



HIT Standards Committee Final Transcript November 3, 2015

Presentation

Operator

All lines 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 from the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee. This is a public call and there will be time for public comment at the end of today's call. As a reminder, please state your name before speaking as today's meeting is being transcribed and recorded. I'll now take roll. Jon White?

P. Jonathan White, MD – Acting Deputy National Coordinator – 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, Jon. John Halamka?

John Halamka, MD, MS – Chief Information 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.

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

Hello.

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, Health Care Practice – 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. Angela Kennedy?

Angela Kennedy, EdD, MBA, RHIA – Head & Professor Health information Management – Louisiana Tech University

Here.

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

Hi, Angela.

Angela Kennedy, EdD, MBA, RHIA – Head & Professor Health information Management – Louisiana Tech University

Hello.

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

Anne Castro?

Anne Castro – Vice President, Chief Design Architect – BlueCross BlueShield of South Carolina

Here.

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

Hi, Anne.

Anne Castro – Vice President, Chief Design Architect – BlueCross BlueShield of South Carolina

Hi.

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

Anne LeMaistre?

Anne LeMaistre, MD – Senior Director Clinical Information Systems & Chief Medical Information Officer – Ascension Health

Here.

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. Kevin Brady for Charles Romine?

Kevin Brady, MS – Group Leader, ITL Interoperability Group – National Institute of Standards and Technology

Here.

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

Cris Ross? Dixie Baker?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

I'm here.

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

Hi, Dixie. Liz Johnson? Eric Rose?

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

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? Jitin Asnaani? 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

Hi, John. Josh Mandel?

Joshua C. Mandel, MD, SB – Research Scientist – Boston Children's Hospital

I'm here, hello.

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

Hi, Josh. Keith Figlioli? Kim Nolen?

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

Hi, 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

Here.

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

Hi, Leslie. Lisa Gallagher? Lorraine Doo?

Lorraine Doo, MSWA, MPH – Senior Policy Advisor - Centers for Medicare & Medicaid Services – Health and Human Services

Hi, Michelle, I'm here.

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

Hi, Lorraine. Nancy Orvis? Patty Sengstack? Becky Kush? Rich Elmore?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Good morning, Michelle.

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

Hi, Rich. 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. Okay with that I will turn it over to Jon White to get us started.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Okay, thank you so much Michelle. Everybody it is wonderful to hear your voices as always and I'm very much looking forward to the discussion today. We've got a...although we are virtual it's going to be a good agenda.

Of course, you'll recall at the last meeting we all left thinking it had been a, you know, great day and suddenly there was a tremendous release of different information and rules, and policy documents and things like that. So we hope that you have had a good ride home to wherever you were going and that you had good reading material with you along the way and today we're going to hear a more detailed presentation on the different rules and discussion of those. So, appreciate everybody's attention to all of this and I'm looking forward to both hearing the discussion as well as your thoughts on it.

I will give you a logistic note, as occasionally happens, I do have a scheduling conflict with today so I'm definitely here for the opening comments and I will...but for a large portion of the meeting probably the excellent Dr. Halamka will be your emcee for things.

You know the last thing that I want to do is that at the last meeting we also bid a fair au revoir to Jodi Daniel, as I have said in previous policy meetings there is no goodbye in health IT we always see our friends and colleagues again in different places and different roles. However, I did want to take the time to introduce to you Elisa Anthony who is the Acting Director of the Office of Policy, and although there of course can be no replacement for Jodi, is serving in her capacity quite ably I might add. So, I wanted to offer you her Bio and you've met Elise before at different meetings where she's briefed you on materials but I just want to give you a little bit more information about her. She is a tremendously valued colleague for us at ONC and I'm looking forward to you getting to know her better as well that said, here's her Bio.

Elise Sweeney Anthony is the Acting Director of Policy at ONC. Elise leads ONC's engagement on a range of high priority federal policy efforts including regulatory development, information blocking, MACRA implementation and governance.

Her portfolio also includes emerging issues in health IT policy matters impacting EHR Incentive Program participants and other care settings. Prior to this position, Elise served as the Deputy Director of Policy for several years where she led the Division of Strategic Policy, the Division of State Interoperability Policy and the Division of Federal Policy and Regulatory Affairs.

She also led ONC's coordination with CMS on the EHR Incentive Program Regulations including the 2014 certified EHR technology flexibility rule and the Stage 3 modifications to Meaningful Use rule and the 2015 through 2017 final rule.

Elise is a very experienced health policy attorney and advisor. She spent many years at a leading law firm where she spearheaded a variety of health improvement initiatives including initiatives impacting care delivery, health innovation and at risk rural populations.

In addition, she has served as a Senior Director at a global development consultancy where she focused on health improvement in international conflict zones on addressing health disparities in developing regions.

Elise has led initiatives across the policy landscape including with congress, the United Nations and the World Health Organization. Elise received her Bachelor's Degree in Political Science at Morgan State University as a Ralph Bunche Scholar and earned her JD at the Georgetown University of Law Center where she was, yes, the Trial Advocate of the Year.

I love reading stuff like that because, you know, you all get a chance to interact with, you know, kind of selected individuals from ONC but the chance to shine a light on just the depth and the talent of folks that we work with at ONC is always a lot of fun for me because I love the folks that we work with. So, I hope you look forward to giving a warm welcome to Elise and working with her in the months and years ahead and with that this is the end of my comments. Thank you for listening and Dr. Halamka the floor is yours.

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

Well, thanks very much and as Jon said today a very important agenda. We will hear the Meaningful Use Stage 3 and modification rule overview and the 2015 certification rule and I really want to thank Jon for his trust in leaving me in charge of the meeting because of course several articles have appeared lately in the press which take my blog writing out of context slightly and might suggest that I actually feel hostility to these two rules and of course there's some really good work in both the rules and I really look forward to the members of the committee making commentary.

And I recognize that these are final rules, but, you know, Jon White, of course I am not a Fed so you can please correct anything I say that if, for example, there were corrections to be made, hey, there is always potential future regulation, a revision that potentially could come out on either rule.

So, I think the airing of these rules in a public forum and getting commentary from this body of experts is a very important function. I mean is that a fair statement that our feedback is welcome and potentially could be impactful?

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

So, it's Jon White. So, I will defer of course to the speakers who are going to engage you specifically around the rules. You know what I will say is that...just to give you a little bit of broader framing, you know, the incentive program put in place is part of the American Recovery and Reinvestment Act, since then the Affordable Care Act has been passed, MACRA has been passed into law, you know, where we are is, you know, a new and exciting place.

As you heard in our previous meeting the 2015 certification rule is final, that is finalized. The EHR Incentive Program rule is final but with a 60 day comment period and, you know, we don't just drop comment periods idly. I think comments are being solicited and since you all are an advisory committee we look forward to hearing your advice and with that I'll leave more comments to the specific speakers coming up.

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

Great, well, thanks very much Jon. The discussion ahead of course we'll hear the details. I have read...now of course Jon and Steve Posnack always correct me, the nearly 1500 pages of documentation in both rules and depending on whether that's single or double space it might be a 752 page rule or a 560 page rule and so, you know, there things in it that I think are very natural stepping stones from the program as had existed in the past and other things that may be perceived by some of our experts as slightly aggressive or maybe needing some more detail or more standards maturity based on the Dixie Baker standards maturity scale.

And so we will have three hours together to go forward and look at all that detail and make comment and as I promised Jon White I will not bias the jury in any way. So, Michelle, why don't we go forward and begin. And do we have minutes to approve or anything of that administrative nature?

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

We do.

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

Okay and I am looking, did I receive the minutes? Did you send those?

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

I hope so. If we didn't than we can't approve them. We should have sent out the joint meeting minutes.

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

Have others received those meeting minutes?

Anne LeMaistre, MD – Senior Director Clinical Information Systems & Chief Medical Information Officer – Ascension Health

So, John, this is Anne LeMaistre, I received them I think it was last week.

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

I see that was the issue and so if for those who have received them are there any edits or comments, or revisions to said minutes? Well then none being heard Michelle we will adopt those by consensus and move forward to the body of the meeting.

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

Thank you, John. Do we have Rob Anthony on the phone?

Robert Anthony – Health Insurance Specialist – Centers for Medicare & Medicaid

You do.

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

Hi, Rob.

Robert Anthony – Deputy Director of Quality Management & Value-Based Incentive Group – Centers for Medicare & Medicaid

Hello.

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

I'm going to turn it over to you now to walk through the Meaningful Use Stage 3 and modification rule.

Robert Anthony – Deputy Director of Quality Management & Value-Based Incentive Group – Centers for Medicare & Medicaid

Okay and I just indicate next slide when I'm ready to move forward?

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

Yes please.

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

Okay. Well, hello everybody for those who do not know me, my name is Rob Anthony, I'm the Deputy Director of the Quality Measurement and Value-Based Incentives Group that group includes a number of quality measurement programs like PQRS and hospital quality reporting and it also includes the Meaningful Use Program. I'm going to walk through and do a basic overview of what we finalized in the rules and then we'll have a little time for some Q&A at the end of this. So, next slide.

So, we did release a final rule on October 6th if you're looking for a link to that this is provided here. As Jon indicated there is a 60 day comment period on the Stage 3 portion of the rule that we are continuing to seek comments on.

Before I start going through this let me just pause a moment to say that, you know, like Jon said, that is not something that we enter into lightly. We know that there are a number of challenges that are facing providers and I think that as we moved forward and we thought especially of the intersection of Meaningful Use with the upcoming MACRA legislation, the MIPS Program, we really wanted to get feedback and keep options open about what might need to be tweaked in Stage 3 in order to incorporate that overall into the MIPS Program. So, encourage people to send comments, they do have to be written comments, to us on the Stage 3 portion of this. Next slide.

So, overall as we approached final rulemaking for all of these programs for both Stage 3 and looking at previous stages we wanted to align to a single set of objectives that were focused on a specific set of program goals. I think that we had heard loud and clear from a number of folks that there were particular challenges with certain objectives and part of that was the ever increasing number of objectives and measures that providers had to meet and we really wanted to take a look at this and get to a stage of Meaningful Use that we felt that all providers could achieve and that would be sort of the floor, if you will, for what use of health IT could mean when incorporated into overall quality measurement and patient outcome improvement.

So, we really tried to focus on what were the core issues that we thought were critical for Meaningful Use and we really focused on interoperability and patient safety, and patient engagement as you'll see as we went through this.

In order to do that we took a look at a lot of the measures and we reduced where we could to take that burden off of providers. Sometimes we got rid of particular objectives because they were topped out. What do we mean by "topped out" we use that often in quality measure context and it's simply that, you know, once you've achieve a 90%, 90 to 95% average achievement score on a particular measure, realistically how much more are you going to improve, how much more do you want to raise the threshold and really risk people not being able to improve dramatically but really forcing a lot of people without intending to outside of Meaningful Use. There were a number of objectives that fit into that category.

There were other objectives that were redundant to existing quality measures. The great example, as always, the recording of smoking status, we do have a quality measure that goes into this. The smoking status we heard over and over again for a number of folks wasn't necessarily relevant to their scope of practice but we do think that we capture it in other ways.

And then finally we really tried to focus on things that were purely the use of electronic technology. You know that from a variety of other objectives in both Stage 1 and Stage 2 there was the possible provision of things through paper, there was the partial utilization of electronic technology to achieve something that could then be completed using a paper or an alternate form of communication and we really tried to focus what was Stage 3 onto just that notion of electronic usage, so the EHR usage or health IT usage and that got us to a more limited set, a more focused set of objectives overall.

I think that if you're familiar at all with Stage 1 and 2 you're familiar with the core menu concept that we employed there. We went from a core and menu concept of total reporting on Stage 1, I think for EPs about 20 objectives, for Stage 2 it was about 19 objectives, slightly different but about the same for hospitals, to really a focus in Stage 3 on eight objectives that, like I said, support that advanced use of health IT and focus on things like interoperability, patient safety and patient engagement where we really think that you can see improvement of outcomes.

We then, after coming up with that Stage 3, focused on modifying Stages 1 and 2 to get people to those same principles that we had proposed in Stage 3. So, we proposed and finalized a modification of Stage 1 and 2 that is very similar to what you see in Stage 3 and in fact there may not be a one-to-one correlation for all of those things. I think the modified Stage 2 gets us to nine objectives rather than eight but it is very similar in overlap to what those Stage 3 principles are.

So, what you'll see as we go through this is that what you have to do for Stage 3 turns out not to be very dissimilar to what you have to do for the modified Stage 2. There are higher thresholds and there are a couple of additional items that are in there but it is not significantly different and that was intentional.

The intention here has really been to get to what we call a flat stage for Meaningful Use. If you're familiar with the program previously we sought as sort of a ladder or a stepped progression where beginning providers would come in Stage 1 they would move onto higher requirements in Stage 2 and then presumably even higher requirements in Stage 3.

We had gotten a lot of feedback both prior to and during the public comment process from a number of providers and stakeholder organizations that there were particular challenges with that especially as practices had more and more EPs who were eligible for Meaningful Use keeping track of who was at what stage and what people had to achieve was something of a challenge for folks. So, we really strived to get to a focused set of goals and a flat stage of Meaningful Use that everybody could participate and that's why you see the structure with Stage 3 and a modification of Stage 2. Next slide.

So, I'm going to start a little bit with timeline because I think that it's important for people to understand how we broke that down and then what I'm going to go through is mostly Stage 3 and then very quickly through Stage 2 to talk through some of what we did there.

So, what you'll see is what we finalized is 2015 and 2016 providers are actually taking part in the EHR Incentive Programs meeting the modified Stage 2 requirements. There are a number of exceptions for people who would have been at Stage 1 so that they aren't required to do more and above.

The 90 day period is in effect for 2015 so you would report to a period of any continuous 90 days within the calendar year, we did align hospitals to the calendar year in this final rule, so hospitals actually have an extra period of time they have from October 1st of 2014 through December 31st of this year so any 90 days within that period for Meaningful Use.

For 2016, most people who are returning participants they will use that full calendar year. If you are a new participant it's still a 90 day period within the calendar year and a continuous 90 day period for new participants only. And again, everybody in 2016 will be on the modified Stage 2 requirements.

2017 is sort of a flexible year. If you, again, are a first-time participant you would do a 90 day period within 2017. All other returning participants would do a full calendar year. You can stay on the modified Stage 2 criteria and meet that in 2017 but there is an incentive if you are prepared and if you have the certified EHR to move to Stage 3 requirements in 2017.

If you move to Stage 3 requirements in 2017, and again that's completely an option, it's completely up to the provider, you can also do a 90 day reporting period in 2017 and that was done very specifically because of the experience that we had with people transitioning to 2014. We wanted to make sure that in that first transition period if you were transitioning early that you would have a 90 day reporting period.

In 2018, we will get to everybody being on exactly the same stage and that will be Stage 3. In 2018 the only folks who would do 90 day reporting during 2018 would be first-time Medicaid participants but otherwise everybody will be on a full calendar year reporting in 2018 and you'll be doing that for Stage 3 requirements and at that point in 2018 we'll probably stop talking about them as Stage 3 requirements and just talk about them as EHR Incentive Program requirements. Next slide.

So, this is just a participation timeline that outlines which criteria you would meet, 2015, like I said, there is...everybody is going to do the modified Stage 1-2 criteria with accommodations for those who would have been at Stage 1, 2016 everybody will do the modified Stage 2 criteria, 2017 providers will have a choice of either the 2015 through 2017 criteria or a full version of the Stage 3 criteria in which case they could do a 90 day and then by 2018 everybody will be on the Stage 3 criteria. Next slide.

So, the first thing I'm going to do is I'm going to go through the Stage 3 requirements. I know that previously we may have done this a little bit differently, but I think it's probably important to think of Stage 3 because that's the ultimate driver of where we're trying to go to. And the modified requirements were really modified to align with what Stage 3 is. And Stage 3, again, is that focused set of objectives on advanced use of health IT. So, next slide.

So, we really did strive, like I said, to provide a pretty clear, simpler framework on this, some flexibility, you'll see that there are some choices within those individual objectives, we did want to get to a flat stage for everybody that would be more easily understandable that could be built upon for people who want to use additional areas and that could be incorporated more easily into the MIPS Program overall. Next slide.

So, as I said, we are moving to the single stage reporting, we're moving to a single reporting period. By 2018 we will have everybody onto a calendar year. Everybody will be on the same objectives. You can see as we went through this that we removed certain objectives that were paper-based redundant, that were topped out, that were duplicative of where we have the measurement in other areas and we focus on these advanced use objectives of which there are eight. Next slide.

I won't go through this again, there is a 60 day comment period specifically on this area, we will consider that for future rulemaking, it is likely that we would look at the upcoming rulemaking that proposes some of the MIPS requirements since this will become all of a piece as we move forward in 2017. You can submit, I encourage people to submit through regulations.gov, obviously you can always submit a separate letter to us as well but the quickest way of getting comments to us is usually through regulations.gov. Next slide.

So, I'm going to go through and cover all of these objectives and measures, I may go through very, very quickly on some of these and just highlight a couple of things like the threshold or where we might have made a change from the proposed so that we have a little time for questions at the end. This is a fairly large slide deck it's just sort of our giant overview of everything that we proposed and finalized so I want to just highlight some things, this group being a little bit more familiar I think that might be a better use of our time. So, let's go to the next slide.

And as you can see these are the objectives that we focused on. I keep stressing these areas of interoperability which, you know, really health exchange or information exchange, patient safety and patient engagement. So, protecting electronic health information this is something that should come as no particular surprise to folks who are familiar with the program. We've had this from the beginning it is making sure that people do the security risk analysis that is required by HIPAA.

It is also, as time has gone on, we have asked people to engage or begin to think about more and more activities that can also impact the safety of patient information so encrypted data, the type of authentication factoring that you do, so on and so forth. All of that is sort of bundled in here.

Electronic prescribing, of course this has been with us since the beginning it was a requirement of the original HITECH legislation and is certainly a factor in patient safety as are things such as clinical decision support, computerized provider order entry.

We move on in five to providing patient electronic access to their health information and we'll talk about a couple of the things that are new in there. I think that is not only a matter of patient engagement but also really supporting that infrastructure of electronic information exchange which is certainly true of both number six and seven coordination of care through patient engagement which leverages some of the EHR technology and health information exchange which a transition of care and an electronic summary of care following the patient that is something we introduced as a menu item in Stage 1 and we have refined with every stage and we introduced some new things in Stage 3 as well.

And then finally, public health reporting, we started this, again, in Stage 1 with looking at reporting to an immunization registry or a syndromic surveillance database and we have expanded those options with each stage in the flexibility so that providers can engage in public health reporting in a variety of ways. Next slide.

So, I will go through each of the objectives very quickly, highlight where we can. I think there's probably not a huge amount for us to say about protecting patient health information. It really is a security risk analysis and considering some of the other ways to keep patient information, electronic information, safe in the same way that we thought previously about keeping paper records and other information safe. Next slide.

ePrescribing, this is a measure that I think most people are familiar with. We have had ever increasing requirements for this one. EPs would be required for 60% of their permissible prescriptions to be ePrescribed and we have also moved querying a drug formulary into this as well. On the hospital side, it is now a requirement and it is for 25% of hospital discharge medication orders for patients as well. Next slide.

Clinical decision support, I think, you know, we started very early in this program with a very basic idea of clinical decision support and we have adhered to an ongoing principle of trying to leave this as flexible as possible for providers. We did link this to a relevant point in patient care. We really focused on the idea of linking them to clinical quality measures with the idea that clinical quality measurement drives improvement and we wanted people to be able to make these relevant to their workflow, their patient population and their practice.

As we have moved forward and heard from folks we do note that there are a number of folks that do not have clinical quality measures that are necessarily relevant to their scope of practice. So, if you don't have those you can certainly choose CQMs that are more relevant to your patient population and your workflow. Next slide.

CPOE, we started looking at computerized provider order entry as just looking at medication orders but we have expanded that to now include lab orders and diagnostic imaging orders and the benchmark here is for 60% of those to utilize the functionality. Next slide.

There are two measures here for patient electronic access to health information neither of these are new to the program. The first one is essentially to provide patient information electronically, previously the way that we measured this was provision of electronic information through the portal, a previous percentage was 50% of all unique patients that were seen by the provider or discharged by a hospital would have their information available electronically for what we call VDT, view, download, transmit and most often that uses an Internet portal technology for people.

What we have introduced new here is the second part of measure one which is that the health information is also available to access using an API from that certified EHR. This will be a functionality that is required in the new certification; it will be an ONC certification, for that API. And so essentially, this will simply need to be turned on and then the combination of either those methods, how patients are actually provided this either through an API or through the portal would add up to that 80% measure.

And measure two is using information, clinically relevant information, from the EHR to actually identify patient specific educational resources and then providing electronic access to those materials to patients and the threshold here has been raised to 35%. Next slide.

So, this is really the heart and soul of what we think of as interoperability, it is the idea of getting to care coordination through patient engagement and then the next objective of course for health information exchange. This is where we really think, and I think that most people who are involved in this really think, that an EHR can be most useful. You'll see that this particular objective...and we did, by the way, group objectives around a common advanced use idea that's why you may see several measures to each objective this time where you might not have seen that completely in Stage 2, although there were, in Stage 2, a couple that had double measures.

But in this case we've got three particular measurements here one is that during the EHR reporting period more than 10% of all unique patients are actively engaged with the EHR that has been made accessible by the provider that can be through an API, it can be through the VDT function of the EHR and this is part of what we began as a patient a use measurement in Stage 2. One of the things that you will notice when we get to modifications area is that we actually have built this measurement as a ladder.

So, initially, in Stage 2, previously, we had proposed and finalized this as a 5% measure. We have heard from a number of providers that either because of their patient population or because of the very newness of this that they were having particular issues in getting to that 5% at this point in time. So, what we have done is we have built something of a progression into this measurement where we are starting at a single use case and then we have measurements that are ever increasing until we finally get to this measure in Stage 3 of 10% of all patients.

For measure two, we are measuring that a secure message was sent using the electronic messaging function of the EHR. In this case it's actually a switch from how we were measuring previously. In Stage 2 previously we were measuring this as a patient access or a patient engagement so we were measuring patient use of secure messaging, so it wasn't the provider sending a message to the patient it was a patient sending a message to the provider. Again, we heard a number of challenges with this and got a lot of feedback about it and so we have shifted to measuring what the provider's action is here. So, it is, in this case, sending from the provider to the patient and we have raised the threshold to 25%.

And then finally, measure three is something that we had heard from a lot of folks that they wanted to see start happening in EHRs and actually was asked for by a number of provider associations and a number of consumer associations as well and that was the incorporation of patient generated health data into the record. This is a very flexible measurement. A large number of things could actually be used to meet this and we have set the...there isn't a particular electronic standard at this point associated with this, it is very much a free text incorporation at this point because we wanted to be as flexible as possible in how this gets implemented and the bar here is for a fairly reasonable 5% of patients seen having that patient generated data incorporated. Next slide.

Health information exchange, most of this has been seen previously. This is about sending a summary of care record electronically. We are only measuring electronically at this point in time and you'll see in measure one what is very familiar I think to most folks, which is what we're moving to in Stage 2, which is that more than 50% of the transitions of care and referrals you actually create a summary of care record using that certified EHR and then you electronically exchange that summary of care record.

And then measure two that for more than 40% of those transitions or referrals in which the provider has never before encountered the patient the EP or the hospital incorporates into the patient's EHR an electronic summary of care document. Again, this is really leveraging the technology that is already in an EHR and it will be sort of a closing the loop not only are we measuring now whether something is sent but we are actually measuring whether it gets incorporated into the receiving providers record and that really is what care coordination health information exchange is about it's not we want to make sure that this record isn't just sent off into the Internet ether but that it's actually received and incorporated and from there used by providers. Next slide.

Measure three here is for that information that is received, for 80% of those, that the provider actually performs clinical information reconciliation. So, again, this is about...measure one is about sending, measure two is about receiving and measure three is then about using that information that gets received. So, in this case, you know, there's three information sets that you would take a look at, you would review medication, you would review medication allergy and you would review the current problem list to reconcile with the new information that comes in. Next slide.

And then finally, we have public health reporting. We set a bar of two of these, there are a variety of these that can be done and really the reason that we have this is so that we have the maximum flexibility for folks. It should be said that...I'm sorry, on some of the previous objectives like health information exchange and patient engagement that those are selection objectives as well. All of those measures don't have to be met it is a two out of three with those measures. It's the selection by the provider of which two out of three they actually want to do that was a very deliberate choice. We know that while all of those things are important it may be a challenge for a number of providers depending on their setting or their particular clinical workflow to implement all of those. So, we provided as much flexibility as we could in which one of those things gets implemented.

It's the same here in public health reporting, in fact, I think if you look at the beginning of public health reporting from Stage 1 to where we've ended up with here we've really tried to implement as much flexibility as possible. We started with the first two measures and over time we have added clinical data registry reporting, public health registry reporting, case reporting there is a large number of options that providers can choose from to do public health reporting and that is also intentional. Next slide.

I'm going to actually go through this section very, very quickly because, as you'll see, it's very much a repeat of what we aligned with in Stage 3 but that was very much the decision here when looking at Stage 1 and Stage 2 measures to go through and make sure that we aligned with what we had settled with on Stage 3, now you can't do a one-for-one alignment, there's not going to be any API functionality because the current edition of certified EHR doesn't include API functionality.

You can't include any patient generated health data as a requirement because that wasn't something that got certified to. So, we were certifying within what we already had. We were deciding on objectives that would align with what we were doing in Stage 3.

So, you'll see that not only are these aligned with Stage 3 but they are completely a subset of what was already in Stages 1 and 2 and it is really focused on what can be done with the existing technology. So, in many ways this is sort of a less than what was previously required. Next slide.

So, like I said, we restructured these objectives, we got down to...it ends up being 10 objectives with the public health reporting and nine objectives for hospitals and critical access hospitals. It does begin this year, like I said there was a 90 day period in 2015, we did modify some of the patient engagement objectives from Stage 2 that require specific patient action and then we did the same thing, as we talked about earlier, where we removed redundant and topped out measures.

CQM reporting remains as we previously finalized it and as you know we'll update CQM reporting for Stage 3 later when we start talking about MIPS reporting as a whole. Next slide.

Because there are providers who already started working on Meaningful Use in 2015, as would have been expected to, there was already a requirement in place, and there were providers who had already been scheduled to do Stage 1 in 2015 that had a lower bar we were sort of at the tail end of a number of those folks there are alternate exclusions and specifications within each of these individual objectives to handle those cases. We were very cognizant of not putting people this year in a situation where they had to hit a higher bar than would have been previously required. So, you can look through each of these, I won't cover all of those. Actually, I probably won't cover most of those in this session, but they are in each of the slides that you will see. So, next slide.

So, these are the objectives and measures that we got down to for the modifications area for 2015 through 2017, so protecting patient health information the same as what you see in Stage 3, clinical decision support, identical to or similar to the objective that you see in Stage 3, in fact CPOE, electronic prescribing, health information exchange it's slightly different but it is still the summary of care transition of care, patient specific education although we combined that into a larger patient engagement objective in Stage 3 as a separate measure that is already here in Stage 2, medication reconciliation, you know, that is a part of the overall health information exchange objective in Stage 3, it's that third measure that includes three different areas one of which is medication reconciliation, patient electronic access, this is part of the patient engagement objective that you see in Stage 3, obviously, VDT the view, download transmit is the only thing that we can measure here because there isn't API functionality in current EHRs, secure messaging, again, another measure that is in the patient engagement objective in Stage 3 and of course public health reporting which is its own separate objective in Stage 3.

So, you can see these all exactly align to what the areas were in Stage 3 though there are certainly different thresholds here and some fewer requirements and modified. Next slide.

So there isn't much changed in many of these objectives from what was required in Stages 1 and 2, patient health information doesn't really change it's a HIPAA security risk analysis. Next.

Clinical decision support, this is...there is an alternative objective and measure for Stage 1 providers in 2015 because the Stage 1 CDS is a little bit different but it's still what you see here in measures one and two are aligned with what were already there in Stage 2 which is the five clinical decision supports and the drug-drug, drug-allergy functions. Next slide.

CPOE, we do have some alternative exclusions for Stage 1 providers because there were requirements, these requirements for lab orders and radiology orders were new in Stage 2 and we are not holding Stage 1 providers this year to moving into that. There's also a difference in percentages so you'll see an alternate measure for Stage 1 but otherwise this is the Stage 2 CPOE that you see, 60% of med orders, 30% of lab orders and 30% of radiology orders.

By the way we changed radiology orders to diagnostic imaging orders to be more...to cast a wider net than just calling it radiology there are diagnostic imaging orders that aren't necessarily just radiology that's why you see a change in Stage 3. Next slide. Next slide.

Okay, so, health information exchange, this is the transition of care, you will see that we have the same that we had in Stage 2 it's creating that summary of care record and then it's electronically transmitting it to providers for more than 10% of those transitions of care and referrals, there is obviously an exclusion for this because it wasn't a required thing in Stage 1 for providers in 2015. Next slide.

Patient specific education, it's using that information within the EHR to identify this for more than 10% of patients same on the hospital side, some exclusions for Stage 1 providers based on the differences between Stage 1 and 2. Next slide.

Medication reconciliation, there's nothing really significantly changed here. Obviously, it matches up to the Stage 1 requirements in 2015 but otherwise it is the Stage 2 requirements to do this medication reconciliation for more than 50% of transitions of care. Next slide.

Patient electronic access, this is the view, download, transmit that is very much what is measured here is the view, download, transmit. It is for EPs that they are providing timely access to that information, that's EP measurement one.

And then in measurement two it is the ramping up or the progressive scale that I had talked about that finally ends up with a measure of 10% in Stage 3 but you can see how it's laid out here where we do a single use case in 2015 and 2016. We move to an EHR reporting period in 2017 where we're measuring more than 5% and then we finally move on to 10% and that's where it stays fixed at Stage 3. Obviously, there's an exclusion for measure two for Stage 1 providers because that was not measured in Stage 1. Next slide. Similar for hospitals on the same end. Next slide.

So, you can see this is how we changed that measure two threshold, so, 2015, 2016 and 2017 one patient, one patient and then up to 5% and then finally 10%. Next slide.

Secure messaging, previously we did a change for this because we had heard a lot of issues with engaging in this technology it's why we changed in Stage 3 to measuring the provider using secure messaging and we also altered based on the feedback we got during the comment period the measure for 2015 through 2017. So previously it was measuring that 5% of patients had sent an electronic message using that secure messaging function to the EP. But now for the EHR reporting period in 2015 it's that the capability to send and receive an electronic message to the EP was fully enabled during that EHR reporting period. So, essentially that this technology was on and available to patients. Next slide.

And then we did a similar sort of ramping up on this where in 2016 and 2017 we moved to a one patient in 2016, so one patient is using secure messaging functionality and then five patients using that functionality as we move forward.

We get the question about, well, why didn't we change that measure completely to being a patient measure and part of the reason that we did not do that...I'm sorry, why didn't we change it completely the way we did in Stage 3 to make it a provider measure. And part of the reason we didn't do that is because we were very focused on not changing the technology that providers have to use for 2015 through 2017. We don't want vendors to spend their time redoing current technology, currently certified EHRs and for them to have to roll out new units. We'd rather see vendors spend their time actually focusing on the new 2015 certified EHRs and the current EHRs do measure for this particular objective what patients are doing. But we are putting a ramp up or a progressive type of threshold for this 2015 through 2017 that should make it easier for providers. Next slide.

And then finally, public health reporting, we did move to a two out of three, three out of four for hospitals on this and it gives some alternate exclusions for different folks. A lot of folks have asked about whether they are going to be required anew to report to new areas that they had not intended to report to. There is actually a lot of language in the final rule about if you had not intended to report to a particular reporting database whether that's a registry or a syndromic surveillance database or whatever it might happen to be that you aren't required to do so and that you won't be asked to get new technology to do that, that was not our intention here. Next slide.

Oh, actually, I think we are at the end of our slides on this. I usually have a wrap up slide, but tried to keep the number low here. So, as you can see, the 2015 through 2017 modifications are directly aligned with what we're trying to get to with Stage 3 it was very much intentional. It is helpful not to think of this as Stage 2 and the Stage 3. I think it's probably helpful to think of this as Stage 3 and Pre-Stage 3 and that was very much by design to try to get people as soon as possible to more focused and less burdensome requirements.

So, I'm going to stop there and I think we have probably 15 minutes or so to do some Q&A and see if I can answer some things for folks. I will warn you that I previously was a writer of Meaningful Use rules and really knew in-depth all of the different requirements and needs and what had been done and things because I had actually done most of the writing but that is no longer the case in my different role, Elisabeth Myers is the person who really headed up our team on policy on this and she unfortunately was not able to make it today. So, I will do my best to answer very detailed questions but I may have to come back with responses to anything that gets truly nitty and gritty.

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

Well, thank you so much and we do have 15 to 20 minutes for Q&A. I have made a list of all the, what I think are, controversial points, but let me open it up to the group and Michelle have folks raised their hands and is there a queue?

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

There isn't queue so maybe you can get us started John.

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

Okay. So, I will just ask the Standards Committee, because this is an area where I used to have expertise but, as Robert said, I no longer have expertise, on the discharge medication ePrescribing requirement, when we reviewed this a few years ago the challenge was that pharmacies had not implemented either the prescription change or the prescription delete function so that it was actually really quite hard for a workflow to support the ePrescribing of discharge medications. It's very common in the discharge process that scripts are changed as patients are walking out the door and therefore that was just not quite so doable. Kim Nolen or does anybody else on the call have any update on the maturity of the standards for discharge medication ePrescribing? Silence.

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

Hi, John, this is Kim.

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

Yes?

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

So, there is a transaction within the SCRIPT standards for cancel Rx is that what you're asking?

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

Yeah and I had just...again, we reviewed it a couple of years ago that although the standard was there pharmacies had not implemented it widely.

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

Correct, but, yeah, well it's not the...the EHR vendors had not implemented it like if a prescription was canceled in the ambulatory side that would not necessarily show up in the pharmacy because it had not been implemented in the EHR.

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

Yes. So, I guess this is just one of those where we'll have to make sure as we hear about the certification rule and look at the maturity of pharmacies and the Surescripts network and everything else that the workflow required here being able to change a discharge medication or cancel a discharge medication is actually supported by the ecosystem.

The second item I thought, of course there's got to be a lot, I believe, discussion today on the API requirement because the API isn't actually specified in the certification rule it's sort of the analogy I've used is tell computer manufacturers you need to leave a whole in the chassis because we're going to plug something in at some point. We think this USB standard would be useful but we're not going to specify it yet, you'll end up with square holes in circular holes and 12-pin connections, and so it felt early. And so, I think it would be interesting to hear commentary from CMS on the idea that an API would be required to connect to any consumer App including those provided by the Chinese Government.

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

It is not required to connect to any App because I think that would be very difficult to even make possible. I think that I would not choose the Chinese Government example but I think that if you just look at the marketplace of applications that are available for any fairly common function and the Android or Apple Store you can already begin to appreciate how difficult that would actually be.

So, the requirement is to make it available so that any App developer could choose to access that language not so that any App that the patient chooses would make it available.

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

And that's a very important distinction.

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

It is.

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

Of course I mentioned the Chinese Government just to be very controversial. You know that all of this is purely to make sure that the folks on the phone have an opportunity to vet these issues. So, when the language says "any App developer" I mean, again, this will be one where from an ecosystem stand-point if there are five good App developers and one bad App developer does an EP or hospital say "well, we actually don't want to accept incoming requests from joesendoscopyapps.com."

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

So, I think if that is perceived to be an issue, I have to be somewhat careful in what I can opine about because the Stage 3 is a final with a comment period.

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

Sure.

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

If there is a perception that this poses a particular risk or hurdle, or whatever it might be then I would definitely encourage people to submit comments.

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

So, before I go on further on the list...I mean, we have of course some experts on the phone here. Are there any folks who would like to comment about the API elements of Meaningful Use Stage 3 and modification rule?

Joshua C. Mandel, MD, SB – Research Scientist – Boston Children’s Hospital

Yes, so this is Josh Mandel, I would make a quick comment which is the only requirement for data to flow occurs when there is an agreement between the patient and the App developer, so the App developer has made an App and connected to a system and a patient has to approve that App and say “I want to use it and I want it to have access to my data.” So, no data are flowing just because the App developer developed a crappy App and no data are flowing until that App has successfully connected to the system and the patient has approved it.

And for me, if you take those things together than this becomes more simply a question of right to access just like with data tends to have access to the data in the portal, it should be easy for the patient to feed those data into an App in an automated way.

So, from my perspective I don’t necessarily see the concern as long as we make it clear that this is a patient who is going to use the App we don’t have to worry so much about a bad actor making a bad App or something because they have to convince the patient before it’s usable.

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

Josh?

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

Thank you, I think you actually described that better than I did.

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

This is Arien, I think...

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

Well, Josh...

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

It would be useful for OCR to clarify the breach issues incumbent on providers to clarify that in the case that Josh describes a patient who delegates access to an App to download the patient’s data that this clearly falls under the patient access provisions and any breach that might happen with the App developer is on the patient’s side of the balance sheet rather than the provider side of the balance sheet. I think some policy clarification from OCR would help this considerably. I don’t know if Deven is on the phone or listening, or whatever.

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

And to the point, I mean, of course Josh and Arien have made very thoughtful comments but let’s imagine that the patient decides to download an App from the Chinese Government and says “okay, connect me.” Is that, as was said, okay because it’s an insecure App and the patient has initiated this and we’ll do whatever the patient asks or is there a sense of responsibility here that the handoff from an OCR perspective really has to be from the provider to a secure endpoint and then what the patient does with it from there is up to them. Don’t know.

Joshua C. Mandel, MD, SB – Research Scientist – Boston Children’s Hospital

This is Josh...

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

Yeah, I will say that I do think that OCR is going to clarify some of that from the HIPAA perspective, you know, what constitutes an okay handoff. There have actually been some discussions with CMS and ONC, and OCR about making some of that information available and we should see some of that relatively soon.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

This is Leslie Kelly Hall, I think that clarity is very important but it’s also really important to describe in plain language to the patient at the point of registering an App what does this mean? What are your responsibilities now that you have registered an App of any kind whether it’s secure by the providers point-of-view or not by explaining and educating the patient the choices they have and the risks associated with those choices I think we fulfill a large obligation and doing it without any sort of Surgeon General type warning or explanation I think would irresponsible. So, having that built into any sort of App registration is important, education is more important than restriction in my mind.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Well, this is Dixie, it’s also important...I think it’s pretty clear that a provider organization would not be expected to voluntarily subject itself to security risks. So, it’s not just the risk to the patient it’s the risk to the organization as well when you allow arbitrary applications to connect. So, you know, that has to be considered. I am not a lawyer but, you know, I can’t imagine that anybody would expect a hospital or a provider to put themselves at risk.

Robert Anthony – Deputy Director of Quality Management & Value-Based Incentive Group – Centers for Medicare & Medicaid

I have to admit, this is Rob from the CMS...

Joshua C. Mandel, MD, SB – Research Scientist – Boston Children’s Hospital

This is Josh...

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

I have to admit that HIPAA doesn’t fall under our jurisdiction so I am probably not the person to speak to this particular area and it may be more useful to have something of a conversation with some of the ONC certification folks to talk about what they’re looking at as far as the API functionality from a technical perspective. I really can only comment on the requirements from the Meaningful Use side.

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

Well, so these are exactly the sort of comments that I was looking for from the Standards Committee. I raised the Chinese App again purely to be controversial as to what is the responsibility of the patient, as Leslie has articulated, and what is responsibility of the provider organization to provide at least some level of assurance that this is not a breach by offering access to such an App because...and I think Robert your answer is correct which is we all love APIs and we all love patient family engagement it’s just sort of the devil in the details here and probably needs some further clarification from other agencies.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And there may be a tiered approach John, this is Leslie, where a provider chooses to have their Good Housekeeping Seal on their App library that they choose to interact with without question with the patients they serve. However, there might be another tier that is clearly a hold harmless tier where the provider may in fact take data put it in a more secure area with regard to their risks and make that more open. So, there could be a market response too but it should be an educated response whatever it is.

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

Right and so, you know, Robert I guess we would...to Leslie's comment, when the language reads access their health information through the use of an API that can be used by applications chosen by the patient is it allowable, from the perspective of CMS, to have a curated App Store and only allow access from those Apps that have been qualified by the provider?

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

So, we're in a comment period if that is something that people seek clarification on I would encourage you to submit that as a comment.

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

Because, as Leslie said, it may be some providers will say "sure, you know we like angry birds health edition" and others may say "actually there's a curated set of 12 Apps and one of those 12 should meet your needs." So, great. I think we will...

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

I will say the flipside of that though, John, is definitely that a not as well-meaning organization that does not want to widely disseminate health information could keep their curated App library very specifically small and only limit it to maybe Apps that they have developed or a partner organization that they have a business arrangement with has developed and that could potentially stem the free flow of patient information.

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

Okay and of course what we hope is that one can't change culture necessarily by regulation alone, that there's going to be some market forces and patients will move from provider to provider if they are dissatisfied with the services they are receiving.

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

John, this is Michelle...

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

So...

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

We have lots in the queue so I think that we should move onto the next question.

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

Very good, well, let us move onto the queue then. We were just filling time.

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

Dixie Baker and then Arien Malec?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yeah, thank you. First of all I wanted to say that I'm glad to see the increased attention to patient access and engagement and also to the addition of integration of patient provided data with the EHR.

I've been working with some patient advocacy groups who would like to implement the capability to receive structured EHR data that are sent to them at the request to the patient and so my two questions really come from that perspective and my interactions with them and what they're looking for.

So, first, regarding secure messaging, many of these EHRs provide secure messaging within the patient portal using TLS instead of Direct and it looks like, just based on the slides, that eligible providers and hospitals now we get Meaningful Use credit for secure messaging means other than Direct messaging and so my first question is am I misreading that? And secondly, is there a requirement to be able to send a structured data in a C-CDA to a patient or a third-party if the patient requests that be done?

Robert Anthony – Deputy Director of Quality Management & Value-Based Incentive Group – Centers for Medicare & Medicaid

So, I believe that the standard is open on this. So, although we had previously gone Direct. Do we have ONC folks on the phone who want to talk about this particular standard being used? Okay. And I think that this then opens it up to a variety of different things that could be used to count on it toward the measure. I would have to go back and look very specifically at what the legislation says or the regulation rather. And I'm sorry, the second question?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Is there a requirement to be able to send structured data in a Consolidated CDA document if a patient asks for that?

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

There is a requirement within the view, download, transmit that there is that set of data that can be transmitted in that structured data format but there is not a measurement of patient request for a separate transmission of C-CDA.

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

This is Arien, I believe, per OCR, there's a requirement for providers to offer data in the format the patient requests if they have the means to do so.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Okay. Thank you both.

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

So, Arien, I believe is next.

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

Yeah, I've got a lot of questions, I think the biggest one for me, and you may not be able to comment in depth on it, is the relationship between this rule and MACRA and what I presume would be an upcoming rule relating to MIPS. I'm wondering if you can help me just connect maybe or just point out the dots that maybe we can connect using our own pencil.

My understanding, per our last presentation on this topic, is that starting in 2017 providers are on the hook for measurement relating to a 2019 first initiation of MACRA either fee-for-service increases or decreases per a MIPS incentive and there's 2017 and 2018 or this somewhat awkward period where providers are being measured for a MIPS incentive where my understanding is the Meaningful Use incentive and the PQRS incentives go away.

So, I wonder if you can first clarify, you know, do I have the facts there and if you can maybe point out the dots that, as said, we might want to connect with our own pencils regarding the connection between this rule and enablement for MIPS?

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

Sure, so, I think you have the basic architecture correct. It is likely to be a 2017 performance period with a 2019 associated payment adjustment period whether that is a positive adjustment or a negative adjustment according to the way that MIPS works.

Obviously, the other side of this is if somebody was participating in an eligible alternate payment model they would go down that route and that may work slightly differently as far as the performance period that will all be proposed within an upcoming MACRA regulation.

But basically, I think you do have the argument right and we are looking at 2017 as sort of the area then where what essentially happens is that Meaningful Use and meeting the Meaningful Use requirements as we have laid them down already in regulation are going to become part of the overall scoring methodology for MIPS or alternately however the eligible APM model might work. So, they will definitely draw on this, one of the things that we are currently seeking comment on in the MIPS RFI is how exactly that might work. We've talked about a variable scale with EHRs related to these particular requirements and we're seeking feedback on that overall.

But, essentially, what you see now would become part of the overall MIPS requirement and roll up into that total composite score for the scoring methodology.

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

And, so, just for clarification that's an EP set of requirements and there isn't a...

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

Yes.

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

Consolidated track as it were for eligible hospitals?

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

Yeah, sorry, no that is an excellent point. We talk a lot about eligible professionals because obviously we have the MACRA onset looming in the immediate distance, but it is important to say that, yes there is not a similar program on the hospital side and therefore these would be the requirements for hospitals moving forward.

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

Great, thank you.

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

Others in the queue Michelle?

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

John Derr and then Patty Sengstack.

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

John Derr?

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative

Hi, thank you for the presentation, this is John Derr and I represent long-term post-acute care and I don't want to take over what you have to do legally in doing the eligible providers and the hospitals, but I was disappointed that we put all this work into somehow including nursing homes and home care agencies, and LTACs into something pertaining to Stage 3 so we are part of the whole spectrum of care as well, and security and trust and those things plus we're very active in HIEs and ACOs, and the public health and I was wondering, Rob, if you were going to comment on the fact that in a way we were left out of this?

Plus there is not as many things, as I've said over the years, in the 6+ years on this committee, that there's nothing...we send things electronically from nursing homes and home care agencies to the hospitals but there's nothing in most of these pertaining to them receiving information not just sending things out and you can say you're going to comment later, but it's difficult for us to comment on something like this when we're not included in it and we've sent numerous things plus we had a Workgroup on the Policy and the Standards Committee pertaining to the whole spectrum of care and not just eligible plus ONC said at the beginning of this year that now ONC represents all providers and yet we're now going into 2018 and I don't see us in this at all.

Robert Anthony – Deputy Director of Quality Management & Value-Based Incentive Group – Centers for Medicare & Medicaid

So, let me say first of all that I absolutely agree that post-acute care is a critical part of overall care coordination. One of the things that I oversee in my group here are a number of the post-acute care quality measurement programs and some of the value-based purchasing programs and we are always sort of cognizant of the importance of that sphere in overall patient care, especially for the Medicare population as we look at chronic care. So, I absolutely agree with you.

The issue of eligibility as I think that we've long said it's completely out of our hands. We're not able to place requirements or incentives, or payment adjustments around the use of health IT. The HITECH statute was very limited to what could be done for certain eligible professionals and certain defined hospital entities.

That said, I will tell you that we have ongoing conversations in the post-acute care side with our colleagues in ONC about standardization of certain data elements. As we implement some of the impact requirements for those of you who are not familiar there was legislation that was passed called the impact legislation that required the standardization of data elements across multiple post-acute care settings just so that information could be adequately measured across those different settings.

But we're also looking at that as, you know, the standardization of those elements to think about how that information can also be transmitted across settings. But the challenges are exactly what you identified that we don't have authority in this area to require post-acute care settings to actually use an EHR and therefore we don't really have a way to be able to measure that usage or at this point in time a way to drive that usage. We're doing what we can about standardizing. But I think that until somebody gives us specifically that authority we're going to be against that challenge.

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative

Yeah, this is John Derr again, the hard part is that we're trying to be part of this whole spectrum of care and when we are not really...and I thought what we decided on, a year or two years ago, was some volunteer things to be put in at least on security and privacy and HIPAA, and also as participants in this whole spectrum of care and that was going to be included in this 2015, 2016, 2018 and it didn't get in here and what we're faced with...and I commented on this at roundtables and that, that will get edict to do certain things when we put a lot of work into doing volunteer and saying we want to be part of this whole motion of digitizing health care.

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

But there probably is...

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative

And I know that Impact Rule and I know the cures thing and all these things are starting and we are concentrated on chronic care and comorbidities and there is a lot of work on that, and end-of-life and yet we couldn't even be in this on a volunteer type basis. Sorry to be sort of argumentative...

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

Hey, it's all right...

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative

But I...

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

So, if I can say, there's...on the Meaningful Use side, and we are discussing the Meaningful Use regulation that's what CMS does, we don't have any authority in those areas so we couldn't include things in Meaningful Use.

I think there's probably a larger conversation to have with my colleagues in ONC on the certification side and what might be certified for different settings and what that might look like. I do know that some conversations have taken place. But, I would not be the person to address that side of it.

I will tell you though on the Meaningful Use side, you know, one of the things, one of the measures is a transmittal utilizing the EHR of a summary of care to the next provider or setting of care and it absolutely, moving somebody to a long-term care or a post-acute care facility counts as a transition to a setting of care and one of the reasons that you see something of a broadening of how that can happen electronically is so that we could account for those sites actually receiving it.

So, if you have a post-acute care facility that is interacting with an HIE and can receive that information electronically that is certainly one method that can be counted to the positive for that particular measure for providers.

And we've also expanded it so that if you're using it electronically, your EHR, to send that and then it goes to a service that then converts that on the other end to a fax or an email that reaches a provider that doesn't have an EHR, you could actually count that as well. So, I do think that there are some provision for getting that information from an EHR to a referred to post-acute care facility but, again, mostly on the Meaningful Use side, we are truly limited statutorily to whom we can apply these things.

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative

I understand that's what I've been told for six years and the only thing I would just end it, because I know you guys got to do other things, but you could put something in there about receiving in the ER we send things electronically, we are participating in this whole thing even though we didn't get any money to do so. So, you might do that and maybe we'll comment on that, because I know people are telling me all the time they try to send something electronically to a hospital and they can't receive it. Thank you very much for everything.

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

Michelle...

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

So, we still have four people in the queue and we're already over time. So, if I could ask if we could keep our questions brief going forward and hopefully we can get through everyone. So, Patty Sengstack, Wes Rishel, Rich Elmore and then Andy Wiesenthal.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Thank you it's Patty Sengstack from Bon Secours, thank you for the presentation it helped clarify a lot of things. I have two what I think are really quick questions related to Meaningful Use Stage 3.

My first question is on clinical decision support, and I was wondering if there was any conversation about measuring the effectiveness of the CDS that's implemented and I ask this because here at Bon Secours I know that we have configured several of our alerts that are creating alert fatigue, we a little button that says, remind me later and everybody is just clicking that, and I know that we evaluated one recently that had fired something like 10,000 or tens of thousands of times in one week. So, we can implement them but was there any discussion about requiring organizations to evaluate if they are actually effective?

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

Yeah, actually there's been some conversation about that since the very first day that we started talking about clinical decision support. I think part of the issue is that we've been very broad in what we allow as clinical decision support that is something that we did by design from the beginning because we did not want to force everybody into the same box. We have heard repeatedly through this program that when we over regulate in particular areas that we are stifling innovation and we wanted to be very careful not to stifle innovation.

Also because there aren't necessarily well-defined clinical decision support for every single specialty and workflow so we did leave this very open so that people could be adaptable because what we really were trying to do here, I mean the whole goal with Meaningful Use is to encourage organizations to begin using that technology in a meaningful way.

I think that as we move forward with MIPS, something like MIPS ultimately, gives us the opportunity to start thinking not of Meaningful Use as a means to an end but as Meaningful Use as part of a suite of tools and information that providers look at to improve patient outcomes. So, it's no longer about is that particular clinical decision support improving patient outcomes?

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Okay.

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

It is about measuring...using that clinical decision support and other health IT tools in concert with the quality measurement that you are doing, in concert with the resource use of your particular practice or organization, in concert with the clinical improvement activities that you are doing and how does that measure overall to better patient outcomes.

And I think that actually is an important step forward because it was very difficult to think in terms of, you know, how do we collect information in a standardized way for clinical decision support that is demonstrating that it improves...

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Right.

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid
Within an organization.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Right no, I get you. I understand how do you keep it generic, but it's just what I'm seeing out here, you know, a lot of the CDS that we use is not that effective and is there a way that we can monitor better. So, thank you.

My other quick question is on slide 17, care coordination through patient engagement, and in measure one it talks about actively engage. We're going to measure that we've actively engaged and then in measure three it's patient generated health data. In the document, the nitty-gritty details of the document, are there definitions of what those, of what they're comprised of? How do we define actively engaged? How do we define patient generated health data?

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

So, this is one of those areas where I would encourage you to take a look specifically at the regulation and what it lays out.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Okay.

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

And if that is unclear then I would reply as part of the comment period.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Excellent, I sure will, thank you.

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

Thank you. Wes Rishel?

Wes Rishel – Independent Consultant

Thanks, I want to go back to the API just briefly and point out there four parties involved. There is the EHR vendor, there is the vendor of a third-party App or developer if it's not a vendor, there's the provider and there's the patient.

As a practical matter, the third-party App is going to have a hard time getting developed without some sort of trust relationship with at least one EHR vendor and is going to be hard to get marketed or distributed without some ability to test with several EHR vendors in an environment where there is no secure patient data.

Ideally, the magic will happen with FHIR and it will become unnecessary to test but I don't perceive that as a short-term possibility. We have talked about the sort of mixed security and privacy in our discussions about the trade-off between encouraging responsible use and allowing regulations to be used to block data and it's important that we separate those two points, well you need security to maintain privacy, but in general the discussions we've had about the patient's responsibility for the App, I mean, for what happens with the App relate to privacy and perhaps the security of the patient's own laptop or phone if they use...whatever device they use.

In security, it hasn't been that long since we began to debate how to put holes in firewalls to allow web access. I guess I'm old so it has been a long time, but what we found was that it's very hard to predict where exploits will turn up. We're simply offering the service that's being offered on a good basis creates substantial vulnerabilities that are even unrelated to that specific service and we have to find a way...I mean, if we get in a position where we regulatory require providers to open up access without the sort of due process of seeing what happens and learning what the security risks are then we have the potential for using regulations that create a substantial nightmare.

So, I'm not saying that there isn't a concern about data blocking, I personally believe it goes more to the providers than to the vendors, but I am saying that this balance is critical and sort of a blinders on aggressive push on data blocking could create lot of actual damage and political damage for the administration. Thanks.

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

Michelle, who is our next in queue?

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

Rich Elmore and then Andy Wiesenthal.

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

Rich?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Thanks, John. So, I just wanted to follow up on the answer you gave to Arien around the relationship to the MIPS, MACRA follow up here, you know, if you look at the MIPS structure about a quarter of that is based on quality, it is not really defined more than that, but surely meeting measurement and that starts becoming a reality in about 14 months as a basis for those 2015 payments. In our world 2017 is right around the corner.

And, you know, CMS has this MACRA RFI out right now with a long list of questions about quality measurement and it's entirely clear that the answers would indicate that we're looking at potentially an extremely heavy lift in this area in the near future with development, testing, consumption and training, and new measures and that's going to have to take place and it could be, you know, a big challenge depending on timing and definition and all of that and many of the groups that are starting to look into quality measures development and registry creation really don't have experience in doing either one of these.

And so, I guess my question for you is in the near-term has CMS considered the opportunity to leverage what exists from Stage 2, Stage 3 to give sufficient time for an orderly process and has there been consideration given to the challenge of what's involved with, you know, the quality measure aspect of this?

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

My group is one of the groups that is charged really with leading the development and implementation of MIPS. So, actually I can't even begin to describe how much time has been spent talking about these various issues.

I think we are definitely thinking in terms of leveraging not just what we see on the Meaningful Use side but some pre-existing things that we have already had some experience with physician quality reporting system, with the value-based modifier and some work that has been done in other areas to meet all of the requirements of what we have to do with MIPS given the short time period it absolutely makes sense for us to think in those terms.

I think you are right there are specific areas that are called out for new quality measure development but anybody who knows the world of quality measure development, whether that is a measure that utilizes claims information or whether it is a measure that drives toward patient outcome or something in between, the measure development process is not an overnight process it can be anywhere from a three to five-year process to go from conception of an idea to actual implementation of a measure and that's regardless of whether it's an electronic measure or whether it is a chart abstraction-based measure.

So, you know, given that I think we'll have to look at ways to leverage what a number of the existing places are and that is somewhat by design too because MACRA legislation specifically sunsets the PQRS Program and the value-based modifier and payment adjustments that are associated with the EHR Incentive Program and then combines all of those requirements and some new activities into this overall MIPS methodology. So, I think it is no surprise to anyone to say that we'll be looking at all of what we have existing and all of what we have learned to begin formulating the basis of MIPS.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So, from a Standards Committee and from an ONC perspective being able to come up with something that's more standardized, computable more easily consumable perhaps thinking about some of the new technology work that's being done maybe an important part of our agenda. I guess I'm throwing that out for the committee to think about. Thank you.

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

And then finally, Andy?

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

John, hi, it is Andy, thank you. We've been staring at the public health reporting slide so I need to ask a question about that because there's not a lot of detail here. Is there any definition of the target state for providers to aim their public health reporting at because they currently face multiple jurisdictions with multiple data definitions and multiple, literally mechanical ways of doing electronic reporting so it's one thing to put the requirement...the onus on them but the target state is highly variable. Is any discussion of that in the detail of the regulation?

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

No, we don't go into a lot of detail about that and I think some of that is by design. We are very much and have designed public reporting very much to be as flexible as possible for providers because people have a variety of access. It really is truly the distribution can be mind-boggling. There are people who have all those options open to them. There are people that have one and we have tried to be as flexible about that.

When we begin putting requirements around specific registry reporting or specifically around case reporting or jurisdictions we begin to close the net very quickly on a lot of options for people and we didn't want to be in a situation where we were excluding certain registries from participating at all or what we had heard as we had talked through this, especially in Stage 1 or 2, different specialties from being able to participate in public reporting.

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

So, we'll take it off-line but I was actually talking about the opposite putting the onus on the public health community and the registry community to get their act together because what you just said...

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

Ah...

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

Is highly variable depending on where you are geographically.

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

It is and I'd be happy to have a conversation off-line about it. We obviously run into some issues on that side. We can't regulate in that area. What we can regulate in is requirements for providers.

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

Well, great, a robust discussion and just to quickly summarize, I think we heard from the Standards Committee the chief concern is the alignment of the rule with MIPS and MACRA recognizing that in the next two years there is going to be a lot of moving parts and so I'm sure there will be a lot of public comment in that regard.

I highlighted the question about the ecosystem readiness for discharge ePrescribing. There of course was a lot of discussion on APIs and Wes nicely explained that there are four parties that have to cooperate here and what are their roles and responsibilities of each of those four parties to ensure data integrity and security. Of course we want an ecosystem that gives patients access, we don't want information blocking but we also don't want breach.

I'll just add two final comments and that is that we did in, as you described, going from Stage 2 to 3 ramp up the patient and family engagement from one patient to 5% to 10% for the access of records and the secure e-mail at 25% but recognizing that to send not necessarily engaging the patient in a conversation and it will be interesting to watch as we go from what is today a very low threshold to these 10 and 25% thresholds how culture changes and how the ecosystem responds.

And finally, I think Andy said it well, the issue with all these public health measures is the EHRs can implement transactions but there's such variation in local public health department participation and lack of true standards implementation guides on transport to them that the ecosystem, the two parties, often don't meet in the middle and make the connection.

So, I look forward to the public comment period and I certainly want to thank you for your presentation today and for all the comments to the committee. And Michelle, no worries...

Robert Anthony – Deputy Director of Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid

All right, thank you, all.

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

Yeah, don't worry, Michelle, we're okay, we gave extra time, remember? So, it looks like we are now ready to move onto what will be, hey, an even longer rule, the certification rule.

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

So, do we have Elise and Mike on the phone? I know Elise is on from earlier.

Elise Sweeney Anthony, Esq. – Acting Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Hi, Michelle, I'm back, I'm here and I think Mike is on as well.

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

Hi, yes, it's Mike.

Elise Sweeney Anthony, Esq. – Acting Director, Office of Policy – Office of the National Coordinator for Health Information Technology

So, we are running a little...hey, Mike. We are running a little behind so I'll try to move through the first half of the presentation a little bit faster so that we can really spend a fair amount time talking about the specific criteria which I'm sure is of key interest to the committee.

First, I also want to thank Jon for the introduction earlier. It is a pleasure to be more involved with the FACAs I've done a lot of the behind-the-scenes work working with Jodi as her right-hand, so it is my pleasure to serve in this acting role. So thank you so much, Jon, for that as well.

So, I'm going to go ahead and jump into the presentation. I'm going to be presenting with Mike Lipinski who is the Director of the Division of Federal Policy and Regulatory Affairs and our amazing Reg writer who is responsible for the numerous pages that Jon put together.

That said, before I even go further, it is a fair number of pages, however, we did try to divide it so that it's easily accessible and we'll talk at the end about some resources that we've made available on line so that the information can be easily or more easily consumable. We have some fact sheets as well as some charts that we'll be putting up shortly and then the presentation in long form itself is also available and is a quick guide to what the rule entails. So, with that, next slide.

So, today we're going to do a couple of things, one, we're going to talk about the goals of the final rule and how we arrived at the provisions that it includes. We'll also talk about the Health IT Certification Program and the particular provisions that attach to that and then we'll talk about some of the changes compared from the proposed to the final and then some of the use cases that we think can apply to our rule. Next slide.

So, looking at the overview, so the 2015 edition final rule is part of a larger effort at HHS to really think about interoperability, to think about delivery system reform, to think about improving care. So, to that extent, kind of the things that we've kept at the top of our mind are better care, smarter spending and healthier people what you'll see that kind of flows through a number of different activities that are ongoing at HHS as a whole.

In addition, the rule builds on the foundation from the 2011 edition and the 2014 edition. As part of that we also looked at stakeholder feedback we received from the proposed rule in addition to kind of what we've heard from the Federal Advisory Committees and as part of that we reduced the burden of the rule.

So, you'll see that there are less provisions, less criteria finalized than what were actually proposed and that's part of our real listening to what we're hearing on the ground. What we are hearing is workable, what is ready and what is necessary in terms of health IT and improved care.

I said before we're also focused on interoperability as a whole, exchange, what that looks like, the standards that attach to that and thinking not only about kind of Meaningful Use providers but also beyond that part of the continuum.

We've also left some space in terms of having a reduced burden so we've left some space we're hoping for new market opportunities and innovation to continue in a number of these areas, part of the rule also focuses on info blocking and continued reliability of certified health IT. Next slide.

So on this slide you'll see these pop up throughout our slide deck and these are not just add-ons, these are really the key goals that we thought about in developing the proposed rule initially and then what led us to the final rule. So, I'm going to highlight a couple of them here just in case folks can't stay on for the kind of longer dive that Mike is going to do in a little bit, but improved interoperability as I said already, ensuring privacy and security capabilities that continues to be a hallmark of what we're doing here at ONC. So, we've updated the framework for privacy and security.

Health disparities, so we've heard a lot from stakeholders who have said "look, we think health IT is crucial and important and is going in the right direction, but how can we use health IT to think about health disparities and consequently disparity reduction." So, we've included some provisions that we think are helpful there in terms of sexual orientation, gender identity, race and ethnicity standards, the DS4P as part of that and the social determinants of health criteria, the psychological, behavioral and social criteria that we've included as well.

We are thinking about the care continuum. So, while we continue to think about Meaningful Use and supporting the EHR Incentive Program we do recognize that there is a need to have health IT available for the larger care continuum.

We do thank the FACAs for the work that they did a bit ago focused on voluntary certification and thinking about other setting support. In addition, data access and exchange continues to be key in terms of how that information moves and what protections attach to it when that happens.

Patient safety, we've included some pieces on safety-enhanced design and usability and then transparency and reliability of certified health IT and that really goes to the updates to the program itself and I'll talk about that in a second. Next slide and one more.

So, here let's talk about the broader care continuum. What does it mean to have a certification program that supports the broader care continuum? So, one it's things like changing our language. So, before we talk about EHR modules and that's how the program was constructed. Now we're talking about health IT modules and as many of you may know there are diverse health IT systems, right, it's not just EHRs, EHRs are one part of the health IT system landscape that can help advantage care. So, now we are calling them health IT modules instead of EHR modules.

In addition there is no more complete EHR in the 2015 edition which means that the program is completely module-based. So, a provider can work with their vendor to come up with the pieces of the program that work for them and together put together the puzzle that is right for that provider and the patient population that they serve.

And we talked a little bit about some of the care continuum. One example is long-term post-acute care which was part of the work of the Policy Committee a bit ago. Next slide, please.

So, on this slide, how will it work, how will it work for us to support the broader care continuum? I think the key word on this slide, out of the many, is agnostic. Our program is agnostic to MU or to any other particular program at HHS or in the private sector by that we mean that a number of different programs can point to the provisions that we've included. So, I often use the description of our program being a buffet of sorts, right, it provides a foundation of health IT technology and a program.

MU, for example, can point to our CEHRT program and say these are the criteria that we think are important for the providers that were covering under our program. Likewise, whether it's a private system or a private association can do the same to get to the providers they're serving. So, that would include long-term post-acute care for example, chronic care management, behavioral health and a number of other settings.

One other key that many of you may be interested in as you look at the two rules you'll notice a difference on where the certification definition for MU lies. So, the certified EHR technology definition is what is required of a Meaningful Use provider for purposes of successfully attesting to Meaningful Use in a given reporting year, long phrase to say that ONC has the technical capabilities that CMS points to for purposes of provider attestation.

That definition, that CEHRT definition, is now housed in the CMS rule and that again goes to our program being agnostic, we're not just focusing on MU although we continue to recognize the importance that this program plays in terms of health IT. So, that definition is now in the CMS rule, we continue to work closely with CMS where we think that...we as well as CMS think that this is the appropriate place for the technology specification to be required which then points back to our rule. Next slide.

So, here we list some of how this broader care continuum support is happening already. While we continue to update our program to reflect that task of thinking about how to support the care continuum more completely as opposed to just Meaningful Use there are some things...some places where this already happening. So, you have the physician, self-referral law exception and the Anti-kickback Statute, safe harbor that's one place that's a Stark Anti-kickback that many of you may know it under that rubric.

In addition, CMS's chronic care management services rulemaking addresses and includes references to certified health IT, the DoD's efforts to modernize their system as well as the Joint Commission. So, those are some examples of where we're already seeing and working across the landscape to think about how health IT and standards-based health IT can advantage care. Next slide.

So, now I want to talk about some of the updates we've made to the program itself. So, this is the structure, the framework that attaches to the certification program, so, one is transparency. We've done a lot to really think about how to give our health providers the information they need to make the right decisions for them and for their patient population regarding the technology that they were purchasing or, you know, whether they already have their vendor of the technology they continue to use.

So, ONC and ACBs must ensure that health IT developers are conspicuously disclosing in plain language on their website and in all marketing materials, communication statements and other ascertains related to certified health IT some key information, one is the type of cost. So, this is cost that the users might incur to implement or to use the health IT for whatever purpose and it doesn't have to just be for program support, so if the provider is using the program to meet Meaningful Use the types of cost don't only have to relate to Meaningful Use it's what the products can do and the information about what that product can do.

In addition, disclosure about limitations, so those could be contractual, they could be technical or other limitations related to how that product can be used and how the user would implement the product and the goal again is to think about making more information available to the providers about the technology and we think this is helpful not only to the provider but also to the vendor to enable a communication to happen between the provider or the potential provider purchaser about the technology and what it can do. Next slide.

So, how will we help to kind of disperse that information into the larger landscape? So, one, we are requiring that a hyperlink to those disclosures be provided to ONC. ONC would then post on our website, on the CHPL, the Certified Health IT Products List, that link to the disclosure. So, you can envision where a provider who is interested in purchasing a product, they go and they look on the...they look at the CHPL site and they're able to see not only the product but they're also able to see a link that provides them with more information on what that product does and what the types of costs or charges might be for that particular product.

In addition, we include a provision on transparency attestation and that would require the vendor to indicate whether or not they would provide the required information regarding the disclosures and make that available upon request. We think that this also will be helpful in terms of providers knowing what information is out there and if there's any...if the vendor has made that information available. Next slide.

And this goes to a larger goal of what we're doing with the Certified Health IT Products List, affectionately known the CHPL, and that is to make it more of an open data resource. So, we are converting the CHPL to an open data file to make the reported product data, such as the test results and the information I just indicated regarding the product and the disclosures, more accessible for product analysis. And we're also requiring that the ACBs report on additional information and expanded set of information about the health IT products themselves. Next slide.

Privacy and security, so, I touched on this very briefly in the beginning but I wanted to take some time to talk about what the framework is and how it's different. So, the framework that we've adopted is a framework that takes some of the onus off of the provider to figure out whether the product that they have before them or are considering is certified to the privacy and security pieces necessary and required by our program.

Now we are pairing each of the modules, each of the criteria with the privacy and security pieces that we think are appropriate for it and that way when a product comes to us for certification it would not only have to have the requirements of that particular module but it would have to have the privacy and security requirements that we are attaching and this again is a perfect example of where there are a number of charts in our rule that describe this in more specificity.

So, going to the next slide, here is how this would work. So, for example, in 315(a) you see you have CPOE for example, you have drug-drug, drug-allergy checks, you have CDS those types of criteria. Under the middle column approach 1 you'd see what are the privacy and security pieces that would be required if a vendor is coming to us to be certified to some of the pieces under 315(a) and the same this as you go down to 315(b) you see the privacy and security pieces that would likewise be required.

Again, we think this removes some of the responsibility from the provider and makes sure that the technology has the appropriate privacy and security pieces attached to it when it arrives for certification. Next slide.

So, surveillance that's another key update to the certification program, we've included new requirements for in the field surveillance and our goal is to be able to look at how the product is operating not only in a test lab environment in the controlled environment but also when it is implemented and when it is used by a provider.

So, there are two types of surveillance that fit in that category, one is reactive and that's if we receive a complaint or we hear that there is a problem that we are then able to go in and take a look at that product.

In addition, there's randomized surveillance. And randomized allows us to take a look, even if there is not a complaint we would be able to take a look, and it would be 2% of annually certified health IT at one or more locations. So, there's two different ways to think about surveillance and the goal is really, like I said, to think about how do we make sure that the product is operating in the field as it is when it arrives to us in a test lab type environment.

So, these are mandatory, the enhanced surveillance are mandatory transparency requirements and also I wanted to note that this is also part of the expanded set of information that would be available on the CHPL and so nonconformity and the corrective action that's reported would be available on the CHPL starting in 2016. Next slide and one more.

Okay and with that...so those are some of the updates of the overall framework and the goal of how we're thinking about...how we thought about and approached 2015 edition final rule and also some updates on the program itself. I want turn it over to my colleague Mike Lipinski now and we can do a deep dive into the criteria and what we adopted versus what we did not.

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

Thank you Elise, and thank you to the committee for allowing us to provide this presentation today. So, good afternoon and I'm going to talk to about the second part of our final rule. So, the first part that Elise spoke about was one our overall goals but then particularly about the ONC Health IT Certification Program which goes beyond just supporting the 2015 edition and continues to support certification to the 2014 edition and as she noted certification for other settings as well.

But I'm going to focus right now just particularly on the 2015 edition and then at the end explain how the 2015 edition can support particular use cases including the EHR Incentive Program.

So, obviously, in terms of improving interoperability we looked to and have done...have adopted new updated vocabulary standards, even transport standards an updated version of Direct, I'm going to talk a little bit more about those later but two of the key proposals that we adopted in terms of supporting interoperability are the 2015 edition-based EHR definition and the common clinical data set. So, let's move onto the next slide and jump right into those.

So, this is just a brief slide reminding folks of where the base EHR definition comes from it comes out of the HITECH Act. There is also that key reminder there, that third bullet point, about, you know, when we certify, well now we'll just be certifying health IT modules and you can have a health IT module that meets the base EHR definition as well as everything else a particular provider would need to participate for example in the EHR Incentive Program but you could also have a health IT module that only meets part of the base EHR definition and then is combined with another module to meet the full definition. So, the point being is it's a definition it's not a product that gets certified particularly and we seem to always have to have some questions about that so I thought I'd emphasize the fact that it can be met using multiple modules or just one module. Moving onto the next slide.

So here it is the 2015 edition base EHR definition. What you see on the left, in that left column, is coming directly out of the HITECH Act. These are capabilities that the HITECH Act used to define what was called the qualified EHR we renamed that in the 2013 edition rulemaking as the base EHR definition and we did that because I think it provides less confusion with other uses of the term qualified within the department related to EHRs and also emphasizes the point that it's a foundational set of capabilities. So that was the reason for the name switch for it compared to the statute.

And on the right column, you obviously see the criteria that are included in the base EHR definition which within themselves has those capabilities. What you see here in red are new so this is compared to the 2014 edition. These are new capabilities that have been included in the base EHR definition and the API criteria or capabilities is now three as compared to proposed as one, it's actually five criteria now as compared to the proposed criterion and we'll talk more about that later.

In the privacy and security, as Elise already discussed our new approach to privacy and security, we removed it from the base EHR definition and now it's part of certification to any health IT module as applicable and we think this will obviously, as she noted, provide clarity to vendors as well as relieve a potential burden, so to speak, on providers to ensure that they were meeting the base EHR definition by having technology certified to all of the specific privacy and security capabilities. So, let's move onto the next slide.

So here's a common clinical data set and it used to be called that common MU dataset and consistent again, as you'll hear this refrain that Elise mentioned, we are moving away from just focusing on the EHR Incentive Program and more broadly supporting the care continuum and thus the name change to the common clinical data set.

What you see here is a list of the data included in the common clinical dataset and in blue you see where we've changed the standard or, you know, either gave it a standard where the data element didn't have a standard before or we've either changed it or added more standards.

So, for example, race and ethnicity we're still using OMB standards but we're also now using the CDC PHIN VAD code for race and ethnicity. We changed the preferred language one, I'll talk about that more. We've added one for sex. So, to give more structure to this data and to improve interoperability obviously that's what we're doing there.

We've also added new data that we think is important to capture particularly for exchange across the broader care continuum, you see the data related to goals, health concerns, assessment. We've also added UDIs for patient safety and then immunizations as well to improve care and we've done that in a structured way pointing to CVX and NDC vocabulary codes. Moving onto the next slide.

So, in a nutshell, this slide shows you the 2015 edition both in comparison into what we proposed as well as in a quick numbers comparison to the 2014 edition and then I'm going to walk you through this, but at a rather brisk pace so that we can open it up for comments. Okay, so let's move on to the next slide.

This is just the key and this key is here simply because we wanted to make this slide deck usable if our stakeholders downloaded it from our website and weren't able to participate in an actual presentation where I or one of my colleagues were talking to the slide. So, this should provide the information to help understand the slides I'm going to talk about next. Moving on to those slides.

So here are the criteria we did not adopt. We explain these...but were proposed. These criteria and the reasons for not adopting are explained within the rule, they are in section, I believe, 3(h)(5) of the rule and then there's also some requests for comment that we had in the rule that we did not go forward with as well. So, let's move onto the next slide.

So, these are the unchanged criteria and again, just for a refresher that means compared to the 2014 edition they're considered "unchanged" for the purposes of testing and certification, what that simply means is that test results that a vendor used to get their products certified to the 2014 edition can be used for certification to the 2015 edition at the discretion of the certification body. So, while there may be some minor changes, as you can see, here as compared to the proposed rule those changes don't rise to the level where they...where test results to the 2014 result edition could not be used for certification to this criteria.

And what you'll see here and throughout the discussion of the criteria we focused on reducing burden and reducing or, you know, cutting potential proposals in the interest of giving vendors more time to focus on interoperability as well as usability. And so as you can see here there are a few that we cut.

I do want to just mention on the labs we have strong support for lab interoperability, we think that's a key component to patient care particularly across the continuum, however, based on the status of the current standards we think it's better to focus on piloting them than going forward with direct adoption of them. So, that's going to be where our efforts are focused in the future for labs. We can move on to the next slide.

Again, just some more criteria that are unchanged compared to the 2014 edition. I will note on the lab one again here is another example where we had proposed a different version of the standard but based on our discussions with SDOs, through fact-finding, as well as stakeholder feedback we understand there is a potential for a newer version coming out soon to make sure that all lab IDs are aligned and with that in mind it didn't make sense to go forward as we discussed in the rule with what we proposed so instead we relied on the 2014 edition standards of which the data shows over 80% of hospitals are using and therefore, again, reduction in burden for vendors and providers. So, let's move onto the next slide.

So here you have a total of 25 criteria in which there are some changes that would lead to new testing but as I'll discuss we've tried to limit the "burden" here wherever we could and still improve interoperability.

So, demographics we've obviously adopted a lot of new standards there to improve interoperability. We went forward with all of those proposals but also added sexual orientation and gender identity data in a structured way using SNOMED.

Problem list, we...in response to stakeholder feedback, and I'll mention this at the end of the presentation about the test procedures that are out now for comment as well as the certification companion guides, we did get comments about, hey, for products that have already been certified to SNOMED can you consider potential attestation to the newer version of SNOMED because that's all you've done in terms of finalizing a new baseline. So, that's something we're considering through the test procedures.

For CDS, a lot of clarifying being done, a lot of...some draw proposals really the only adoption here is a newer version of InfoButton, same with patient specific, education resources and then let's get to transitions of care.

So, based on comments received and concerns expressed and working, you know, with the SDO, working with them, we went ahead and adopted a newer version that came out through HL7 which is Release 2.1 and we also limited it to just three templates as compared to what we proposed which I think was something like 10 to 12 I can't remember exactly. And then we did it in a way that we still believe will lead to interoperability both in terms of exchanging with a product certified to the 2014 edition as well as potential, you know, future products and future versions of the C-CDA. I think we can move on.

We did adopt some of our patient match data and we did a few in a structured way such as sex, such as telephone number and then address, well not...excuse me name, while not to a specific standard we identify how it would have to be represented and then address itself while we didn't adopt a particular standard we do rely on essentially the HL7 postal format for address since this will be wrapped up into the Consolidated CDA. Moving onto the next slide.

So, again, you'll see that, you know, I guess I'll call it a theme going through where we've moved to Release 2.1 everywhere and focused on just the template that made the most sense for each particular criteria. For ePrescribing we did not adopt structured Sig, we did provide some clarification and we did adopt the rest of our proposals there like for instance the different types of prescriptions that with health IT we should be able to capture.

Data export, a big one here, obviously we changed the name but another thing was we looked at that three-year look back period that we were proposing, we thought about it, and this is explained much better in the rule, but, you know, how that would impact a new developer, like how would they have a look back period how that would be...the capabilities would be so contingent on, you know, the quality of the provider's data there. So from a testing and certification perspective at this time we didn't think that was feasible so we dropped that proposal. As you can see on CQMs we moved, based on public comment, to the newer version Release 3 and we can move onto the next slide at this time. We have a lot to get through.

So, just quickly I'm going to focus...as you can see on the privacy and security we went raising the bar to SHA-2. We did go forward with requiring auditing of user privileges.

VDT, so what we did here, a couple of things worth mentioning, we did add in some more user capability so you have the filtering capabilities based on time and date similar to what we had proposed for data export and that actually goes into the API criterion as well.

We made it consistent with our privacy and security framework so anything that was an embedded security requirement we pulled out of criteria and just made it part of a specific, you know, of the privacy and security framework and then we applied it back to that criterion as appropriate. We did the same thing with secure messaging as you can see.

Another thing worth mentioning on VDT obviously is that for the how to transmit, so now we were more...we focused on what is happening in the marketplace so we focused on e-mail but we also focused on an encrypted method which could be Direct but we're not focusing on just Direct anymore.

So, I want to move down to public health. So, much here, we kept all of the criteria but you're seeing like what we've done is we've moved to, in some cases, a newer version of the standard to improve interoperability, most of these newer versions are just addressing any ambiguities that were pointed out through comment as well as any errors. So that's what happened there. Okay, I lost my screen for a second. Let's move onto the next slide.

Okay, so worth pointing out, safety-enhanced design, we came in at a...we had requested comment and we came in at a minimum test participant threshold of 10. I think the data that we cite in the rule and was presented even to congress is that as you...the more test participants that you use, particularly if you get up to 20, you can reduce errors as much as 95% I think at the...the data found that using a minimum of 10 reduced errors by 80%. So, considering, you know, we had just adopted this criterion in the 2014 edition and we wanted to take an incremental step forward we set the baseline at 10 in this rule. We also expanded it to more capabilities where data has shown that this could lead to potential safety errors, so, like, you know, for instance the input of demographics data has shown when it's done incorrectly can lead to medical errors. So we're applying the safety-enhanced design requirements to that criterion.

So, QMS, we just clarified about that it was identification of QMS but as compared to the 2014 edition now you must show you either use a QMS or map to one. No longer saying you don't use one at all if you are a developer and still passing certification that is.

Direct, we did a few things here to improve interoperability so we went to the newer version of the spec, we actually required delivery notifications. This all came out of comments where they were presenting that pointing out concerns if we didn't do certain things. So we went forward with, as you can see here, these finalized provisions that we believe will improve interoperability in relation to using Direct. Moving onto the next slide.

So here are the new criteria. API, which I'm sure we'll have some discussion on. Here's a list of some of how it changed. We split into five based on comments which provides flexibility and I always like to drive home the point, while we may have a...what looks like "a lot of criteria" many times we're splitting criteria to provide or splitting criteria based on functionality to provide more flexibility in certification so API went from one to five in the past CDS went from one to three.

And so here essentially is the five, as you can see the trusted connection and auditing are the security capabilities applied back to API through the privacy and security framework. We do focus just on the CCD template and we spent a lot of time in the rule talking about if you want to talk in terms of page numbers, eight pages we spent talking about security in the rule related to API and I'm sure we'll talk more about it in terms of questions and answers. Let's move onto the next slide.

So, implantable device list, it went under some minor, I'll call minor, revisions based on public comment on how things could be achieved and where the focus lied. So, you know, it's not necessarily having to be able to act specifically access the GUDID, the Global Unique Device Identifier Database, but being able to get that data so if you can get it from a local source that's okay too from a certification perspective but, you know, the database has an easily accessible interface now through NLM so that addressed some of the commenters concerns. What else worth mentioning here? I think that covers it.

I mean, for the most part our proposal was as...we went forward finalizing most of what we proposed and again it's part of the base EHR definition and data as part of the common clinical dataset and again that focuses on patient safety.

So the patient health information capture criterion, there seemed to be, not I guess, surprisingly, some confusion about that criterion. So, what we did is we combined some of the capabilities. So, we initially had it set up like capabilities to, you know, record and capture like documents and then we had a separate like provision related to directly and electronically accepting information from patients and we essentially combined that capability together as one capability for certification because that's what we were looking for is like essentially getting information from the patient electronically.

And we did point out while this can support Stage 3 it was not intended to be a one-for-one proposal to fully align and support the measure that was proposed and finalized under the EHR Incentive Program and that for example is why it was included specifically in the certified EHR technology definition to ensure that this was a, you know, foundational ability of health IT to support capturing that information and we provide definitely a lot of flexibility in how that's achieved, we're not specifying any particular standard, while we are specifying some privacy and security requirements in terms of getting certified we're not specifying a specific format or standard in which to capture that information.

Case reporting, another public health one, where we, in this particular incident based on the status of standards we tried to focus more on functionality and didn't go forward with SDC or another standard particularly like a C-CDA, while that could be used in terms of getting certified to it, we're not specifying the standard there. Let's move onto the next slide. A couple more.

We did go forward with the accessibility-centered design, it is a structure that's very similar to originally how we did QMS so that you can, if you're a vendor, you don't use any accessibility-centered design, you don't do anything consistent with federal law related to accessibility, you can still pass certification however that information will be on our Certified Health IT Products list and can be easily downloaded by associations and other entities that care about that information and they can analyze it and repurpose it as they deem necessary and that's what we think, you know, with the open data sample can happen in a lot of areas in terms of analyzing health IT that's certified to the 2015 edition.

So then we have seven criteria that we adopted that support use cases I'll say just beyond the EHR Incentive Program. I think a lot of the functionality that supports the EHR Incentive Program can also support use cases beyond the EHR Incentive Program but here what I'm going to talk about very quickly is a few criteria that aren't actually associated with EHR Incentive Program but where we believe have tremendous value in improving both interoperability and patient care.

So the social psychological and behavioral health data criterion was adopted as one criterion with all the measures that we had proposed in terms of capturing certain information about like domestic violence, alcohol use and so forth and it's available in certification against structured standards, as you can see there LOINC, so we think that, you know, use of that functionality and capturing that information would obviously improve individualized patient care and also for certain, you know, at risk populations of patients.

So moving onto the next the row the common clinical dataset summary record. So this is essentially focusing on the Consolidated CDA and the common clinical dataset for certification without the transport standards requirement. So, this is the B1 criterion without transport. So, this is to support other settings.

So for example, a good example is chronic care management where there is a requirement to be able to, you know, create the Consolidated CDA but we didn't want to force upon other entities or other programs the need to have products say certified to something that supported a different particular use case in this instance, the transport standards, that are associated with B1. So based on public comment we adopted these two criteria and we split them out actually based on create and receive to provide more flexibility for certification. Moving onto the next slide.

So you have the care plan one that we adopted, that we proposed and adopted to support the broader care continuum. You have data segmentation for privacy that we also adopted at the document level tagging and that is to support what we think will facilitate the sharing of more information about patients particularly some areas in addressing health disparities as well.

And then the filter criterion we also adopted which will support other use cases such as group practice reporting or ACO reporting that relies on the QRDA standards. We can move onto the next slide.

So, I just want to real quickly highlight, we've talked about almost everything on this slide but we wanted to kind of bring it together on one slide to show that ONC, even through certification and definitely outside of certification, has a strong interest and focus on patient safety we always have whether it's the action plan that we've put out in the past, the roadmap or where we can through certification. We've tried to focus on patient safety and this kind of just brings all that together for you in one slide but I've talked pretty much about all of that already. And then moving onto the next slide.

So health disparities also a goal in terms of trying to reduce health disparities through the use of health IT for ONC. So, here brings together, again, things that we've already talked about that have been finalized but showing how together some of our proposals that have been finalized should help providers in addressing health disparities. And moving onto the next slide and the next slide.

So here in one slide for you I tried to show you all of the criteria adopted. So real quickly, the first column is mandatory criteria and what we mean by mandatory means any health IT module brought forward for certification no matter what other capabilities were within that module they must be certified to both of these.

In that second column is what we call conditional certification criteria and so depending on what else is in that health IT module they will have to be certified to these criteria as well. So for example, if you had CPOE you were going to get certified to the CPOE criteria you would also have to get certified to the safety-enhanced design. If you're going to get certified to the transitions of care criterion you're also going to have to get certified to the Consolidated CDA creation performance and practically in every instance you're going to have to get certified to certain privacy and security criteria. So, depending on, you know, if you go back to that table that we talked about depending on what other capabilities are in your health IT module you will have to meet certain privacy and security capabilities.

And then the middle column is all the criteria that are associated with the EHR Incentive Program. Obviously, with the public health ones there are choices there for providers as to which ones they'll choose to meet and we'll talk a little bit more about that in the next slide, but overall really what's new is just the patient health information capture, the API criteria and the implantable device are what's new beyond public health.

And in the last column, we've talked about those criteria that support other use cases and settings beyond the EHR Incentive Program and the key there I think is I think we caught everything based on feedback to make it more understandable in terms of what all the different colors and highlighting mean. So as you can see red means unchanged and so forth. So, let's move onto the next slide.

So, this is a backdrop slide to help understand the following slides so this just lists all the objectives for Stage 3 of the EHR Incentive Program. Moving onto the next slide.

So, one thing...this is how you would possibly build your certified health IT meeting the certified EHR technology definition to participate in the EHR Incentive Program Stage 3 and as you see underlined here we're talking about 2018 and beyond because, I should mention, prior to that you can use a mix of 2014 and 2015 edition products to meet the requirements under the EHR Incentive Program and I should particularly note that if you're attempting to do Stage 3 in 2017 you can continue to use 2014 edition products and really the only particular areas where you're going to be looking to have to use 2015 edition products are going to be API and then with the patient information capture objective potentially.

So, this is another way, this slide, how it would look in 2018 for a potential provider and a developer in terms of getting their product certified. So, once again, you see those mandatory and conditional requirements then you build, which is part of the CEHRT definition, the base EHR definition that we talked about. Then there are additional specific requirements within the CEHRT definition, these are listed here, particularly related to CQMs, capturing family health history, the Meaningful Use measurement capabilities and then above that you have the criteria that particularly support objectives of Stage 3 and there are charts actually in the EHR Incentive Program that we work closely with CMS in terms of putting together to identify essentially like this what criteria support each particular measure and objective actually so it goes down to the measure level in those charts and we're working with CMS to put together supplemental material which will pull all the criteria together including like the base EHR criterion and so forth.

And just real quickly, the dark blue just identifies criteria that are already in the base EHR definition so once you've met that you're going to have these capabilities already.

And so that's just it kind of in a graphic way showing you how you would meet the EHR, excuse me, the certified EHR technology definition in 2018 in support of Stage 3. So, we can move onto the next slide.

This is just a little bit of data about comparing the two, you know, what's required now compared to what was required for the 2014 edition. The numbers, as you can see, don't change too much in terms of how many criteria need to be met but let's move onto the next slide.

So, this is, you know, using the 2015 edition to support other use cases particularly in this instance long-term post-acute care so we just have an example here, I would emphasize, of what a potential module could look like that would get certified supporting another setting beyond inpatient and ambulatory.

And then the next slide that we go to is a behavioral health example. These are very simple to the examples we used with the proposed rule. And then the last slide, I believe.

So, this is additional information and resources, a couple of things to emphasize, there is no comment period on the 2015 edition final rule. So it is final but it is not effective until January 14th. We had a 90 day, actually delay in effective date which is normally we have a 30 day but we extended it to 90 day and then some provisions related to the certification bodies aren't effective until actually April 1st.

And you can find more information including this presentation at that link there in the middle. And last I want to point out as I mentioned earlier we have out for comment right now some of the test procedures and they'll be coming out on a rolling basis as well as the certification companion guides and these are geared towards developers in terms of meeting the criteria so, you know, those interested in that I encourage you to review those and provide comment as appropriate. So, I think we are now finished and open for comment.

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

Okay, well, thank you so much and Michelle I have to imagine there is a queue that I don't need to seed.

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

Dixie Baker.

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

Dixie?

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Holy cow I was the first out of the shoot how about that? I just want to tell you guys, on behalf of everybody who's been on what used to be the Security Working Group, how please I am to see that you've implemented exactly the certification approach that we recommended which is to require that all HIT modules to be certified against the security, those security criteria that apply to the functions that the module actually performs. I realize that many current members of the Standards Committee may not be aware of the protracted discussion the Security Working Group engaged in on this topic and so I do want to thank you for that.

Also, I was pleased to see the recommendations add security to the API and to not adopt esMD were followed and so I just want to personally thank you for listening to our recommendations.

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

Well, thank you. We always try to...always try to take stakeholders feedback into account and weighing in, you know, of competing interests, but we do believe that we've hit the sweet spot on privacy and security certification. Hopefully that's the case moving forward.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

Yes, I think you have. Thank you.

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

So, Michelle, who is next?

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

Leslie had her hand up but did you change your mind Leslie?

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

Leslie?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Sorry, I was on mute. I just had one question I wasn't sure whether it was a combination of this group and the previous group about secure messaging and secure e-mail. The requirement is that its e-mail in the clear can be used but there is a lot of confusion about can it be used all the time and by design or by exception? So, it's both a policy question and a standards question about what can and can't be used in secure messaging.

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

So, I'll take a crack at this not my...so, you know, what we do from our perspective is enable the health IT we don't necessarily...I think that's where you start to see some of the HIPAA policy come into play particularly if you're a covered entity. We're just enabling health IT to do it in an unencrypted way I guess is the way to say it but also in an encrypted way and that's based on what we've seen, you know, from both stakeholders in the way of patients interact. So, I mean, I don't know if that necessarily answers your question.

From a standards perspective we are, you know, like we would apply for like secure messaging that particular one they would have to show an encrypted, you know, method for either, you know, hashing or through encryption at the minimal level of SHA-2. So we've actually increased that security requirement there if that helps.

Elise Sweeney Anthony, Esq. – Acting Director, Office of Policy – Office of the National Coordinator for Health Information Technology

And this is Elise, so, just to echo that, from our side of it we can discuss it and because the Stage 3 components are out for public comment, we, in the same way CMS is restricted, we cannot comment on it, but if there is some clarification that would be helpful to the language in the Stage 3 provision I think that they would be open to comments on that.

Dixie B. Baker, MS, PhD – Senior Partner – Martin, Blanck & Associates

May I add something here? Your question, Leslie, is really a policy question not a technology one. In the introductory material for HITECH they addressed the use of e-mail to communicate with patients and basically the policy, as I understand it, you know, is with the patient's permission they can use unsecured e-mail but that's not a technology issue that's really a policy issue.

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

Well, very good. So, Michelle, who is next?

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

Floyd Eisenberg.

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

Floyd?

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

Wow that soon, so my question is about safety-enhanced design. I apologize for not having read all the details but when I see you indicate a minimum of 10 participants are you talking about summative evaluation and user centered design?

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

Yes, summative.

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

All right.

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

We're not requiring any formative...while we took comment...we asked for comment on that we did not adopt any proposal or excuse me any final provision related to formative testing. I think there was, if I can just characterize stakeholders feedback, there was not consensus about that there is value to it but the question was there value to it for certification and then also considering burden. So, as we have before we focused on summative testing and, yes, to directly answer question that is in relation to summative testing.

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

The reason I ask is from what I've seen I thought a valid summative test required 20 participants. So is this kind of a compromise valid to what was there before?

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

So, I would say that is subjective, right, whether how many is the right amount. I think there is data that shows, and we cite that data in our rule, that if you were to go to 20 that you could reduce errors by up to 95%. So we, as to the reasons discussed in the rule, settled as a minimum, and I want to say minimum, threshold of 10. So, we continue to encourage, and as we say in the rule itself, for developers to use more than 10 and particularly to use test participants that are appropriate for that particular capability that's being tested as well consistent with the NIST guidance and rely heavily on that NIST guidance.

But, I think, you know, going from...we just, as we discussed in the rule, determined that 10, and we did get comments...well, I should note we got comments from, you know, all interested stakeholders. We got comments from usability experts at various academic settings. We got comments from both large and small vendors, comments from patients and so forth, providers and with all that information...and a lot of them suggesting different numbers. We had numbers from 10 to 12 to 15. We didn't actually get many comments or any I believe suggesting 20 only recently we saw data come out suggesting 20 was a more appropriate number.

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

One more follow-up and then I'll stop, but, I was under the impression that to do the evaluation...are there criteria for what the report should include to make it acceptable?

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

Yes. So, again, another, I think it was a point of while we always intended that there was a point of confusion with the 2014 edition and we saw, as I think you are all aware, different public, I guess reports or analysis, as to what vendors were actually doing but we made that more explicit now and not only have we made it explicit as to what is required, what information must be reported, we also went back and we've issued guidance to our certification bodies to address that with the 2014 edition as well. So we expect that data to be there for the 2014 edition but with the 2015 edition we've actually put it into Reg text as well to make it is clear as possible.

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

Okay, well, Michelle, who is next?

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

John Derr.

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

John Derr?

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative

I just, first I wanted to apologize I think I was premature in my comments before, I want to thank you for including post-acute care and all the comments and the work we did in this certification and this will be very helpful. Thanks a lot.

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

Thank you.

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

Next?

Elise Sweeney Anthony, Esq. – Acting Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Thanks.

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

Rich Elmore.

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

Rich?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Hi, thanks, I have a couple of comments and questions. First on the field surveillance I think that our experience is that, you know, customizable solutions, the auditors I think have been somewhat challenged in the complexity of regulations and applying with these applications it's only going to be exacerbated with field audits and I just wanted to find out if there had been...what thought had been given to what process had been put in place to ensure that there was adequate dialogue with the developers as well as with the providers to ensure that there was, you know, good lines of communication?

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

Yea, so that's not specifically addressed in the rule but it will be addressed for our surveillance guidance. So, we initially issued surveillance guidance to our certification bodies early this summer which is being updated based on this final rule and should go out shortly to them and one of that is including a meaningful opportunity for any comments or dialogue based from the vendor that's consistent with the ISO standards that are required, you know, for a certification program. And I think you'll have the same thing with the providers.

I mean, some of this, I won't say all of it, I mean, first let me go back and say that in field surveillance has always been within the purview of our certification bodies. What we've done with this rulemaking is try to give some parameters that provide consistency and ensure that it's actually happening. So starting there I think when they go...what we think from a provider perspective is we've heard that there has been concerns. We've heard concerns on multiple grounds. We've heard concerns about needing additional assistance from vendors to use certified capabilities. We've heard that there were additional costs that they were not aware of and, you know, we've tried to address that through to the transparency pieces as well.

But we've also...we've heard about, you know, information blocking and so we think that they will be receptive based on these types of feedback that we've heard to having our certification bodies come in and do this type of surveillance of a product. And I think they would obviously maintain a close dialogue with both the vendor and developer in terms of trying to figure out if there is a problem at all with the product and then why that occurred because I think in the end I think the goal of every...us, the provider and the developer is to correct the problem and ensure patient safety because that's, you know, one of our main focuses within the field surveillance is not only ensuring that the providers get to use these capabilities that they've, you know, contracted for, but also to ensure that any potential error or missed implementation or so forth, or use of the capability doesn't lead to, you know, a patient safety issue.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Thank you and just moving onto another comment. I mean, I think that you have a few opportunities with this final rule. So, my comments are more towards, you know, Steve Posnack...what to expect when you're done expecting the final rule, you know, and I think there are a number of steps that ONC is taking, which I applaud, related to testing and other things that you can do which I think will help the industry to do a good job of implementing the regulations.

And, you know, as we look at for instance the ability to detect and display errors in content, you know, this whole notion of a robustness principle of being able to gracefully receive information I'm very concerned about that requirement and what it could actually do to, you know, bad implementation, what it could do to providers and what they have to try and do with this information.

And I think we should really be forgiving about what we import. And so, I would just encourage you, as you're looking at how you test and what examples you put forward, that you're very thoughtful about that.

So for instance NIST today has examples of content tests on its site, there are errors of properties and attributes that probably we shouldn't care about and so I think thought given there can make sure that we do, you know, a good job in encouraging interoperability rather than discouraging interoperability and given our overall focus as an industry on that I think this is a particularly important area.

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

I appreciate those comments and I'm sure you've made them to Steve and I'll definitely relay them to Steve and I just want to say one kind of point on that in that we've always tried to be responsive to stakeholder feedback but also provide flexibility which is always a delicate balance. So, you know, we try to definitely not be prescriptive to clinical workflow but then on the other side, I just want to say, like we do want to enable the provider or address their comments. So, like some of the new things, I guess you'll see in the final rule related to transitions of care and particularly related to display, is that we had, you know, some requirements to enable the user to display, you know, only the data within a particular section to set preference for the display order or specific section and also the initial quantity of sections to be displayed. So, that was directly in response to stakeholder feedback and, you know, like I said while we don't want to try to specify a particular clinical workflow we do also want to try to address some of the provider feedback that we got.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Thank you and if I may, just one last comment. Along in the same spirit, which is, you know, the examples that use set and the guidance that you can give kind of post rule I think will make a difference as it relates to data segmentation for privacy.

When a coded document arrives, you know, kind of what is done with that document I think is not necessarily clear in the final rule and I think that there's a really important decision to be made about how that is going to be handled and, you know, kind of what then is an important question to be asked and to be answered and if the industry kind of understands that I think it will evolve, it will really be helpful and it's an area where I think that ONC can really have an impact. Thank you.

Elise Sweeney Anthony, Esq. – Acting Director, Office of Policy – Office of the National Coordinator for Health Information Technology

We can...

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

Just to comment, and I was going to say, like I mentioned, I will definitely take that back to our folks but I'm not sure if that test procedure is out yet but obviously a worthwhile comment as well on that test procedure too.

Elise Sweeney Anthony, Esq. – Acting Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Yeah, I was actually going to say the same thing, Mike, we're on the same page here.

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

Okay.

Elise Sweeney Anthony, Esq. – Acting Director, Office of Policy – Office of the National Coordinator for Health Information Technology

I also think that we will definitely share that with our team, our privacy team here as well, I think we're always open to guidance that can help in terms of how things are kind of put together it is something that we're really committed to and hopefully you guys have seen we've done a lot that this round of rulemaking in terms of releasing fact sheets as well as the PowerPoint pretty early on. We're also doing some charts. I will take that back to Lucia and our privacy team.

I think there's also a part where, you know, our rule is obviously technology focused in terms of technical specifications. There is also a larger conversation, as you were discussing earlier with, you know, Rob was discussing where there is an intersection between what we're doing and some of the work that OCR is doing. So, we work with them closely and I think that's something we can also share with them.

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

So, Michelle, how are we doing on the queue?

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

There is no one else in the queue.

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

Well, one last question and then we'll go to our public comment, and that is that I recognize that ONC tries to debate between specificity and under specificity and in the use of the API there is no standard required.

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

Right.

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

And I just wonder...I mean, we know that there is standards advisory and so hopefully that will provide the industry guidance but if there is an API requirement and every vendor implements those APIs differently I worry about that not actually enhancing interoperability but causing more chaos. Any comment on that?

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

So, I think that John that's a point that was also raised by commenters and we just...as discussed in the rule, didn't think, both from a security one, because we looked at like a lot of those and this is way out of my league, but like OAuth and HEART, and so forth and just the readiness for that part of it as well as the other part in terms of identifying a standard we just didn't think that was there yet.

But I can say, because it says it in the rule, is that we intend to move to standard in the future. So, while, you know, how long you wait on that and how much problem that could potentially cause if different divergent ways are implemented we're, I think, appreciative of that potential but at this point in time we didn't think it was appropriate obviously to adopt a particular standard or standards.

We do though through the documentation piece require those vendors to document what standards they're using both from a privacy and security perspective and from a content perspective and that should at least help in terms of, you know, building Apps to the API. So, that's about all I can say on it right now.

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

Very good. Okay, well, Michelle, it does seem like we have exhausted everybody and the slide stacks were actually much shorter than the actual regulation so bravo. So, Michelle, I presume our next administrative item is to open up for public comment?

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

Yes. Operator can you please open the lines?

Public Comment

Lonnie Moore – Meetings Coordinator – 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 telephone and would like to make a public comment, please press *1 at this time.

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

And Michelle while we're waiting for public comment could you just remind us about the details of our next meeting?

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

Yes, so our next meeting is December 10th and it will also be virtual.

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

Very good currently I have in the books for 9:30 to 12:30.

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

Yes and it looks like we have no public comment.

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

Okay, well, certainly, again, thanks to everybody at CMS and ONC for all of their hard work and presentations. I think we all look forward to getting additional feedback from the field and seeing how all of these policies rollout in the ecosystem ahead. So an interesting time for us all. So, with that...

Elise Sweeney Anthony, Esq. – Acting Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Thank you very much John.

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

Indeed, well, thanks. Michelle, any final words before we close?

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

No, thank you everyone.

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative

Thank you.

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

See you in December. Thank you.

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

Bye.

M
Bye.

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative

Have a nice Thanksgiving, bye.

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

Yes, you too, bye-bye.

Meeting Attendance							
Name	11/03/15	10/28/15	09/22/15	08/26/15	07/29/15	06/24/15	06/11/15
Andrew Wiesenthal	X		X	X			
Angela Kennedy	X		X				
Anne Castro	X					X	
Anne LeMaistre	X		X	X		X	
Arien Malec	X			X		X	
Charles H. Romine	X						
Christopher Ross						X	
Dixie B. Baker	X		X	X		X	
Elizabeth Johnson			X			X	
Eric Rose	X		X	X			
Floyd Eisenberg	X		X	X		X	
James Ferguson			X	X			
Jitin Asnaani			X				
John Halamka	X		X	X		X	
John F. Derr	X		X			X	
Jon White	X		X	X		X	
Josh Mandel	X		X				
Keith J. Figlioli				X		X	
Kim Nolen	X		X	X		X	
Leslie Kelly Hall	X		X	X		X	
Lisa Gallagher			X	X		X	
Lorraine Doo	X		X			X	
Nancy J. Orvis	X		X			X	
Patricia P. Sengstack	X		X				
Rebecca D. Kush			X	X			
Richard Elmore	X		X				
Steve Brown			X			X	
Wes Rishel	X		X			X	