

**HIT Standards Committee
Transcript
July 17, 2013**

Attendance

The following members attended the meeting:

- Dixie Baker
- Kevin Brady for Charles Romine
- Steve Brown
- Anne Castro
- Jeremy Delinsky
- Lorraine Doo
- Tim Cromwell
- Jeremy Delinsky
- Floyd Eisenberg
- Jamie Ferguson
- Keith Figlioli
- Lisa Gallagher
- John Halamka
- Leslie Kelly Hall
- Stanley Huff
- Elizabeth Johnson
- Rebecca Kush
- Anne LeMaistre
- David McCallie, Jr.
- Kim Nolen
- Jonathan Perlin
- Wes Rishel
- Eric Rose
- Christopher Ross
- Andrew Wiesenthal

The following members were absent:

- John Derr
- C. Martin Harris
- Arien Malec
- Nancy Orvis
- Sharon Terry

Presentation

Michelle Consolazio – Office of the National Coordinator

Good morning everyone, this is Michelle Consolazio and this is the 49th meeting of the Health IT Standards Committee. This is a public meeting and there will be time for public comment, there will be time before lunch and at the end of the meeting and all public comments will be limited to three minutes. Please keep in mind that the meeting is being transcribed so please identify yourself when speaking and for those of you who would like to Tweet the hash-tag for the meeting is “#HITStandards.” Today we’re going to do roll call a little bit different. We haven’t been together for a while and we’re going to allow people to provide just one or two quick sentences to describe who they are and introduce everyone. So, I will do roll call and you can announce yourself. John Halamka?

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

Present. You want two sentences, I’m the CIO at Beth Israel Deaconess and I oversee a lot of healthcare information exchange activities in the Commonwealth of Massachusetts.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Can you guys just speak closer to the microphone; it’s a little hard to hear.

Michelle Consolazio – Office of the National Coordinator

Jon Perlin?

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

Good morning, Jon Perlin, Chief Medical Officer at HCA and adjunct Faculty in Biomedical Informatics at Vanderbilt.

Michelle Consolazio – Office of the National Coordinator

Dixie Baker, she is here, but not here, oh...

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

Yes, I’m Dixie Baker; I’m with Martin, Blanck and Associates.

Michelle Consolazio – Office of the National Coordinator

Anne Castro? Jeremy Delinsky?

Jeremy Delinsky, MBA – Senior Vice President, Chief Technical Officer – Athenahealth, Inc.

I’m Jeremy Delinsky I’m the Chief Technical Officer at Athenahealth up in Boston.

Michelle Consolazio – Office of the National Coordinator

John Derr?

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

He’s not here.

Michelle Consolazio – Office of the National Coordinator

Floyd Eisenberg?

Floyd Eisenberg, MD, MPH, FACP – Independent Consultant

Hi, Floyd Eisenberg, I’m an independent consultant in quality and decision support.

Michelle Consolazio – Office of the National Coordinator

Jamie Ferguson?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning – Kaiser Permanente

Hi, Jamie Ferguson here, I'm the Head of Health IT Strategy and Policy at Kaiser Permanente and a Fellow of the Institute for Health Policy.

Michelle Consolazio – Office of the National Coordinator

Keith Figlioli? Lisa Gallagher?

Lisa Gallagher, BSEE, CISM, CPHIMS – Senior Director of Privacy & Security – Healthcare Information & Management Systems Society

Hi, this is Lisa Gallagher; I am Vice President of Technology Solutions at HIMSS and have a background in data security and privacy.

Michelle Consolazio – Office of the National Coordinator

Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Leslie Kelly Hall, Healthwise Consumer Advocate helping people makes better health decisions.

Michelle Consolazio – Office of the National Coordinator

Martin Harris? Stanley Huff?

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

Stan Huff with Intermountain Healthcare I'm the Chief Medical Informatics Officer.

Michelle Consolazio – Office of the National Coordinator

Liz Johnson.

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

Hi, I'm Liz Johnson from Tenet Healthcare, Vice President for Applied Clinical Informatics.

Michelle Consolazio – Office of the National Coordinator

Becky Kush? She is here, but she's not here right now. Anne LeMaistre?

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

Hi, I'm Dr. Anne LeMaistre I'm a Medical Informaticist and I'm the Senior Director for Clinical Information Systems for Ascension Health.

Michelle Consolazio – Office of the National Coordinator

Arien Malec? Dave McCallie?

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

Good morning, David McCallie, Senior Vice President for Medical Informatics at Cerner in Kansas City.

Michelle Consolazio – Office of the National Coordinator

Kim Nolen?

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

Hi, I'm here, I'm Kim Nolen I work in Medical Affairs at Pfizer.

Michelle Consolazio – Office of the National Coordinator

Wes Rishel?

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Hi, I'm Wes Rishel, I'm an analyst with Gartner in the healthcare space and I've been working on Healthcare IT standards since they had to do with how big the strings were on the abacus.

Michelle Consolazio – Office of the National Coordinator

Eric Rose?

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

Here, I'm Director of Clinical Terminology at Intelligent Medical Objects.

Michelle Consolazio – Office of the National Coordinator

Cris Ross?

Christopher Ross, MBA – Chief Information Officer – Mayo Clinic

Good morning, Cris Ross, I'm Chief Information Officer for the Mayo Clinic.

Michelle Consolazio – Office of the National Coordinator

Sharon Terry? Andrew?

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

Andy Wiesenthal.

Michelle Consolazio – Office of the National Coordinator

Any Wiesenthal?

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

Hello, I'm Director at Deloitte Consulting.

Michelle Consolazio – Office of the National Coordinator

Steve Brown, he's not here but he is the new VA representative for Tim Cromwell.

Steven H. Brown, MD, MS – Veterans Health Administration

Hi, I'm Steve Brown; I'm the new VA representative for Tim Cromwell.

Michelle Consolazio – Office of the National Coordinator

Lorraine Doo?

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

Hi, Lorraine Doo, Senior Policy Advisor with the Office of eHealth Standards and Services at the Centers for Medicare and Medicaid and a fan of Wes Rishel as long as I've been alive.

Michelle Consolazio – Office of the National Coordinator

Nancy Orvis?

Michelle Consolazio – Office of the National Coordinator

Okay, oh, Charles is on the phone?

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

Kevin Brady for Charles Romine, Dr. Romine is the Director of the Information Technology Laboratory at NIST.

Michelle Consolazio – Office of the National Coordinator

Thank you everyone, and with that I will turn it over to David Muntz.

David Muntz, MBA – Principal Deputy National Coordinator – Office of the National Coordinator

Thank you and appreciate everybody participating today and all the participation that has occurred prior to today, 49 is quite a remarkable milestone to get to. Wes said that he was around when the abacus was done, well when I started in computers they only had zeros the one's hadn't been invented yet. So, we are pretty close in age I think.

First of all we are going to smile and shed a tear at the same time this morning. I think many of you know that MacKenzie who has done an extraordinary job is moving on elsewhere. So, that is a tear, we would like to at least go ahead and applaud her.

[Applause]

Thank you for the extraordinary work and succeeding her will be Michelle who helped us open, its Consolazio, so there has been a name change. She has done work on the Meaningful Use Workgroup staff as a lead and so I am sure that she will do a great job and you will be getting the e-mail and consistently high service that you are used to so we are very pleased to have her. So, welcome aboard and glad you've got the new thing.

I'd like to welcome everybody the weather here seems to be a lot of discussion. So, usually Washington is topical, this time it's tropical, so we appreciate that everybody made it. It's a pretty unusual day. We've had some good public press that represents or at least talks about the work that is being done by those who are around the table here and the people you represent. ONC has the – I guess the privilege of being able to talk about all the work that gets accomplished and we get an opportunity to do that a lot in the trade press and so we are very happy about that but when it gets into the earned media we smile a little bigger, we stick our chests out and again we are not bragging on what we've done, we're bragging on what you have done.

So, this week we've had Farzad do an interview on NPR which was played either the night before – I think the night before last or last night, nonetheless, it's easy to find and we hope that you will do that.

And then today, I don't know what newspaper this hotel necessarily puts out in front of your hotel room but USA Today is the largest publication in the world and if you happen to look in the money section you will see an article that talks about the fact that we have now moved most of the patient records to electronic format which is a pretty remarkable pick up and it's the people and the work on this committee that makes all that possible. So it is with wonderful gratitude that I say thank you.

The other thing that's going on today and it's another measure of success, if you will, and by the way I'm somebody who believes that the glass is all full, half liquid, half air. So, necessarily I'm optimistic given the fact I was a CIO, it's a survival quality that's nearly important – I remain very positive.

Nonetheless, the fact is that the Senate hearing, the Center for Finance Committee today has asked or invited Farzad Mostashari and Patrick Conway of CMS to come to their chambers and he will be doing an interview, if you will, with the Finance Committee this morning and it starts at 10:00 o'clock. So, a moment of silence as 10:00 o'clock nears if you don't mind it would probably be appropriate.

But, people say isn't it tough when people ask hard questions, it's actually not because that's when you get to have the meaningful conversations about Meaningful Use and when we get a chance to explain to people what their investment is getting them, I think that's a real opportunity for all of us and there is nothing we shouldn't be proud of. This is very, very hard work and when people understand that I think they are more empathetic and more supportive.

And so, I really am happy that the Finance Committee has asked people to come up and explain what it is that we're doing. It would be irresponsible if they didn't do that and so the transcript of this is available, actually they're going to streaming live which is very nice, it gives people an opportunity who have the interest to actually look in and learn what's going on. And I'm sure there will be tough questions and I hope there are, because we've got great answers for what it is we're doing and why this is just not as easy as sticking a CD into your drive, for those of you who remember CDs, and installing software. So, at 10:00 o'clock he will have that privilege and again, I just want to thank everybody for making the effort to get here today.

I got a chance to see all the materials that were going to be presented today and I look forward to looking at those presentations and hearing from you all live. So, welcome to DC. And John I will turn it over to you.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

Well, thank you, David and it really is I think an exciting time. It is hard to believe that we're at the 49th meeting, but I think when one reflects back on the cumulative agenda it's quite extraordinary and as Dr. Mostashari testifies this morning I think there is a great story to tell and that story is reflected in today's agenda. It's an agenda that doesn't speak only to the foundational aspects of interoperability and health information and support better health and healthcare, but it's an agenda that speaks both to providing the care and supporting the commerce and it's really extraordinary because those are properties that really rest on the strong foundation that has been provided and so much credit for that goes to the Office of the National Coordinator, great leadership and I want to thank all of my colleagues throughout not only ONC but on this committee and the Policy Committee and those throughout the field who have really turned policy direction and standards support into real-world implementations.

And John and I were chatting before and our organizations reflecting of the number of go lives that are occurring and these aren't go lives that are planned, this is now in the rearview window of systems that have been initiated, systems that are allowing, in our estimation, better care and systems that are endowed with the capacity not just to link providers but to link with patients and isn't that tremendous as well.

It was I think a milestone the past couple of months in a number of ways. Of course, one milestone, as David Muntz remarked, is reflecting on the great support and leadership that MacKenzie Robertson has provided for this committee and our thanks to her as she moves to ... to Spain, yes, okay, that's the secret. I didn't know if she was announcing it but she is going to be at least, for the immediate future enjoying discovery of Spain and we thank very much in advance Michelle Consolazio, I hope I did okay with that, for her leadership that she'll provide us. Many of you know she has been working for a long period of time with Micky Tripathi in Massachusetts and more recently with the Policy Committee's Meaningful Use Workgroup. So, there is a great continuity and nexus there.

Pieces of continuity and nexus with both the agenda and the future; when we think back on what has occurred both at the last meeting, albeit it virtual, Dixie Baker is due great credit for an absolute tour de force presentation. The NwHIN presentation ever so modestly presented a vision that really looked at a RESTful approach to health information exchange and invoked a number of standards and my goodness if you didn't feel sort of a chill at the back of your spine, because if you could imagine what it was like at the birth of the Internet, you just got a sense that this was a constellation of standards that would make that exchange of information for better health and care imminently possible and that is a really exciting proposition and this body's endorsement and concept of those leads to a lot of work that this group will be put in place with the Office of the National Coordinator to really define and refine those recommendations.

I think it's interesting because that commerce in the broadest sense of care provision as well as the financial transactions is supported in a way that's reflected in today's agenda and I'll come to that momentarily, but the inclusion of the patient and advocates for patients was very much a part of the discussion since our last meeting, I want to thank Leslie Kelly Hall and again the Office of the National Coordinator, if one looks at the hearing on patient generated data it was an absolute powerhouse alignment or array of individuals who brought diverse perspectives on how information from patients can and might be used in the future and I want to thank you Leslie for your leadership and work around that and really if people haven't had a chance to review the summary or look at the transcript of that it's absolutely fascinating and also provides I think a glimpse at the future.

As we move from the clinical aspects of interoperable health information there are requirements for the financial transactions and look forward John and Jamie and team to your reports on the very complex area of formulary and benefits management, would really be a boom to helping providers and pharmacies, and all of the different participants in the process of medication delivery and the transaction supporting it really move to more supportive electronic platform. A platform that also has the potential for the sort of real-time information that supports safety and just use that as a loose segue to later in the conversation when Jodi Daniel and her team talk about the organization or ONC's support for assuring not only that health information allows the improvements that are expected over paper, but as we move forward also supports a robust safety agenda.

I think Doug Fridsma and the team have also just done yeoman's work and the S&I snapshot is absolutely compelling in terms of the amount of work not that lies ahead, which there is quite a bit, but what's been done already and as Dr. Mostashari tells that story it's just really quite extraordinary what exists in terms of making this commerce possible.

Of course we always seek feedback and the Federal Advisory Committee process itself is built to engage feedback, it's built to really convene discussions in the most transparent and public way possible and that includes not only the important public comment session but also the conduct of hearings and seeking feedback and Implementation Workgroup will be preparing for July 23rd, next week, a number of really terrifically thoughtful and compelling questions to probe about both the challenges and the opportunities of the future.

So, as we close in on meeting number 50 as Dr. Mostashari goes to the Hill as we look at today's agenda, David, I'm with you it's not a glass half empty in fact this is a glass that's very full, it's full of potential, but I think as we reflect on what our colleagues around us have done I think it's a glass that's full of accomplishments.

So really excited and for the new members I want to welcome you formally and in person to this process, thank you very, very much for your commitment. We've often joked that the ONC is the office of no Christmas and you know that the work is fast, furious and doesn't obey the boundaries of holidays or other breaks. So, with that let me turn over – actually one formal piece of business which I'll come to momentarily, Andy Wiesenthal you have your card up?

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

Jon it's a classic engineering school joke I'm told that the glass is neither half-empty nor full but must be redesigned.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

Thank you for that, thank you for that, so new members will also find that the committee operates not only with diligence but good humor. Having had a chance now to take a look through the minutes are there any amendments or changes that are recommended? Okay, hearing none will assume consensus on those and without further adieu let me turn to Co-Chair John Halamka for additional comments. Dr. Halamka?

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

Well, certainly amplifying the comments both you have made. So, David was a CIO and he knows that it does stand for career is over, it is a very challenging time for those of us in the operational trenches, in fact you guys talk about a glass half-full, I would say it's over full and we have a challenge I think as a committee in keeping our momentum giving the operational pressures that we're seeing in all our organizations, ICD-10, Meaningful Use Stage 2, ACO formation, the necessity to control cost for these new reimbursement models that all of us are facing.

And so, I hope that as we look at today's agenda that the standards that we will be working on today and in our 50th and onward are standards that will contribute to some of these things that are really weighing heavy on the minds of operational people.

I mean, I sometimes worry about the Federal Advisories Committee's ability to sustain their energy given our day-to-day operational responsibilities. We're all volunteers. So, I look at the agenda and I think, well, okay on clinical operations we'll hear about two major themes the formulary and benefits transaction, which has been a major gap. We'll hear about some of the gap fillers and there will be a proposal with formal recommendations for you. And I'll give you the first, with Jamie who is on the phone, he is in the UK with a computer disaster so he is flying blind, but he knows everything so it will be okay.

I'll be giving you the first glimpse at our image exchange hearings especially as we think again about ACO formation and the need to control costs. We want to reduce redundant testing and sharing of images, provider to provider, provider to patient, provider to group, patients having stewardship and being able to direct images across caregivers, these are all very important standards and important concepts that aren't yet widely deployed. So, I think those two topics do align with the headaches that CIOs are facing.

Now, importantly, from Liz and Cris they are always getting a pulse of the field. We'll see from them a presentation that reflects on some questions where they need to ask all of these overburdened stakeholders are we doing the right thing, are we filling the right gaps, and are there accelerators, enablers or barriers? Because all of us, especially in 2014, think of healthcare information exchange as foundational to surviving global capitated risk and health care reform.

Now the interesting presentation after lunch on esMD and digital signature and Dixie's group has been assigned to work on some digital signature elements. We'll talk through how her work will dovetail with that work, but if we are transferring data from party to party how do we deal with non-repudiation and how to you deal with provenance and do you build up digital signature, do you build PKI, and do you build federal bridge? I mean, these are heavy questions and we of course have to balance, Jon just as you said, when she presented her new vision for RESTful simple interfaces, well, in the past we sometimes have used a bulldozer to swat a fly and we have to be very careful what we actually impose upon society is that right balance of overhead and functionality and what we do with this non-repudiation question? It will be a very interesting discussion.

And then Doug and Jodi will give us some updates on the S&I Framework and some pretty, as you say, remarkable progress that has been made on those fronts. When you see the sheer number of implementation guides in the pipeline coming out of the S&I Framework it's quite impressive. So, again, my closing comment would be keep our momentum going but also be kind to all of our stakeholders. It will be a delicate balance for us to focus on the things our stakeholders can pay attention to.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

Well, thank you John for those comments. It's interesting in that – your points are well taken I'm sure they resonate with our colleagues who are not only in the throes of implementation but the throes of operational responsibility for healthcare.

As I look at these challenges and the challenges that exist for vendors as well with the evolution there is a lift it's just unequivocal that there is a lift, that's, you know, I think what we all share is the optimism that the lift is worth it and a commitment to a set of standards and helping to the degree that we can work with the Policy Committee to influence policy so that it's as clear, as rational and direct a course as is humanly possible and so that's what keeps me excited and inspired by the work of everyone around this table. Along those lines let me then turn John to you and to Jamie and team for their Clinical Operations Workgroup update and look forward to the across the pond and immediate local presentation.

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

Very good, well we have Kim at the table now, is John Klimek...

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Here.

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

Okay, great, so, yeah, please join us. So, let me introduce the topic of formulary and benefit standards with Kim, you'll never believe this, but it's true, I just received an e-mail that at Beth Israel Deaconess this morning the formulary and benefit download process failed and why? Because the formulary and benefits file this morning was 10 gigabytes and we were unable to process it because of its sheer size.

So, this is a challenge we all face is that formulary and benefit files in America are not standardized and when they are using every NDC code possibly imaginable, Tylenol doesn't have acetaminophen as a chemical it has 10,000 variations of packaging and I have to load into my systems from this enormous multi-gigabyte formulary file, the difference between the 500 caplet bottle and the 250, 20 percent off purple label and this is of course not right. I mean, how more salient could your discussion be then my process failed this morning.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

How convenient.

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

Yeah, similarly, when my father who passed away a few months ago had to get his multiple sclerosis medications trying to figure out what his insurance company would pay for and the sometimes esoteric medications required this delicate mapping of the payer and the plan and the coverage and more than once he went to a pharmacy and was told "oh, for a co-pay of only \$5000, you know, we'll be happy to give you this new bio engineered medication." But, wait the doctor said...

And so what we're going to hear today are these real world problems being addressed, shrinking the formulary and benefits file, standardizing its format and ensuring the mapping between the patient's coverage and the formulary is more robust. So, Jamie, I know you're on the phone any other framing remarks you want to give before we turn it over to John and Kim?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning – Kaiser Permanente

Yeah, thank you, John, just one for me and one sort of framing comment and that is, you know, we started the discussion on this in our last committee meeting and I thought that was a good discussion and what it really highlighted for me was that it's very easy in this area to move from the formulary as it's used in clinical operations into the requirements for prior authorization and eligibility and co-pays as you mentioned and then you get to the accumulators and everything else about the plan side and so my – what I personally would like us to have is an objective anyway for this discussion today is to see if we can draw the line appropriately between the use of the formulary in clinical operations versus the administrative transactions as they would be appropriate for certifications for Meaningful Use of an EHR.

So, I think that, you know it is a complex area that really can mix up sort of the clinical utility of the information with the actual administrative transactions and so if we can figure out at least some parameters for drawing that line I think that would be a very good discussion to have.

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

Very good and Jamie my recollection was is that since we have this is the second iteration of this discussion with some Q&A they've actually gone through your questions from June and hopefully give you all the answers that you sought, that we would actually seek the sponsorship of the full committee to the recommendations to go forward at the end of the presentation?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning – Kaiser Permanente

That is an objective, absolutely.

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

Very good, so John and Kim take it away.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Okay, Kim will be the driver for most of this I'll be here to assist.

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

Well, thank you for letting us present today, can you all hear me okay? Okay, so John and I wanted to go through – this was – we went through – John went through it in pretty detail last month so we wanted to go back and do a little bit of an evaluation of the landscape for formulary and benefit because there were a lot of questions and comments that came around that and then also talk about the steps that we need to take to get to that point where you do have the fluid flow of information.

So, when you look at Meaningful Use in the formulary and benefit process you can see that with Stage 2 it's been moved into a core measure. So, we're really changing how the provider utilizes and views the formulary and benefit information at the point of care. So, this is a change in how providers are utilizing this information from the past where they had to seek it out either from a website or from some other source.

And so when we look at this we want to know, how do we improve this end to end process so that the information that we're sharing with the provider is useful, it helps improve health and efficiencies while also achieving that fluid flow of information that we desire and it's not an easy process and so what John and I have tried to do today is kind of lay out those incremental steps that we need to be able to get to that end game of that fluid flow of information that is accurate at the point of care for that patient so that the provider can utilize this as a tool that assists them in their decision-making process.

And when you think about ePrescribing it was never meant to be just an authoring or a storage tool, it was meant to assist in the clinical decision-making. And formulary and benefit as it was put in the Meaningful Use stage measure is part of the ePrescribing tool. And when you look at the part of ePrescribing that we've hit out of the park it's with the clinical drug knowledge, drug-drug interactions, drug disease states interaction we figured that out, but then when you look at the formulary and benefit process we still have a ways to go with that.

And so what we did is we took what standards are out there that was kind of ask from the beginning and what are the gaps in the process. And I put this quote on there because I thought it was so appropriate. Standards like any structural component of the healthcare should be assessed based on the extent to which they able improvements in healthcare processes and outcomes. And when you look at formulary and benefit it is a healthcare process and it could be utilized to improve outcomes in the healthcare environment.

And there was just a study this month that was published by IMS and it looked at responsible use of medications and it is a 200 billion dollar problem and if you looked at that over half of it was medication non-adherence and also using medications to appropriate evidence-based guidelines. So, almost half of those 200 billion dollars could be lumped into those categories, and there was a study at the end of 2011 that was done that looked at non-adherence with the advent of ePrescribing it was with ePrescribing utilizers and what they found is that 24 percent of the time patients didn't even pick up that primary prescription but then when you broke that down, they actually broke it down into formulary status. If the drug was not covered 80 percent of those patients did not pick up their medication and if it was non-formulary 30 percent of those patients did not pick up their prescription. So, I make this point because we think of formulary and benefit as a financial model for other entities but it's also a patient safety and outcome delivery tool that can help improve the outcomes in non-adherence and other issues with healthcare.

So, we went through before, last month, but it's good to look at this because if you look at the blue box that's really where the standard can play its part but then there are other parts in there that also influence the process and we have to keep that in mind so that as we build the standard we make sure to incorporate those other pieces so that we do have all the information that's needed and delivered at the point of care.

And when you take something like the pharmacy for instance and you look at the drivers that influence the pharmacy it's very influenced by reimbursement. I mean, they need the NDC codes, they do updates daily and they have the systems to do that whereas most EHRs, and we talked about this last month, they don't have the capability to upload all of the information with all of the NDC codes and that's where RxNorm comes in. And so, they also have a source of information that gives you at a point in time exactly what the patient owes to the pharmacy and what the formulary status is of that drug.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Can you just go back one second? The key point here – and the reason why NCPDP looked at this from the stand-point of how it affects the pharmacy, especially the formulary and benefits standard, is because that's where most of the problems with being seen.

The patient comes into the pharmacy such as John Halamka's case of his father and finding out that either the drug is not covered or the co-pay was unexpected and that's where there is then a backlash of that information then going back to the provider trying to clarify some of that information may be making some changes in the prescribed product to better serve that patient and get them the medication that they need.

Again, NCPDP and our membership looked at that from that stand-point. We didn't see the formulary and benefits standard at being a direct effect on pharmacy but an indirect effect. So, that's the reason why our membership looked at this and built that standard to help that process.

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

So, when you look at the landscape assessment for formulary and benefit, and I have the references at the end of this slide presentation so it is available for everybody to view, there's kind of four categories that you can lump formulary and benefit information, data quality, data availability, system design and data usefulness.

And when you look at data quality there are issues and part of it is with – our recommendation is to go to RxNorm because that can help with the interchange of information, it can make the file smaller so there is easier upload and capabilities with that information and it also helps with exchange of information for other things with quality measures.

There's also incomplete information. The granularity of the information that is delivered today is mostly a representative formulary for that plan and it's definitely not the patient's formulary. So, there is an issue there. So, what happens is the provider does not see that patient's actual drug benefit so you're still going to have some of the issues, administrative issues with efficiencies and callbacks and having to change those medications due to the patient getting to the pharmacy and not having it covered.

Data availability, today it's a voluntary process for commercial patients. So it is up to the payer or PBM to decide if they want to share that information or not. Medicare they do have something in the physician fee schedule where it is but for the commercial patients there is nothing for that.

There can be inconsistent matching with patients and this was one of the recommendations that we made at the end with the addition of the PCN, BIN and group number, because not only would that help with the match of the patient but it also would help match that patient to their formulary at a group level which would give the provider more accurate information.

And then the updates are cumbersome at the point of care and as John mentioned this morning they just had an issue with it. So there are some systems that – and we talked about this last time so I'm not going to go into a lot of detail, but there is the push and pull method. So, there are some systems that push all the information to the point of care so the provider has very little that they have to do but some of them are pulled and they have to do their updates themselves.

With system designs, again, with the large files, also the manual and the automatic updates which we talked about. And then data usefulness, and a lot of these studies were done before Meaningful Use so I think we're going to see some changes in this information or we may see that it's more prevalent than we thought or less prevalent I'm not sure, but when they looked at using the formulary and benefit information at the point of care they actually didn't see a difference in the number of callbacks and efficiencies.

So, if we're going to push to have this information at the point of care, again we went it to improve those efficiencies and improve the outcomes for the patients. And it also leads to a lack of trust in the information. The physician may look at it and he's like "well, I've already gotten 10 callbacks this week I'm just going to keep doing medicine as I was doing it before."

So, John and I took all the comments and questions that were brought up at the last meeting and we were just going to run through them and address them. And the first one was, is RxNorm a replacement for NDC or an addition?

And so we had a couple of conversations with different industry stakeholders around this and after our conversations we did decide RxNorm needed to be an addition to NDC and the reason was there are things that are ePrescribed and covered in the pharmacy benefit that do not have RxNorm codes, medical supplies, diabetic supplies, some OTC products.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Some OTC products, yeah.

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

So, there were some elements in there where RxNorm would not work so we did not want to break down the process with that. And also, when you think about everything going through and the pharmacy needing that NDC you still need a match somewhere in that process.

The second question was where is the PCN, BIN and group number exchanged or seen? So, in the formulary and benefit process to get that patient match they have to do an eligibility transaction the 270/271 and in that process they submit a five-point identifier to match the patient, their last name, first name, date of birth, gender and zip code.

When that is sent in if there is a match there is the possibility that the PCN, BIN and group number is there and it can be sent with a script to the pharmacy and the pharmacy can see it but today the providers really do not see that and we think that it's important for the provider group to see that and have that information so that you can get a more accurate formulary at the point of care and that is one way to help improve that process.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Yeah, and again, in the pharmacy world, this is how we process claims. We identify the patient not only by their ID but we also identify what plan they belong in as far as the PCN, BIN and group number as far as processing that claim, that gets that specific patient to that specific plan and then identifies what formulary they do have and then that process then returns back a paid claim to the pharmacy or a rejection with some identification as to what the pharmacy has to do to clarify that claim, either the drug is not covered or it is not a formulary product or whatnot.

Again, this is the primary information that the pharmacy uses to process that claim and what we're saying is that to better identify that patient from the provider's side, from the physician's side this is probably a clearer way of exactly identifying that patient and exactly identifying which formulary they have.

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

Okay, another comment that was made, RxNorm versus NDC, because the level that the prescriber prescribes a medication versus the level that a pharmacy dispenses the medication is very different and so that is true and so we did talk to some large pharmacy industries to find out about this and so what would happen is that you do have the RxNorm for the prescriber end of it, it goes to the pharmacy and it matches to a list of products based off the NDC code. Because the pharmacy needs the NDC code for inventory for reimbursement, if there is a recall with lot number they would be able to have that information for patient safety issues. So, at the pharmacy level you would need to have both RxNorm and NDC codes for that reason. Did I miss anything else?

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

No.

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

Okay, is F&B data directional or actual? So, today it is directional, it is not the patient specific formulary and prescription benefit. So, it is a directional tool that can be used to help providers make decisions.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Right.

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

Okay, what version of formulary and benefit is needed for electronic prior authorization? And this came up somehow in conversation, but the electronic prior authorization transaction that was just balloted and approved in May at NCPDP is actually under the script standard, which is the ePrescribing standard and it's a transaction within script which makes it more of a real-time transaction versus the formulary and benefit as a batch transaction.

And within the earlier versions of formulary and benefit there were some data elements in there to enable electronic prior authorization, however, to my knowledge they were never really utilized and I'm not sure any vendor has ever adopted them for use. So, the transaction under the script standard is how it's moving forward.

How feasible is a real-time transaction? There have been private entities that have tested the real-time transaction and if you just look at the formulary and benefit information it seemed pretty feasible. However, if you added in – they had added in mail order co-pays, some alternatives with cost, so they had to build different databases for that so it made it more cumbersome.

But, I think in reality, and I will let John speak a little more on this, in my opinion this is – our incremental step should lead to this, is that under the script standard there probably could be a real-time transaction where you could ping that information and get at a point in time if that drug is covered or not based off the directional information that is given today.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Yeah, I believe that the information, as far as formulary coverage, would be something that's feasible. I think what would be difficult and what was found out in some of these original tests where is when co-pay information was trying to be obtained and in certain instances of percentage co-pays or specifically for Medicare Part D where a percentage co-pay depended on where that particular patient was at in their co-pay structure really varied and between the time that the physician would do a ping to identify what the co-pay is and then for that patient to actually go to the pharmacy and get that prescription filled there were gaps in time, which would then affect or possibly affect the co-pay structure depending on what that patient did in between that. So, that's where the co-pay was really in question with this real-time transaction. I think the formulary and benefit information, the structure is possible but when it gets to co-pay information that may be a little bit more difficult.

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

Okay. And is this in alignment with Medicare Part D? So, as you all know the physician fee schedule came out on July 8th and it's in a comment period and NCPDP pulled together all the stakeholders and the consensus from the stakeholders were we were going to recommend to Medicare that formulary and benefit version 3.0 be the version that is used moving forward from that regulation. And so we don't know what the outcome of that will be but that has been the recommendation so if the recommendation here is for version 3.0 then it will be in alignment with Medicare Part D.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Exactly.

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

Okay, any other?

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

No.

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

And then John was going go through the proposed recommendations.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

So, again, from our original meeting in June we had some recommendations and we would like to come back with some of those recommendations with some modifications. And again, short-term is that the NCPDP formulary and benefit standard version 3.0 which is again the current standard for batch files should be supported for the transmission of files to the EHRs. So, again it's version 3.0 that we're recommending.

Again, formulary and benefits transmission with NCPDP 3.0 should be requested to use RxNorm in addition to NDC to facilitate accurate exchange of data and to reduce the file size. This is where we're going to have to do some work with some of the stakeholders to make sure that they use the RxNorm codes where possible to reduce that file size and we might be able to work with CMS in the Medicare Program to help facilitate some of that processing to make sure that that happens. We're finding that some of our stakeholders today that it is happening in some of the cases but not all the cases. So, they would like to see where that push comes a little bit stronger from the recommendations that are made from this committee.

Certified EHR technology should have functionality to match the patient not only for their medical benefits but also their pharmacy benefits. Again, as we discussed using the PCN, BIN and group number to better identify the patient.

Certified EHR technology should be required to support acceptance of automatic updates or push functionality to update formulary and benefit data to provider level to minimize latency and information at the point of care. Again, we find that that's important that information is being received at that provider in a timely manner.

And then lastly, formulary and benefit data presented at the point of care should at a minimum represent the patient's group pharmacy benefit. And again, this better identifies the patient's true formulary and benefits status as to what medications they can receive.

And then we kept with the long-term of where certified EHRs should develop the functionality to run patient level formulary checks against the patient's actual drug benefit for a specific drug and dose in a timely manner. Again, we're looking at that as possibly a new standard or transaction which would be required very similar to the ePrescribing process that happens today. So, that's really it.

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

That was it.

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

Well, very good, we have 4 cards up Leslie, Eric, David and Wes on the phone. So, Leslie?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you very much, I applaud your long-term goal and I wonder if there are opportunities for alignment much earlier and let's leapfrog over this idea of huge downloads, huge file levels, huge management and look for potential harmonization in other efforts.

For instance, this is just another expert system that can support clinical decision-making or shared decision-making with patients and we do see efforts in the standards organizations under Health eDecisions as well as in patient specific education material that uses standards to check an external expert system using the InfoButton standard.

And I bring that up because it is very difficult to be a content provider and to be current all the time. And now you have changes in a patient's status which changes their benefit marriage, divorce, death, age of a child. We have so many complex issues that will change it. Being accurate with a data download seems somewhat narrow and old-school.

In addition, today we don't feel the pain of our inaccuracies because we largely wash our hands of it, we say, we say nobody knows so therefore it's not my problem when the patient presents at a pharmacy, it will be resolved there.

So, implementing something now that just gives us partial complete information not necessarily timely or real-time gives the burden of the responsibility back on the provider with not accurate current information.

So, I am concerned that the proposed recommendation has this bias for consuming large information that may not be helpful so that we could be doing the wrong thing very well. Instead moving toward an expert system approach that could help benefit us and harmonize us in other expert system approaches like what's being discussed in the S&I Framework around Health eDecisions. So, I would like your comment and maybe I'm wild in this idea but it seems to me that we are being narrow and old-school. Thank you.

Michelle Consolazio – Office of the National Coordinator

I just want to remind everyone on the phone if you're not speaking please mute your lines.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Thank you very much for that comment and we totally agree with you as far as we're just scratching the surface with this recommendation. One of the things that we talked about is that this is giving the provider something. It's giving them some tool to be able to identify what that patient's formulary is rather than them seeking that information themselves via website information or whatever. You know, we could take back to our membership that a real-time transaction is needed but that's going to take some time. It's not going to be developed overnight.

And what we're looking for here is something that has been proven to work. Right now version 1.0 of the formulary and benefit standard is being used by people out there today. It is providing information. Is it 75 percent correct? I would probably say yes. Is it 90 percent? I would probably hesitate to say that but pretty close to that.

And to my view-point working in a pharmacy, I've worked in a pharmacy for a long time, I would rather have a patient come into my pharmacy knowing that the provider was able to check that formulary and benefit information and get somewhat of an idea that that patient information was correct as far as the formulary and benefit information that they received rather than nothing at all and basically that's where we are at today, you know, requiring the provided to seek that information themselves is quite cumbersome and I would look for comments from other people as to how that would be performed.

Here again, we're providing a tool that we know works, it's not 100 percent and I don't think we're going to be able to say that it's going to be 100 percent but it's something that's going to at least give them something that's going to work for them today.

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

I agree with you, Leslie and I think it's very important for that patient level information to be available at the point of care. I mean, I've personally gone to my provider, but I'm an educated patient and I know my formulary.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Right.

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

And I've seen that it's not accurate but I know how to address that with my provider and it minimizes the opportunity that the provider and patient can have that conversation. So, I agree that we should be looking at solutions that are going to fix the problem, but what are the steps that we have to take to get there?

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Right.

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

I think your analogy to the Health eDecisions work is I think quite apt because there are two kinds of Health eDecisions activities, the download of knowledge in batch, and the query response to knowledge in the cloud. So, sort of in a sense what you're saying is you look at the systems that we all have today that all depends upon the download of knowledge and boy is that not ideal and it's fraught with peril, but alas it is what we have and sort of Phase 1 that at least standardizes what we have shrinks the file size and makes the interfacing a little bit better on the path to getting to a query response approach which will require some novel standards and maybe the Health eDecisions work will actually inspire us for the kind of real-time knowledge in the cloud that we actually want to consume.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Can I comment, just in follow-up, if we think that costs are not going to be included in decision making in the future we're nuts and this is our first opportunity to set a standard for costs to be included in shared decision making.

And I believe, from a consumer point-of-view when I make a decision about my care without cost if becomes irresponsible just as if I made a decision about quality and my car I'd really like a Jaguar but I can afford a Honda and so it is material to my decision making.

So, I just would encourage us to look more broadly as this as a first step to integrating cost in shared decision making between providers, patients and others and it should be with that in mind as we go forward and not narrow.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Thank you.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you.

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

Eric?

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

So, I'm a practicing family physician and I've been using this technology for over three years in my clinical practice in Seattle Washington. The ability to get formulary benefit information at the point of care is a golden opportunity; it's a triple win when you have the opportunity to reduce administrative hassle for the physician and his or her staff, because of call back issues. You have the ability to give the patient a better experience of care because there are fewer surprises about the cost of their prescriptions and you potentially have the ability to reduce costs at a societal level although that there should be a big asterisk next to because what you're really reducing are costs to the PBM and potentially costs to whoever is paying for the health plan and maybe ultimately cost to the society.

But the big issue that I have from my experience as a user and also, actually I also had to design the EMR functionality that digests and displays the formulary and benefit information to the end user in another life, is that there is a qualitative issue with the data and it's what I think Kim you called data usability.

The formulary and benefit standard is a very, very rich standard and has the ability to incorporate a lot of different kinds of formulary information, you know, percentages of co-pays, flat dollar rate co-pays, percentages of the total cost of the prescription, but there's a lot of complexity around the Medicare Part D stuff with a donut hole and it can handle a lot of really, really complex formulary information, but in my experience, almost without exception, the PBMs make use of the most unhelpful type of information, which is a Tier 1, Tier 2 or Tier 3, I forget what it's called formulary preferred, formulary non-preferred or non-formulary I think are the three categories.

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

Yes.

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

And that is next to useless at the point of care. What do you think a patient says when their physician says "oh, I see that the medication I was thinking of prescribing for you is non-formulary preferred" what do you think they say? They say "well, what does that mean I'm going to have to pay?" And the physician says "I have no idea but 15 minutes from now when you walk down the block to the pharmacy, they will tell you." Well, that is absurd. Okay, we can do better.

Now to do better my sense is that the gap that we have to fill is the mapping between NDC and Rx or between NDC and whatever is the representation, is behind the representation of the medication at the level that the prescriber is prescribing, whether it's NDC or whether it's, you know, a proprietary Medi-Span or First DataBank or whatever code.

But, I think that our proposed recommendations should occur that something to the effect of do whatever it takes to give the patient at the point of care the same darn information about what they're going to have to pay that the pharmacist will give those 15 minutes 100 yards away.

And if it depends on different NDC packaging then give them a range. Say for all of the NDCs that correspond to fluoxetine 20 mg capsules of which there may be, I don't know 10 or 15 whatever, the possible amount you have to pay is between \$20 and \$40, you know, that's information that I can use. And if we really want a patient centered health care system that is what we have to do.

What we have now is a PBM centered way of implementing this technology, because what we're doing is the cost is transparent to the patient so the doctor either ignores the information or will just go for whatever is formulary because they want to not take the chance that the patient might have to pay more than they might want to, but that really should be a patient decision if we want a patient centered health care system.

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

And just a comment on that with your example with the preferred, non-preferred, on formulary, non-formulary not covered that's how the formulary status file works in the formulary and benefit file. And there are issues – there can arise issues at the point of care with that because you could have a green that's preferred that has a PA but it shows up as a green and you don't see the PA because that comes in another file and that's not always shared and it's not at the patient level. So, you know, that's why it's so important to get at minimum to that group level because then more of that information can be shared and it can help with the decision-making process.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Yeah and getting back to our comments, especially as it pertains to Medicare Part D, I think the physician getting some type of a range of a co-pay might be feasible, but to get to an exact co-pay would be I think near impossible. Again, seeing from the stand-point of me working physically in a pharmacy and knowing that that patient could be getting a prescription filled someplace else that would change that co-pay within minutes.

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

Well, that's a fair, I think that's a very fair point, I think that what – but, as a patient, if I were told "well this is what you would pay if you fill this prescription right now, and if you – if something else happens..."

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

If you filled it now?

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

Yeah.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

That's the big point.

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

Yeah, sure and that's – but that would be – what I'd say is that would be a little short of perfect and it would be light years better than what we have today. Because what I'm telling you is in practice as carefully thought out as the formulary benefit standard is and as carefully implemented as it is, it's really not nearly as useful as you might think.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

And I could tell you from the pharmacy stand-point that could cause problems, because that patient is coming into the pharmacy saying that they saw the physician and the physician said their co-pay was \$15.30, now all of a sudden the patient comes into the pharmacy and guess what that co-pay has changed because of the order the prescriptions were filled or something else has changed and now all of a sudden that co-pay is \$32.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

Let me suggest a triangulation here is that I think there are some principles that have been very well articulated, which is that they are inherent efficiencies in having to download large files, that there is an aspiration toward real-time, that the data should be present at the point of prescribing, etcetera.

You know, this is going to come up again in the electronic submission of medical documentation, documents is that we have the dual challenge of rational standards to support interoperable health information and building for the world as it exists, which is, you know, obviously has many irrationalities from the perspective of how and a clean slate.

And so, I think let us take this piece and let's think about how we actually mark a path that allows us to operate with the peculiarities of the world as it exists but also be aspirational in terms of where we want to go. I think that this discussion has been absolutely terrific for all the reasons that have been alluded to in terms of higher value, higher patient centricity, but it is fraught with the complexity of the administrative peculiarities of the world as we know it.

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

And to Eric's point some of this is actually structural. So, my father-in-law is on albuterol and albuterol of course changed propellant to be a non-chlorofluorohydrocarbon and so his payer says all formularies of albuterol are non-formulary.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Right.

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

Well, wait a minute so I have to pay \$25.00 because everything that I could possibly use and there's no alternative is non-formulary. Well, wait a minute that's not right. We should be more patient centric about this. So, we have two more comments and then let's get to, if we can, a summary on this. I will give you a 1 minute overview on the image exchange stuff. So, David?

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

Yes, David McCallie and Eric, thanks for going first you captured my thoughts probably more eloquently and maybe more calmly than I would have, but given the opportunity to reinforce them enthusiastically, I mean, it is really silly that you can walk 100 yards down the corridor and get the exact price, but you can't get even a guesstimate or a range of prices from the provider. It's the same number of transactions, I mean, roughly speaking the number of prescriptions that are written and the number of prescriptions that are fulfilled is going to be an order of magnitude very similar or very close and maybe a factor of two. So it's not a transaction explosion problem. It's the way the system is structured.

And even though I favor incremental-ism in our standards, requiring the vendors to implement an incremental change to the way these massive files are distributed with incremental updates and not to address this more fundamental problem that the patient doesn't have – the doctor and the patient cannot rationally discuss the cost of the treatment options at the bedside just seems like a step in the wrong direction.

Shouldn't we fix the problem that you can't have a rational discussion about cost of treatment choices at the bedside? And we should do that that should be our priority. And it's hard work, but the pharmacist knows what the cost is.

And if it's, you know, an edge case that one out of 100, or one out of 1000 times there is a discrepancy between what the doctor said and the pharmacist charges the system will figure that out, it will use language like approximate cost or if you bought it today it would be this cost. I just think with what Leslie stated and Eric picked up that just has to be our goal otherwise we're just – we're buttressing a broken model by doing incremental-ism without actually fixing it.

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

Well, let me ask John and Kim who are very familiar with the NCPDP processes, if in fact what we say, as John pointed out, this has got to be a statement from the Standards Committee about the need for phasing and directionality that we all want to get to patient centric cost reported real-time knowledge-based transactions, but at the moment, you know, there are some things we can do to shore up the current flawed process. Does NCPDP have on its road map the kinds of things that you've heard from Leslie, Eric and David?

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Well, part of our discussions have been to move in that direction, but there is that complexity of the co-pays that we just talked about and then building that into the structure of the transaction, is this something that will happen by the end of this year? There is no physical way that's going to happen. Even, I would hesitate to say 2014 only because of the complexity that we're talking about here.

It took us probably a better part of two years to develop the electronic prior authorization process, because we had developed a process which was then looked at by our membership that needed some improvement. We didn't see any uptake in that process. So we went back to the books, we redesigned the electronic prior authorization which now has been approved by our membership. So, I'm just looking at that as an example of something that takes time.

From my viewpoint, again, I'm not trying to be short-sighted on this by recommending something that's going to at least give the physician something that's going to be a tool. Again, I go back to my original statement is it 100 percent? No. And that's not something that we ever saw as being 100 percent. But is it something that's going to improve some of the patient care in identifying products, at least up front, what's going to need a prior authorization because from my view-point that was probably our biggest issue, products that were being prescribed by the physician that needed a prior authorization. And so that's the reason why electronic prior authorizations were top on our list.

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

And so maybe, David, the role of the Standards Committee is to create a sense of urgency for NCPDP to move onto the next phase.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

I do hear that and, you know, I do think there's a difference between incremental-ism and trajectory and what would really be helpful John and Kim is for you to work with us in helping to think through not only in committing the urgency but thinking about a trajectory that gets us to that goal.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Well, and again, I'm pointing back to the electronic prior authorization which was part – the prior authorization piece was part of the formulary and benefit standard which we then moved it into the ePrescribing tool which is now real-time or as best real-time as you can get. So, we're looking at the same things with the formulary and benefit standard.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

I think Doug Fridsma wants to weigh in.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

So, I just wanted to make sure, I understand some of the recommendations and I think there is a conversation that needs to happen about the trajectory, but it sounds to me like the recommendation is for standardizing meaning vocabularies and terminologies is a movement away from NDC and towards RxNorm, okay? So, that's a fairly consistent standard that will be present regardless of the transport mechanism or the like.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Right.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

The second piece is that there's a content standard that currently is being recommended to be this formulary and benefit standard version 3.0 which is sort of set to a batch file. It sounds to me like the discussion here is that we need a new content standard that has more granularities associated with it that would allow us to get to that more patient centric view so it isn't a big batch download but that there is some other mechanism to both convey and get the information back.

The third is that there is a transport mechanism. Right now the batch suggest like an FTP or something like that but maybe we need to get to more RESTful approaches that have subscription models. Maybe we need to even get to something where we have formulary and benefit as a service related to the HED. So, the thing is, I know you put your card up because you were upset about my content, but you need to have some way of specifying the information even in a subscription model where you've got it as a service.

So, if the batch model, that standard is not appropriate, we need to think about how we can take that and create those more granular pieces so that I can ask a question about a particular patient and get a response back in the HED formalism and what that question looks like and what the answer looks like.

So, to me there is some consistency in what we need around vocabulary. It sounds to me like there's some work that needs to be work done around content, perhaps leveraging the information in the batch and figuring out how we can break that up and that if we take a look at our existing transport mechanisms that we've got, which is Direct and sort of a web services approach right now, that as an optional certification criteria, we may need to look at some of the other activities going on about the RESTful approaches both in terms of a push and a pull. And then there will be an authentication framework around that, maybe that's going to use OAuth or OpenID or the like.

So, to me these are very nice recommendations, I think the trajectory is probably going to be articulated in terms of the different buckets that we need to fill and how long it's going to take us to get each one of those in place.

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

Okay.

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

And since we are running out of time for this discussion, at the same time multiple cards have gone up. What I wonder is if we can take Doug's summary, which was eloquent, to say we would like to respond to your proposed recommendations by suggesting that directionally moving from NCPDP to RxNorm for vocabularies seems like a very reasonable thing.

On the content side you've heard feedback that, okay 3.0 at least standardizing at a place in time reasonable, not sufficient we'd really like to see more granularity as we try to get to consumer focused pricing information and that ultimately we'd like to move away from this transport and batch to a more real-time query response or RESTful type approach and even for batch it certainly would be nice to move to Direct or the SOAP transaction as a delivery mechanism for that.

So, in effect, you know, what we're giving the committee as a choice, do you want to improve life today while setting a specific trajectory for the work of NCPDP which hopefully John and Kim can take back and in due time, urgently, hopefully report back to us on progress.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning – Kaiser Permanente

John, this is Jamie if I could...

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

So, comments on that proposal briefly?

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

John?

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

Yes, go ahead, Wes.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

So, I think two topics that I haven't heard fully explored here that I think are important. One is, NCPDP has developed a number of excellent standards that have moved the industry forward, but in this area it's not clear that NCPDP has the appropriate membership to represent the requirements of the physician/EHR community in a completely equal way and I think there is room for some cross SDO harmonization in that regard.

I think it's specifically important in that process to think about the workflow from the physician, because what we really want I think is not for the physician to get to a conclusion and then ask, what's that cost? We want the physician to be able to look at some therapeutic alternatives which are different than substitution alternatives and get some approximate idea of the cost as of the current status of the patient, yada, yada, yada.

So, I think we need to understand the request better than we do now and that we – that it's probably incumbent on ONC to look at policy levers for improving – once the work is done, the standard's work is done, policy levers for improving uptake just as it had to do with clinical labs.

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

Very good, so as we – okay, I know Andy, you get just one real quick comment.

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

I think that the pace or the urgency is going to be increased by the need for Accountable Care Organizations to do things differently from a money standard. They're going to push real hard and need that financial information in real-time right away and if you want to understand where that opinion comes from all you have to do is look at the integrated delivery systems today because they do deliver that information in real-time to the doctors at the point of care and expect it to influence decision-making by the patient and doctors today. So, others that integrate will want it as soon as they integrate.

Jeremy Delinsky, MBA – Senior Vice President, Chief Technical Officer – Athenahealth, Inc.

This is Jeremy, one quick comment, so tremendous consensus I think on the long-term direction and the comment I would give as an EHR provider is, hold your powder for the things that really matter when you want me to build something in my system.

And so I hear a great vision of what we could do and make that be the certified EHR technology rather than sort of make us keep on doing things, because I'm guessing there are higher opportunity areas that you would like EHR providers to focus on in the short-term.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

Yeah.

Jeremy Delinsky, MBA – Senior Vice President, Chief Technical Officer – Athenahealth, Inc.

And that's it.

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

So, synthesizing the recommendations, I think we've heard consensus from around the room that alas the status quo is not sufficient and that there is much more excitement about building in some kind of cost reporting mechanism and some kind of real-time query mechanism but directionally the things that you said on vocabulary, exactly right, is certainly trying to get us to having a standardized batch approach is certainly good for providers like me, but as we think about what Stage 3 of Meaningful Use might offer, it would be ideal if in Stage 3 timeframe NCPDP could have a RESTful real-time transaction to be a certification criteria.

John Klimek, RPh – Senior Vice President, Industry Information Technology – National Council for Prescription Drug Programs

That would be very possible, yes.

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

Okay. Do we have any objections to that as a set of recommendations? Okay, well thank you so much.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

I do think you need to talk through the – you need to take into account the real needs of the physician rather than all of the speculation I'm hearing about the real needs of the physician.

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

Very good, well last comment before I turn it back to John Perlin, if I can have the slides up for image exchange? There should be just two slides very quick. No, I guess my slides are somehow not there, but, ah, there it is, okay, good.

So, remember that Jamie and I with the Clinical Operations Workgroup continue to work through the image exchange use cases where we have provider to provider, provider to patient which includes, Leslie, patient mediated provider to provider exchange and group sharing of images.

We originally gathered some wonderful testimony from some experts who had worked extensively on an IHE image sharing pilot that was actually PHR mediated, it was very patient centric, you were on that call and we are going to gather further information from these new generation of cloud hosted image exchange providers and just to very quickly summarize some of the lessons learned we heard.

So, we heard from David Mendelson and Keith Dreyer and consumer, by the way participated with Clinical Operations Workgroup, zero footprint for consumers was important, the idea that I could use a web browser, I didn't have to download some sort of complex heavy DICOM client or worse yet, vendor specific DICOM clients and the sort of things that we see on CDs today don't scale across multiple operating systems and multiple vendors.

And that this pilot that was run with the MGH and other sites was able to take edge servers, deliver risk reports and PAC images to an edge server and from the edge server then get a push to a cloud hosted patient health record controlled facility where the patients could view the images in a low footprint fashion as well as mediate their exchange and access to physicians and they were available in both, sort of what I'll call, the low res, easy to view, easy for a consumer to share, as well as rich original DICOM format where it might be necessary to download and incorporate into PACS at a provider location.

This was actually done with significant numbers of images at MGH quite successfully. The cost of doing so was actually about \$.50 per shared CT. So, with it was actually very reasonable cost. Still work to do in expanding the pilot and making new versions of this software available.

This testimony we had on June 28 was one approach, but on the 19th, on Friday, we are going to hear more about some more different approaches provider to provider, cloud-hosted mediated kinds of things. So, more to come, we don't have any specific recommendations for you yet I just wanted to give you that progress report and Jamie any comments you would offer on the testimony so far or the work ahead?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning – Kaiser Permanente

No, I think that was a great summary. Thank you.

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

Great and real quick comment from David and that we will turn it back to you Jonathan.

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

David McCallie, I'm just curious as to why it has to be moved to an edge server, why is this extra cost required as opposed to just appropriately authorized view into the existing copy of the image?

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

And so the testimony we received was that from not a technology but from a policy perspective the participating institutions didn't really want to allow Direct pulls from their systems of record inside their firewall and this is a DICOM through a firewall question and that the edge server by doing a push rather than a pull seemed to alleviate policy concerns, scalability concerns and other such things. But, again, we are looking at other alternative models here. This just happened to be the experience they had that cut through some of the barriers they perceived.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And they felt it was a cheaper, this is Leslie, they felt that that was a cheaper solution than trying to do it other ways because the images could be coming from different several expert systems. So you might have cardiology, pathology, radiology and so they felt that that approach would be less expensive, more scalable in general. Am I paraphrasing it correctly?

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

Right.

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

But, this is David again, a URL, you know, with appropriate authorization where authorization is the tricky part, but the URL should be pretty simple. So, publishing the URL shouldn't cost all this extra money.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

With the same ability.

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

Right, certainly agree with you, but I have heard from radiologists similar questions like what if we Internet connect our PAC system and make query response available to all comers “oh my God” you know this could impact transactional performance.

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

But that’s what we used to hear from physicians before we put Meaningful Use into place, right?

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

I know, I know so more testimony to come.

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

We’re trying to change things I think, right?

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

That’s right. Well, Jon Perlin, I’ll turn it back to you and unfortunately I have to go take a phone call, I will return in 15 minutes.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

Yes, thank you John, and thank you everybody for an impassioned discussion. It really is evocative that great Robert Kennedy quote “some people see the world as it is and wonder why, others see the world as it might be and ask why not” and I think this group asks the latter in terms of both the previous formulary and pharmacy benefits discussions as well as this image discussion. And, you know, what I really appreciate and Doug very eloquently summarizing some of the work that is fundamental to that ultimate as well as the more immediate.

And I think what we owe Jeremy to your very thoughtful comment about, you know, saving your fire power for the work that supports the most effective or most highest levered trajectory is really to be very clear on what the paths are towards an ultimate goal or desirable state and the steps David not necessarily micro-steps are wasteful in incremental-ism but just necessarily sequential based on the world as it is and really in transit to the world as it might be.

So it was just a terrific discussion, appreciate everyone’s passion and input around that. It’s really an ideal segue then to the Implementation Workgroup and to Liz Johnson and Cris Ross because they are hearing feedback about just those sorts of experiences or preparing to hear that feedback and let me without further adieu then turn to Liz and Cris to take us through the set up. I think they are going to very thoughtfully going to elicit feedback from a number of stakeholders and inform our process.

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

So, thank you, John for that segues to us and we’re really looking forward to talking with the Standards Committee about the testimony that we’ll be receiving next Tuesday. Let’s move to the next slide, please. So, first, we want to recognize the members of our group. This has been another journey where we’ve met numerous times and spent significant diligence on preparing questions and panelists lists, but we’d also like to thank Paul Tang and the Meaningful Use Workgroup, and Marc Probst in the Certification Adoption Groups, both off of the Policy Committee, who have worked hand-in-hand with us in preparation for our, shall we say, our next adventure next Tuesday. So, let’s move to the next slide, please.

And while we're going to look at this slide I'm going to provide a significant more amount of information. You will find following this, and Cris if you want to lead us through the questions following this explanation, we've actually provided for you the actual questions that have been posed to our panelists. But, I want to talk a little bit about the purpose of the panel and the purpose of each one of the panels that we are describing for you.

The genesis for this hearing was that we recognize with where we are in preparation both as hospitals and physicians in preparing for Stage 2 that there was an opportunity to really gather information about innovative solutions to the new requirements. But in meeting with Paul and his group we also recognized that this was an opportunity to provide input into the future design of Meaningful Use Stage 3. So, this will really be an informative hearing on both arenas.

And then obviously, and again I'll talk about in more detail, the usability and interoperability panels, but we also realized that we have some real issues around human factors and usability as well as a topic that we often have discussed here in this Standards Committee which is interoperability and where are we and where should we be and so on.

So, we created four panels, the first one being the eligible provider panel and in essence their charge was really to bring us what they're really being successful at for Stage 2 and then how can we enable more providers to participate in Stage 3. One of the queries that we've had and comments that we've had very consistently into the Implementation Workgroup is that the eligible providers, as a whole, don't feel like we have quite made it to inclusion of the specialists and that we continue, not intentionally, but just as a byproduct of the process to create data recovery needs that are not part of their workflow. So, this will give us an opportunity to really talk with them and get their input.

When we look at the types of eligible providers that we have included you'll see a variety when that final list is published where we went to small practices, large practices, and academia to make sure that we really looked at, across the board, what were our opportunities not just in a singular setting but across a variety of eligible provider settings.

We also this time really looked at could we get a specialist to come and talk to us about what we can do to better include them so that the ultimate goal of Meaningful Use can be met which is obviously to improve the quality of patient care and engagement of patients themselves.

So, if I move on down the list of panels the next one we will be looking and speaking with is the eligible hospital panel and much like the charge that we gave to the eligible provider panel we're really looking for how can we take your innovations and promote them for solutions to meeting Stage 2, but also how can we provide and inform the Meaningful Use Group as to what might be included in Stage 3. Where should the focus be? What should be included? What might be a change from their original suggestions? And there again, we chose a group that is representative of academic large urban, small rural, and for profit. So we're trying to cover that whole continuum of the types of eligible hospitals that are participating in the Meaningful Use Program today.

The next panel that we'll then be moving to be the – let me make sure I'm on the right one here, is the information exchange and interoperability panel. And here's where we really think again we need to look to what the requirements of the current Stage, Meaningful Use Stage 2 is, but even more importantly, how can we really start to advance interoperability across the continuum of healthcare. You know, we have all struggled with this and so it became clear that we should go out and get more feedback into the Standards Committee, into the Policy Committee for the future. And we looked at panelists for that particular panel. You know, we were looking at things like New York eHealth Collaboration – Mayo Clinic, Healthway and so on again trying to get a very diverse set of panelists that can inform us and challenge our thinking going forward.

And then finally, we're going to do a usability panel and I want to mention to you that we're going to open the hearing with a report back from a group of the human factor engineers that have gone out and talked with the vendors and they'll spend about 30 minutes talking to us about what they found in terms of what the vendors are doing today to help increase the usability of the products which we use in our settings.

Then we'll have, at the end of the day, on Tuesday, we'll have a usability panel that will be consistent of persons like Allscripts, CCHIT, KLAS, HIMSS looking at from the academic perspective and from AMA. And again, we're really trying to cross that gamut to say, what are you finding, what are you seeing, and how can we begin to look at Meaningful Use Stage 3 in particular, what kinds of requirements should we have but equally as importantly how can we inform the vendors of the needs that we have so that the products that are delivered to us for use in our clinical settings truly begin to improve our ability to get our adoption and our engagement in a way that the product substantiates and becomes a tool for the clinician and nothing else.

So, if you think about that whole set of panels and participants for those types of goals then that sort of sets the framework for the hearing that takes place next Tuesday. Next slide, which is just a cover slide and then we'll move to the questions.

And at this point I'd like to ask Cris, and Cris and I can do it together, we don't intend to go over the questions obviously individually, but wanted to share them with the group so that you – not that we've already provided these questions to the potential panelists, but we certainly, Cris and I and others can insert additional questions if you recognize that we've omitted something that you think would be informative to us. And Cris with that would like to sort of just give us an overview of the questions?

Christopher Ross, MBA – Chief Information Officer – Mayo Clinic

Sure. So, as Liz pointed out we're living at the cusp between Stage 2 and Stage 3 for purposes of thinking about implementation and so we've tried to ask questions that address both, both some sort of practical considerations of what can we do to make the upcoming attestation for Stage 2 efficient and effective and then also look forward to what some of the considerations might be for Stage 3 understanding that at this point our view of Stage 3 of course is somewhat speculative.

I think another sort of big picture component here is what we're trying to do with the Implementation Workgroup is to braid together feedback from a variety of sources and that could include comments that, you know, were received on Stage 2 Meaningful Use, even going back quite some time up to this testimony, to try to create a realistic view of what the challenges and opportunities are as we move forward with Meaningful Use.

So, I think the flavor here if you read through the questions with respect to provider and hospital is really practical questions around, you know, what challenges you face and what can ONC do to help you be more effective or efficient in getting to Meaningful Use certification?

The questions around HIE and interoperability really are aiming at a lot of the questions and opportunities as well as challenges that are going to come forward as we – you know, Stage 2 really implements interoperability in a production mode for the first time.

And then usability has been an enormous question, what we wanted to avoid in the usability panel questions was either, you know, a lot of testimony pointing out the somewhat obvious which is that clinicians are frustrated with and struggle with their products, we know that to be the case and we also didn't particularly want to have vendor testimonials around why their products is really, you know, "the best." So, hopefully, we've drawn a middle line to get to a good result.

The format for the hearing will be the members who testify can provide written comments along with questions. We've asked them to provide five-minute verbal comments and our hope and expectation is that we'll get a lot of dialogue between the panelists and between those asking the questions and those answering.

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

And then I would say, Jon, before we take input from the Standards Committee, is that the criticality of this discussion at this hearing is very time worthy and what I mean by that is that we're going to the next morning meet all of the participants from the various Workgroups the next morning to really help formulate what we hear from the panel and put that into recommendations that would be presented back to both the Policy and the Standards Committee around what we heard and where it might move forward.

And it's very helpful to the Meaningful Use Group as they begin to truly finalize their recommendations around Meaningful Use Stage 3. So, we think the timing of this discussion will be very relevant and we're looking for some very positive input into that process from the persons who are actually taking those Meaningful Use standards and applying them into their practices. So, with that Jon we will turn it back over to you and to the group for suggestions, input, and comments.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

Well, thank you Liz and Cris for a very thoughtful presentation, very thoughtful process that you've outlined as well. The first card up is Andy Wiesenthal.

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

Good morning and thank you again also for the work. I think it's extremely valuable. As a physician I'm on the receiving end of a lot of messages about usability both directly or with my clients that I work with and in the sort of niche blogosphere related to electronic health records. Most of it is pretty negative and I'm wondering how you plan on objectively interpreting whatever you hear from practitioners and others so that you can sort through the general complaining about this is a hard thing to be using and it's getting in my way and real comments about UI and workflow that could be useful to the vendors as they retool their products.

And at the same time what do you expect to hear from the vendors about their scientific approaches to usability evaluation, because to my knowledge that's been strangely absent from this entire sphere. So, just two questions, how are you going to sort through between complaining and objective critique from the user community and how are you going to address scientific usability evaluation on the vendor's side?

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

Terrific question, Andy, and I think very clearly insightful of what our, you know, our apprehension about these hearings always is, but we've been very successful at as our panelists testify both as Cris alluded in writing, which we review in advance as well as in the hearing room, we're often able to take an issue that they bring to us and work with them to look at potential alternatives and just as yourself I think you probably have experienced where a workflow has been disrupted or a requirement has been made of you that didn't come into what you would have considered part of what you had done in the past, but working with this panel what we've been able to do in the past, and we did this about three years ago, was come up with some very interesting innovations for how people were able to do that.

The other part of that answer is there may be some requirements that don't contribute to ongoing quality and to what the ultimate goals are and this is our opportunity to identify that so that potential changes can be made in the future. Cris, did you want to...

Christopher Ross, MBA – Chief Information Officer – Mayo Clinic

Yeah, Liz if I could just add to that. Andy, it's a great question and I guess the thing that we've kept in mind as we were putting these panels together and in general seemed that we always try to keep in mind on the Implementation Workgroup as we work through various issues is that our role is as a Federal Advisory Committee to ONC. And so what is that can we do to help ONC's mission?

So, we may be able to accomplish perhaps three things in these hearings when we talk about usability, one is the general just raising the issue and bringing it to industry and public attention is important in and of itself, and I think that's what you're alluding to, I want to come back to that. But the second is, you know, what can ONC do to advance usability and the typical levers and, you know, Dr. Muntz or others may want to comment on this, is it feasible to think about some sort of Meaningful Use 3 standard around usability? Is there a way to do that that effectively advances the industry? Can you in fact, if you will, regulate usability yes or no and I think that's a complex question with a complex set of answers.

The other is what other levers does ONC have to pull and I think that's a third purpose of what these hearings might be and I think about things like the Standards and Interoperability Group and the work that they have done to support and supplement the regulatory work of ONC. So, are there opportunities through, you know, S&I Framework for example and I'm making this up and Doug Fridsma may strongly disagree or strongly agree, I'm not sure which, you know, think about a way that we can advance usability.

So, I guess the temptation is always there to think about this as sort of the broad bully pulpit and there's a component to which we do want to do that, but we also want to keep our eye on the prize that we serve at the pleasure of ONC in order to advise them and receive feedback from the industry and recommendations.

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

Yeah and I would think, Paul, that we also would want to say that the fact that they commissioned a human factors group to go out and really talk with the vendors and begin to start that discussion really plays into your question about, is their scientific evidence around usability, can we move that forward, as Cris said, and, you know, I think that this is a new topic that we've all been clearly aware of, it's not new in terms of the understandings that there is an issue out there, but this is an opportunity to really bring it forward, much as we did with the consumer role and bringing Leslie into the group and really taking something that we've always been concerned about but putting some leadership in place and really beginning to address it on a routine basis.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

Cris and Liz...

Lisa Gallagher, BSEE, CISM, CPHIMS – Senior Director of Privacy & Security – Healthcare Information & Management Systems Society

So, this is Lisa Gallagher. I want to put my hand up. This is Lisa Gallagher, I'm in transit, but I want to put my hand up.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

Okay, we're going to take four comments let's keep them fairly succinct, okay three comments and why don't you go ahead first and then we'll take Stan Huff and then Dixie Baker and then come back to David Muntz for some closing comments on this particular part of the agenda. So, go ahead, please.

Lisa Gallagher, BSEE, CISM, CPHIMS – Senior Director of Privacy & Security – Healthcare Information & Management Systems Society

Okay, so relating to usability, we heard a lot about usability at a CMS hearing on coding issues with EHRs and I know that – you know, I'm not sure of the scope of this, but I wanted to mention that because it was cited by the user community of the EHRs as part of the challenge with regard to the EHRs and usability was something that they were asking for more research on relating to how it could improve with coding. So, I just wanted to bring that up.

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

Thank you, Lisa.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic

That's good, thank you.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

Stan, go ahead please.

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

So, I think, you know, our experience at Intermountain Healthcare has been – I could say a couple of things that we're really concerned about and it in a way goes kind of the opposite way of some of the discussion that I have heard. So, one is sort of completely unexpected consequences of the Meaningful Use criteria in particular environments and the second is that the way that we're approaching this tends in fact to decrease innovation and capability within the system and rather than trying to regulate or understand usability more I think we need to get away from micromanaging this process.

So somehow, I guess my general comment, I'll say a little more to try and create understanding about what I am worried about. But, sort of the questions are sort of – seem to me to be, you know, tinkering at a level of our existing sort of presupposition about how this is working and I'm trying to think how we engage a bigger discussion sort of outside the box of this.

In terms of unexpected consequences I would say, you know, we came up against an interesting situation, in our particular case what we've done in immunizations for childhood immunizations, all immunizations is we actually have integrated a state provided web kids application. So, you know, we just open a window into their database and actually add the data directly into the state's database.

In terms of certification they came back and said "well the requirement says you need to demonstrate you can send an HL7 message with immunization data in it the state." And we said "we write it directly to the state" and they said "the criteria says you need to send an HL7 message with the immunization to the state." So we created an HL7 message to send data to the state that was already going to the state directly through service oriented architecture. And so these, I mean, there are these kinds of things that are the requirements and I understand some of that, I'm just sort of whining I guess about regulation and how things get implemented, but it's real and it causes things.

So, you know, I'm worried about that and then the other thing that I worry about, you know, we're doing things, we create criteria that are reasonable at, you know, how could it be bad, you know, to, you know, not count, you know, to not have people do order entry and have electronic orders, that's a good thing, but then, again you look, you know, what that tends to do is companies say "we have to do the order entry" and somewhere I hope there is somebody who is saying "hmm, I wonder in fact if it's actually the best thing to have physicians have their hands on the keyboard and do that." Are there in fact ways that it can be done in a different way that's more efficient for the physician, better uses ancillary personnel and addresses the other issues that come back in terms of when there is a problem how do we get a hold of the clinician.

And, you know, the world is changing in a way that in fact when the physician needs to re-interact, you know, could we do that through a mobile device, could we do other things. Medication reconciliation, again, a wonderful idea, all kinds of issues around folks saying "yeah, but if I'm an ophthalmologist and a guy comes in with 20 cardiac medications and you're requiring me" you know, really we want the ophthalmologist to tune the cardiologist medication? I mean, there are just these things.

And I worry that we're now focusing on the process and focusing how sort of to tweak what I would call a fundamentally flawed process we're now working with where what I would much rather see is a focus on really saying, putting in extremely well designed and architected standards for interoperability of information exchange and just holding groups available, groups accountable for their outcomes rather than from meeting a particular process measure, because the process measures are getting in the way of innovation and getting in the way of people being efficient and having efficient workflows. So, I'm just whining, but that's what I worry about. And I worry about thinking about those broad issues as opposed to tweaking the little things in the middle.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

So, I can tell this is going to be a very energetic hearing. Let's take Dixie's comment and then come to David and, you know, Stan I think the other piece is that the other vehicles for contemplation of these issues are not just this hearing or indeed the Standards Committee but indeed some of the problems that we certainly – and John and I will commit to addressing with Paul in our ongoing discussions and certainly there are parallel conversations in many quarters that would offer the highest leverage. Dixie, let's get your input, please.

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

Yeah, first of all I want to thank you guys for even planning this hearing. I think it's obviously very important, will be a very important hearing and it definitely will produce some interesting comments.

I noticed in looking through the questions that they are very health system focused like transitions of care to home care agencies versus exchange with home care devices for example. With the increasing focus on patient generated data I'm wondering, you know, maybe, you know, how we might think outside the box outside this traditional healthcare system, especially we get a lot of comments about how you integrate patient generated data and the usefulness of patient generated data and also mobile Apps that will be providing data that will be consumer generated as well as home care devices I mentioned earlier.

I was wondering if you considered asking these people about receiving data that comes from outside covered entities or outside the traditional healthcare system and exchanging information with consumers and with non-regulated entities.

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

Dixie, that's a terrific question. I think what we'll do between Cris and I is there are several panels that that question could be introduced to and we can do that, you know, that's a great addition.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

And again, I'd commend everyone's attention back to the terrific hearing that was held about patient generated data. The synthesis of the transcript is terrific and I know MacKenzie or Michelle we can make sure that's as broadly available as soon as possible, but just terrific discussions. This has been obviously a very robust discussion and Dave Muntz terrific to have you here and appreciate your perspectives on what we might learn from the Implementation hearing that's coming up.

David Muntz, MBA – Principal Deputy National Coordinator – Office of the National Coordinator

Well, I think it's wonderful the work that's been done and I want to compliment everybody. The one thing that I would recommend that you do is that you repeat the question that you have in the eligible provider's section that really looks at outcomes as a way of deeming functionality when you're having that discussion with the eligible hospitals as well. Just thought it was wonderful to bring that up to the forefront.

I think one of the things, and, you know, I keep using this phrase over and over again, but the meaningful conversation that occurs especially around usability is critically important and there are a lot more elements that probably should be brought into the discussion when you are talking mostly about technology. But there are the workflow issues that really impact and the process changes associated with workflows that impact the provider section.

And when you're talking about what needs to happen for the patient it's the life flow implications that should also be discussed because usability of a product on one side without the appropriate balance on the other side gives you an incomplete outcome and if you're going to be more discussing outcomes then measure, than functional measures in the future, you want to make sure that all of the parties who are represented are participating in those conversations.

The other is to think about broadening usability and again just, this is provocative not meant to be a recommendation but to think about discussing pragmatism as opposed to usability and that's to get to some of the criticisms that when you do regulations you may take it too far in one direction or to shallow in one direction. And talk about what are the pragmatic implications of what it is that we're trying to accomplish instead of focusing just on gosh this should be a policy or this should be a standard's issue. I think that would probably help with some of the discussions.

And the other thing that we don't really talk enough about, I think when we talk about usability, and I know this is a bit of a stretch, but stretch goals are how we get to other places, but discussion of competent, culturally competent care should be a dimension of usability. What means something to a person who is not educated versus somebody who is educated substantial difference and there are some cultural differences about how data is requested, how it's represented that can have some significant implications.

And so I'm making this necessarily more complex because I think as you are designing something you want to think about what's happening now and I do like the incremental-ism that was discussed in the future, but I think if you don't have the broadest discussion you won't build the incremental steps appropriately to get us to where we ultimately want to go. So, I do appreciate the opportunity to share some of those thoughts.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

Well, thank you David very much for your comments and Doug Fridsma you were invoked on the second of three questions, so I'll give you a chance.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

Thank you, David, for the summary. There are two things that I want people to sort of consider as we think about usability, so the first question is, is where in the process do we want to kind of create the incentives or create the impact of usability? So, you can do it before something is marketed and you can do it after something is marketed.

And I think, you know, there are different things that FDA does with devices and things like that that have to do either with pre-marketing or post marketing. And so, as we think about the development cycle of health information technology, I think we need to be cognizant of where in that process we want to try to begin to push the levers, if you will, towards better usability.

The second thing that I would say is, whatever our solutions are let's make it actionable, because we could have the most fantastic scientific review of usability, but if I'm locked into a 15 year contract and I don't have the ability to move my data and it's going to cost me – it's going to be cost prohibitive to move from a system that I thought was going to be good, but it doesn't really work in my work process, we haven't necessarily advanced the ball.

So, I think whatever we do, let's make sure that it's actionable for the people who are affected by it so that they have the tools and resources, because it might not be a usability standard it might be a way to get my data out of a bad system and into a good one.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

Thanks for that counsel Doug. People on the phone always get a little bit short changed and Keith Figlioli your card is up so one brief comment.

Keith Figlioli, MBA – Senior Vice President, Healthcare Informatics – Premier, Inc.

Sure, just brief to try to tie some of this together and I'll try to be brief about this. But I'm thinking back to the presentation on the last call that Dixie and I believe another gentleman made around APIs and sort of opening up sort of platforms, if you will, and then I'm trying to tie it to the comment that was just made as well as what Stan I think was mentioning.

You know, I've been doing a lot of stuff around usability for almost 20 years and to give you a little bit of background, you know, in my former life at an EHR vendor one of the major EHR vendors, you know, we rewrote our clinical documentation system three times and the intent of that was all in the heart of usability. We rewrote our medical reconciliation module two or three times as well within that time period and it never hit the mark.

What hit the mark for our customers was when they could actually customize and write their own application. So we had many customers that actually rewrote the clinical documentation system the way they wanted to have it or subcomponents of it.

So, I just think another point that I'm really trying to make here is we need to really think about these concepts and I think this is where Stan was going in that there is a lot of connectors in some of these discussions that if we literally go down and think about it as a usability issue without saying how do you let innovation get to usability. Because, I firmly believe that you cannot put a regulatory or a standard component to usability. You have to let innovation get there because depending on stakeholder it's going to change fundamentally in terms of what you see.

So, if you look at the iOS, the Apple iOS, you know, that's a usability set of principles whether if you design an application in iOS and using that functionality gives you different usability principles compared to designing an application and phone gap that limits some of that.

So, we've just got to allow for that end point to happen, because I think the point about the maintenance is a good one, which is once you tie people into long-term contracts and all the other things that the vendors are actually juggling, you know, you get what – sort of you get there if you will.

But if we have many people having the ability to iterate on top of all of this, back to the point I was making about Dixie's presentation last time, we get an ecosystem that will flourish in usability way farther than we will get if we try to control it on a hand full of three or four, five major EHR vendors.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

Appreciate your points and, you know, the thing is it's a shame that a number of the members of this committee won't be testifying, at least not planned to at this hearing, but indeed your First Amendment Rights for input throughout the process are there as well and I want to make sure toward that end we get to the public comment session momentarily, but a lot of great input.

I just draw together three or four things, first Liz and Cris thank you very much for keying up what's obviously a very thoughtful and provocative set of questions that elicited great discussion here and I'm sure will elicit great input at the hearing as well, things that come back and are very helpful. As always, appreciate David Muntz and Doug Fridsma your perspectives on seeing ONC actively work to incorporate the feedback.

Third comment is that in a sense this discussion takes us back to the very inception of this process and there is a challenge. There is a sweet spot between not being prescriptive enough and giving no signal around which one can develop and being overly constraining and giving signals that arrest innovation and that's, you know, something that I think we need to provide input to the Policy Committee and certainly something that we have to contemplate from a standard's role because if we think about an ecosystem that has absolutely no specifications there is no convergence.

On the other hand for obvious reasons overly constricted sort of arrests development, just candidly it's something we struggle with in my own organization and what I'd say I hope we all think about here as we bring our personal experiences is how do we give enough signal that allows maximum utility and a forward path that supports innovative processes.

Keith you alluded to building an API layer that allow, you know, sort of reuse of data or use of data in novel ways. I'd commend again ONC the SMART Grant is really interesting, Substitutable Medical Applications Reusable Technologies, there is – that couldn't exist in absence of the signal of many of the standards that are there. So, look forward to this discussion coming out. Finally, just an observation many of you called for the need and feedback to ONC the need for the ability for – research and that allows comparison of different approaches in all of their dimensions and that would also include, as was alluded to and David thank you for your support, that the patient experience as a key stakeholder and user, so, a lot of ground, a lot of ground to be covered in the hearing, look forward to the feedback from that.

I want to thank both you, Liz and Cris for this discussion, John Halamka and Jamie Ferguson, great appreciate the content coming forward, John Klimek and Kim Nolen just terrific presentation, terrific discussion and a monumental charge but we know you're up to that and we'll look forward to continuing conversation along those lines. So, a lot has occurred in the first half of the day and let me now turn to Michelle Consolazio for invitation for public comment, the first of two sessions.

Public Comment

Michelle Consolazio – Office of the National Coordinator

Operator, can you please open the lines for public comment and while we wait for public comment on the phone if there is anybody in the room that would like to speak please come up to the desk.

Alan Merritt – Altarum Institute

And if you would like to...

Michelle Consolazio – Office of the National Coordinator

Sorry, if you would like to – please keep in mind that public comment is limited to 3 minutes and please announce yourself before speaking.

Alan Merritt – Altarum Institute

And if you would like to make a public comment and you're listening via your computer speakers please dial 1-877-705-6006 and press *1 or if you're listening via your telephone you may press *1 at this time to be entered into the queue.

Thomas R. Bizzaro – Vice President Health Policy & Industry Relations – First DataBank

Hi, my name is Tom Bizzaro, I'm a Pharmacist and Vice President of Health Policy in Industry Relations for FDB, First DataBank, and I should also mention I am Chairman of the NCPDP Board of Trustees. I found the F&B conversation this morning fascinating and look further to further conversations on the issue.

Formularies are not built at an NDC level they are built at a much less specific level using identifiers from companies like FDB. The thought that we can use RxNorm or RXCUI to decrease the size of those files is certainly something that is possible and seems to make perfect sense and I would endorse that.

On the issue of having a physician have access to specific information about a drug product for a particular patient I think that's also doable using something like the NCPDP telecommunication standard that pharmacies use for the adjudication of a claim, so a variation of that makes that possible.

There are two issues that would need to be addressed, one is that the EHR ePrescribing vendor would have to be willing to integrate into that physician workflow both standards for the transmission of that information and then there is also a cost involved by the physician, a cost involved in time and taking the time to send that transaction, get a reply and then react to that and I think secondly, the cost of a transaction fee for us which is going route that particular inquiry and those two things need to be considered. But, I think that it is very doable and look forward to further discussions on the issue.

Gary L. Dickinson – Director, Healthcare Standards – CentriHealth

Good morning, Gary Dickinson, Director of Healthcare Standards at CentriHealth. The formulary and benefits discussion is a very interesting one and probably opens some serious doors to economies of use and scale if we were able to get to them.

My anecdote, which isn't directly related, is that I've had chronic bronchitis for a number of years and one of the ways that I've been treated is with Levaquin and that has actually been very effective with five pills of Levaquin I'm generally over whatever my current episode or current situation is within a matter of two or three days.

As it turns out, when I went to get my first prescription filled for Levaquin they told me that the five pills would cost \$220.00, of course my co-pay was much less than that so I appreciated that. In any case, I was traveling to China two or three months later and came down with the same symptoms. I went to a clinic there, knew about as much Chinese as the doctor knew English, which is very little, but we were able to communicate and the brand name Levaquin was understood and so that physician gave me a prescription for Levaquin, I went to the pharmacy out in front of the hospital, of course I did not use my insurance for this purpose but instead was given the same five pills and it costs in Chinese Yuan, it cost less than \$3.00 for the same five pills.

I'm wondering if there isn't an opportunity here if we were able to move a query response back to the physicians so that the physician could review the alternatives with the patient but before the patient steps foot into the pharmacy, okay, because once they get into the pharmacy then they're probably locked into having made a decision to get there medications from that pharmacy.

But if the options are available at the point of prescribing, at the physician where they could not only determine what's covered, but also put a query out and say, okay local pharmacies who is going to give me the best price on this before I actually step foot in the pharmacy, that's going to make a huge difference I think in the economies and leverage that patients and physicians have over those kinds of costs and I think it's worth, particularly if we get into the query response, for formulary and benefits management that we really take a close look at how that might be able to impact some of the significant cost factors that we face in health care. Thank you.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

Thank you.

Michelle Consolazio – Office of the National Coordinator

Thank you, are there any other comments in the room? Are there any comments on the phone?

Alan Merritt – Altarum Institute

We have no comments at this time.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

Terrific conversation this morning, let's stand adjourned until 12:30 Eastern Standard Time. Michelle any other administrative instructions before we break or MacKenzie?

Michelle Consolazio – Office of the National Coordinator

I just want to announce that Keith Figlioli and Anne Castro were present for the record. Do you want to change the time for lunch and give everyone an hour or just do 45 minutes and start at 12:30?

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

I think if everyone is good with 45 minutes there may be some travel plans that folks on the committee have and afraid of running up against Washington traffic for folks. Is that good with everybody? Okay, 12:30 it is, thanks very much, everyone, terrific discussion.

Michelle Consolazio – Office of the National Coordinator

Hi, everyone if you could take your seats we're going to get started in a few minutes.

Operator

Thank you for your patience your teleconference will begin momentarily.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator

You can open the lines up now.

Michelle Consolazio – Office of the National Coordinator

Yeah, operator can we please open the lines?

Operator

The lines are open.

Michelle Consolazio – Office of the National Coordinator

We're going to switch the agenda around a little bit. So, we're going to go to ONC updates with Jodi Daniel and Doug Fridsma.

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

It's asked that I moderate this portion of our meeting and so as I said in my introductory remarks this morning that you'll see some very remarkable progress on the S&I Initiatives and Doug I particularly like your score card of projects taken on and outputs and deliverables made. So, Doug, take it away.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

So, before I begin, Bob Dieterle you're on the phone, right?

Robert Dieterle – esMD Initiative Coordinator – Signature Consulting Group

That's correct.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

Yeah, have you tracked down Melanie?

Robert Dieterle – esMD Initiative Coordinator – Signature Consulting Group

I didn't know I was supposed to.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

Okay.

Robert Dieterle – esMD Initiative Coordinator – Signature Consulting Group

I will go track her down right now.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

Okay, thanks. Okay, so while Bob is doing that we'll do our updates on some of the activities that are ongoing. So, first with regard to the Standards and Interoperability Framework one of the things that's nice about the Standards and Interoperability Framework is that our job there is to sort of enable the success of the communities and so I get to report on all the good stuff that's going on even though it's really the community that is driving this and has been so passionate and so engaged in the activities.

Our operating metrics gives you a sense for that, we've got now – we're approaching about 2400 people who have signed up with the wiki, of those there's about 700 that are committed members, that means they show up on weekly calls and things like that and are actively engaged. There's about 500 or so organizations that are represented and at this point we've held over 1500, about 1600 different working groups that have been held.

So, there's a whole host of things that are going out there in the community. We are now pretty much about 2.5 years into this process and again it's always humbling to just sort of see the enthusiasm and the way in which the community has come together. Our job is really to facilitate that and then to get out of the way so that they can continue to do great things.

We've tried to split – our initiatives now no longer fit on a single page so now we have two slides to represent it's essentially the same activities and information. Obviously, we've included the Direct Project. There's a lot of work going on not so much in the Standards and Interoperability Framework but just about Direct in general as people are beginning to implement that.

We've got a number of folks that are part of our federal partners the VA and the DoD that are looking at Direct and really trying to make sure that they can integrate it into their infrastructure. So, it's really some good work that's going on that includes a whole host of different folks trying to include that.

Transitions of care continues, in fact I think that we have moved a lot of those activities into our what we call SITE which is our Standards Implementation and Testing Environment and we are working through relationships with HL7 to see how we can best support the implementation of those standards and when there are challenges, remember the transitions of care standard based on the Consolidated CDA is actually a draft standard for testing and use, and what that means is that it's a draft standard intended for testing and use, which means there are going to be challenges that will come up and when we find those challenges we're working very collaboratively with HL7 to help us feed that back into the standards process and make updates to that.

The laboratory results interface is actually paired with the laboratory ordering initiative and those two together plus a description of the orderable that you can order as part of that, a standard for how to describe those things, provides the three sets of capabilities that allow you to sort of order something electronically, track it, understand what can be ordered and then get back those results in an electronic format and so they're working through the summer to sort of figure out how best implement that. There are discussions around how that interacts with CLIA and we're working very closely with our policy folks to make sure that we have those activities in place.

Query Health is an activity that is ongoing but we are actually folding that into an initiative that just launched yesterday and we'll talk a little bit about that as well when we get to it on the next slide.

Data segmentation for privacy, we've been working very closely with IHE as well as with HL7 to get that through the ballot cycle to make sure that it gets balloted appropriately. There have been some ongoing pilots, we had some demonstrations at HIMSS even a few months ago and that work continues.

Public health reporting, those activities have been folded under the structure data capture activities to try to create that more granular way of describing data and we'll talk about that on the next slide.

And esMD I'm not going to say anything about this because as soon as Bob Dieterle finds Melanie Combs-Dyer we will have a deeper dive in the activities of the esMD Project.

With regard to the longitudinal coordination of care, you know, this is my favorite group and I – you know, it's my favorite of all my children that I love. But, it's a community driven activity and they have been so passionate about the work that they do and so they are continuing to look at trying to identify those requirements that are necessary for longitudinal care coordination.

They've been focused, in large part, based on the direction of the HIT Policy Committee and the work that you guys have talked about here around care plans, care plans in Meaningful Use Stage 1 and Stage 2 were an element of the Consolidated CDA but it was not structured.

So, what they're doing is they're creating sort of an incremental path to go from free text descriptions of those care plans to structured descriptions of those care plans and I think eventually we'd like to get to the notion of computable versions of those care plans that then could be incorporated through APIs or others to create actions, if you will, as part of the sharing of that information.

We talked a little bit about the laboratory ordering initiative and they're sort of completing the loop. This should be ready by the end of the summer. They're going through some of the ballot efforts at this point as well and so we should be in good shape should we want to include this in some of the ongoing requirements.

Health eDecisions, as we talked about a little bit earlier in some of the discussions use case one is about having computable ways of sharing information around clinical decision support rules. And use case two is about creating clinical decision support as a service and how you might kind of send information to that and get that back. It's an important initiative not just in HED but in other activities as we've talked about today.

You can imagine that not only might you want to do that for clinical decision support but you could use it for immunization for example as one of the use cases where you send the current status of immunizations and get back the recommendations for the next set of immunizations that a child might need. So, it has ties to registries and other things like that that might make sense.

And I think as we get a more distributed ecosystem and where things are virtualized as services some of the first APIs that we're going to look at and how that might function are going to come out of the HED use cases and so we've been tracking that very closely and trying to figure out if we can keep them generalizable and integrated into some of the other pieces of our portfolio as we move forward.

The Blue Button activities have continued. Of course, you know we've got Blue Button which allows us to provide capabilities to patients to take their clinical information and with a Direct secure message be able to send it to a personal healthcare record or the like.

But I think it's important to recognize that Blue Button is about access to information supported by a portfolio of standards that extend additional functionality. So, access to clinical information is important but access to financial information may also be important and that is also part of Blue Button.

So, we're working now with some of our Presidential Innovation Fellows to begin building out a portfolio of additional functionality that allow patients to have access to an increasing number and type of information. As we do that we begin to separate out different content specifications, so one for clinical, maybe one for financial, maybe images and cardiology and other things could be different kinds of content types. But as soon as we start to do that we also have to look at the ways in which we convey that information around are transported.

And so there has been work with the Blue Button activities to look at RESTful approaches of exchanging information and ones that have underlying them OAuth and OpenID some of the other kinds of authentication and authorization frameworks as well. Those are important because just like with HED those aren't going to be restricted just to Blue Button functionalities. If there is a RESTful approach that works with Consolidated CDA and provides access for patients there's no reason why some of those kinds of transport mechanisms could be used in other kinds of ways of exchanging information.

So, in addition to sort of push we've explored this notion of a pull almost like a pub/sub model where you subscribe to updates of information and are able to then receive those. In the discussions that we had this morning we talked a little bit about how, you know, benefits, you know, the formulary and drug benefits could be not only just here's a big download but maybe what you do is you subscribe to updates of that information and find other ways to do that.

So, again it's the reason why as we start separate out those content and transport mechanisms we can then leverage activities of some of these other initiatives across new use cases that we've got as well. So, the Blue Button activities and with our Presidential Innovation Fellows are beginning to build out at least how that might look within the Blue Button activities and then our job within ONC is to make sure that those building blocks are general purpose enough that they can be applied to other kinds of initiatives in use cases as well.

The structure data capture is moving along quite well. We've got the target is at the end of the summer to really have identified a potential standard for granular data, containers that include that granular data and then API or functionalities that allow you to access, display, populate and save that information.

The most recent initiative that we've launched, one is our first international initiative. I think we talked about this last month. So, we've launched an international collaboration across member countries within the European community and that includes the UK as a principal partner. We have some special relationships with them as well. And in fact, much of that work is going to, we hope, align with some of the work we've got with Blue Button.

So, the idea is can we create a content specification internationally recognized, encourage the ability of different countries to provide access to their citizens of their healthcare data and combine it with a subset of the vocabularies of the most common kinds of diagnoses and in that way begin to align the standards, the transport mechanisms and patient empowerment not only in the United States but much more global than that.

And the most recent one that we launched just yesterday is what we call our data access framework and that's really an effort to provide access for providers into their own electronic health record if they want to do small data analytics rather than big data analytics so that they can ask questions and generate reports and sort of create an ecosystem of folks that can provide analytics to practices. If those practices are interested in meeting certain quality marks maybe what they need to do is get that information merges it with some other information and begins to provide that sort of advice.

We also then if you add to it an authentication, an authorization framework we can start to provide support for targeted query. So, I can ask the question about getting information out of an electronic health record, properly authentication that is authorized in a remote way.

And then the final phase is really to think about taking Query Health and merging that in which more de-identified information at a more granular level is. So, the idea is that although we've talked about Query Health and we talked about targeted query and we've talked about query as sort of the initiative, what we realized is that it's not about query. Query is the mechanism by which we gain access to the information and it's about accessing that information and providing it to providers, to HIEs and to public health in a way it is secure and is respectful of the patient's needs.

We put this map up here, I can't tell you what the name of each one of those dots are in terms of what the actual initiative is but what I like to do is just look at this and say we've got the country covered in the number of pilots that are going on. We've got engagement across the country east to west and all the places in between in which people are taking those standards testing them, trying to see if they work and then providing feedback to the community about how we can improve the work that we do.

We've got some short-term activities that are I think very high priority for us. We really think that the structure data capture, the ability to capture structured data and extend the functionality of EHR is an important part of the learning healthcare system and if we want to include research and clinical research and the ability to do quality improvement dynamically it's an important functionality.

The data access framework that we've just launched is going to be important for data portability so that patients who move from a provider who uses System A can also bring their data to the providers that may use System B and then the work that we're doing with Jacob and his team around quality and CDS. We'll continue to work on this and we hope to be able to learn more about HED about APIs and how best to handle those that kind of functionality and we hope that over the next year or so we'll be able to include activities around the EU/US cooperation as well as we move forward.

This is just I think included for your review. I'm not going to go through all of these activities we've sort of covered them already, but this is really to take a look at the initiatives that we've got, the different standards that we're using and where we are in terms of its readiness. We tried to go across all of our standards determine where we are in terms of our ability to get it through the ballot cycle and where it is in terms of the standards development process.

And once we've done that then I think this is the group that needs to sort of take a look at this portfolio of things and say "well, what's ready from a clinical, from a business perspective, where are our priorities, what are the things that we really want to push on?" And our job is to really provide you those basic fundamental building blocks so that you can make good choices about what are the next steps that we need to do. So, with that I'm going turn things over to Jodi who has now finished her lunch and let her take it from here.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

Are you – is that – did you want to do that too?

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

Oh, I'm sorry.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

Now I get to finish my lunch.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

She has just two more bites so then she added slides for me. I didn't realize we had this as well. So, just a quick update about the standards implementation and testing environment, we talked about this about two years or two months ago, it seems like years, but it was only two months ago. And this is our effort to take are our draft standards for testing and use and make sure that we are responsive to challenges that are out there and figure out ways that we can then feed that back rapidly into the – both in our standards development process as well as to provide additional tools that will help people with implementation.

So, we've built within that an issue tracker it's based on JIRA, for the geeks in the room, that allows us to sort of track issues and within the quality activities just as an example sometimes it's because our quality measures aren't well articulated and we need to work with CMS and the quality measure developers to improve the syntax of that, sometimes it is because there is a problem with the standard that we need to update because we aren't able to necessarily create it correctly and sometimes there are policy issues about how we implement and use and the like.

And so the important thing is that using the issue tracker we can triage this effectively so that if you're a policy person and you don't apply policy to all of the things even if might be a technology problem or an implementation or a standards problem. So, that's been very, very helpful we're still working out the bugs, if you will, of our bug tracking system, but we are trying to make sure that we are working very closely with CMS with the Office of the Chief Medical Officer and working with HL7 and some of the other standards organizations to make sure we do a good job of that.

We've got forums and discussion boards that allow us to sort of get input from the community and I certainly would encourage people to use the implementation and testing environment to tell us what works and what doesn't so that we can help then bring that to the attention of this group and that way we can then get some feedback with boots on the ground particularly as our programs that we have related to the RS Stimulus Bill begins to wind down, we need a way of ongoing engagement that is cost effective and that provides a mechanism for you folks sitting around the table here to get feedback from a broad swatch of folks that can tell you what's going on.

We hope that over time we can develop a knowledge-base that says here are good questions, here are good answers, here are best practices and we can provide that so that if people are later adopters they can learn from those that have gone before and we can provide that as well.

And we're only slowly beginning to develop now a sandbox and we've got some things that have come from the SMARt Project looking at how to use a Consolidated CDA that has extended the testing tools that provide better input and feedback around vocabulary bindings and things like that and we anticipate adding more of those kinds of functionality, because there's a difference between going through certification and debugging the things that you're trying to build and sometimes the tools you need to support that need to be slightly different and so we're trying to feel our way through that. I think the innovation community and some of the engagement we've had there has been very helpful.

So, right now we've got work on the Consolidated CDA, we've got work on transport related to Direct and web services and then we've got work within the QRDA which is really the kind of quality measurement work as well. And so we're slowly building out this functionality. We don't want a big bang but we want to kind of learn as we do this how we can do this a little bit better.

Just a screenshot to say it's actually there and there are some places that you can go to get information about the Consolidated CDA and some of the other resources regarding Direct and web services as well. And then we're going to begin to build out some work on the QRDA and the other resources there. We've got the bug tracker, the issue tracker if you will, to help us with that and then we're going to add that to the implementation and testing environment as we go forward.

It's been about three months into this, we've got 31 form registrants, 18 form topics and about 35 posts, you know, this is because we're just early in this but we hope that this kind of operational metrics will begin to track along with the Standards and Interoperability Framework as people find it to be a useful tool. Its called sitenv.org is the place where you can find that. So, with that...

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

Before we turn it over to Jodi there are two questions, so we have Jeremy and then David.

Jeremy Delinsky, MBA – Senior Vice President, Chief Technical Officer – Athenahealth, Inc.

Thank you, one of the things that struck me particularly in the S&I Framework review was all the wonderful things that could come of that that I think will be bounded and potentially smothered by some of the disclosure requirements that providers are going to be looking at and I know that there is some work I think coming up in the Tiger Team to rationalize what those disclosure requirements might be but I think it will be absolutely critical for some of these things to actually be born into the world and be very useful and I hope – so just a comment that I think we can't lose sight of that because I think that there is so much exciting possibility here that is potentially gated unless we are reasonable there.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

Well and I think part of our approach, and thank you very much for that, we have to work very closely with our policy folks. So the Privacy and Security Tiger Team, often times we engage them early in these initiatives as they begin to sort of flush out their use cases and what we asked them is that for the purposes of pilot tell us what the guard rails are because we don't want to get out in areas that maybe there are developing policies or we're trying to sort it out.

We want to make sure that our pilots are well-bounded and that we don't get ourselves into uncharted territory with the kinds of pilots that we might do. So, that's something that we learned when we did the Query Health activities. It's something that we learned with the Direct activities. And so, you know, we're trying to really take that and make sure that we have that early engagement for exactly the reasons that you've described.

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

David?

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

All right, thank you very much.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

Oh, no David.

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

David?

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

You can finish your sandwich while I...

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

Good.

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

First, Doug, thanks for the update as usual comprehensive, second I think that new SITE environment looks really promising and I hope it pays off like it looks like it will, that looks really cool and long perhaps overdue.

Third though is my concern and I've raised this before, and I know that this is a complicated subject in the sense that there is as much responsibility on our part as there is on ONC part, but from the point-of-view of maybe the Standards Committee and some of these far-reaching projects like the data access framework get rolling to have some way of surfacing for Standards Committee purview a checkpoint along the way, particularly around the use cases and assumptions as to where it's going and what it will mean if it gets there for our review for those of us who can't participate in every call.

So, you know, for example, you rattled off, you know, three or four really important use cases that could come under the data access framework rubric. It's hard for me to imagine a single framework that could deal with all of those use cases. So, which use cases are actually going to get pushed and which ones will – do the vendors need a lot of advanced notice about because they're really complicated?

So, you know, using for example, FHIR as a way to do a simple straightforward RESTful access to a particular patient's record I think makes a tremendous amount of sense and is leverage-able all over the place like with BlueButton Pull and the SMARt platform if they would switch to FHIR and to a number of other use cases moving them past the XDS model to something a little bit more modern, on the other hand using it for population analytics is not a good fit and those are really distinct technical challenges and somewhere along the way the vendors need to be sure they're aware of where you're headed with these things and maybe the Standards Committee review process in that – at the use case level before you get into the deep technology decisions would be a useful step. I don't know if that makes sense to you?

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

No, I think that's wise counsel. I think one of the things that I would welcome doing is that perhaps in another couple of weeks or months at whatever timeframe seems appropriate that we can come back and report on the recently launched activities, give a report back to this committee, get the feedback about where we need to go or if there are some midcourse corrections that we need to do. I think that's going to be very, very valuable.

I think there is the presentation that I gave yesterday in sort of the webinar that kicked off, the activities around this data access framework, we've had ongoing conversations with IHE looking at their XEA infrastructure about how they access various documents and things and really had a heart-to-heart conversation about how can we take the functionality in those IT profiles and create more modularity and substitutability that allows us to sort of envision this different sets of contents with different ways of both authenticating and the like.

We've also talked with CommonWell to get their take on this to see if there is a way that we could incorporate their approaches to this and we've had very, very positive responses from both organizations to sort of create that modularity. That then provides an opportunity for us to sort of build out these building blocks and know that CommonWell and the XEA infrastructure can also be integrated into this data access framework in some fashion.

You'll also be happy to know that we've been talking with HL7 around FHIR as well, because we do see that as an important activity for us to take a look at and we're looking for some early use cases that we can get vendors or the community to sort of take up the mantle and say "here is a use case for which FHIR is applicable and we're going to demonstrate its ability to deliver on that."

So, that is all part of it and we've actually broken out the layers in this kind of data access framework. We've mapped it to some of the IHE profiles and where there is concordance there. So, you know, what is it the EB RIM and some of the other things that they've got within those profiles and then we've included both the Direct stack and some of the web services stack just to get a sense for where that might fit and we've inserted some of the FHIR objects as well.

So, it's all just to, sort of give a lay of the land. Our next meeting, the first kind of meeting on follow-up is next week. All of the information is available on the S&I Framework website if you go and take a look at the data access framework the presentation is there you can take a look at kind of what we're thinking. But, again this is really just to kick off the initiative and have the community set the stage in a direction so they can help give the feedback that we need.

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

Yeah, just a follow-up on the mention of FHIR and just to endorse the pursuit of that; from a vendor perspective if you could unify for example the Blue Button Pull, which is currently based on FHIR, the SMART platform which is not currently but is very close, and the notion of a standard API to pull data out as, you know, kind of the core use case of the data access framework, all around one thoughtful resource definition model which FHIR is that is ideally suited for REST even if you use it in some other way, that would make tremendous sense to the vendors because it means one particular bit of well implemented technology could serve a lot of different valuable use cases. So, we are very enthusiastic about that.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

So, again without picking favorites, I totally love what you just said and we hope that the...

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

There's a rare moment of unanimity over here.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

We've been working on this. And so I'm hopeful that the community can take a look at those resources and stuff, we anticipate the next HL7 meeting, where we'll have an opportunity to get together with some of the FHIR folks, will be in September that's really good timing to kind of get some of this work and discussion out there and figure out if we can then use that as a leverage point.

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

Don't I recall that the SMART platform actually uses RDF as a...

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

RDF.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

You're right.

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

Not FHIR so it's not an HL7 or XML construct, well, I mean RDF is an XML construct, but...

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

I've been lobbying with the SMART group to consider switching to FHIR as the resource definition, you can still encode it in RDF if you want to, but the resource definitions themselves it makes sense, since they overlap so much with what SMART needs you might as well use the same one that works for Blue Button Pull and the same one that would work for the data access framework because they're so close. I mean, you need medications, you need problems, you need allergies, you need encounters, and you need all those things that FHIR has very clean definitions for.

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

And in a rare moment of total unanimity I am actually a Co-PI of that grant and I support your ideas. So, Jodi, go ahead.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

Great, thank you. Now, I'll let Doug eat. Okay, so I just wanted to focus on a few things in my update. I'll keep it fairly short primarily focusing on our safety plan that we recently released and figured folks would like to hear the latest on that and a couple of the announcements that we made along with that that are relevant to you all and then touch on a couple of other issues.

So, our Health IT Patient Safety Action Surveillance Plan we released the final plan on July 2nd and just to give folks – remind folks the history of this, we had commissioned the IOM to do a study and report on Health IT and patient safety which they released back in November of 2011.

In that report they identified a few things, they identified the need for more and better information about Health IT and whether or not Health IT can sometimes have an impact, a negative impact on patient safety as well as a positive impact, which we're well aware of, as well as strategies for mitigating those risks and creating a culture of safety from all the stakeholders involved.

In that report they called on ONC to put out a surveillance and action plan which is what we've done. We put it out for draft in December of 2012, we asked for public comment and this final plan reflects the input from IOM, the input from our Health IT Policy Committee as well as public input in coming up with the final plan. It was developed in close collaboration across HHS, we worked closely with AHRQ, with FDA, with CMS and others to make sure that we were leveraging the various priorities that folks have and that we were coming up with a joint plan for addressing Health IT and patient safety.

So, the goal here was really to advance patient safety and increase the Health IT enabled landscape. We were focusing both on the benefits and the risks. So, we know that Health IT has the potential for substantial benefits to improve patient safety which is what all of the ONC initiatives and efforts have been based on. But we know also that whenever you introduce new technologies, that also comes with some new risks and there were still some questions about the type of risk, the magnitude of risk and what kind of strategies we could take to address some of those risks.

And so in our plan we did try to address the benefits as well as the risks and how we can use Health IT to advance patient safety with respect to both of those issues. As I mentioned, this was very collaborative with all of the federal government entities but we also made sure that our plan addressed how the public and private sector can work collaboratively and in their own space to advance Health IT impact on patient safety.

So, very brief overview, there are two objectives aligned with the benefits and risks, one is to use Health IT to make care safer. So, continually to use the technology to improve patient safety as well as to align with the other patient safety efforts that are going on in the department and use Health IT as a for support for that and second to continuously improve the safety of the technology itself. So with those two objectives we had three strategies to learn, improve and lead.

So, learning, we knew and we heard from the Institute of Medicine that we needed to improve the quantity and quality of data and the knowledge about Health IT safety through strategies and tactics around that using that new knowledge to make improvements in Health IT safety and patient safety more broadly and targeting resource and corrective actions based on the learning and knowledge that we can obtain. And then third to lead, to help promote a culture of safety related to Health IT within the federal government as well as between the public and private sectors.

I'm not going to go through all the strategies in detail I just wanted to give you them so that you have a flavor of some of the activities that we have in our report, it is all up on our website and those see slide number, number, number never got filled in, so you'll see them coming up.

So, in the learn space we talked about three general categories, encouraging and making reporting easier for instance by leveraging our common formats and helping to enable folks use, EHRs to use Health IT to support reporting, to support and strengthened patient safety organizations. So, building on the authorities we already have AHRQ is going to help to de-identified and aggregate some of the data from patient safety organizations so we can have better information about patient safety events and the role positively or negatively of Health IT in those events.

And third to analyze data from multiple sources and we provide a couple of different things that we'll be looking at as well as two announcements that I will talk more about in a minute our ONC EHR Surveillance Program and the Joint Commission Sentinel Events Program which we announced when we put out the plan.

With respect to improve, we talked about establishing and advancing Health IT patient safety priorities. ONC plans to lead a public/private process to help development improvement priorities as well as to continually work in our Meaningful Use and Standard and Certification Rules to use those levers to advance patient safety and Health IT safety.

We've talked about developing and disseminating tools and interventions. We are developing safer guides which are really to help folks in understanding where they may have safety risks and then some best practices for addressing them.

And then third to investigate serious adverse events and take corrective action and we have the Joint Commission which will be doing some investigation of Health IT safety related events. We have CMS that is intending to train surveyors on Health IT safety and then we have a – we are working collaboratively across the HHS agencies to respond to any issues that we become aware of.

Finally, in the lead category, I'll just highlight a couple of these, we have established an ONC Health IT Safety Program this is housed in the Office of the Chief Medical Officer under Jacob Reider. He is working collaboratively with my office, the Office of Policy and Planning, in implementing the safety plan and establishing the Health IT Safety Program.

And I also wanted to remind folks of the work we have with the Policy Committee on FDASIA to get recommendations on a risk-based regulatory framework to oversee health information technology including mHealth and we are expecting recommendations at the Policy Committee meeting or draft recommendations, draft input at the August meeting and they will be finalized for the September meeting at that point ONC, FDA and FCC will work on drafting a proposed framework for risk-based regulatory framework for oversight of Health IT that both supports safety, promotes innovation and reduces regulatory duplication.

So, the two things that were announced at the time of the safety plan that I want to highlight is we put out guidance regarding surveillance of certified EHR technology. This guidance was also issued on July 2nd and we talk about what we expect ONC, ACBs, and the Approved Certification Bodies, to do surveillance of. So, they are expected to do live surveillance of certified EHR technology of the products that they have certified and we specifically asked them to focus on safety related capabilities including CPOE, drug-drug and drug-allergy interaction checking and medication reconciliation and to help provide insight into how these capabilities perform in actual clinical environments in which they're used and help us understand so that we can target efforts to mitigate risks that maybe associated with those capabilities.

We've also asked them to examine the developers processes for receiving and responding to user complaints related to safety of the products that they have certified and I think that that will also be a good source of information and intelligence that we can build on. We have strongly encouraged the ONC ABCs to make the results of their surveillance publicly available in order to promote transparency and provide better information about Health IT products and any issues that are coming about.

The second announcement we made when we put out the plan was, wait hold on a second, collaboration with the Joint Commission. We contracted with the Joint Commission, a one-year contract, which does have an option year to do three things, to help us with near-term data and analysis, to support early detection and mitigation and to examine and provide recommendations on the role of external oversight bodies.

With respect to the data and analysis we have specifically asked and they are going to conduct investigations of Health IT related sentinel events in both hospitals as well as some ambulatory practices which I think will be very helpful for us to have a way of understanding the root cause of some of the events and how Health IT may or may not have played a role.

We also have asked them to conduct research on their database of information of sentinel events to help provide us some more analysis and information. They will provide ONC with de-identified reports on the actual investigations including findings and recommendations as well as their research of their database and they will provide preliminary research on identification, classification, types, frequency and severity of Health IT related events.

With respect to early detection and mitigation we expect that they will issue some public alerts and guidance to help target some mitigation activities and develop resource and training for providers. And then finally, as I mentioned, to provide us some recommendations on how external oversight bodies can help to ensure Health IT patient safety as we're looking at this as a multi-stakeholder plan for looking at patient safety more broadly.

Turning to the next topic that I wanted to mention, ONC has recently released a new mark for certified EHR technology we unveiled this on July 10th. This mark may appear on EHR products that have been certified by the ONC ABCs and indicates that the product meets the 2014 edition standards and certification criteria. There are marks both for complete EHRs as well as modules and we have an entire term sheet on our website about the terms of use for using our certification marks. The ONC ACBs will begin to issue the mark for certified EHR products immediately and, as I said, if you go to our policy tab, the red tab on our website, you can find more information about the use of the certification mark.

And last but not least, just quickly and you have the link here, I wanted to let folks know that there was a report to congress providing updates on the adoption of Health IT from January 1, 2012 through April 30, 2013. This report describes CMS and ONC efforts to facilitate nationwide adoption and exchange of electronic health information and I just want to let folks know that it was out there and that you could find it on our website and that is all I have, thank you.

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

Okay, well, thanks, very much and I neglected, because of my peripheral vision to see Dixie's card which was a question for Doug and then we'll move onto Dave McCallie and to Becky.

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

He ignored my kicking under the table.

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

Oh, yes.

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

Thank you, yeah, Doug, I had a question about your presentation. You mentioned initiatives and building blocks and standards and the question that frequently comes up especially within the NWHIN Power Team is at what level does ONC expect to see standards for regulations?

Like on slide seven in particular you have a column that says standards, you have one that says initiatives, and you also keep talking about building blocks. And we found – and to use an example of my presentation from last month we found for example like the BlueButton Plus Initiative actually is tightly enough constrained that it could be a standard even though it uses standards such as OAuth2 and OpenID Connect, right?

And so my first question is, what does ONC consider a candidate at what level of granularity as a standard? And secondly, as Jeremy mentioned before, there are dependencies on policies here and one of the most obvious is the data segmentation for privacy that really – we have a technology there, but we have no policy in place at all. So, my second question is, it's not clear, again what readiness means on slide seven? So, I'd like you to clarify those two things for us.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

So, I'm going to take – I'm going to do last in first out. So, when it comes to the data segmentation for privacy activities the key lead on that has actually been Joy Pritts and her office and so that more than perhaps any other initiative is really very closely linked to some of the policy discussions as well.

So, I think though your point is well taken and generalizable which is to say there are so many dependencies with these policy activities I think a lot of times what we try to do is at least get the technical pieces done.

We work with policy to just sort of say give us our guardrails so that we can kind of get some of the technical work figured out but then feeding that back and connecting it into the policy I think becomes an important aspect of sort of, you know, technology might be ready policy may not. When it comes to our ability to implement in regulation maybe we need to make sure that we get those things matched up and ready at both aspects.

With regard to like standards and things like that I'll go back to the HITECH Act of 2009 in which congress said this group here and ONC has the authority to identify standards, implementation guides and certification criteria and what we've typically done with many of the standards, so for example, Consolidated CDA is based on CDA but there is an implementation guide that takes that standard and constrains it for a particular use case and says here are the other dependencies, here are the other pieces you need to solve that use case.

So, you know, OAuth is a standard, you know, the STMP is a standard, Consolidated CDA with an implementation guide is a standard, combing all those things together to solve the problem probably goes into what we would consider an implementation guide that is tightly constrained. Now those things can still be adopted in regulations. We have the ability to adopt those. So, whether you would say it's an implementation guide or a standard may have to do with ballots and things like that.

We've taken many of our implementation guides and actually ballot them through HL7 as well. So, one could consider those to be standards even though we would call them implementation guides in the sense that they pull those pieces together.

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

Like Direct?

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

Yes.

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

Direct is a good example.

Doug Fridsma, MD, PhD, FACP, FACMI – Chief Science Officer & Director, Office of Science & Technology – Office of the National Coordinator

Exactly. So, we haven't made clear distinctions about what a standard is or an implementation guide but that's been our sort of general approach and whenever we think even bundled together this is tightly constrained and represents a fairly cohesive group in those situations we even will go to HL7 and try to ballot those implementation guides, again, to get as broad a participation and input into what we do so that we can make it better.

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

All right, so, David McCallie?

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

Yes, so, Jodi, that was really a clear presentation of an incredibly complicated space.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

Thank you.

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

So thank you for that. But I was just for fun keeping track of the number of federal agencies that were mentioned in your presentation and it's a long list that I won't repeat, because everybody else has heard them all, but my question is, you know, given that ONC has one of its goals is to promote the adoption of HIT technology, are you worried or I guess I should say, what are you contemplating doing to address avoiding just a regulatory thicket that no one can get through with shared responsibilities between ONC, CMS, FDA, FTC, Joint Commission, AHRQ, the PSOs there I went and named all of them, but I mean, it seems that starts to get really complicated.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

So, yes and no. So, we here at the Office of the National Coordinator so it is in fact – it is our role to try to coordinate all the different activities. So, the PSO program has been in existence since before ONC was I believe, obviously CMS's survey and Cert Program has also been in existence for a long time. FDA's Regulatory Program has been in effect for a long time. What we're trying to do is actually coordinate all of those activities so that it's easier for folks to navigate what's going on.

When we put out the plan we did leverage existing authorities. We weren't talking about new requirements or new activities that folks had to do but how can we leverage what's out there, how can we coordinate it, how can we take advantage of what AHRQ is doing on common formats when we're looking at certification for EHRs and standards for EHRs? How can we leverage the data that they already have in the PSOs to improve our understanding of Health IT and patient safety? And that sort of thing, how can we make sure that the folks that are out doing the survey and Cert work for CMS understand what's going on with respect to Health IT so that it's part of what they're doing rather than something new or conflicting.

So, what we're trying to do is connect all those dots and I think the plan is designed in many ways to bring the agencies together and in the last year we've actually had a lot more collaboration than we've had in the past because of trying to pull this together.

We did talk in our plan about an interagency committee so that we can actually coordinate what we're doing so that we're not all responding to different things in different ways and providing mixed messages so I think that can help, and so we're taking our coordination role seriously.

With respect to, you know, kind of oversight, and we've worked also very closely like with FDA and their draft medical Apps guidance to make sure that what they're putting out in guidance is consistent with what we're doing with respect to Health IT and EHRs so that we're not, you know, creating different requirements that are not connected where people have to do – talk to multiple agencies about overlapping requirements.

The FDASIA work I think really – that's one of the requirements that we had in putting forward some proposals for draft framework is to address regulatory duplication and that's why I think congress in its wisdom asked us to work collaboratively with FDA and FCC, it's not all of the players and part of our challenge internally is to bring in some of those other players. But it is one of the conversations that are going on right now at the Workgroup level is where the regulatory duplication is?

Where is there – because there are so many different folks minding the shop nobody’s minding the shop, so, you know, what happens when there’s a safety event is that something that FDA cares about, ONC cares about, FCC cares about, FTC cares about, like who should find out about that? How do we make sure that there is some accountability and knowledge about what really happened?

So I think that some of those conversations are happening at that Workgroup level and hopefully we’ll try to address when we put out a framework from the agencies, which by the way we will ask for comments on, it will not come out in final form.

So, you know, I think you raise a really important challenge. I think it’s something we are, actually much more on top of than we have been in the past and if there are specific issues that people are aware of that we should make sure is on our radar screen we actually do have a Request for Comment that is open right now on the FDASIA work so folks can submit comments in that process as well or else just let me know.

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

Becky and then last question Andy.

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

So, my question is kind of building on what David said and I think it’s great that somebody is addressing these issues and trying to coordinate around all these agencies, but I’m not sure which way to ask the question. The selection of the AHRQ’s form, I mean, what was the incentive behind that, because it doesn’t match the FDA’s form and there are some other terminology standards behind that that have for a long time been an issue when we’ve talked about safety between research and healthcare?

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

You mean the reporting?

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

The actual AHRQ form because that’s become a little bit of a challenge with the structure data capture work as well, because one of the use cases is safety reporting. So, the fact that the AHRQ’s form doesn’t match the other federal agencies forms, I’m just wondering what the rationale was there and how we could try to coordinate the standards in that area.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

So, I’ll say two thoughts and then it maybe a longer conversation off line to better understand the heart of the issue. But, the two things I’ll say is one, we are talking about – we have gotten AHRQ and FDA to work collaboratively to try to coordinate their reporting and I know they have been doing that. So, if they’re still – you know, if there either is not – if there are challenges there – but let’s talk off line and tell me what they are. Because, I know that they have been working more collaboratively than they ever had, which was that they weren’t before.

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

I can see that from this, from what you’ve done.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

Yeah and I think the reason honestly that we've focused on the common formats, our common formats is because when we're looking at patient safety, we're not just looking at it as "the device" "the technology" the health information technology but the whole ecosystem that has a role to play in the safety event. So, the common formats are really what the providers, the hospitals are using to report the events, they're the ones who are identifying that there is a problem, that there is an event and it may not just be about the technology but there may be lots of other things that are coming up and so it seemed like the right thing to do.

It also, I think, you know, quite frankly people tend to be more comfortable with reporting to patient safety organizations and it was something that we're trying to encourage to happen more. But, I would be happy to have that conversation off-line to understand where some of the disconnects are better.

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

Okay, thank you.

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

Thank you, I was wondering in particular with reference to the Workgroup, the Interagency Workgroup that you're describing, is it possible that you're contemplating some kind of air traffic control for initiatives? That would certainly be a desirable outcome from the perspective of every stakeholder community I can think of, from the vendor communities to the user communities so that at least initiatives from one agency aren't across purposes with another and there's some idea of the general burden of initiatives in any one particular rolling 12-18 month period for the people who are affected by that.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

With respect to safety and safety reporting?

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

Yeah, well, you know, certainly, yes safety.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

Yes.

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

And if you get it to work there it would certainly be nice to broaden the idea.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator

Yeah, I mean, I think that is – like I said we have I think made great strides to improve the coordination of the various agency activities with respect to safety and we have this Interagency Committee, you know, so we have folks who are kind of committed from all of the agencies to work collaboratively. So, I think we're moving in that direction, you know, I don't know if we'll ever get to the perfect scenario where we've got it all mapped out and figured out but were trying to move in that direction.

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

Thank you much.

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

Melanie we want to turn to you and Bob, and now before you got here I of course talked about the importance of your work and how Dixie especially is going to be very interested in the digital signature activities, because she was charged by ONC to begin a digital signature investigation in her committee.

Melanie Combs-Dyer, RN, MS – Deputy Director, Provider Compliance Group, Office of Financial Management – Centers for Medicare & Medicaid Services

Wonderful, well thank you so much for inviting me here today, I do have Bob Dieterle on the phone, Bob, can we do an audio check are you there?

Robert Dieterle – esMD Initiative Coordinator – Signature Consulting Group

Yes, I am.

Melanie Combs-Dyer, RN, MS – Deputy Director, Provider Compliance Group, Office of Financial Management – Centers for Medicare & Medicaid Services

Wonderful, thank you so much, I am the Deputy Director of the Provider Compliance Group at CMS and that is the unpopular part of CMS. I don't hand out incentive payments. I'm the person that oversees the contractors that hassle the providers, ask for their medical records and take their money back. So, if you see a big target on my back that's why.

Bob and I are going to split the presentation today. I'm going to be doing the first half and then Bob will pick up on the second half. I'll talk a little bit about the background of the electronic submission of medical documentation or esMD Initiative. We'll talk a little bit about what we're doing with ONC through S&I which has to do with sending secure electronic medical documentation requests to providers, replacing wet signatures and moving to structured documentation instead of the PDF world that we're in today. Then Bob will talk a little bit about some of the work that the author of record or AoR Workgroup is doing.

When I tell people how many dollars are paid improperly by the Medicare and Medicaid Program each year people are appalled, it's \$28 billion every year from the Medicare Program that we estimate are paid improperly and almost that much in the Medicaid Program each year, and people look at me and say "why on earth would you pay improperly that amount of money, it's American taxpayers dollars, are you just wasting it frivolously away, why don't you have in place better programs to stop those improper payments."

What I try to remind people is that we receive over 4.8 million claims every day and we have a mandate from congress to pay those claims within 14 days. We also get a very small amount of money from congress each year to stop a very small number of those claims and subject them to manual medical review. By manual medical review I mean sending a letter to the physician or the hospital, or the DME supplier, or the pharmacy and asking them to send back in the medical record and then having that medical record reviewed by one of my contractors, those medical documentation requests are sent by a host of contractors. We have a typical alphabet soup of the names for them. They're called Medicare Administrative Contractors or MACs, Recovery Audit Contractors or RACs, CERT, PERM the acronyms go on and on. But, collectively I call them review contractors and they send out about 1.5 million requests for medical documentation each year.

Before the esMD Program came to be in September of 2011 those requests letters were sent by the review contractors to the providers through the U.S. Postal Service and those providers had two ways to send in their medical documentation they could either photocopy the medical record, box it up and give it to the mailman or FedEx or they could fax it, mail and fax those were the only two options.

But starting in September of 2011 we opened up the esMD system and that gave providers a third way. Instead of relying on mail or the fax machine they could esMD their medical documentation to the review contractor who requested it. That's what we call Phase 1 and that's where we are today. We have about 18,000 providers who have actually used esMD since September of 2011, that's pretty small given the number of providers that are out there, but we are rapidly increasing and we're very happy that we've gotten to that level of penetration and the numbers continue to increase.

The total number of medical records that we have received through the esMD system since September of 2011 is now over 400,000. So, again, small compared to the 1.5 million requests that go out each year, but we are ramping up, we're getting up there. This is becoming a viable alternative for providers. We're well past our pilot stage of a handful of medical records each week.

But the great vision is to get to esMD Phase 2, esMD Phase 2 is where we get rid of the U.S. Postal Service. No I don't mean we're getting rid of all mailmen across America. I mean that we will now be able to give providers the option to receive those documentation requests electronically and that will be the Holy Grail to most providers.

They absolutely hate opening up the mail and receiving those requests for medical documentation because they have to key in all of those numbers, it's, you know, 200 medical records that are needed this month and somebody has to sit down and key it all in and there are always mistakes and it's always a pain in neck and they're really looking forward to being able to receive all that electronically. We of course are also looking forward to getting to that stage where we don't have to print and mail all those medical documentation requests every year.

So, the goals of esMD are to reduce administrative burden, reduce some of those improper payments, because if we can be more efficient in the way that we're doing review, we can review more claims. We would like to be able to move from what we call a post payment audit world where we are reviewing months or years after the service is delivered and after the claim was submitted to a world of more prepayment review, which is where the service has been delivered, the claim has come in and we're stopping that claim before we pay it, right or wrong, we're looking to the medical record, we're making a decision and we're paying it correctly the first time.

And we now are running a demonstration program to use prior authorization, which would be to review the medical documentation before the service is even delivered. So far, that has been a very successful pilot for us. We're doing it with power mobility devices, those scooters you see advertised on TV, we have seen a huge decrease in the utilization and no complaints from beneficiaries that they are being denied access to care. So, we think it's a really good model and we're hoping that we may be able to replicate it.

Our requirements in the esMD Program are to move from paper to electronic communication, to replace wet signatures with digital signatures and to migrate from structured data to unstructured data. Again, on the wet signatures to digital signatures there are really two main places where that's important to us, one is in the actual medical record itself, there are many times where in order to be covered by Medicare we need to see that a physician's signature is there or that a particular medical practitioner's signature is there.

And in the paper world we could see a pen and ink signature, it's much harder in our world of EHRs. We see some words that are typed out on the page, but in PDF we're really not sure what do those words mean maybe it has signed by John Smith, well is that an MD, what was the date? Sometimes we even see verified by and a string of numbers, we can't even tell who is associated with that. There are a great range of standards out there in terms of what EHRs are using today in terms of what signature shows up in the PDF extract of a medical record.

Secondly, we have a really important mandate from FISMA, I'm going to back up a couple of slides and just remind you in Phase 2 here where we are trying to send the medical documentation request electronically to the provider FISMA says that we cannot send that because it contains PHI unless we know exactly who the end user is. We have to validate the identity of the end user or we have to go out and do a full security test and evaluation of that doctor's EHR system, their whole system, which we don't want to, do, we'd rather just verify the identity of the end user. What that means is that there is going to need to be a sign-up process, providers are going to have to communicate to us, CMS, who they want to receive that PHI on their behalf and we'll be talking about that a little bit more as we go along.

Here is a picture of what we are aiming for in our esMD system. Today across the top you see the red little buildings those are our review contractors and remember that they are sending out documentation requests to the providers who are there on the left. Those are physicians, hospitals, pharmacies, radiology facilities, skilled nursing facilities and the like. Today we only have one type of gateway that is working at the Baltimore Data Center and that's the one that's listed at the bottom, CONNECT.

So, the health information handlers or the HIHs who have built a CONNECT compatible gateway have providers that they have a business relationship with. They receive the medical records from their providers and they send them to our CONNECT gateway and we ingest that into our system that we call the Enterprise Content Manager or ECM and then through content transport services deliver it to the review contractors who requested it. That piece is what's working very well.

But we do have envisioned adding some additional capabilities to our gateway. We would like to build a Direct gateway. We would like to build an EDI gateway, an X12 gateway. We want to be able to speak to all the content providers out there, all the providers don't necessarily keep their medical records in the same format, they don't necessarily have the same intermediaries or helpers helping to manage their medical documentation. And so we want to make sure that we can speak to all of them or we can receive content from all of them.

We also believe that we're going to have to have a provider registry or a provider directory inside CMS so that we can keep track of the digital certificates from each provider who is signing up to participate in esMD Phase 2 and we'll talk about that a little bit more as we go along.

Here's what the process flow would look like for a provider who wants to be able to receive electronic medical documentation requests. On the far right-hand side you see the box that talks about sending medical documentation that's in place today. You see I have that labeled at the bottom as esMD Phase 1, that's where we are. I can give myself checkmark for getting that part accomplished.

What I have not accomplished is what is in box two and what is in box one. Again, FISMA requires that I know exactly who I'm sending PHI to. It doesn't matter the other way around, providers can send me anything, but when I want to send something out I have to make sure that I know exactly who I'm sending it to if I'm not using the U.S. Postal Service, if I'm doing it through electronic means I have to know who is at the other end, who is going to be the end recipient and what that means is that a provider would need to register with me.

We are envisioning they would send in their digital certificate, they would say "I'm signed up with HIH number four, please send all of my documentation requests, letters, electronically" and they won't be letters they will be transactions. "Please send my documentation request information to HIH number four. I authorize that HIH to receive my PHI. Please send it to them and they will forward it onto me and I will update this transaction once a year. I'll make sure that you have my valid digital certificate and I'll make sure that I am authenticating that that particular HIH I still have a business relationship with." That's what we're envisioning.

Once that registration is in place then we will authorize our review contractors to send electronic medical documentation requests to that provider and that's box two. At this point I'm going to turn it over to Bob Dieterle. Bob you have the floor.

Robert Dieterle – esMD Initiative Coordinator – Signature Consulting Group

Okay, thank you very much. I will go through the remaining slides fairly quickly and only touch on the high points much of the material is here for your review. As we look at the overall workflow through the esMD Program the approach we've taken is that all of the actors, meaning all of the participants in this, will have a digital identity, a non-repudiation digital identity that they can use for two purposes. One, to sign transactions and the other to sign documentation.

So, when they want to become part of the esMD Program they will submit a signed, digitally signed transaction indicating that they wish to become part of the program. Their digital certificate will have been, and we'll talk about this in a minute, have been issued under a specific set of assurances. It will include as part of it for CMS, their NPI and the transaction will indicate that they wish to sign up for the service and if they don't do it themselves there will be a delegation assertion allowing someone else to do it on their behalf.

Once that has happened, or as part of that happening, in addition to validating that they have an NPI, in addition to validating the certificate we'll go out and validate that they have indicated a provider directory that will keep their electronic service information so we can continue to send to them directly even as their service points change going from one HIH to another, going from an HIH to an internal process within a healthcare organization and we'll check that before we send out any transaction that contains PHI.

So, as part of being signed up they now have the right to receive these electronic medical documentation requests and that's what we will do is send them out signed from CMS centrally for all of the various contractors and send them to the end point directed by the provider. The provider then can process these electronically because they will be structured. They can respond back electronically using esMD Phase 1 approach. We have created the process, and we'll talk about this in a second, where they can sign the submission as a submission and within that submission they can have signed documents. Next slide, please.

Broadly, where validation of electronic signatures goes in the process is once we've received something or if we're ready to send something we will validate the signature and let's look at an in-bound at the moment. So, we will validate that the digital certificate is current, meaning it hasn't expired, that it's been issued by a valid authority under a valid certificate policy. We will validate any delegation of rights that have occurred, meaning if you give your right to sign to someone else like an HIH, we'll validate that the signature artifacts are appropriate meaning correct date and time, purpose of signature, etcetera and then we'll validate the integrity of the submission. Next slide, please.

I'm not going to go through the definitions. They're here just for review and for those people that aren't as familiar with the whole digital signature process. The one I'm going to point out is non-repudiation, which is a big part of what we're using digital signatures for and that is to provide, and the part in red is the important part, the integrity and origin can be verified by a third-party. So, unlike electronic signatures that require system audits and audit logs, this stands alone by itself and its fundamentally why we have moved to digital signatures. Next slide, please.

So, we broke the author of record work which is focused on these signatures, digital signatures on transactions and documents, and contributions into three levels. The first is the focus on a digital signature on what we're calling a bundle of documents, think esMD Phase 1 where I send one or more PDFs and I'm attesting to the fact that those are being sent to satisfy the request for documentation. We also are addressing a number of other, I'll call it, structural issues related to the use of digital signatures in Level I. We've done this already, we'll talk about this in a second. On Level II we're focused on digital signatures on individual documents and our example primarily is going to be on the Consolidated CDA which we've recommended it should be the basis for and is in esMD Phase 1, the basis for exchange of information including for attachments rule.

Level III gets more complex. In Level we're looking at individual contributions for example, who contributed to the record that is created in the emergency department, if two surgeons go and perform a surgery together who contributes what part of the documentation, etcetera. So, that part we have not started yet. Next slide, please.

The three topics we took on as part of author of record Level I were identity proofing standards, and process, how to issue and manage digital credentials for signing, and what the signing and delegation artifacts need to look like. Next slide, please.

On the identity proofing side we looked at all the standards that might be relevant for us we settled on FBCA X.509 certificate policy, the FICAM Roadmap and the NIST 800-63-1 for identity proofing. We required that it be at FBCA medium assurance and we'll talk about this in the second. Next slide, please.

So, the recommendation is that you're identity proof compliant with FBCA medium assurance and that requires either an in person event or an acceptable antecedent event. You must also, as part of identity proofing, have validation of your NPI or alternative provider ID if this is going to be used for author of record work, meaning the signature is being used for the author of record purposes for signing documents for medical/legal purposes.

One identity proofing is our goal with a single identity proofing at this level we should be able to issue any and all credentials that require the same level of identity proofing or less. And we've looked at the need to federate RAs and we believe we can do that using existing processes, for example for credentialing, for licensure, for HR functions where we can take this and start to distribute the process across the healthcare community. We have a series of gaps we've identified that are primarily tied to policy that need to be created and instantiated in this author of record and digital signature community. Next slide, please.

On the signing credential side these are 509 certificates, they are intended to be issued by CSPs or CAs that are cross certified with the federal bridge or their direct subsidiaries and we've identified the fact that the user must authenticate to the signing credentials with at least the two factor authentication, one of which needs to be a hard token. Gaps, we have some gaps related to long-term validation, organizational certificates, and long-term access to – well the two statements are really the same, but basically, long-term validation. Next slide, please.

On the digital signature side we've adopted both an IHE approach to digital signatures on multiple documents using DSG as well as the W3C approach using XAdES for XL for a validated signature, electronic signature, digital signature, sorry, on a particular document transaction, etcetera. So, we have adopted those standards for the signature. On the delegation side we've adopted the SAML assertion as the basis for creating the assertion that someone has the right to sign on your behalf. Some of the gaps are, again, long-term validation and validation or revocation of the assertion. Next slide, please.

So, broadly this is a type of flow you see in a transaction. Inflow applies to a document and that is you have to create a digest of the thing you are signing. Your private keys are used to encrypt that digest. That encrypted digest and your public key is sent to the recipient. The recipient can use that public key to decrypt the digest, the digest is basically a hash function, it is a short representation of the thing that you're signing, and they can compute the same digest and compare them. If they're equal that proves that the document has not been modified or the transaction so it's data integrity and by following the trust chain back for the issuance of the certificate back to its issuing authority and the policy we can validate the identity of the individual. Next slide, please.

As we look at electronic determination of coverage which is really where we're providing a lot of this effort, meaning how we sign documents that are used specifically in CMS to deal with either prior authorization, prepayment review or post payment audit, we have this general workflow that we have to take into account. We have the physician interacting with the patient, the physician may refer to a licensed clinical medical professional who interacts with the patient and creates documentation. The physician may refer to a specialist or a service provider who creates documentation and all of them may interact with the payer, CMS. Next slide, please.

So, we have two broad use cases here that we're dealing with when we deal with Author of Record Level I and II. In Author of Record Level I we have signing certificates FBCA medium signing certificates, we have the IHE DSG which is really an instantiation of the XAdES from W3C and we have the SAML assertion as standards. The environment is you create this signature when you're sending a transaction or you're sending a document bundle, you create it at created at the time of. When you receive it you validate it. So, really it needs to be available as a signature from the time you create the transmission until you've received it and processed the transmission. Next slide, please.

When we go to Author of Record Level II our requirements change substantially now the signature needs to be applied at the time of document creation or modification, or review. And any case for administrative purposes has to be applied prior to claims submission. It has to have multiple signatures associated with it because a document may contain contributions from more than one person. We have to have a way to validate those signatures at the time of creation because this document may persist and have to be validated again against the signatures for as long as documents are required to be maintained which could be 20+ years. We have to have a signature that can travel with the documentation. We can't assume it will be available elsewhere. And we have to have some way of supporting a transition from unsigned to signed documents. Next slide, please.

So, as we approach the problem we think of it this way. We need a method that embeds the signature inside of a document in a way that is acceptable to the existing receiver even if they can't support a digitally signed document. What we don't want to do is create a document with a separate delegation of rights with a separate signature where when they receive them, if they don't know what to do with them, they either throw them away, in which case we now have an unsigned document or they throw away the entire transaction because they don't know what to do with it at all. We're really looking for backward compatibility here. Next slide, please.

The approach that we've taking in working with HL7 and the Structured Document Workgroup is to add a signature text attribute to the header in the CDA document and that signature text attribute will then contain all of the digital signature information that's required for signing that particular document. It will work on both structured and unstructured bodies. Next slide, please.

An example of how this would work, during a normal patient encounter the provider documents the encounter by using their EHR system using whatever type of forms and templates they normally use storing the data in whatever form they store internally within their EHR database. Next slide, please.

At the appropriate time they create a C-CDA. It takes data out of their database; it populates the various structured elements within the Consolidated CDA based on the document template, the section templates, and the entry templates. Next slide, please.

And then using a signing process that goes through and computes the digest on everything except the legal authenticator and the authenticator occurrences of the participant in the header it signs the document by inserting the digital signature artifacts in the signature text. That allows us to have more than one signer. It allows each signer to sign exactly the same thing. So that when you go back and look at it you can determine who signed in what order and the fact that they signed exactly the same information in the C-CDA. Next slide, please.

This work is being put up for ballot for September at HL7 both the standard for using the structured text and its content. We've been working with the Structured Document Group who is the primary sponsor, the Security and Attachments Group who are cosponsors and the Record Management Evidentiary Support Workgroup who is an interested party.

So, we are in the process of finishing the implementation guide that will be balloted, it will be available for ballot on the 16th of August and if it is successful, which we assume it will be, this will provide the HL7 standard for digital signatures and the content of the signature text on a CDA. Next slide, please.

So, broadly, what we're doing with the Author of Record work is to establish best practice work for identity proofing both individuals and organizations, best practice for digital credential lifecycle management including access to private keys, digital standards and their artifacts including the delegation of rights standards. We're addressing the Author of Record Level requirements at the moment down through Author of Record Level II signatures on documents and we're defining the requirements for structured documentation that includes digital signatures for proof of provenance. That's the last slide.

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

Well, thank you and unfortunately we were given 30 minutes to digest 27 slides, have thorough discussion, get input from the entire committee and what I wonder, Michelle, if we might just get any public comments that exist, because I don't imagine there may be many, but then actually extend the meeting a little bit to bring in the comments and discussions of those with cards up and then maybe even return to this topic at our next meeting if that sounds reasonable? And those who can stay, stay, otherwise we know you may need to dash. So, what do you think?

Public Comment

Michelle Consolazio – Office of the National Coordinator

Operator can we open the lines for public comment? And if there is anyone in the room that would like to make a public comment, please come up to the desk.

Alan Merritt – Altarum Institute

And if you would like to make a public comment and you're listening via your computer speakers please dial 1-877-705-6006 and press *1 or if you're listening via your telephone you may press *1 at this time to be entered into the queue.

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

Now, I know Wes is on the phone with a question. I know Dixie probably has some comments and has great desire to align Privacy and Security Workgroup analysis of this and come back with formal feedback maybe the next meeting. We have Jeremy, we have David, we have Andy and I think we have Leslie.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

So, I guess I'm up now?

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

Any public comment?

Michelle Consolazio – Office of the National Coordinator

There is no public comment in the room and it doesn't look like there are any comments on the phone either.

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

Okay, Wes, you're on.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Okay, thanks.

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

And again, if anyone needs to dash because we're going over please do, but otherwise let's try to get in at least those six or seven people. Go ahead, Wes.

Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated

Okay, so to Melanie and her companion, I'll be making the same comments I made at NCVHS last year. There seems to be no attention to the overlap with regards to the burden of getting authenticated between this program and the DEA, which, you know, we can only say, you know, maybe that's something that the Office of the National Coordinator could take up.

At a less sort of urgent level, I think this work has the ability to deal with one of the nagging problems associated with personal health records, which is that if information is passed through the patient from one provider to another there is a concern among providers that it may have been modified. I understand that all the technology exists to solve that problem without going to a personal signature of the, I guess the Author of Record would usually be the right signature, but nonetheless, if all of this authentication and pre-vetting is going on in a very public venue, such as DEA and CMS then it adds considerable credibility to the use of the technologies to confirm that a report has not been changed. Thanks.

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

Great, thank you, Wes. Now, Dixie, I know you have several comments you wanted to make, so I know you were assigned some aspects of this task previous to your presentation.

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

Yeah, the Privacy and Security Workgroup is in the process of scheduling a meeting to review these esMD digital signatures. So, I assume we'll be reporting that back to the committee. But I had two comments. The first is that it seems to me that what is being proposed here incorporates a lot of or a couple of responsibilities that are really internal responsibilities like signing individual contributions, you know, doesn't an individual healthcare organization – aren't they responsible for keeping tabs on individual contributions versus the overall document that is sent to CMS?

And secondly, in a second example is delegation of rights. I can understand why CMS would want to know who to expect to receive documentation from but the whole process of delegation of rights I would think would be a local responsibility.

Melanie Combs-Dyer, RN, MS – Deputy Director, Provider Compliance Group, Office of Financial Management – Centers for Medicare & Medicaid Services

...

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

I'm sorry?

Melanie Combs-Dyer, RN, MS – Deputy Director, Provider Compliance Group, Office of Financial Management – Centers for Medicare & Medicaid Services

No, go ahead.

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

Well, and the only other comment, I know will be, you know, the Workgroup has to add more to this discussion of this ahead of us, but the other comment I would make is that I've been told by multiple people that there is no federal wide requirement for cross certification with the federal bridge in order for a federal agency to accept the certificate or use a digital certificate. So, I would think that unless CMS has a compelling need to require the cross certification of the federal bridge that seems to be overly burdensome. So, those are my comments.

Melanie Combs-Dyer, RN, MS – Deputy Director, Provider Compliance Group, Office of Financial Management – Centers for Medicare & Medicaid Services

May I respond now?

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

Yes.

Melanie Combs-Dyer, RN, MS – Deputy Director, Provider Compliance Group, Office of Financial Management – Centers for Medicare & Medicaid Services

I'll take the first issue that Dixie raised and then I'll probably let Bob answer the other two about delegation of rights and the cross certification. You ask if it wasn't the provider's internal responsibility to manage those digital certificates and I agree that it is their responsibility, but when it comes to documenting to prove that they've met the coverage requirements, remember, to be covered by

Medicare, there are certain things; many things that say in order to be covered and therefore paid it must be ordered by a physician. We don't know, we don't have proof that it's been ordered by a physician unless we see that order coming from the physician with his or her signature on it.

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

But, if Kaiser Permanente tells you it was ordered by a physician you don't believe Kaiser Permanente? Not to – Jamie, don't – but whomever, it looks like you would believe the – Beth Israel Deaconess they say a provider really did order that and you wouldn't believe them? Even though you know that is Beth Israel saying it?

Melanie Combs-Dyer, RN, MS – Deputy Director, Provider Compliance Group, Office of Financial Management – Centers for Medicare & Medicaid Services

Well, everyone that submits a claim to Medicare is alleging that they have met all of the coverage requirements. And yet we find that to the tune of \$28 billion a year, some of those providers are not meeting the requirements. Now sometimes it's not a flawed signature that's causing that problem, but sometimes it is. And if we didn't have an OIG looking over our shoulder, if we didn't have to report our improper payments every year, if we could just pay, I don't think we would be as concerned as we are.

But because we have to watch out for improper payments and because our oversight agencies are looking over our shoulder to make sure that we are doing a good job of looking for improper payments, looking for places where the coverage requirements aren't met where a physician really didn't order something or didn't meet the other requirements, didn't have documented in their progress notes that certain conditions were met, I don't think we would be as worried as we are today. Bob, did you want to take on delegation of rights?

Robert Dieterle – esMD Initiative Coordinator – Signature Consulting Group

Yeah, I'll take on delegation of rights and the federal bridge. The delegation of rights is actually an assignment that would be made by the individual holding the identification or the organization. It's not a delegation that would be made by CMS. So this would be the ability of an individual organization to assign the right to sign on their behalf to someone else. The whole point of this is the following; we don't want someone sharing their hard token, sharing their ID with someone else for the sake of allowing them to sign.

What we want them to do is establish a non-repudiation proof of assignment of that right to someone else and that's what the delegation of right is for and that way someone can sign on their behalf, they can include the delegation of rights to prove it, and we can process that signature knowing full well that that individual organization has given the right to a third-party.

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

Well, can't you do that as part of the identity proofing to begin with if Beth Israel tells them that – you know, John tells you that he's delegated authority to me and you identity proof me than it seems to me like you would then not have to every time look at this SAML assertion contained in every transaction.

Robert Dieterle – esMD Initiative Coordinator – Signature Consulting Group

Well, I don't know that he has delegated you that right, I know you've been identity proofed, I know he's been identity proofed from the certificates and I know they're still valid, assuming they are, but I don't know that he's given you that right nor do I know he's giving you that right for every transaction. That's what the assertion is for.

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

So, I think the Privacy and Security Workgroup should probably issue some formal comment on this. I mean, it's sort of silly but I send 7000 transactions to the SSA every year using a simple SOAP transaction with zero digital certificates and it's working just great, why? Because they trust me and, you know, knowing – I mean, again I look forward to your comments, but building PKI, federal bridge and SAML assertions, okay. I mean, there is a cost. And I don't know – I mean, the benefit may very well be something that CMS from a regulatory and compliance perspective really desires, but would love your comments on what it's buying us.

Robert Dieterle – esMD Initiative Coordinator – Signature Consulting Group

Well, let me comment on the...

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

I wouldn't argue that you can't do this but – I'm sorry.

Robert Dieterle – esMD Initiative Coordinator – Signature Consulting Group

Let me comment on the FBCA. The FBCA requirement for signing is still there. The comment you are making, I believe Dixie, is that as we were exploring Direct where we're looking at what is actually a server to server encryption that may fall outside of the need to have a federal bridge cross certified certificate, for signing purposes that changes fairly dramatically. So, we need to walk through the differences between for example the Direct use for X.509 certificate for encryption and a requirement we have here for a signing certificate.

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

Yeah, I'll follow-up on that, which is a technical issue, the other ones really are policy issues really. I think that the Policy Committee needs to have some comment here as well.

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

Good, Jeremy?

Jeremy Delinsky, MBA – Senior Vice President, Chief Technical Officer – Athenahealth, Inc.

A couple of quick comments and questions, but that gets to may be provider willingness to adopt and participate. So, number one, I think I heard you say that this would require sort of an annual process by which to sort of enroll and sort of revalidate the signatures. I would encourage you to maybe think about this like EDI enrollments where there is a once unless there's a change. The State Medicaid's many of them require annual reenrollments and transactions and what you see is that just really bad things happen administratively and they take a long time to unwind. So, I think a once unless it's changed you'd get greater adoption.

Second, I'm a little worried about this sort of double authentication for whenever a signature is applied because there are a number of different moments that you could think of in a workflow that a signature would be applied. So, anytime something is entered into the EHR you could think of as a signature we think of that as a username stamp and we know who the user is, when orders are signed, you could think of that as a signature, when the encounter is closed you could think of that as a signature. If you have to double authenticate every time you're taking one of those actions the user experience from the physician stand-point it's dead on arrival and they won't do it.

And so what I would suggest if this is an absolute must is that that's a requirement of the EHR that you must have multifactor authentication at the session level, but it can't be at all these sub-actions or else just no one will do it.

And then the last thing is I saw, in big red letters, this sort of what I viewed as almost a very strong policy which is that depending on how these signatures get interpreted and when they need to be applied that the signature, the ultimate legal signature would have to be there before claims submission is a cognitive change I think in many providers minds where they document accurately today, they sign all their orders and for whatever reason an encounter may remain open, it's never edited after the fact but their signature is on file for the claim and they don't feel that anything is inaccurate about it, but to sort of really put that, you know, an electronic signature must be present in the EHR before a claim is generated will be a very significant area of discussion.

Melanie Combs-Dyer, RN, MS – Deputy Director, Provider Compliance Group, Office of Financial Management – Centers for Medicare & Medicaid Services

It's what's in place today for paper or PDF, we don't catch it very often.

Jeremy Delinsky, MBA – Senior Vice President, Chief Technical Officer – Athenahealth, Inc.

Yeah.

Melanie Combs-Dyer, RN, MS – Deputy Director, Provider Compliance Group, Office of Financial Management – Centers for Medicare & Medicaid Services

But when we do we deny the payment unless an attestation comes in to indicate that it was intended to be signed, it was only a few weeks ago but in many cases if it was years ago, that service just goes uncompensated.

Jeremy Delinsky, MBA – Senior Vice President, Chief Technical Officer – Athenahealth, Inc.

Yeah.

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

We have David, Andy and Leslie.

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

Yeah, this is David McCallie – Bob, good summary of a complicated space. What strikes me is it's the same slides we've seen half a dozen times before in other use cases where somebody needs a non-repudiated digital signature of providers and to endorse Wes's comment, we really ought to solve this problem once consistently across all of these federal needs, if in fact we really need it, and it seems like the DEA has taken that first shot, bad pun, to put that in place around electronic prescribing and it sure would be nice if we could leverage that same work and if there are any minor difference in terms of flags that need to be set, etcetera that that could be resolved rather than forcing a provider to go through two complete proofing process and have two completely separate or three completely separate sets of credentials and try to manage all that because that will just guarantee that it never really happens. So, that's just a vote in favor of please coordinate, Office of the National Coordinator, and Doug is nodding his head, as best possible around whether we really need full PKI at Level III, you know, I think we do, but let's do it once and be done with it.

The second comment though is really more towards the point of, do you have any evidence if this was fully implemented what percent of that fraud it would actually address? It's not clear to me what you're going to turn up with this process that you wouldn't find already. What's going to change?

Melanie Combs-Dyer, RN, MS – Deputy Director, Provider Compliance Group, Office of Financial Management – Centers for Medicare & Medicaid Services

Yeah, there are some people that say why you don't stay right where you are, continue to send out those paper letters and continue to receive PDFs and we might for a while. But our vision for the future is that it really does help reduce provider burden if we can send out those documentation requests electronically, which is going to require some kind of a sign up process or a change in the FISMA law.

And number two, the PDF documents that are coming in continue to require a nurse to review them. If I could get to structured medical records, if I could get to the, you know, distance that the patient can walk unassisted is here and every other little data element in a progress note and the digital certificate signature at the bottom, if all that could come in in structured way I can begin to write some computer rules to apply some logic to help me figure out which claims and medical records I can automatically approve and I don't even need to bother the nurses eyes with them.

So, it gets me efficiency for me, for my reviewers, it allows me to catch more improper payments because I can focus the nurse's eyeballs on the 1.5 million that are really most likely to contain improper payments, and it helps reduce the provider burden of having to respond to all of that paper. They can get their documentation requests in electronically.

Now that is all caveated in it will be optional. Those providers that continue to want to submit by fax or submit by mail can continue to do so and probably for the foreseeable future can continue to submit PDFs. We are not going to mandate the structured stuff unless a provider wants to go that way and we will not require that they receive the documentation requests electronically. If they want to receive it through the mail they can continue to do so.

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

People so I just want to get to Andy, Dave, real quick because he's about to dash.

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

Two comments, one good luck with that structure thing. Just participating in many, many implementations that are just not happening right now you're not going to get it. So you can forget it for about five years, maybe longer.

Now just the process of intake of the material is rendered more efficient on both or export of the materials rendered more efficient on both ends that would be good which leads me to my second comment, that's what the SSA did for disability requests and are you piggybacking on top of that, because people are doing that and it seems to me that that's a process that works, it was made relatively easy, there was a good business case for all of the clients. I don't think if you were commenting on that John they did not go through all of these lengths. They are a federal agency so I'm sort of wondering where the disconnect is, between their FISMA requirements and yours. Because FISMA is...

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

I do 7000 a year, no digital certificates, totally structured data, no PDFs, real-time...

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

Kaiser was doing something like 40 to 100,000 a year just disability documentation.

Melanie Combs-Dyer, RN, MS – Deputy Director, Provider Compliance Group, Office of Financial Management – Centers for Medicare & Medicaid Services

Bob do you want to comment on that?

Robert Dieterle – esMD Initiative Coordinator – Signature Consulting Group

Yeah, there are a couple of issues involved. Number one, the SSA is not a covered entity. Number two, they have been trying to move to a structured environment but they're not sure how to do it. This was a big step forward for them.

Number three, the process they're using is basically identical to the process we use right now for esMD Phase 1. So, there is really no substantial difference and so that's how we did start, but we're trying to take it to the next step and we are processing I believe on a monthly basis now more than the SSA does annually just through esMD Phase 1. So, as we...

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

The numbers are much larger, but getting physicians on the upfront end to use structured forms that replicate the kinds of specific data that CMS would like to have for all these different things is several steps down the road after initial EHR implementation for any of them.

Melanie Combs-Dyer, RN, MS – Deputy Director, Provider Compliance Group, Office of Financial Management – Centers for Medicare & Medicaid Services

We recognize that and we've actually started a Workgroup to identify the data elements in a progress note for a power mobility device evaluation. So, one office visit for one type of DME and it's taken us a very long time to get the supplier industry, the physician industry, everybody to agree on what those data elements are and it will take us a while to roll it out to the EHR community and have those built into EHRs. I would be happy if I could get there in five years, five years would be a speedy end point for me.

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

They don't actually do that, they recommend content but that's client discretion.

Melanie Combs-Dyer, RN, MS – Deputy Director, Provider Compliance Group, Office of Financial Management – Centers for Medicare & Medicaid Services

Yes, I recognize that.

Robert Dieterle – esMD Initiative Coordinator – Signature Consulting Group

May I make a comment?

Melanie Combs-Dyer, RN, MS – Deputy Director, Provider Compliance Group, Office of Financial Management – Centers for Medicare & Medicaid Services

Yeah, go ahead, Bob.

Robert Dieterle – esMD Initiative Coordinator – Signature Consulting Group

When we say structured we mean structured in exactly the same way that the CDA indicates structure. It is not necessarily codified it is structured meaning the section has specific information that could well be in textual form. This doesn't require that the EHR be rewritten, it requires specific information, for example, medications go in one place and information related for example the consults go in another; this isn't a major leap for right now. Going to fully codified information will be an extremely big leap and we're not trying to get there in one step.

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

Leslie Kelly Hall, last comment because we are all dashing to the airport.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

All right, I would just challenge the idea of an author always being a provider and as we get the patient and their care team more involved we will see patients, their family members and other people participating in care planning who will be the single source of information with which the physician acts on. So, the idea of then the physician's signature being made to actually authenticate towards a patient generated health data is also not realistic. So, I challenge us to be more holistic in our approach to author and consider a much broader view of the care team and not do this. Thank you.

Robert Dieterle – esMD Initiative Coordinator – Signature Consulting Group

Requirement that the author be a provider.

Melanie Combs-Dyer, RN, MS – Deputy Director, Provider Compliance Group, Office of Financial Management – Centers for Medicare & Medicaid Services

I would just like to say one final comment, thank you very much for your suggestions and I really appreciate the idea of working closer with the DEA and I will be working closely with Doug to figure out how to make that interaction work. So, thank you all very much.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI – President & Chief Medical Officer – Hospital Corporation of America

So, you've been terrific with your time and we are here to help you. I know this was a tough dialogue. I think Bob's last comments were particularly helpful in terms of contemplation of the CDA, because in point of fact as a clinician perspective is that first purpose is of course the care and a byproduct of the care is the record that generates the billing and necessary for both the payer and the provider.

And as we look to that construct I think there will be logical paths we can support and indeed John as you indicated there will be work particularly in this area that Dixie and her team will look forward to working with you so that this introduces efficiencies both for CMS and the provider community, enhances adoption and enhances adoption not only in the interest of care but in the interest of reducing the administrative burden for all and that's a good outcome in terms of leading to higher value healthcare.

We're over time and everyone's been very, very generous, but before we leave the chairs would be remiss, as I believe would be the committee if we didn't in total recognize the leadership, support and hard work of MacKenzie Robertson. We hope that the record will reflect that as consensus of this committee.

[Applause]

So we wish you Buena Suerte and Michelle welcome aboard. We stand adjourned, thanks.

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

Thank you.

Public Comment Received During the Meeting

1. FHIR also fits perfectly into our S&I Simplification strategy for data objects and elements. See S&I Framework - Simplification Wiki - Reference Materials Tab.
2. Common data objects and elements, registered, consensus-approved and immediately re-usable (with computable components).
3. Assume that FHIR resource instances are digitally signed by author at least have that capability.