But the transition of care document has 467 and here are additions that we made on the base. So, absolutely they try to inherit whatever Meaningful Use Stage 2 standards are foundational.

Larry Wolf – Health IT Strategist – Kindred Healthcare

And it might be worth looking going the other direction, too, I guess I didn't say this earlier. But there has been work done to take the assessments that are specific to these care settings that are standardized to the extent that CMS has mandated them. And provided, here's the very thick manual of how you're supposed to do this assessment and what the answers to the questions mean and how to code them. And they've taken those from the local codes, if you will, that CMS is using in each of the care settings and tried to map them to the standard codes that standards has endorsed and are in certification criteria, like LOINC and SNOMED and with varying degrees of success. A lot of the questions are really intended to be very focused and sort of psychometrically validated, you have to ask the question this way and this is what the answers mean and this is how you collect the data.

So there's been an initial attempt to do some mappings and to try to get the existing assessments coded into the ONC endorsed standards, but there's more work to be done on those fronts. And CMS has also identified that they are working on a data standardization effort beginning with some data dictionary work to look across all those assessments and identify what the data elements are. And to the earlier comments about make sure that these come out of a clinical validation process, there has been a lot of clinical input to those assessments to date. And I think there's a growing awareness of the need to look forward to e-Measure type assessments that could be pulled directly from EHRs and that the assessment tools themselves may change over time.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)

So what I would do is, and I'll stop after this, is draw a distinction between what you're describing, which I would call standardization of content. And looking at, as certification criterion, whether not a system...an EHR can handle content like that and do the things that it must do. So can you standardize content is one question, can you store it, retrieve it, pass it on to someone else, parse it and so on is a separate set of questions. And largely has been addressed, I think, by existing certification criteria. And I remember Jacob's caveat, this is not just about Meaningful Use, this is about functional EHRs for the long-term sub-acute care sector that can do the things that they need to do for their workflows.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Good point, thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Michelle, anybody else in the queue?

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

John Derr.

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

Yeah, I just wanted to say one short thing on the assessment standardization, the TEFT Grant by CMS, which is just being kicked off and we'll probably hear more about in the fall, has an S&I Framework part that is looking at standardizing assessments throughout the different care settings and also the different agencies at the state Medicaid level.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good. And Michelle anyone else?

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

No, we're all set. Thank you

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay, well thanks very much for that clearly exciting and important work and we look to having behavioral health and LTPAC as part of the ecosystem. So next Michelle, I believe we are going onto data segmentation for privacy.

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

Yes, is Deven on?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

I am.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Please go ahead.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Okay. Thanks, John. So we picked up on Larry's passing the ball to our Tiger Team to think about the functionality that might need to be built into electronic health records to enable the sharing of behavioral health data that is protected by these enhanced federal rules. That require that patient consent not just to disclose the information, but then on subsequent recipients they are bound by consent requirements to redisclose that information. And so that makes sharing of behavioral health data quite the challenge and we tried to take that on with some recommendations. So, next slide, please. On the Tiger team, we have a number of Standards Committee members, which helps us tremendously in thinking through both the policy aspects of this issue but also the quite complicated technical aspects of it, which is enormously helpful. Next slide, please.

So, just by way of background, right, we don't probably have to spend much time on this slide at all. We didn't...this topic came to us from the work that the Certification and Adoption Workgroup was doing on long-term care and behavioral health certification issues. And they specifically asked us to dive into their initial recommendation that enhanced privacy protective functionality be built into both the behavioral health records as well as the technology on the data recipient side, which many times will be a healthcare provider that is not a behavioral healthcare provider. Next slide.

We want to start with a few observations. We took a look at this issue over a number of months and in fact, we first considered this issue way back in 2010 when we had a hearing on granular consent technologies and their sort of readiness for use in the marketplace at that time. And we acknowledged in 2010, that there are difficult issues that arise from a com...both from a policy standpoint as well as a technology standpoint with patient choice at the level of a certain type of data. And frankly those difficulties still exist, particularly around the policy side and the technology is not quite at the place where we would want it to be, although as I'll note later in the presentation, it's progressed from where was in 2010, thankfully.

The need to provide coordinated care for individuals with mental and behavioral health issues is absolutely clear, I don't think there's any doubt about that. The enhanced consent requirements that are part of the substance abuse treatment regulations, which are known as Part 2, were in fact implemented in order to address the reluctance of individuals to seek care for behavioral health

conditions. So while they present challenges to information exchange, it's important to understand that they were intended to create an environment where people would feel some level of confidence in coming in to seek care for what can often be a very stigmatizing condition. Next slide.

But we also heard back in 2010, and we heard as well when we considered this issue again just a few months ago, that the ability of patients to withhold consent to disclose information is of great concern to healthcare providers. They want to provide the best care for their patients and they have pretty significant concerns both out of the professional obligation to their patients, as well as due to potential liability about incomplete, one of our members called it Swiss cheese records. This was a convenient way of referring to it, nobody likes Swiss cheese records and the concept of providers needing to act on incomplete information is not at all new. It existed in the paper world, but in a digital environment there are sometimes increased expectations that the information that comes in that is in an electronic medical record or that comes from an electronic medical record through information exchange is going to be more complete. Next slide.

So we particularly looked into what is called DS4P, which is the data segmentation for privacy, an initiative ONC's S&I framework. And they looked at piloting promising technologies to enable the disclosure of records that are covered by these Part 2 substance abuse treatment rules that is the use case that was specifically explored in these pilots. But it's not hard to see how a segmentation technology might be useful for other...to assure compliance with other types of sensitive record laws like state laws around protections for certain types of information like mental health data or genetic information or laws protecting the rights of minors to seek care confidentially. So ultimately, because the Certification and Adoption Workgroup had teed this issue up for us, and the pilot for the DS4P had been completed, we thought it was an important moment to go back and take a look at what progress had been made from a technology standpoint. And to consider whether the timing was right to recommend functionality for electronic health records that would enable the exchange of data that is covered by these Part 2 protections. Next slide.

So, the next two slides are really, what we sort of framed as the glide path for the exchange of Part 2 protected data. And this one is really quite short, the glide path for senders, they're the ones who are covered by the Part 2 rules, they cannot send information on a patient that indicates that the patient received substance abuse treatment without having...first of all they have to get the patient's consent. And they have to be able to communicate to subsequent providers that that information is subject to 42 CFR Part 2, which means that it has those re-disclosure prohibitions attached to it.

So at level zero, which is at the current state, without the technological capacity to tag that data in some way and indicate that it is subject to these re-disclosure prohibitions. Even when they get consent from the patient to send it, they can't do that, at least not using electronic health records because they don't have a way to sort of send the re-disclosure prohibitions with the data. And that's really the current state. The next level would be sequester at the document level, where the provider gets authorization from the patient to share and then that behavioral healthcare provider can send the data along and it's got the required...it meets regulatory requirements. Because the information is tagged or there's some sort of indication that it is subject to Part 2 restrictions on re-disclosure. Next slide.

The glide path for recipients of Part 2 data is a little richer and these recipients could be themselves other substance abuse treatment providers. But in many cases, they will be providers that are not otherwise covered by Part 2, until they receive that Part 2 covered data and then they also are bound by the requirements not to re-disclose it without patient consent. And here at Level zero, the current state,

is generally this information is not shared electronically, unless you count a fax machine as digital. Frequently substance abuse treatment providers are not included in state health information exchanges, as an example. And so therefore the status quo is when that information is shared, it is shared on paper or potentially by fax machine.

The next level would be the sort of document level sequester and this is the type of technology that was tested in the data segmentation for privacy pilot. Which is, it enables a recipient to receive the data sent by Part 2 provider and tagged as restricted, but they can only view it. They can't...the data can't be parsed or interdigitated into that EHR such as to enable decision support and other elements of the electronic record software to actually act on the data, but it can be read.

And the reason why it can't be interdigitated or parsed is because we are not at Levels 2 and 3 and without a capability to make sure that that information isn't inadvertently re-disclosed through the parsing, we're sort of at the stage where the data can be viewed, but cannot be sort of consumed by the record. That would be really Level 2, which would be ideal that the data is at least actionable in a digital way by the provider who receives the information. And then subsequently Level 3 would be really this sort of full-scale interoperability with the consent requirement not just attaching to the data and persisted in the recipient EHR, but then when it is subsequently re-disclosed, with permission of patient, it then...that re-disclosure then can be automatically communicated to the next recipient and so on and so on. Next slide, please.

So, with that framing in mind, what we understood from the pilot is that they tested the capability to move from zero to 1 in terms of this glide path. The ability of a sender to send information digitally on a patient subject to 42 CFR Part 2, tagged with the restriction. And then the ability of the recipient provider to at least be able to view the information that is sent, so that they can at least be aware of what the prior care was that was provided to the patient. It is not the world's greatest advance in technology, no offense to the folks who worked on these pilots, but it is advanced from where we were or where we have been in terms of the status quo and it lays a foundation for being able to get to higher levels of functionality.

We also heard from the Assistant Secretary Howard Koh of HHS as well as from Dr. Karen DeSalvo, the head of ONC, that the issue of assuring coordination of care for patients with behavioral health issues is critically important. And there is a very important need to try to be moving along a glide path both from a policy and technology standpoint with respect to the sharing of this very sensitive data.

So here are the recommendations that we put before the Policy Committee that were adopted not at the most recent meeting in July, but at the June meeting. And so we said ideally for Meaningful Use 3, recognizing that timing and whether we are in time in order to get a Meaningful Use Stage 3 recommendation enacted is an open question. But ideally, there would be the level 1 send and receive functionality present in any certification...in any voluntary certification program for behavioral health providers. So that they have the capacity at least to send this information to another healthcare provider where...in order to have care coordinated for the patient.

Ideally, there...that a technology that would facilitate some recognition that the provider who's the recipient of this information is in fact willing and ready to receive it, would be ideal. But that may be something that...that isn't necessarily technologically capable and instead, behavioral health providers need to assure probably by other means that the providers that they're sending this information to both want to receive it and are capable of receiving it. If you're...to use a tired sports analogy, a pitcher has to

have a catcher at the other end or who knows where the ball will go. We may need a capacity for entities to know that the catcher at the other end has the mitt on his hand and is ready for that ball.

Now what about the non-behavioral healthcare providers who are participating in the Meaningful Use Program, well for that we recommend the level 1 receiver functionality so that they can at least view the document that is sent from that behavioral healthcare provider. That should be a voluntary certification criterion for the certification of electronic health records technology program that is tied to Meaningful Use; also voluntary, as Jacob pointed out earlier, but tied to Meaningful Use Program.

We are not recommending any specific Meaningful Use requirement to use this technology, which is one of the reasons why it's voluntary. We believe that providers who have a lot of patients with behavioral health histories and who want to be able to receive the information, even in this imperfect way, to be able to have a capability that they can depend on to receive that information. But for providers who are not comfortable with that, we don't think it's a requirement. So in other words, the way this could be conceptualized is transitions of care involving behavioral health...patients with behavioral health issues should count toward meeting Meaningful Use transitions of care requirements. But you shouldn't necessarily be required to go out and get one, if you're not taking care of those patients today.

Level 2 and Level 3 are beyond Meaningful Use Stage 3 and definitely need additional pilots and work to be done, but we really thought that without the progress made to go from zero to 1, it was unlikely that there would be investment made in getting to Level 2 and then subsequently, to Level 3. Next slide.

Now we also thought there was a lot of work still to be done on this issue of recipient response. Again, as I mentioned earlier, sending providers really should only send to recipient providers who are interested in receiving this information electronically. Is there a possibility to create some technological way to indicate readiness to receive or is this sort of old-fashioned by contract or pre-existing relationships? It's also important to sort of identify the unanticipated workflows and consequences that could result from the fact that this information is coming in and cannot be parsed or interdigitated into the EHR, because it's view only. How will those recipients EHRs, let's say they do get consent from the patient to release it...to release the information, how can they then communicate that information with the re-disclosure prohibition on it. And then of course additional pilots regarding Levels 2 and 3 when we get there.

Lots of need for education of both providers and patients around this, there are a lot of providers who don't probably deal with these patients all that often, who may need to understand what the legal requirements are. We also strongly encourage the Substance Abuse and Mental Health Services Administration, SAMHSA, to provide additional written guidance on how to operationalize what are statutory requirements. This is not just in reg, this is actually in statute, these re-disclosure prohibitions, in order to sort of meet the demands of a digital environment. And SAMHSA did, in fact, have a listening session in June where they collected comments about the Part 2 obligations and how they might sort of re...I don't know if they would refresh the regulations, whether they would issue more guidance.

This is really sort of up to them, but there is a great need to sort of understand how this is all going to work, in particular when information comes from a Part 2 covered source, a behavioral health care provider, it's covered by Part 2. But when the information is provided by the patient, it is not because it doesn't start covered by Part 2. Information provided by patients...so a patient could come to a physician and talk about the substance abuse and mental health treatment that they received and the

medications that they received while they were on there, and none of that would be covered by the same set of restrictions due to limits in the statutory protections.

So what does that mean for sort of, is it possible to subsequently source the information from the patient, even though you might have initially received it from a Part 2 covered provider? And so we're very hopeful that SAMHSA will pick up those questions and try to answer them more clearly in some guidance, because that guidance really doesn't exist out there as of yet. Next slide, please.

And so we're recognizing sort of the limitations that...for what the Policy Committee can and should take on, our recommendations focused around meeting functionality to address the Part 2 obligations and at least move on a glide path from zero to 1. But we are leaving of course to the Standards Committee, the question of, whether in fact what should be part of voluntary certification either for behavioral health providers or for non-behavioral providers is, well as the DS4P or any other standard mature or feasible enough for this certification. And if so, at what level of granularity? And really it's the same question for both pieces because it makes sense if you really want this information to be flowing throughout the healthcare system and not just among behavioral healthcare providers, the question has to be ideally answered for the products that serve both populations. And that was where we landed. They were adopted by the Policy Committee again in June and now there's additional work to be done both from a standards standpoint as well as with respect to the SAMHSA piece of that. And I'll stop and take any questions.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So Michelle, do we have a queue of questions?

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

Yes we do. Arien Malec?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Hello. And hello, Deven.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Hi, Arien.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

So, one of the things that concerns me here is that I can see a reasonable path to tagging consolidated CDA document at a document level with some kind of marker that indicates that it's covered under behavioral health and substance abuse legal requirements and prohibitions. What concerns me is the previous slide, slide 10, where it's not clear what the expectations of the EHR are? So there's...it's not, I think, fully understand what the obligations of providers and patients are and by extension, it's not clear what that means for the certified EHR. What behavior are we expecting for recipients of an electronic document that is tagged with...as being sensitive under a variety of guidelines, in particular the SAMHSA guidelines.

So I'm wondering whether you can address whether we can operationalize the certification requirements...you seem to be focusing just on the document standards and the tagging requirements. I'd also imagine that we want to operationalize the certification requirements for the receiving EHR with

respect to what can be done and not done with that data. Whether, for example, there needs to be any warning if there are data in the chart, for example medication or condition data that are mirrored in the received documents, these are the things I think that worry me the most. I can imagine that we can receive the document electronically. It's harder for me to imagine what we expect the receiving EHR to be able to do with that document, in order to provide appropriate support for the provider to stay on the right side of the law.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Right.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

So I'm wondering if you could address that.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah, well, I mean these very same questions occurred to us. The approach that was taken by the data segmentation for privacy pilot vendors was that it is an entire document that is tagged as restricted. And the tag enables the sender to be in compliance with law and to send it. And what happens at the recipient end is, if they don't have the technology in their systems, they can't open the document. It's unreadable. If they have the technology in their systems, they can open the document and view it. But all of the parts of the electronic health record that arguably make it valuable from a treatment perspective in terms of the decision support, the medication reaction checks, all the sort of pieces that make a record not just a shoebox but actually help make information actionable won't work on the data. It is, in many respects, not much better than fax in that regard.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

That...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

But it does create a baseline of an initial digital workflow that we were hoping would stimulate additional work to be done on the very issues that you've pointed out.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Okay.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

And so if you don't have the technology, you can't view the document, not that that's inconsequential because a provider has sent something, they can't open it and read it. They then have to probably pick up the phone or send some communication back to the sender and say I can't read this, you're going to have to send it in some other way. Undoubtedly, there are lots and lots of issues, and we struggled pretty mightily over whether it was worth such...a step that was very messy and doesn't answer or address a lot of the questions. Because we laid a foundation for moving...we're hopeful...because we could lay could lay a foundation for improvement, and ultimately we were persuaded that notwithstanding all of the messiness and the imperfections associated with just the document sequester approach, that it moved us ever so slightly from the status quo and laid a foundation for the higher level stuff.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

So if I can ask a follow-up question to see if I can clarify what you're saying. The approach that was piloted was an approach where a receiving EHR asserted through some technology means that it was able to do the appropriate thing with that received document. I assume it had a decryption key or otherwise that allowed it to view the contents of that document. And...but the requirements of what it means for the EHR to do that assertion, I know what it means...I know how to handle this kind of document, still is underspecified. And I guess that's the area of concern for me with respect to certification requirements, that we not just look at the certification requirements for the technology signaling, but also have appropriate guidance to EHR developers to know what it means to assert conformance with receipt of protected information.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah, no, that is exactly right. It is another reason why we declared that at least with respect to the certified EHR technology program tied to Meaningful Use, that it should be voluntary.

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

Deven, this is David, can I jump in and...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah, of course.

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

Arien, what we tried to do with these levels on Deven's glide path slide is to come up with an arbitrary but maybe conceivably implementable notion of the difference between receiving but sequestering the document from any kind of automated parsing. Which would be the stopping point for the near-term, while we await better standards to figure out what to do with the parsed data that would then carry those restrictions into the rest of the record. So think of it as a lockbox or a sequestered document that would be annotated for the clinician that says, this document contains restrictions on the data, so we're not going automatically import it into the record.

And it was absolutely a stopgap measure because we just couldn't decide what to do with the data if you did pull into the record, since no EHRs that we were aware of could actually manage the subsequent re-disclosure restrictions in an automated fashion. So think of it as a sequester step as kind of step one towards a more broad solution.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Yeah, and that applies in certification criteria with respect to, what do you do with that document, for example, that if you're responding to a document query, that document not be available. That if...

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

Right.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

...you send a referral, that document not be available. What I'm also worried about is, are there any implied certification criteria with regard to data that are found in that document that are also found in the chart? And whether there's anything that's impactful or implied in terms of an EHRs ability to receive that document. So again, it's that clarification I think that would be worthwhile to put in either certification or guidance to EHR developers, in addition to just the technical requirements.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Deven and David, a process question for you, was it the intent after your delivery of your report today, that we might assign to a HITSC workgroup like Implementation, Certification and Testing, the answering of the questions of, oh, is this ready for a certification step or no?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Why yes, John, it was.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And so Arien, to your point that is, it seems like a next step is, we've heard this very thoughtful approach but we need to now measure it against product realities, workflows, and can we get to their very reasonable next step in a 2017 or other time frame?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah, but with a strong urging to try to do so, again because from a policy standpoint, the need for this functionality could not be more clear. It's just the needs are surpassing what we've been able to achieve to date with respect to the advances in technology. But is there a role that certification can play in some way, shape or form in order to advance the ball?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And Deven, could you clarify, is SAMHSA actually working on a restatement of its Part 2 regulations for digital age, so that in fact, we have urgency absolutely, but there also may be some additional guidance and regulations coming.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

I believe they are. Now they are a little hemmed in by statutory language. So unlike in HIPAA where nearly every single bit of the detail is in regulations, which gives the agency a huge amount of discretion with respect to amending them, there is some statutory language here that SAMHSA will have to thoughtfully consider how...how they can be true to it and still meet the challenges of the digital environment. Now, whether that means just guidance or whether that means that there is tinkering that they can do with their regulations or some combination of both. But they have some hard stops, they can't, for example, get rid of the re-disclosure provision, it's in statute.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good.

W

Deven, do you...a quick question, do you see any or hear any indication of any possible reconsideration of the statute or changes to the statute?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

I have heard none. I haven't heard any. It doesn't mean that there might not be a bill or two out there, but not...I have not heard active discussions along those lines.

W

Thank you.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

It's a bit of a third rail issue.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

May I...

W

Yes, it is.

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

John, this is Michelle, there are a significant number of people that have been in the queue for a while.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Let us go forward.

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

Okay, Eric Rose?

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Hi, sorry, I had to unmute. Can you hear me?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Yes.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

So first of all, I just...I want to congratulate your team on some very, very thoughtful work. I have heard people talking about this issue in one way or another for 20 years now and this is the most thoughtful proposal that I've come across. So, I really appreciate what you're doing. And if I understand correctly, I think you did clarify this, the initial tagging is at the document level whether you are going to do Level 1, 2 or 3, is that right?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yes, yeah and we're...yeah.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

So, I'm wondering...so, I have two questions. One...or actually a question and a comment. My question is, did you give any thought to what happens if the document happens to contain some information that isn't particularly sensitive? Like, the patient not only has paranoid schizophrenia, but they also have hay fever...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Right.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

...or they're allergic to bee stings or something. And/or what happens if, at Level 3, what are the...what would be the rules around if the information were already extent in the patient's record, things like that? And then, let me just say my comment real briefly, and then I'd like to hear your response. My comment as a practicing physician who has, I don't think I have ever in over 20 years of practice received any kind of written communication from a behavioral health provider, MD or otherwise, on a patient whom I've referred, so anything that we can receive is a step forward. Even if it's level 0, you basically you can't get anything electronically out of that document, it's basically the electronic equivalent of a fax, that would still be an enormous step forward in helping to coordinate care and provide good care to patients.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah. So, I do think that one of the areas, and this is me speaking, that one of the areas that's pretty ripe for SAMHSA on guidance is to distinguish between data that is more sensitive in a substance abuse record treatment versus what may come from the substance abuse treatment provider. But not really itself, the data, reveal that the information...that the person is having substance abuse treatment, like the bee sting allergy or they have hay fever or some other physiologic condition unrelated to their substance abuse. Right now, the information that comes from the Betty Ford Clinic, just by way of example, even if it has hay fever on it, came from the Betty Ford Clinic. And so the data that's protected by Part 2 is data that comes from a Part 2 covered provider and in some way indicates that the person is receiving substance abuse treatment. But I do...

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Um hmm.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

...but having said that, I do think, and when you're dealing at doc...at a solution that's document level, it gives you sort of less flexibility with respect to sort of parsing between the non-sensitive...arguably non-sensitive information and the more sensitive information. But SAMHSA specifically asked questions with respect to sort of that type of less sensitive information and whether there might be some way to not have the rules cover that aspect of it. So I don't...I think that they are looking at it.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

And Deven, this is David, one more clarification from what they told us during these discussions was that if you have independently discovered the allergy and the bee sting information before you encounter it via the restriction...re-disclosure restrictions, you're still okay.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yes.

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

In other words, the...if you already know it, you don't have to add the restriction...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Right.

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

...and that even applies to the sensitive data as well.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yes.

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

So rule of thumb is, read the sensitive document last, because if you read it first you're in trouble.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Well, I don't even know it's temporally, like let's say it's the same information, right, you had it already sourced in your own record, right. And I mentioned earlier that if in fact, if the patient were to come to you and read their CCDA, arguably you got that from the patient.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Um hmm.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

So it is quite a confusing environment that is greatly in need of clarification.

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

Agree.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

The receipt of information that is already in your record from a Part 2 source does not taint the information that is in your record.

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

Correct, that was my interpretation.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well Michelle, I know we are running behind time and we don't want to shortchange Dixie. Do we have others in the queue?

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

We have a lot of people in the queue. I do have to ask, I think we could possibly shorten Dixie's presentation and maybe Steve can give us a little more time so we can ask some more questions to Deven.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay, please. Then go ahead with the queue.

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

David McCallie?

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

I'm covered.

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

Oh good, well maybe we don't need...Andy Wiesenthal?

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)

Yes, I have to get off mute, sorry. I think that the experience of my former organization, Kaiser Permanente is instructive here because the things that we're talking about are things that are being sent back and forth between different entities. And what happens in a truly integrated delivery system is nothing is being sent and there's a single patient record with pieces of it that are sequestered because of these laws. And what can happen in a situation like that, of course is that the other clinicians are aware, always aware, when that's true. And when they believe there's a need for use of that sequestered information, they can then use a break the glass function and look at it and use it in the context of that current care episode or longitudinal episode. But it always remain sequestered so the next clinician down the line isn't getting something re-released to them, it's in the record sequestered, and they have to break the glass, too, if they think they need something that's walled off that way.

And I...you all may think well that's pretty weird and that's just Kaiser, but the truth is that more and more integrated delivery systems are being formed and I'm hopeful that either the committee or others can inform the world, or at least the EHR world, what to do if the situation is different. And it really is information in a unified patient record that is protected in the proper ways according to the law, but then available for other clinicians who participate in this same network. So that's one thing.

And just another....a comment, Eric's opinion as a clinician is something that I respect in there are other doctors on the call. My sense is that, and I'm sure you heard this Deven, in an environment where doctors come to rely completely on the decision rules, particularly as it relates to medication interactions or medication allergies, or adverse effects, that to have that kind of information unavailable and non-parsable actually creates a more dangerous situation than having nothing at all.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Well that is exactly why we thought that the criteria...criterion...

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)

So if somebody shows up in an...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

...should be voluntary. Because people...

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)

...emergency department...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

...we heard that we basically heard from your Standards Committee colleague, Eric, sentiments like, some information even viewable...just viewable is better than none, some others who said no, don't even give it to me because if I can't really meaningfully use it, then I don't want it. SAMHSA, I think, is exploring the issue of sort of what it means to disclose and whether it's possible for a patient's authorization to disclose to be sort of for a care continuum that might involve multiple providers or to already they allow for disclosure to an entire provider entity or integrated delivery system. So, I think some clarification if not released on the policy end, may be forthcoming in the near future.

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

There's someone that needs to please mute their line. Sorry, Deven.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

That's okay. Yeah, I mean, they get the voluntary aspect of this, I mean not voluntary in the way that Jacob earlier described the whole certification program...with respect to the criteria that are in your system that you are required to purchase or upgrade to as part of Meaningful Use Stage 3. We really felt like there was enough uncertainty out there that only those physicians who truly wanted to use this capability should have...they should have it if they want it, but they shouldn't be required to turn it on.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Thank you. Next in queue, Michelle.

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

Lisa Gallagher.

Lisa Gallagher, BSEE, CISM, CPHIMS - Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Hi, Deven. First, let me say that you all have done a fabulous job and I appreciate the information and the thoroughness. And I just want to ask an additional question in terms of the future work of the Policy Committee on this topic. So I'm looking at the history of this task and I clearly understand what was asked of you. The Policy Committee had the Certification and Adoption Workgroup working on this, they asked the Tiger Team to look at a specific area and issue and you have then given us a full briefing on your work.

Do you have any knowledge or insight on the additional work for the Policy Committee or the Certification and Adoption Workgroup, your Tiger Team, in terms of any...of the policy issues that will continue to come up? For example, Andy's example was very thoughtful and I think, may require additional policy consideration, so I'm just asking if you either know anything or if you can look in your crystal ball and say, we may have to...

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

If only I had one of those.

Lisa Gallagher, BSEE, CISM, CPHIMS - Vice President, Technology Solutions – Healthcare Information & Management Systems Society

...think about this. Yeah, I know and that's why I was hoping you would, but just what else do you see being discussed on the Policy Committee and the associated groups, if anything?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

So, we don't have anything in the queue right now. This was a really big issue for us to take on, it took us several months to come up with the recommendations that we came up with. I do suspect that if there were additional questions that came up that needed further clarification as a Standard Committee considers this further, we absolutely would be amenable to some cross-committee dialogue where we need to.

I also wonder whether, when and if SAMHSA comes out with some additional either proposed rule changes or some additional guidance, whether there's an opportunity to sort of evaluate that in the context of all of the issues that were raised when we consider this as a Tiger Team. And at the committee level and then here again with you all today, very similar sets of issues raised, that we sort of think about whether...to what extent did they...do those clarifications help the issue?

I think sort of at this point we're sort of stuck with this is as far as we could get for now. And without...with sort of really clear pathway for why we would take it on more, keeping in mind that we...the type of recommendations that we put forward are largely to the Meaningful Use and Certification Programs. We have definitely used our bully pulpit to opine on HIPAA and some other things, but usually in the context of the HITECH Incentive Program, so we have sort of limited, to the extent we have any authority at all, it's fairly limited. But definitely limited as to making overarching policy recommendations not tied to this. So, I never say never on stuff like this because it's an evolving issue, I mean a hopefully evolving issue where a new set of facts and circumstances might necessitate going back, but we don't have any immediate plans to do so.

Lisa Gallagher, BSEE, CISM, CPHIMS - Vice President, Technology Solutions – Healthcare Information & Management Systems Society

Thank you and I do appreciate your willingness to discuss inter-committee discussions on what we come up with going forward and also any discussions on the SAMHSA guidance forthcoming, so, thank you very much.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Next queue member.

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

Wes Rishel?

Wes Rishel – Independent Consultant

I just want to recognize a term that we have adopted and I think it's a great term, interdigitation. Not meaning locking your fingers together as in prayer, but meaning taking incoming data, parsing it, mixing it in with parsed data that might have been generated from direct input or from other inputs and using that combined body of data to provide clinical decision support and many other than beneficial functions to aid the users or for secondary purposes. Great, great new use of the word, William Shakespeare would be proud.

I do have a question for Andy and a question for Deven. Deven, your question's probably easier. If information on a bee sting came in from Betty Ford clinic, wouldn't that automatically indicate that the patient is being treated for substance abuse?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yes.

Wes Rishel – Independent Consultant

So any scheme for using non-sensitive information sourced from a SAMHSA source probably involves being sure you've lost where it came from inside your system, correct?

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Well, I mean I can't speculate on how SAMHSA would feel about that particular approach.

Wes Rishel – Independent Consultant

Yeah, but I think it's an issue that needs to be resolved because if it's left open, it will certainly come up when you turn this thing loose on lawyers and programmers. They're good at finding all of the worst possible cases.

Andy, you described the process in use at Kaiser where sequestered information exists, whether or not it came from a third party, because the...either the moral or the legal requirements associated with providing behavioral health treatment required that it be sequestered. And then it could be available...a physician could know, in some context, that there is sequestered information and then could break the glass. And you talked about the importance of that information in clinical decision support. I'm just trying to understand is the Kaiser system so powerful that it's able to temporarily interdigitate the information from the sequestered record in order to do computer decision support and then de-interdigitate it for future use? Or is it just sim...does the physician at Kaiser under the information you're describing, simply become aware that there's some report he can look at and may use that to cognitively do his own decision support? Andy? Are you on mute?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Andy may have...Andy? Sounds like Andy may have stepped away.

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

Sounds like we lost him. Sorry Wes, that was a great question and we will maybe paraphrase if Andy comes back.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yeah, or maybe that can be part of what gets evaluated on the Standards Committee end. It was an approach that certainly we didn't hear about in our own exploration of the issue and I wasn't aware that Part 2 had break the glass exceptions, which is another thing that struck me as unusual, so...

Wes Rishel – Independent Consultant

Well I would say that you could think of break the glass here as a way of the physician acknowledging that the information made available is covered by SAMHSA restrictions.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Got it.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Next person in the queue and then we should move on to Dixie.

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

Leslie Kelly Hall had her hand raised, but then just took it down, I think.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I've got it covered, thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well that is a rich discussion and I think we have those next steps, Jacob, to hand this off to one of our new workgroups, which you will be discussing the charge of in a few moments, for them to do the validation that we have heard Deven would like us to do.

Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Yes, please.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay, very good. Well hey, let us move on then to Dixie.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Okay, I'm here. We're just going to present a single recommendation from the Nationwide Health Information Network Power Team. Next slide, please. We, the Power Team was assigned three tasks and...to address privacy...make recommendations on privacy directories, query for a patient record and provider data migration. And we're reporting today only on this first task, provider directories. And we're now working on the second one, query for a patient record. Next slide, please.

This is the functionality that was recommended by the Policy Committee Information Exchange Workgroup. And specifically, what they wanted was a rec...was the capability to query external provider directories for Direct addresses and security credential information. And then the responder needs to have the ability to expose a provider directory that would contain this kind of information. Next slide, please.

This one I'm sure you're not able to see well, but let me summarize it. The scope included both the minimal acceptable content and the type of provider directory transactions. We were told to build on Stages 1 and 2, make it simple. It's to...we should address querying an external EHR system regardless of who the vendor was. The transactions are the ability to query for the information, reply...the provider directory reply to it and then administrative capabilities. The most important part in that transactions part is that the Policy Committee Information Exchange Workgroup included the ability to do mutual authentication. So the system that was querying the provider directory needed to authenticate the identity of the directory and the directory provider needed to authenticate the identity of the querier as well. And then the transaction detail just emphasizes that the emphasis is on the ability to find a Direct address and to encrypt the content in the Direct exchange. Next slide.

We asked...Mickey Tripathi is the chair of the Information Exchange Workgroup for Policy Committee and they provided a lot of guidance in their recommendations. So we asked Mickey to meet with us, which was...meet with our Power Team and that exchange was extremely useful to us in clarifying what they were asking for. He recommended that we limit the certification requirement to focus on Direct messages and he recommended that at any minimum, the EHR technology would be able to query an external provider directory for a Direct address. The organiza...an individual Direct address, an organizations Direct address and for relationship between providers and organization providers. And I should clarify that he was really...he wasn't just telling what Mickey thinks, but more interpreting for us what really came out of that workgroup.

We had a discussion with him about this mutual authentication requirement that was passed over to us. The basic transport layer security handshake, TLS, is what all the...Amazon.com, all the sites on the web use to secure the session between the...secure the transport between the users, browsers and the servers. So your...that's what you commonly use on a day to day basis. And it does already include the capability to do mutual authentication of both the sender...both ends of the transport. The default for TLS is to just...to authenticate the server-side, but it's possible to do mutual.

We concluded that we couldn't think of an essential driver for mutual authentication because the querier may or may not need to be authenticated, depending on the content in the provider directory. So that was the outcome of that discussion. The two standards that we ultimately looked at are transport layer security and the exchange profile called healthcare provider directory plus, HPD Plus, which is an exchange profile that's based on the IHE healthcare provider directory profile. Next slide, please.

Our conclusions, we concluded that there's no existing standard that's ready to become a national standard; HPD Plus is indeed a good start, but it needs to be proven in the marketplace. We also felt that there was a slight risk that putting such a standard in the certification criteria at this point might just be making work for vendors and certification bodies for a capability that really wouldn't be used, necessarily. We noted that there exists a national provider identifier directory and we thought well, you possibly could use the NPD...NPI directory to supply Direct addresses and that this might be an interim step forward. We also wanted to encourage other simple approaches such as using the FHIR-based

approaches, which is a RESTful approach. And then the...we concluded that determining whether mutual authentication is required should be a risk-based decision based on...that the provider directory owner should decide whether they want to authenticate the entity that's asking for directory information. And then the final slide, please.

Oh, our recommendations. Based on our assessment of the functional requirements as received from the Policy Committee, we don't know of any standards that currently exist that are both sufficiently mature and implementable to become a national standard. And we...and the criteria we used here were the criteria for readiness that the NWHIN Power Team created. We felt that HPD Plus...or profile is a good start, but it needs to be proven in the marketplace. It's been in a number of interoperability showcases and other demonstrations, but it really has not been widely adopted and used in the marketplace.

We recommend that ONC encourage the exploration of other simple approaches for implementing this required functionality, such as CMS is currently looking the...a RESTful approach. And that ONC should be looking...working with CMS to harmonize CMS' RESTful directory approach with the HL7 FHIR standard.

And then finally, we recommended, as I noted on the previous slide that the federal government...that we might be look...might want to look at using the NPI directory that currently exists and just add Direct addresses to it. And it might be at least good for an interim measure and possibly more, but it should at least be looked at. David, do you want to add anything?

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

Yeah, just a few comments...this is David McCallie. This was a frustrating discussion because we felt like the existing approach of using HPD Plus, which is itself layered on top of some standards which themselves are layered on top of LDAP, was something that is quite a complicated way to solve what is a fairly simple problem. And even though it has been demonstrated in small pilots, the ability to create some kind of nationwide federation of address managers that would pool their resources in some as yet unproven federated HPD Plus network for the vendors to consume, just struck us as an incredibly hard way to solve what ought to be a much simple problem.

So we backed away from endorsing it at this point, simply because we thought there's just got to be a simpler way to solve the problem. And with the release of Medicare data that describes providers and what they've been ordering, I forget what the name of that data set is, it came out a few months ago, a number of sites have created provider lookup searches with simple web tools that allow you to do very sophisticated queries to find providers by name. You can query for all the cardiologists in San Francisco and get your answer back in sub-second time. Those kinds of national scales, simple web-based services, just make so much more sense.

The other thing that we were concerned about or puzzled about was the requirement that came to us that the transactions be secured. And it seemed like it may have been based, at least in part, on a misunderstanding of how Direct works. There's no need to keep a Direct address a secret, you can't participate in the Direct network unless you are on the network. So knowledge of the address doesn't mean that you can send to it as an...outside the network. So we were puzzled by the notion of managing complex security just to protect an email...essentially an email address that's designed not to be abused.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good. Well thank you. I think Michelle, what you had wanted, of course, we'll have discussion by any members in the queue. But that you wanted a general endorsement of the Standards Committee that this idea that we continue exploration of RESTful FHIR based or other approaches learning from what possibly state HIEs are doing or what CMS is doing would be our feedback to ONC. And you are seeking that process step.

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

Yes, please.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So let us go through the queue for other comments.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

And also...

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

There's nobody with their hand raised, just to note.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

And also looking at NPI...at the NPI Directory as well, John.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Right. And so Jacob, I've made the offer before that in the Massachusetts HIE implementation, we used a simple RESTful approach, non-authenticated, for all of our 22,000 providers. And that has been very simple to implement and scaled extremely well. So I'm happy to contribute that implementation guide if it's of value.

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

Thank you, John.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck and Associates

Thank you, John.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, if there are no comments or discussions, it sounds like then we are asking our Standards Committee to accept these recommendations that...

Wes Rishel – Independent Consultant

Wes Rishel, I raised my hand.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Oh, okay, please go ahead.

Wes Rishel – Independent Consultant

I just wanted to suggest that exploration of the NPI include exploration of the effectiveness of the NPI as a national provider identifier. I may be out of date in my information, but in working on reliance on the NPI in HIPAA transactions in the past, it's been my understanding that there are still duplicates, there are many classes of providers that don't have an NPI and so forth. So I would want to suggest that not only the technical feasibility, but the practical ability to rely on the NPI be considered. Thanks.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So Wes' comments are very important. I am an emergency physician at Beth Israel Deaconess, I'm a CIO at Beth Israel Deaconess. I also happen to practice as part of a poison control system. There are multiple ways to find me and direct messages to me and so you may want to use a Direct address at the Poison Control Center or the Emergency Department and not to me as the CIO and so, it is a very important question to ask. NPI isn't necessarily canonical and is that a construct or not? Agreed.

Okay. Well so the three recommendations are that at the moment there is...yes, existent standards but based on the NWHIN Power Team's own criteria, they don't quite meet the measure of maturity and adoption and simplicity. And therefore examining additional standards that might have been used, considering the NPI both as a mechanism of hosting a Direct address, but as Wes has just suggested, is that actually going to support the workflow that's required? Are there objections to proceeding with those recommendations? Okay, well none being heard, then Michelle, we I presume draft the letter to ONC and then have probably just created some additional work for ourselves.

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

Perfect. Thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good. Okay, well next we will move on to, I believe, Steve Posnack will give us an S&I Framework and then we'll conclude with Jacob and his announcement.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

Sure, this is Steve Posnack, good to go. So Jacob and I had been discussing how we could provide more regular updates in case those of you felt any longing for the updates that the Policy Committee was getting. I will probably likely do some type of equivalent update on our standards and technology activities, largely expecting them to be around the S&I Framework as well as the ONC HIT Certification Program. Actually I have an update for each of those today, the first is going to be covering, I think more informational for folks, many of the slides are for your reference. You can go to the next slide.

So this is our usual new heads up display of the activities that are ongoing through the S&I Initiative's Framework for the active initiatives and the community-led or other agency led activities. And then our third bucket that we'll likely phase off of our heads up display here. Next slide.

So the next two that I'm going to cover are...I'm not going to go into great detail and depending on what your resolution looks like for the webcast, may be hard to read. The slides obviously are in a better larger version. So, there are a number of different S&I Framework activities and many of them have correlated work that goes on with respective SDOs. And so what we wanted to try and do here was to give folks a forecast and a little bit of roadmap for we expect the SDO engagement to look like, as the S&I Framework initiatives begin to output many of their accelerated work products.

So, this just shows the type of work products that are coming out. Sometimes it's a white paper or a concept paper, in other cases it's a document that is being prepared with the relevant SDO for a ballot. And so that's the...the first like covers a number of the active initiatives, which is why it's all crammed on there. And then...you can go to the next slide...covers the community-led activities, which I'm waiting for it to refresh on my screen, to make sure that I don't get too ahead of folks.

All right, there we go. So these are the committee-led or other agency-led and you'll see, especially for the laboratory orders, which has been around for a while, that it's going through a second and third turn of the crank and that there's...the targeted work on the cancer registry reporting for CDA implementation guide is going to ballot for September is the target date.

So the following slides, and whoever's driving the slides can tab forward, are just really for your reference. They're more detailed visuals for each of the actual S&I Framework initiatives and where we are today versus what we have planned through the S&I initiative. Someone can leisurely tab their way through the presentation as we go through. That's really my update on the Standards and Interoperability Framework. And as that person is still clicking through the slides. Again, those are for your reference, I'm going to turn to the ONC HIT Certification Program. So, we'll look for areas where we can provide updates, I think some of the things...here will provide some input into updates that I will be making in the future.

So for the Certification Program overall, I wanted to give kind of just a general status check on where we are from program participation and what the components of the program are. So, many of you are likely aware that the CCHIT withdrew itself from participation in the ONC HIT Certification Program. When they participated, they served as both an accredited testing laboratory through NIST's NVLAP, National Voluntary Laboratory Accreditation Program, as well as being an ONC authorized certification body. So I wanted to give folks a sense, just in case you were wondering what the current makeup of the program looks like, that today we have five accredited testing laboratories, so it's ICSA, Drummond, InfoGard, National Technical Systems, which is a rename from the prior test lab, and then SLI Global Solutions.

So we have five accredited testing labs that perform testing and we have three ONC authorized certification bodies, ICSA, Drummond and InfoGard. So that's the makeup, very healthy amount of participants. And to give you a sense of an interesting program metric that's kind of come to my attention in the past few weeks is, I asked all of the accredited testing labs how far out are you booked if I contacted you today for testing? And so I think Jacob may have used the analogy in a past conversation of trying to book a hotel for Times Square on New Year's Eve and being told, you've got to wait three years. So the response that I got was a range, as could be expected, but generally, the range was available today and booked through or into October, depending on the accredited testing laboratory.

And I would also say that it also depended on the scope of testing, some indicated that if an EHR module scope of a certain limited number of certification criteria that could be fit in earlier than a later date. But

that was an interesting, I think metric, that goes...that we can kind of keep an eye on as time goes forward to get a better understand how the program is functioning and where any potential backlogs could occur in the future in getting some additional information from the testing laboratories. So even though there are some that were booked out further, into the future months, I would say that even those indicated that they definitely attempt to accommodate testing needs as they came in as a result of cancellations and reschedules. But that's just to give you an overall sense of the program.

And overall, we'll be looking at other program metrics that we'll be able to share. We've obviously done past presentations on the number of the products certified through and the number of EHR technology developers or Health IT developers that have been certified through the program. And those are things that we can certainly come back with for those of you that like statistics.

So the next thing I'm going to turn to has to do with our overall evaluation of the ONC HIT Certification Program and a specific action that we are announcing today. So our regulatory framework for the ONC HIT Certification Program has always had an open door policy when it comes to testing materials. Provided that certain basic process characteristics are met, any stakeholder or group of stakeholders could submit test procedures and testing tools to the National Coordinator for approved use as part of the program. To date we have not received any outside stakeholder submissions and as a result, ONC in partnership with NIST has resourced most everything necessary to support testing.

So our testing infrastructure approach has largely followed a sequential process where we develop the testing resources, we then have a period of public comment where we solicit public comment and then we go about revising the testing resources and make them available to the accredited testing laboratories after approval by the National Coordinator. This approach has always been met with some criticism over the years because certain stakeholders believe that testing does not always reflect what they believe are the necessary tests or focal areas or appropriate test data. And so as we reviewed the HIT Certification Program overall, finding a way to expand stakeholder engagement in testing resource development seemed like one area that we could immediately improve.

So today, I'd like to announce the kickoff of a pilot, which we're calling the Open Test Method Development Pilot. In a nutshell, instead of ONC developing the test procedures, the steps, the data and going through what may be that kind of sequential process, then making those available for public comment, we're going to invite the industry at large to throw their collective wisdom into the testing process. This pilot program is open to all stakeholders willing to contribute their expertise toward the development of the test methods that could ultimately be used by accredited testing laboratories for Health IT testing.

The pilot program is designed to provide stakeholders with an expanded opportunity to apply their in the field experience to test method development. So that includes the test procedures, the test data and the test tools, depending on their level of expertise and interest. The pilot program will be focused on two 2014 edition EHR certification criteria, which will be chosen by the community. And at its conclusion, we will work to evaluate the pilot process and the open test method development process for feasibility, efficiency and scalability relative to future certification criteria edition.

And the pilot program will have a few steps. Obviously, we're going to...we announced it today, there is a URL web address that I'll be able to give in one second, and that I can point people to it. But overall, the steps that we aim to complete will result in two test methods that have been openly developed through this process that we hope to be done by the end of October. So we're going to go through the

community selection process for two certification criteria that we can pilot. Then stakeholders will work on the kind of structural template development for those two certification criteria and then actually dig into the meat of the content for the remaining months.

And that is basically the end of my public service announcement here on this one. The URL that folks can go to, and we will certainly make it available, will be www.healthIT.gov/open-test-method. And that will direct you to the appropriate location where many of the contents that I just spoke aloud to you are included, with the steps in a nice crisp graphic and more information about how to signal your interest in participating in this new process.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well hey Steve, thanks very much. And I...same sort of question that I asked on the behavioral health LTPAC presentation, which is, have you heard from stakeholders in the provider or vendor community of their interest in developing their own test processes?

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

That's a good question. I think we've gotten specific feedback relative to the test procedures and the test data themselves, yourself included, not necessarily an interest in ownership of the test procedures and other methods that we include. But in reflection of our current processes that I would say are the status quo, we have had a lot of engagement from the EHR developer community, among other stakeholders. And it's in our interest to broaden and make available to as many stakeholders, especially the clinical community, who have asked the question, how did this get certified, to have a role in helping us improve the test procedures.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good. And to the discussion you and I have had previously, if I look at the fact that it took five people, six months to ensure that we had passed every one of those certification criteria, the time investment in creating a more streamlined testing procedure could potentially have been significantly less. And so in effect, your message to the community, stop your whining, be part of the solution, my words, not yours.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

We would certainly like everyone to be part of the solution.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good. Well thank you. Other comments or questions?

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

There are a couple of people in the queue.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Please, go ahead Michelle.

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

Arien Malec?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation

Thank you so much. So first of all, I'm just very pleased, Steve, to hear about this approach. One of the things that I'm not certain about, I'm wondering whether you can comment on is, how this approach could lead to different ways of composing a certification process. And what I mean is that, I think many of us who've gone through certification have had the experience of, for example, going through a Surescripts certification process and all of the testing and planning that goes with that and then having a parallel exercise from NIST with NIST test methods with Drummond or others. And one of those really matters for certification, but isn't terribly useful in the real world. One those matters a lot in the real world and doesn't actually count for certification.

As another example, we recently got green all the way across in our DirectTrust HISP-to-HISP testing. That was extraordinarily useful in looking at a number of edge cases related to Direct message interoperability and as a result of that, we've significantly improved our underlying implementation. We also breezed through the NIST test methods. And in fact encountered in some of those test methods, as you know, some issues that are truly corner and edge cases that don't truly...that didn't really meaningfully impact interoperability. And what I'm getting at is there are a number of cases where success in the real world and success in the testing process don't necessarily correlate with one another. And it would be useful to, if possible, simply reuse the test methods that are used in the real world testing and ideally actually deem that real world testing good for the certification process. I'm going to pause there and see if you have any comments.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

Yeah, thanks Arien. I mean I think those are fair points that you yourself have raised, among others and we can certainly look into the concept, I think for lack of a better word, is some type of mutual recognition. I think the community as part of being part of the solution, has a role in helping define and maybe deal with the way that the process has been in the past that they had as much influence as they really do in making sure that the scope of testing is clear and understood. And that's part of this increased or expanded participation that we'd like to see, so that there aren't really surprises at the end of the...or in the testing process that folks have been engaged from day 1. And how there can be tighter alignment or some type of mutual recognition in other testing that goes on with...that are business relevant to stakeholders.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good. Thank you. Others in the queue?

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

Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Hi, Steve, thanks for the report. I have a question back on your update. And for the projects that are ongoing, what are your thoughts on making sure that we institutionalize patient inclusion? For instance, the Provenance Project coming up and others, so that we're not going back and revisiting things?

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

Good question, I think that that is part of the general openness of the S&I Framework and we could certainly work with you or you could have suggestions about different groups or stakeholders to engage, to make sure that they're paying attention to the initiative and that we can get their input.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, I just would like to see if we do something a little more mindful so it's not always dependent upon someone being there when there is a strong opportunity like the provenance area. So perhaps we can have a discussion offline. And in general, that gets to when there is an ongoing issue in the Standards Committee that's brought up, how do we make sure that that's executed? I think it...think about Wes' asynchronous upgrade problem that we've talked about over and over again or my desire to make sure that the patients are included. What do you think the best approach would be?

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

Yeah, I mean I think an offline conversation can unpack this would be helpful.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay. I'll do that, thank you.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

Great.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Michelle, next person.

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

I think we're good with the queue...oh I'm sorry David McCallie has a question.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

David.

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

Yeah, Steve, I just want to second Leslie's concern. This is something I've raised in the past, you've heard me say it before but just because the S&I process is open doesn't mean that the right people actually show up and participate. And when some of these projects start to get to the point at where they look like they're going to intersect with actual certification requirements or Meaningful Use...have

Meaningful Use impact or certification in this broader sense that Jacob reminded us of at the beginning of the call. We really need some mechanism to make sure that adequate review occurs before final consensus is reached.

I mean, my personal experience is that some of the framework projects that I've been asked to come in and kind of audit, have really missed some important stuff and they're along and all of a sudden somebody comes in from the outside and says, wait a minute, this isn't right. You missed a lot of stuff or you're solving the wrong problem or you're misunderstanding the problem space. So, I guess my point is simply that there's no guarantee that an open process guarantees a good result. It guarantees that it's open, but it doesn't guarantee that it's good and I don't have a magic bullet to suggest. But as these things near impact on actual certification, we really ought to pay more attention somehow. I'll stop there.

Steven Posnack, MHS, MS, CISSP – Policy Analyst, Office of Policy & Planning – Office of the National Coordinator for Health Information Technology

Absolutely, and I definitely appreciate your feedback and we're looking at ways, kind of in a holistic way, to take this feedback into account with the initiatives that are ongoing. So, may reach out to you to get more detail, but certainly appreciate it.

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

David, this is Jacob Reider. I just, to maybe dig a little deeper than Steve's response. We agree with you, we're not saying that we think that openness = high quality. But by the same token, closed process does not necessarily equate with high quality either. So all volunteer projects, as we've seen through I think a number of iterations of standards development activity have their challenges because they're driven by who steps up and who participates. And the government's role here is to coordinate and collaborate and sometimes we may need to poke and prod or even hire folks to become engaged so that we have broad representation and adequate technical representation so that folks who really know what ought to happen are present. And so there's always an opportunity for bias, especially if the process is closed. And I think that's been a primary motivator here is, to be as open as we possibly can, knowing that that doesn't solve all of the problems.

So thank you David for your comments and I think I will emphasize, perhaps with a little less declared as to what John was saying, we really want people to engage. And so the more folks who are engaged from a broader representation of the community or communities, the better this is going to become. And we can't compel folks to be engaged, but certainly, if they didn't even have the opportunity, then, this is better than that.

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

Yeah, and this is David. Jacob, thanks for the clarifications here. I hope I'm clear that I'm not advocating that closed is preferable to open, I'm simple saying that open is not sufficient to guarantee the best result or good result...or even good results and...

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

Yeah, we know.

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

...we have plenty of failures...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And my point was when there...this is Leslie. When there's direction provided in recommendations provided from the Standards Committee, how do we see that those are met or discussed? Maybe they're not agreed with, but at least there's a due diligence for that effort and report it back.

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

Yeah, that makes sense and I want to make sure we're not conflating two activities here, as I hear our conversation evolve and then I hope John will cut us off and move us to the next part of the agenda. What Steve described is post standards, even post regulatory, right? So what Steve described is when the certification test procedures are developed, that's another opportunity, and it's at a different part of the lifecycle, right.

So the lifecycle where Standards makes recommendations to the National Coordinator, the National Coordinator in some way puts those into regulation. Regulation then informs certification criteria, certification criteria then inform test procedures, which then are made available to the test labs for administration of the tests, which validate certification. It's those test procedures that may or may not align perfectly with a clinical workflow or the exact intent of the policy that was expressed in the regulations. It's that part of the lifecycle that Steve is describing this activity in and I think that folks understand that. I just want to make it clear that we're not talking about necessarily be other end, which of course as we've seen throughout, is quite transparent and we are all, as we speak, participating in the transparency of that process. I think that...

Wes Rishel – Independent Consultant

This is Wes. I...maybe I'm incorrect, but I interpreted David's comments as being addressed to the overall S&I process and its openness as opposed to simply the development of tests. And if I interpreted his comments correctly, I concur that I think there's a lot of work that goes on in an open but nonetheless constrained environment that doesn't necessarily represent a full view of the concerns that will arise when the work product comes out. David, you can tell me whether I'm standing alone or whether I interpreting you properly?

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

This is David. Yeah, my comment was really to the first part of Steve's presentation and not so much about the open certification, that's new enough to me that I don't really have an opinion on it yet, I need to learn more. But on the first part of Steve's quick summary of the current S&I Framework. I look at some of the things, for example, like the esMD work, I haven't looked at it in the last six months, but when I did look at it six months ago, it struck me as having potentially profound impact on providers and provider productivity. And even though it may be a coherent approach from a security point of view and from the needs of the federal partners who require digital attestation for submitted documents, it might in fact be really disastrous to the clinicians.

And I just...I get concerned that sometimes considerations like that get filtered out and then we land with something that isn't going to work in the real world. A little bit like some of the DS4P work, which sounded so good on paper until people started calculating what the impact would be on receiving systems that can't handle restricted disclosure information. And so it's...I don't have a solution other

than to say that you need to really ensure that all of the stakeholders that might be affected by this have meaningful representation in this open process. Meaningful meaning smart, thoughtful, high-level people, which is of course the problem, there are not enough of us, and we're busy.

Wes Rishel – Independent Consultant

It's a bandwidth limitation.

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

Absolutely, absolutely.

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

This is Jacob. Thank you, David and Wes for the clarification, and I think that's actually a good segue into...

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

In effect, we heard from Steve Posnack that there's a commitment to increase communication and a standard communication form. And so Jacob, I would never cut you off for a discussion you were leading, but please, so we can get to public comment, tell us about your announcements.

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

Thank you, John that was where I was segueing. Here we go. So, I'm just...whoever is the slide master, do you want to quick...watching the slide update. Okay, so I'm going to talk before we get the slides and here we come. So this slide, as those who are watching on the inter-web can see, is the same slide that we have presented in the past and yet with some additions. So the additions, as you see here, are the naming of the Co-Chairs of five of our committees. And so what...the process here, speaking of transparency, was that various folks from the community either were nominated or self-nominated through our website. And the URL for that website, I made a bit.ly link to enhance the usability here. It's on our website but if you choose to go there, and now it's in the public record is <http://bit.ly/SCNOM>, so S-C-NOM714. Bit.lySCNOM714 if folks want to go there and nominate somebody else for something. And so we went through those, reviewed with the National Coordinator and with John the nominees. And a guiding principle was that one of the two members of the Chair roles for each of these workgroups would be a Standards Committee member. And Michelle, correct me if I'm wrong here, that is actually required by our bylaws. Is that correct?

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

Correct.

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

And so you see in the Steering Committee role, we have one Co-Chair. While it's been suggested that I be Co-Chair, I'd really like two members of the extra-governmental community to be co-chairing the Steering Committee. I will obviously be present and will still have an opportunity to weigh in, of course, because I'll be a member of the Steering Committee, but I don't think that I need to be one of the two

Co-Chairs. This is another opportunity to bring somebody in from outside to Co-Chair it with John. And we have a list of folks, we just haven't made final determinations there.

So Semantic Standards, the two Co-Chairs will be Jamie Ferguson and Becky Kush. In the domain of Content Standards, the two Co-Chairs will be Andy Wiesenthal and Rich Elmore. Transport and Security Standards will be Dixie Baker and Lisa Gallagher. Architecture, Services and APIs, the two Co-Chairs will be David McCallie and Arien Malec. And Implementation, Certification and Testing, the two Co-Chairs will be Liz Johnson and Cris Ross. So, first, A) congratulations and thanks to the new Co-Chairs of our workgroups for agreeing to serve. We know that this is a non-trivial investment of your time. Speaking of bandwidth, Wes, and so we thank you all for participating. Let's go to the next slide.

And this is a depiction of the transition from where we are to where we will be. As you can see, it goes over a number of months because we want to allow some of the current activity to finish out. And those who were listening in on the Policy Committee meeting last week, you heard that there are a number of their workgroups who in a similar fashion, are being redefined. And some are finishing their work and are closing out so that they can launch the reincarnations and others are working forward a little bit.

So as you see here, in July the Transport and Security Standards Workgroup will launch itself. Through...August through October the NWHIN Power Team is going to continue to do work and then will transition and align its activities with the JASON Task Force that is joint Standards Committee and Policy Committee Task Force. And then most of that activity will migrate into the Architecture, Services and API Workgroup in November, when that one will launch. The other three, as you can see, will launch in September and October. We're giving Implementation some time to migrate it's activity into the Implementation, Certification and Testing Workgroup. That'll happen in September. And in October, the Semantic and Content Standards Workgroups will launch. And so as you see, there's a transition period that we're going through now.

The next steps for ONC and for the Workgroup Chairs is that there will be work that will actually begin, which is to identify the workgroup committee members. And so this is where we will once again dip I to the pool of our website nominees, so folks who have submitted their names, so I'll say out loud, we've had lots of follow-up with a number of people who have submitted their names or other's names into the pool. And so we're getting lots of emails, have we been named yet? Is this happening yet? And the answer is, not yet. We will have those announcements at the next meeting on August 20 of the Standards Committee.

And during that time, each of the workgroup Chairs will work with us at ONC and a dedicated ONC staffer, to define these workgroups so that the members are engaged, expert as per the conversation that David was just causing us to have, and diverse. We want to make sure that there is diversity of perspective, diversity of representation, whether it's provider, technologist, race, gender, and so on. So we want to make sure that this is a diverse group and that's the opportunity here with our workgroups to enhance and maintain good diversity overall. So that's all I wanted to say about this. There are appendix slides that those of you who are downloading this from the Internet can review the charters and what the charges of these workgroups are, but my intent wasn't to go through that today, because you've seen it before. So, I'll take questions quickly and then I think we do want to get to public comment. Any comments?

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

This is David. I have a comment, are we going to go through a queue or should I keep going?

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

You're the only one in the queue, David, so go ahead.

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

Oh, okay. This looks good. I've raised this concern once before and I assume the answer is with the help of the Steering Committee we'll just have to work it out. But, a lot of these things need to be very tightly coordinated across the groups and not just within the groups. So the groups aren't going to be making decisions that make any sense independent of decisions in the other groups.

And just to give you one worked example that some of us are deeply engaged in already would be in the new emerging FHIR APIs from HL7, which basically cover the transport issues. They are based on RESTful principles, they cover the content issues, because they specify the core elements of a resource and they cover the semantic issues because they specify via the FHIR profiles, which are required in order to use FHIR, the value sets that are required for particular fields or parameters in the resources. So, you can't talk about the API without also talking about semantics and about the content value sets. So, how we manage to coordinate conversations across these groups on important subjects like that will be an interesting challenge...stop...keep it at that level.

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

We agree and that's actually why we have the Steering Committee. Those who have been paying attention to policy will notice that we don't have a mirror image Steering Committee on the policy side. Many of the policy issues are a bit more autonomous. Because these issues, I'll steal Wes' new word...word of the day, interdigitate, many of these issues interdigitate and have dependencies on each other. So our hope is that the Steering Committee will be able to coordinate those activities. And we'll see David, I think that you're right to call it out. We are well aware of the need to make sure that these dependent parts are well coordinated and we'll see how it goes. We're actually quite hopeful that it will go well and if it doesn't, we're sure that you all will tell us, and we'll make adjustments.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

And so Jacob, even more motivation for a strong Steering Committee Co-Chair. Nominate early, nominate often.

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

There you go. So, remember the link. Thank you folks for engaging on that.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well Michelle, are there others in the queue?

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

No. I think...

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well then, with 2 minutes to go, I think we should move on to public comment. Jacob, any other items of business before we go to public comment?

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

No, thank you all for a great meeting today and let's go to public comment, Michelle.

Public Comments

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

Okay, thank you. Operator can you please open the lines?

Caitlin Collins – Junior Project Manager – Altarum Institute

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. If you are on the phone at this time and would like to make a public comment, please press *1. We do have a comment from David Tao, please proceed.

David Tao, MS, DSc – Technical Advisor - ICSA Labs

Hi, yeah, it's David Tao from ICSA Labs and wanted to comment on the point about openness in the S&I Framework not guaranteeing a good quality result. I agree with that statement, though I think lots of good has come out of S&I. But from my experience in participating in many S&I initiatives, typically there are like 100 people who sign up as committed members, only a small fraction who actually have the time to participate in calls, maybe 10 to 20% and then an even smaller number who actually submit comments and vote during the consensus process. And I've heard in previous Standards Committee calls it was that there are just too many initiatives going on at once and there just isn't time to track them all, let alone participate deeply. So I would agree with that as well. I think S&I's intentions and goals are great, but I think that there ought to be some retrospective analysis of how many people are really registering versus attending versus voting and actually commenting on each initiative. And if that shows that there just isn't really enough and that people are spread too thin, then I think that S&I leadership should assess whether there should be a narrowing of the focus to fewer initiatives. And also should, I agree with the comment that it's not just the number of people but whether there are the appropriate technical subject matter experts participating in each initiative. Thanks for the opportunity to comment.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Other commenters in queue?

Caitlin Collins – Junior Project Manager – Altarum Institute

We have no additional comment at this time.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, Jacob, that was a lot of material that we covered on time and as you said, I certainly want to thank everybody for taking out time on a summer morning to review all these important issues. And Michelle, I believe our next meeting in August will also be virtual.

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

Yes, that's a change to the schedule, so please note that we're going to be virtual in August.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good. Well, closing comments Jacob?

Jacob Reider, MD – Deputy National Coordinator, Chief Medical Officer – Office of the National Coordinator for Health Information Technology

I have none. Thank you very much folks, have a great afternoon.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good, thank you.

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

Thank you, everyone.

Public Comments Received

1. I have a public comment about " DuBois Regional Medical Center CIO Tom Johnson" recent testimony and is this the method that ONC wants hospitals to do patients VDT by having an IT person go to the sick patients room and have them VDT?

Meeting Attendance								
Name	07/16/14	06/17/14	05/21/14	04/24/14	03/26/14	02/18/14	12/18/13	11/13/13
Andrew Wiesenthal	X		X	X	X	X	X	X
Anne Castro		X	X	X	X	X	X	
Anne LeMaistre	X	X	X		X			X
Arien Malec	X	X	X	X	X	X	X	X
C. Martin Harris	X	X			X			
Charles H. Romine	X				X	X		
Christopher Ross	X	X		X		X		X
David McCallie, Jr.	X	X		X	X	X	X	X
Dixie B. Baker	X	X	X	X	X	X	X	X
Elizabeth Johnson	X	X	X	X	X	X	X	X
Eric Rose	X	X	X	X	X	X	X	X
Floyd Eisenberg	X	X	X	X	X	X	X	X
Jacob Reider	X	X	X					
James Ferguson	X	X	X	X	X		X	X
Jeremy Delinsky				X	X	X		X
John Halamka		X	X	X	X	X	X	X
John F. Derr	X	X	X	X	X	X	X	X
Jonathan B. Perlin		X	X	X	X	X	X	X
Keith J. Figlioli			X		X			X
Kim Nolen	X	X	X	X		X	X	X
Leslie Kelly Hall	X	X	X	X	X	X	X	X
Lisa Gallagher	X	X		X	X	X	X	X
Lorraine Doo	X	X		X		X	X	X
Nancy J. Orvis		X			X			
Rebecca D. Kush	X	X	X	X		X	X	X
Sharon F. Terry		X	X	X	X	X	X	
Stanley M. Huff	X	X	X	X	X	X	X	X
Steve Brown			X	X	X	X	X	X
Wes Rishel	X	X	X	X	X	X	X	X
Total Attendees	21	24	21	23	24	23	21	23