



HIT Policy Committee

Draft Transcript

May 22, 2015

Presentation

Operator

All lines are bridged.

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

Thank you. Good morning everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Karen DeSalvo?

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Present.

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

Hi, Karen. Paul Tang is on his way he is in the airport.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

And I'm here.

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

Oh, good.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

I'm here.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Good morning, Paul.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Good morning.

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

Alicia Staley? Anjum Khurshid?

Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health Institute

I'm here.

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

Hi, Anjum.

Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health Institute

Hello.

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

Aury Nagy? Brent Snyder? Chesley Richards? Chris Lehmann? David Kotz? David Lansky?

David Lansky, PhD – President & Chief Executive Officer – Pacific Business Group on Health

Here.

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

Hi, David. Deven McGraw?

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

Here.

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

Hi, Deven. Devin Mann? Donna Cryer?

Donna R. Cryer, JD – Principal – CryerHealth, LLC

Here.

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

Hi, Donna.

Donna R. Cryer, JD – Principal – CryerHealth, LLC

Hi.

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

Gayle Carol, Gayle Harrell, I'm sorry?

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature

Here.

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

Hi, Gayle.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature

Hi.

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

Kathy Blake?

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

Here.

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

Hi, Kathy. Kim Schofield?

Kim J. Schofield – Advocacy Chair – Lupus Foundation of America

I'm here.

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

Hi, Kim. Terry Cullen? Neal Patterson? Patrick Conway? Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Here.

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

Hi, Paul. Scott Gottlieb?

Scott Gottlieb, MD – Resident Fellow & Practicing Physician – American Enterprise Institute

I'm here.

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

Hi, Scott.

Scott Gottlieb, MD – Resident Fellow & Practicing Physician – American Enterprise Institute

Hi.

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

Thomas Greig? Troy Seagondollar?

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente

I'm here.

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

Hi, Troy. And do we have Micky Tripathi?

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Yes, I'm here.

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

Hi, Micky. And Larry Wolf?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

Yes, I'm on.

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

Okay, and I don't think...is Christine Bechtel on yet? Okay, she had told me she would be running a little bit late. All right with that I'll turn it over to Karen and Paul. I think now that we have Paul he might be able to get us started but I'll defer to you both.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Paul, I will yield my time to you. Good morning, everybody. Unless we lost Paul.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Good morning, everybody. This is a follow-up call to our last May meeting a couple weeks ago and what we're trying to accomplish here is to look at the updates since the feedback from the Policy Committee to the Workgroups, in particular to the Implementation, Usability and Safety Workgroup, the Privacy and Security and Interoperability.

So each of the Workgroup Chairs are going to present some of their updates in response to the comments from last time and then we will seek approval so that we can forward on our...the Policy Committee's comments onto ONC and CMS.

So, we're going to start out with David Bates and Larry Wolf presenting an update from the Implementation, Usability and Safety Workgroup.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, good morning it's Larry Wolf, I don't think David is able to join us this morning so I'll be walking through the slides and hopefully we've listened and heard and are offering up some useful edits to what we did and a couple of new ideas here. So, let's go to the next slide.

As you know it's been a robust group of diverse opinions in our Workgroup so I want to thank the Workgroup members for that diversity of opinion and discussion. We have had some pretty deep dives on some of these topics. Next slide.

So, some overarching introductory comments, let me begin with our footnote, everything should be made as simple as possible but not simpler and that seems to be sort of the struggle we had as we read through the NPRM and thought about the certification process.

I think in general we would like this to be the guideline that the certification criteria should be as focused as possible. That they should be as clear as possible but that we shouldn't, in the interest of simplistic simplicity, as it were, ignore necessary complexity and where we need actually richer specifications or allowing for certain kinds of options that those should be brought in judiciously. So, having said that we have a lot to say. So, I guess we didn't have the time to really make it as simple as possible.

We see overall that the certification criteria and the process as a whole is continuing to evolve and that's both a good thing in terms of it looks like there has been an attempt to respond to feedback and learn from experience but it raises some new challenges and possible repercussions because there are some new things and we don't yet know how they're going to play out, that's how things are with new things.

So, part of the suggestion in the wrap up is going to be look at, is there some kind of way to think about some kind of test or provisional criteria may be in the same way that we have draft standards for trial use. So, we'll come back to that theme at the end.

Given the complexity of the certification criteria and how we expect them to be used it really emphasizes the need for the National Coordinator to actively coordinate among the federal programs so that requirements are aligned.

As I've already said, and I think we talked about the last time, there has been a fair amount of diversity across the Workgroup and that will surface in this presentation. And we have a lot in the appendices that were intended to represent the specific positions and information brought forward by the Workgroup members and so given the time we have today we're going to be pretty brief in going through these but there was a fair amount of discussion from the Workgroup that's recorded in the appendices. Next slide.

So, we we're given a pretty broad set of things to look at in the NPRM not everything but it sort of felt like everything at times and let's go on, we broke these into three groups, so next slide.

So, this is what the first Workgroup looked at and the Workgroup members, so again, thanks to the Workgroup members for all the work that went into making this. Next slide.

So, we've attempted to actually come up with a binary agree/disagree on each of these and having said that there is note on all of these that says that were many caveats so pay attention.

In general on the field surveillance and maintenance of certification we disagreed mostly because of the implications of decertification and the potential burdens created by the survey process. We think it's really important to get feedback but we think it needs to be explored further how to do that in a way that's minimally disruptive to providers but still provides rich information back. And we'll come onto the other things later.

Transparency and disclosure requirements, overall we agreed although there was discussion about the concern that even though you're being transparent it might not actually be helpful. We like that the CHPL is going through a redesign and more data will be available in a structured way for reuse seems to be the general theme that we want to learn from experience, improve usability and make things better.

Complaint reporting, it seems important capture complaints from the field about what was actually happening with the system so we agreed with that. There are a bunch of minor tweaks or maybe not so minor to the certification program. So we agree in general with them and again on decertification we disagreed primarily because of the large ripple this could have to providers and we felt there needs to be some way for providers who find themselves with software that is no longer certified to have some graceful transition out of where they are.

It was also pointed out that there may be many reasons why a provider finds themselves no longer having certified software from vendors going out of business to vendor decisions to discontinue of a particular version of software or a generation of software, if you will, to lineage of software because they're moving to some other products as well as problems with the certification process. Next slide.

So, here's some of the specifics, I think I've pretty much touched on all of these, let me take a quick look, yeah, so I'll pick up one line that's here on the complaint reporting, recommend ONC develop a more rigorous and protocol-driven complaint process.

So, I think in general that we felt that one of the advantages of really good certification criteria was that they were very clear in what was being tested, how it was being tested, what information was needed, how you would know you did a good job and where there were actions to be taken, what really were the specific parameters of what needed to be done. Of course, having said that there is a counterbalance to doing it in ways that are actually helpful and not...that are overly constraining so, again looking for this balance between simple but not too simple. Next slide.

I think I hit on most of the major points here as well. One other thing about data blocking, so the ONC report to congress on data blocking was not reviewed by the Workgroup and it does provide definitions for data blocking and some specific examples and those were not reviewed by the Workgroup.

So, we had concerns about, you know, exactly what was the meaning of data blocking and so ONC has taken some steps to define that but as a group we haven't discussed and evaluated where that is. Next slide.

So, this was the second grouping that we looked at. These were more focused around safety enhanced design and user center design. And again thank you to the Workgroup members for your efforts on this. Next slide, please.

So, overall we agreed with what was in this whole set of criteria although, again, there was a lot of discussion in Workgroup and there are many footnotes, if you will, on pretty much all of the agrees and particularly a lot of discussion around testing, summative testing, formative testing, the people who are experts in the testing process were very clear in their statements about needing both summative and formative and why those were important and how you went about them and some others were concerned that given vendor size or possibly target population that there might be overkill in the testing requirements. Next slide, please.

So, some of the more details on individual items here, overall we agree with the user centered design process as a requirement. There was some concern that there was variability among what people were submitting for documentation and so the current NPRM lays out seven criteria, seven new criteria that we think would be very helpful as people go through this process.

There was also a suggestion that came out of the Workgroup discussion that patient history should be considered as an area for safety-enhanced design and that there might be scenarios developed by NIST that would help people understand the usability testing better and might form a baseline for people to do comparisons.

On quality management system, I would say the biggest discussion here was that the name of this, unfortunately, has word “quality” in it and so everyone immediately jumps to thinking of health quality or healthcare quality rather than software quality which is really what this is about. So the quality management system is about ensuring that quality software is produced. So, again, some concerns that this might be heading in the realm of increased complexity, but in general felt that this was an important activity for vendors to take on.

And a reminder here that not all software is developed just by commercial vendors it often comes out of an open source community or pushed out of an open source development stream, or it might be self-development and making sure you have a quality system that makes sense for the context in which you’re working is important. Next slide.

So, on the accessibility, there was some confusion when we presented this last time so we agree that accessibility is an important part of the technology, but, again there was concern about how to do this in a way that wasn’t overly burdensome and exactly what was needed to have accessible technology.

And some of the suggestions might be hard to implement so the text-to-speech might create problems with privacy and other things like that or might require additional adaptations in the clinical setting or where the systems were being used behind what was in the software to actually make it accessible.

And finally, in terms of summative testing we’ve been over this several times already that really the notion of replacing formative testing with just summative so just looking at the end result was felt to be not sufficient, that you really wanted to build in the feedback that formative testing gives you as part of a user centered design process and so an overall sense that formative testing was also necessary as well as summative testing. Next slide.

So, finally for the third group, this looked at a variety of elements of the certification Regs and much of it was minor rewording to adjust some change in focus but the change in focus might actually be more important if the committee has any thoughts about that rather than the specific details of what is proposed here. Next slide.

Okay, so you see across the board we agreed overall on the pharmacogenetics, this was a Request for Comment and I'll talk about the comment on the next slide. Next slide, please.

So, pharmacogenomics is an area where there appears to be potential for great benefit but it is also an area where there isn't a lot standards today and this is exactly the kind of balancing act that we feel is really important to work at getting right and so we think it's important for ONC to be signaling this as an area that needs development and looking for standards and putting it forward as a priority and perhaps even aligning with other efforts to work in this area. And we felt that this was an example of something that wasn't far enough along to have certification criteria but was something that needed to be moved forward as an area of potential benefit to improving health.

In terms of some of the rewording, spelling out "health" in HIT seemed like a good idea. There were some questions about full dataset, what does it mean to supply a full dataset and we've heard concerns that depending on how the receiving systems accept that data that this could often create information overload on the receiving side.

And we think it's important to continue using Direct as an option to share information. In many ways we're just at the beginning stages of Direct adoption and it feels like this is a technology that could offer benefit but we actually need to see it get used and then learn from that use. And a lot of the value here is not necessarily in the details of the standard but in then how it gets used and workflow gets built on top of it and information exchange gets built on top of it. So, we'll just have to see how that develops in the field.

There were some other changes to the details of the certification program that seemed fine and a concern we've talked about in the past about all of the focus on interoperability doesn't address a concern that providers have had really for a very long time that if you...when you buy multiple modules, sometimes even from a single vendor, they don't necessarily play well together and that that's very hard to assess in the abstract and given the multiplicity of options here would really be something that would be close to impossible to have good test suites for.

So this an area where we think it's another trade-off in modular software that as a consumer you need to pick and choose your modules wisely and as an organization building software it certainly leads to better user experience the more your modules work well together and probably is a marketing advantage for modules to work well together but often offerings by a single vendor bridge multiple development streams and there are differences in the modules and there maybe limitations to how they relate.

And finally that there could be, you know, modules the providers actually put together and the vendors had no reason to believe they'd ever need to interoperate and so there could be problems with that as well. Next slide.

So a number five this answered removing Meaningful Use measures for certification is part of an overarching direction that ONC is heading in to make certification criteria be mutual with respect to other programs that might reference it and so disentangling itself from things that were specifically dedicated to Meaningful Use one hand is a good thing, on the other hand could create complexity if the programs actually require that capability in the software so it means that both developers and the users of the software need to look really broadly at what are the requirements for a particular program that's

not sufficient to just have certified software at this point. It would require that you understand additionally what other program requirements are.

In general we support the expansion to other types of care and practice setting and again, you know, we're the certification criteria are really clean and focused this becomes a good base that other people, developers and providers can then rally around for standards and improvements of information exchange, but also runs the risk of overly specifying things that don't really need to be specified.

So we think this shift away from functional requirements into more data standards, transport standards and things like that is in general probably a good direction to head in recognizing that there are also still some hot areas of functionality that need to understand so when we talk about reconciling information when it's received or how data provenance could be a good thing or a problematic thing. I think these roll over into the actual functionality of the applications. I think we've touched on other pieces as well.

So, we have an open question from last time that sounds like it's actually going to rely on some information from the Standards Committee about how exactly the privacy and the security requirements play out in the new certification rule. Next slide, please.

So, a couple of slides worth of some specific things that we want comment on overall, that utility of the CHPL the latest update appears to be a much more user-friendly update. Some of us in the past relied on the download as a spreadsheet as the best way to look at information in the CHPL and so I think this notion of getting value from the data is probably a good one, but again, this is a place where applying user centered design principles would be really good as ONC moves forward with its own work.

Where software comes from multiple sources or from others, so there seemed to be an assumption that most of the software is going to come from very large vendors that can support the diversity of functionality across all of the certification criteria and the depth required in some areas.

And so there was a concern that we may be pushing out of the market a whole host of innovations because the overhead required to create the software is too large to actually go to completion and get it certified.

So this notion surfaced of is there any other way to address this, could there be, for example, some certification criteria where you went through certification but certain things maybe were in kind of a provisional status or a limited use status like you have this capability but, you know, it needs...just like experimental aircraft, you know, the flight rules for experimental aircraft are different from commercial aircraft and maybe there is something in there that could address some of the variability and alert potential consumers that the software was actually going to meet their needs or might need additional compensation or controls to be used safely.

And on expansion of use of certification, I think this is really a question of policy. So in general the Workgroup was supportive of certification as a tool for policy but there were concerns that it was being used too heavily and that there might be other ways to move ahead, for example, that a lot of good work has been done with, I'm forgetting words here, the S&I Framework as a place to bring the community together to increase the speed of a standards development process and that this was an example of providing focus and moving forward on some initiatives in addition to certification criteria as a way to move forward on standards.

And this came up again in discussion last time at the Policy Committee, it was clear to us that ONC had defended that they have authority to do this so we didn't want to imply, but it was nonetheless being asked about, that this is moving outside the realm of the initial Meaningful Use Program and in a lot of people's minds certification is to support Meaningful Use and so there needs to be both judiciousness on the part of ONC as it expands what it's doing and I think education about what it's doing and why it's doing it, and validation that in fact what it's doing is going to be helpful. Next slide.

So, some timeline comments I think are important, this has been a recurring theme and in general we think ONC and CMS have been responsive to providing more time for people to get up-to-speed on new versions of software but as we saw with the transition to Meaningful Use 2 that that's a very tough thing to do and probably requires more runway than is in the proposed rule specifically by giving providers optional...an optional early year, if you will, to try out Meaningful Use Stage 3 or to see, you know, get it into use, but that really meant that the software needed to be available at the beginning of 2017, which in many ways is really right upon us, we won't have final rules for a while so we need time to develop tests, distribute, you know, implement software, modify workflow, verify that you actually could use the software in the way you thought you'd be able to use it before you start the clock on Meaningful Use for this next round. So, again, really looking closely at the timelines and we felt that this timeline is probably too tight.

I already talked a fair amount about complexity, maturity of standards. So, the Standards Committee has proposed a framework for assessing how and when standards are mature and we think that this should be brought forward and used as a baseline.

And again, this notion of that maybe there is a way to have certain certification criteria function the way early standards work does where there is a draft standard for trial use, there might be draft certification criteria for trial use that would allow the whole of the process to be tested and might put forward some early work on standards for incorporation but it would be clear to vendors that this was optional, it would be clear to providers that using that capability might run the risk that the standard would change or the capability might completely even go away in future versions if it turned out it wasn't a good thing or wasn't broadly seen as a good thing. So, we put this forward as possibly another thing to talk about that hasn't gotten a lot of attention in discussions of certification criteria before.

Variations among partners, so, you know, information exchange is at least a two-way communication it's not a multi-way communication and that means that all the partners in the communication need to be at a compatible level and we've seen variation here for example public health and public health reporting requirements that potentially every public health jurisdiction could have their own rules, that every registry might have its own rules about what information it's looking for and how it wants to receive it and that those create real burdens for providers and for vendors because of the huge diversity of small variations that create a lot of, you know, operational issues with actually trying to reuse software you wind up rebuilding and redeveloping it.

In terms of certification for other healthcare providers expanding outside of the scope from the Meaningful Use Program, on the upside we look to certification to help address some of the challenges of interoperability to the extent that the standards are clean and actually create plug-and-play interfaces, but we also recognize that there is a maturation needed in the software itself and in the work process on the provider's side to actually have information available in ways that support the standard information exchange. Next slide.

We talked a fair amount about user centered design, I think I've already covered most of these points so let's go onto the next slide.

So, again data blocking and decertification, we felt that these were areas where decertification as a very blunt instrument needs to be used judiciously and we maybe need a better definition of how providers would manage if their software were decertified.

And the discussion on data blocking it's one of those tough areas, right, one person's data blocking is another person's data protection and good stewardship as well as clearly issues of business practice and what the multiple incentives are to either keep or exchange information and that those need to be in balance for information to flow.

And we like, in some ways, the approach that ONC is taking in terms of...or a beginning to gather information on examples of data blocking and bringing this forward for further discussion and there is a link here to the report to congress. Next slide.

So, finally, as wrap up we have the considerations for conditional or provisional certification, which is sort of a new thing that we offered to discussion on is there a way to create a test, if you will, a broad test environment for certification criteria before it becomes locked down and importantly to alert other agencies that are looking at certification criteria as building blocks that this particular set of criteria might not be ready, in fact would not be ready for them to reference in a required way, but again might be valuable for them to encourage testing on as well.

Again, needing to get good alignment across federal programs to address complexity and cost, to looking at given the tight timeline does it make sense to further reduce the scope of what's in certification criteria so that it becomes more achievable and finally that the user centered design process, while there was a lot of debate within the community, there seems to be a very strong consensus among the experts of how to do this right. So, that is it I believe. Any feedback from the committee or further discussion?

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

So, thank you, Larry. I'll open it up for committee members on comments on this update and Karen you had asked about strategies for certification and non-meaningful users for information blocking and for usability. I want to make sure we get the answer to your question.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Well, thanks, Paul and Larry and David, and the committee. I just want to thank you guys this is a pretty great evolution even since the last really in-depth report. So, I appreciate the feedback. It does provide the clarity and looking forward to the transmittal letter. Thanks.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

All right, thank you. Paul Egerman?

Paul Egerman – Businessman/Software Entrepreneur

Great, thank you, Dr. Tang, and I just want to say thanks first to Larry Wolf and David Bates. Larry did a great job presenting this and Larry and David Bates did a terrific job in leading the group and it wasn't easy to lead and I was one of the people who made it not easy because I was one of the people who spoke in opposition to a number of these issues, and while this is a good summary, I'm actually opposed to what is in this summary and I'll try to just briefly explain why to re-emphasize a point that Larry made.

My view of certification is that it's a vehicle for software testing and to use certification to try to regulate the HIT industry on things like pricing policies, data blocking, even the methodology used for software testing it's just...it's not the right tool to use and I think the reason ONC is using certification is that it is it's only tool but it's not the right tool especially when you realize that there is no teeth to it at all, in other words, if a vendor makes a false attestation there's nothing that can be done, you know, I mean ONC doesn't have any way to audit a vendor and there is no penalty to the vendor and so it's not to me the right tool.

The other comment I would give, as it relates to some of these issues of user centered design and software testing, I found those discussions personally a bit frustrating because those are discussions, detailed discussions about process as opposed to outcome.

And the outcome that we want is usability and we want, you know, EHR systems that do not cause users to make errors that can harm patients, that's the outcome we want and we should have been talking about what needs to create that outcome instead of this very deep discussion of software testing and that software testing discussion with these people that are experts, especially the people from NIST, was frustrating because they had almost a religious view of exactly how things should be tested but it's very hard for me to see how that necessarily impacts how these systems are installed or implemented, or how vendors deal with restraints, or things that are placed on them from external sources like ONC or like CMS where frequently there are requirements as to what data you have to gather and that can be very frustrating for physicians but the software testing process does not address that at all. So, those are my comments and so I appreciate what Larry has just said and if we do a vote I'll actually be voting against the Workgroup's recommendation as a result.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thank you, Paul. Any other questions or comments from the committee members? Okay...

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

So, this is Deven...

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Yes?

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

So, sorry, Paul, I would just add that given that a lot of times in a process where what we're doing is providing input during a public comment period whether we...when we vote on this I still think it's worthwhile noting some of these dissents because that's feedback to ONC to take into consideration and so I just make that as a suggestion.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

No that's a good point.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

And Paul, this is Kathy Blake, just I'd like to go to...and briefly comment on the issue of the conditional certification option, which I think is certainly something that is worthy of consideration because I think someone said it doesn't cast it in stone or concrete right away, but I'd ask the ONC to think about the downstream implications of that with respect to is there a point at which those conditions need to be fully met so that it does become a fully certified system and a point at which some things will fall off or lose their conditional certification.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

That's a good point. Larry, do you have a response to that, a brief one?

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

So, it's going to be brief because this really was an idea that came up as we were discussing response to some of the questions from the last committee meeting, it hasn't had broad discussion with the Workgroup. It was really just with David and I, and some of the ONC leads.

So, our thought was that we were really looking at two variations, we were talking about some new possibilities, one was where software was sort of conditionally certified to say, you know, like maybe on the user centered design you did do formative testing but you didn't use as big a test pool as the guidelines say to use and so we're going to star this to say there may be an issue here, but we don't feel it's...and this gets into a grayness, right, about, well if you don't meet the criteria it's no longer black and white and so how do you then, you know, report back out?

So, our sense was that these ideas were really pretty new and needed broader vetting and maybe that's the right level of response.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay, thank you, any other questions or comments? Why don't we go ahead and use the feature of voting which is near the hands raised icon towards the upper left and if you do the pull down there is an agree or disagree. Agree would mean that you agree, concur with the Workgroup recommendations as presented and disagree is the opposite. If I had music I would play it now, but, okay, if people could finish up quickly on their voting. I'll start counting the for's is one...

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

...my screen.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Who is that Gayle?

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

No, Kathy Blake...

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Kathy.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

I am navigating to find the screen.

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

Paul, this is Michelle...

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay, well it turns out...

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

Yes, go ahead.

Scott Gottlieb, MD – Resident Fellow & Practicing Physician – American Enterprise Institute

Paul, this is Scott...I haven't been able to...I'm not on a line right now but I'm on the call and have been listening and following with the printout.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

So, who is this speaking please?

Scott Gottlieb, MD – Resident Fellow & Practicing Physician – American Enterprise Institute

Scott Gottlieb.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Scott, okay and you're voting...

Scott Gottlieb, MD – Resident Fellow & Practicing Physician – American Enterprise Institute

I have concerns about the recommendation I'm going to vote "nay" a lot of them have been raised already on the call.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay. Okay, so Michelle you were going to say something?

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

So, Paul, this is Kathy, can I ask are we voting on everything, all four items that we see above or...

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

Actually, Kathy, so the new members should still abstain from voting and wait...

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

All right.

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

And won't be voting until June. So, Donna, Kathy and, oh, my goodness, Brent should not vote today.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

Okay, thank you.

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

Sorry.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Sorry.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

No problem.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

So for...

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

And the four items on the screen are just final highlights...

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Right.

Larry Wolf – Senior Consulting Architect – Kindred Healthcare

We've actually had a whole series of specific responses to the individual NPRM questions earlier in the slide deck.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

So, to vote yes is to agree with the recommendations, the comments really as presented by the Workgroup and that would be included in the transmittal letter. Okay, so I'm counting now, 1, 2, 3, 4, 5, 6.

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

Is there anyone else on the phone who is not logged in?

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Hi, it's Christine Bechtel, I'm on the phone but not logged in. I think I have to abstain because I don't think I saw the materials in advance and I only joined about half way through Larry's presentation so I don't feel like I can actually vote, sorry.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay so we have...

Diane Montella, MD – Clinical Informaticist, Knowledge Based Systems, Office of Informatics & Analytics – US Department of Veterans Affairs

And this is Diane Montella can you hear me?

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

We can hear you're in for VA right?

Diane Montella, MD – Clinical Informaticist, Knowledge Based Systems, Office of Informatics & Analytics – US Department of Veterans Affairs

Yeah, great...yes, I'm standing in for Dr. Cullen and when the meeting began as the public meeting I couldn't be heard and I had to get out and come back in through the operator so you didn't hear me at roll call, but I'm unclear whether I should be voting in her stead or not?

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

No, ex-officio members don't vote.

Diane Montella, MD – Clinical Informaticist, Knowledge Based Systems, Office of Informatics & Analytics – US Department of Veterans Affairs

Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay, so I have six in favor.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

And Paul, I'm going to...this is Karen.

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

We do have an e-mail Neal, Paul.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay and what's the e-mail say?

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

He approves.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

He approves, okay, so seven, eight. So, eight in favor and I'm going 1, 2, two recorded and one on the phone so that's three opposed.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Paul, this is Karen, I'm going to abstain.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay. Okay and two abstains. So, it was eight, three and two and so the motion passes and we can certainly note the comments we've heard...

Scott Gottlieb, MD – Resident Fellow & Practicing Physician – American Enterprise Institute

Yeah, and Paul, this is Scott, I appreciate you, you know, passing on some of the comments with respect to the folks who had the concerns and my concern, this is Scott, really echoes some of the ones that have been raised about trying to do more than I think is feasible with respect to these requirements from a regulatory stand-point. I think it was articulated well by one of the commenters.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay. Okay, so we'll include that as part of the vote. Anything more? All right, thank you. I neglected in my haste to get through security in the airport to ask for approval of the minutes so if someone...I actually will be submitting a couple of corrections, but if someone else could move approval for the minutes please?

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature

Move approval, Gayle Harrell.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Thank you and second?

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente

I approve, I second it, this is Troy Seagondollar.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

Okay and any other discussions or corrections? Okay, all in favor?

Multiple

Aye.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

And opposed or abstain? Thank you, take care of that housekeeping element. Now we're going to move onto the Privacy and Security Workgroup. I think the major discussion here was around the API and VDT around what's the best way that the government can help protect the privacy of the consumer...

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

Yes.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

And the consumer data information.

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

Yes, thank you, Paul. So, in the interest of time since we are essentially updating our presentation and adding some more details per the request of the committee at our last call I'll try to highlight what we have done in the interim to augment the presentation rather than going through all of the slides.

Paul Tang, MD, MS – Vice President, Chief Innovation & Technology Officer – Palo Alto Medical Foundation

That would be great.

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

So, if we can jump to slide five that would be great. I believe my Co-Chair, Stan Crosley, is on the line but I'm going to carry the water for presenting this material.

So, essentially what we're continuing to recommend as a Workgroup is a combination of guidance and a further...looking into an evaluation program that would enable consumers and providers to differentiate among tools for connecting into APIs or through view, download and transmit. We had, in the last meeting, called it a certification effort and we realized that upon further deliberation that part of what should be further evaluated is whether such an effort would be one that would be certification or would be registration, or a sort of best in class kind of listing that there are sort of multiple ways to create a way to elevate...to both evaluate and elevate Apps and patient provider connectivity software that might not necessarily be certification.

So, I'm going to go through now what our updated recommendations look like kind of highlighting what we've done in the interim so that we can sort of focus on the pieces that the committee has not seen.

So, on the guidance issue we do still think that guidance is very important and our first recommendation is to highlight that ONC is already working with the Federal Trade Commission and the Office for Civil Rights to develop mobile health best practices guidance for developers to promote protection of user data.

And what we emphasized here that we didn't emphasize as much in our prior recommendations is urging these agencies to work quickly so that this guidance can be disseminated in time to be useful for Stages 2 and 3, otherwise the guidance effort is not going to be as helpful for the Meaningful Use Program as it could be.

And so the guidance would include of course best practices for protecting the privacy and security of information collected by the App and connecting with EHRs covered by HIPAA so that vendors sort of have a better understanding of how best to protect that data.

But of course, providers and patients, and consumers are going to need guidance as well, check lists on what to look for in a privacy or data use policy and mechanisms for consumers to be able to compare privacy policies across Apps.

ONC had an effort several years ago that was a model PHR notice that had categories for comparison of Apps across various domains of privacy and security and that effort didn't really take off at the time that it was introduced, but now the timing is more ripe for something like that and we believe that that's an effort worth pursuing at the federal government level. Next slide, please.

But we also acknowledge that there is guidance that providers particularly would need to address the intersection between the Meaningful Use patient engagement objectives and the certification requirements as well as HIPAA's basic patient access right they are not the same program, HIPAA is separate and different but there are potentially a lot of overlap between the two and I think a lot of misunderstanding in the provider community about how to reconcile the legal obligations under HIPAA with the expectations under Meaningful Use and certification and that would include how do you do a security risk assessment as a healthcare provider on patient Apps and device connections such as through the API.

Paul Egerman in our last meeting and the prior meeting was relaying some very significant concerns about some Apps that he had seen in the Apple Store and purported connectivity or compatibility with certain healthcare providers and he had some serious concerns about what he saw, it really is already an expectation of providers to be able to evaluate those risks, but there is not a lot of guidance out there that's directed to providers to help them do this and to help them understand the extent to which they can reject a patient's request to be able to connect to an App or another piece of patient's controlled software where that is going to introduce security risks for the provider and then similarly to what extent can the provider reject a patient's request to make that connectivity where there is no security risk but there might be other concerns and providing some very clear guidance on these points, again, in time, ideally for providers to be able to use this in Stage 2 which is frankly already begun, but certainly the expectations are picking up in the next couple of years and of course for Stage 3.

So, the next recommendation is, again, on the next...can we go to the next slide, please. Highlighting the fact that the Health IT Policy Committee has already issued some recommendations on view and download that included elements of sort of best practices around privacy and security and alerting patients that they're going to be in control of the data and this guidance, to the best of our knowledge,

not acted on and also needs to be updated to reflect whatever additional risks come with the transmit capability which was not on the table when we had originally put those recommendations together back in 2011, this is how much time has passed since then, and so we make a very strong point of saying this guidance really needs to be acted on and now it needs to be updated to address the transmit risks and the fact that we're calling for capabilities that are both the view, download and transmit as well as the API functionality. Next slide, please.

So, this was the topic that the sort of "certification program" that got a lot of discussion at the committee and that we had some subsequent discussions about needing to beef up because it was a recommendation that the Workgroup was very eager to put before the committee, there were members of the committee at the last call that expressed some interest in seeing us further flesh this out and in addition we had the benefit of now having had the presentation from the Consumer Empowerment Workgroup and the needs that they have in terms of evaluating Apps for a range of functionalities that go beyond privacy and security.

So, here, this recommendation is the one that we have teased out much more in the interim between our last call and today noting very clearly that while timely guidance is still very important it may not be enough in this space and we call for further exploration of a multi-stakeholder developed program to be able to evaluate patient-facing Apps and we believe this needs to be further explored because there are lots and lots of elements that we didn't have enough time to flesh out.

We believe that we are not the only Workgroup interested in fleshing this out, we may not in fact be the best lead Workgroup in fleshing these things out and we're not sure that the NPRM deadlines necessarily require a timeframe that we finish all of this by that time.

We wanted to put a marker down to say, hey we need an effort to evaluate these that we think is worth exploring and it needs to take on not just privacy and security aspects but usability for consumers and patients as well as clinical validity in circumstances where the App is being promoted as something that has clinical value for patients and how do people evaluate the claims that are made in those Apps. Certainly, such an effort should leverage the guidance that we have recommended in the prior slides.

We also note that voluntarily adopted best practices and guidelines can have some teeth. The Federal Trade Commission already, under its congressionally granted FTC Act Authority, can enforce voluntary best practices when for profit companies adopt them. And the evaluation effort also has the benefit of potentially increasing transparency about privacy and security practices. Next slide.

But, again, it really needs to be evaluated further and frankly since this is ideally about more than privacy and security we believe the Consumer Workgroup should take the lead on this but with assistance of members from our Workgroup and possible other Workgroups could be involved as well. They should continue the work to flesh out the details of such a program considering issues such as whether it should be a certification program that includes testing or some other evaluation vehicle, whether it should be voluntary or in some way connected to the certified EHR technology or Meaningful Use Program, what would be potential incentives or disincentives for vendors to participate, what should the program focus on, what should be the role of ONC and other federal entities and what are the costs and potential impact on innovation?

Unless you think it is our Workgroup voluntarily signing up another group without their knowledge to take this on, I have talked to Christine and she is pretty excited about it, although if she tells me today

that she is not we can reconsider, but I think it's best housed in the Consumer Workgroup...from us and with that I'll stop and take questions. Paul I think you are on mute.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Actually Paul is not on mute I am, I'm in charge now. This is Karen.

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

Oh, you're in charge, okay, thank you Karen.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Everyone be afraid. All right, so, thank you Deven.

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

I don't see anybody with their hand raised.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Okay.

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

But if anybody has any comments?

Christine Bechtel, MA – President – Bechtel Health Advisory Group

Well, it's Christine...

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

...

Christine Bechtel, MA – President – Bechtel Health Advisory Group

I'm just letting you know I'm on and I'm really grateful Deven for all the thoughtful work that you guys did in addition since the last Policy Committee meeting. I think it's really, really thoughtful.

I really like the idea of evaluating whether it will help consumers to kind of create or, you know, what some sort of evaluation mechanism might look like. I say that having, you would be so proud Deven, literally been in my doctor's office picking up my electronic copy today, and so I'm staring at this lovely CD-ROM and it's a CCR apparently and I don't know what I'm going to do with the data but it needs to sit somewhere and so I just am feeling like it's really good timing to start thinking about...for people like me who want to put their data somewhere what kind of a marketplace should exist to help us evaluate the safe ways and secure ways to store that. So, I appreciate just the additional work and thoughtfulness of the recommendation.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Thank you, Christine and thank you Deven, and thank you to the committee for the evolution of this. So, there are still no hands raised Michelle?

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

No hands raised.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Anybody have any comments or questions for Deven?

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

This is Jodi Daniel, I do have just a question. I'm just trying to understand what you're...the recommendation about this additional body of work and whether this is something where you see the federal government playing a role or where the private sector would be playing a role?

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

Those are exactly the issues that we would look to the Consumer Workgroup to flesh out. It's on the list of, you know, what should be the role of ONC and other federal entities, should it be voluntary, should it be connected. We think that those are all pretty meaty issues that we did not have sufficient time to delve into but we think they're worth delving into and therefore we think the Consumer Workgroup should take on all of those considerations.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Okay.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

It's Christine, I would just add to that the...I think you also raised the question about whether this is actually a good idea.

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

Right.

Christine Bechtel, MA – President – Bechtel Health Advisory Group

I'm not...or whether and how it might work. I mean, sort of conceptually it seems like a great idea, but on the other hand, there have, as I understand it, been some efforts at it before that haven't worked and so I just think we need to understand is this a good idea, is it doable, why didn't it work before, what would it take to make it work or is there some other mechanism that would be a better, you know, leverage point in the marketplace.

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

That's exactly right, it doesn't say we believe this program should be established. What our recommendation is, is that we believe this should be further explored that there is potential value but there are lots of issues that need to be further considered.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature

Yeah, this is Gayle, I'd like to jump in on that too. I think you need to...ONC needs to take a look really at what is their authority under statute as to what they can and cannot address. You're getting into personal health records, you're getting into Apps that really are not within HITECH and I don't know whether there are provisions within other legislation that controls ONC if they have the ability to really go down this line. So, there is a whole lot to be discussed along this way before, you know, any concrete recommendations ever come out.

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

That's exactly right Gayle and hence why we're calling for further exploration of all of those points.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature

Thank you.

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

Kathy Blake has a comment.

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

Yes, thanks and I think it's been alluded to in some of the other comments but it does have to do with the size of the task that's being considered here because there is such an enormous number of developers of these kind of Apps you do start to get into questions about would the commitment be to evaluate each and every one of them or to evaluate some, or to evaluate only those that ask to get, shall we say, that Good Housekeeping or Blue Ribbon seal of approval. So, I think it's a wonderful concept but I am very supportive of it being further scoped out.

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

That's a great comment and that's exactly what we're recommending further scoping.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Okay, any additional questions for Deven about the committee's recommendations? Hearing none then we take a vote is that correct Michelle on the recommendations?

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

Yes.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

All right and I'm unable to see the hand raising so we should probably do a voice vote if that's okay with everyone. Everyone in favor say "aye."

Multiple

Aye.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

And opposed? And abstaining? Excellent, well, thank you all very much and thanks again for your work on this. I look forward to the transmittal letter.

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

Thank you.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

All right so we're going to move on now to our last agenda item which is Interoperability and Health Information Exchange Workgroup that's Micky and Chris. Micky and Chris are you all on the phone.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Hi, this is Micky I'm on. I don't think Chris is going to be able to make it today.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Okay, great, well then I'm going to hand it over to you.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Okay, great and I know we're running a little bit late and if all you promise to be well behaved we can do this on time. So, next slide please.

We were asked to look at a number of different things, one was a request to review the recommendation that we had made to not allow the inclusion of so called selfies and we'll discuss that in a little bit more detail.

The second is to take a look at a recommendation that the Policy Committee approved from the Consumer Workgroup to move over a part of one of the requirements or objectives that was in objective six under patient engagement to move that over to objective seven and for us to think about incorporating that in our recommendations so we'll spend some time on that.

And then three to six are actually relatively quick and dirty ones that we can get through pretty quickly if we don't get to those there is a slide on those and I think the answers are relatively self-explanatory, but we were asked to look at a suggestion to develop criteria for determining which specialist should be excluded for measure three which is the reconciliation, the information reconciliation measure.

There were a couple of factual questions that were asked about can reconciliations that happen prior to the patient visit count for measure three, how are transfers or referrals counted if the patient doesn't show up for the appointment and then finally there was a general question about impact of data segmentation certification criteria on transitions of care.

As I said, we do have one slide that has, you know, sort of responses to those I'll cover if we get to them, but I think that they are also relatively self-explanatory on the slide itself, but I will spend more time on number one and number two. So, next slide please.

So, wanted to first make sure that we are all absolutely clear what selfies are because I think in the Policy Committee discussion we had there was, you know, a little bit of confusion about what exactly is this concept of selfies, what does it cover, what doesn't it cover. So, I wanted to make sure that we, you know, sort of lay the appropriate groundwork there so that we're all clear on what it means.

So, this is the language from the FAQ that CMS published in response to questions related to Stage 2 and the transition of care requirement there which remember was for a send. So, this was for 10% of your qualified transitions of cares or referrals you had to send via the Direct protocol a C-CDA to the recipient.

And in this case the question was related to providers who are on the same EHR, so just reading here in the highlighted, if the receiving provider already has access to the CEHRT of the initiating provider, of the transition or referral, simply accessing the information does not count toward meeting this objective.

So, in this case we're all on the same EHR, call it Cerner, call it MEDITECH, call it, you know, EPIC let's say it's an inpatient setting as well as an employed ambulatory setting, we're all literally on the same database but it is a change in the clinical setting and as the patient is being discharged and is now going back to their PCP who happens to be a part of the same integrated delivery network they're literally on the same record. There is no segregation of the record even they are on the same record.

So, this question is asking if, you know, what if I...does that count and the CMS response is, just because you're on the same record just looking up the information in the record does not count to meet this requirement, however, if you basically send a secure e-mail to yourself, in this case, the hospital setting sending a secure e-mail to the ambulatory setting, which are both a part of the same organization, they're both on the same EHR, if you do that it says it counts. So that is the selfie issue.

It does not apply to the case where I am a part of the same integrated delivery network but I happen to be on two different EHRs, perhaps we were purchased, you know, over time, so I'm on MEDITECH in the hospital, the ambulatory providers are on athena or they're on eClinicalWorks or what have you, that is not a selfie that actually would count under the existing rule, CMS did not need to issue an FAQ on that. This is again, the issue where I'm on the same instance of the same EHR, same database.

Okay, so I just want to make sure we're all clear on what exactly this covers because there seemed to be a little bit of conversation about how this would prevent care coordination that IDNs are very complex and we're ruling out, you know, the complexity of these and just wanted to make clear this isn't for every IDN, this is for the particular case of an IDN who are all on the same EHR instance. Next slide, please.

So, this is the language from the Stage 3 NPRM where, you know, as you can read, I won't read it word by word, but basically what it says is that in the FAQ previously we allowed these, we have gotten a lot of comments back that note that even though there isn't full more information necessarily that is passed we believe that these can still serve an important alerting function and therefore we're going to allow those, we're going to continue to allow them. So, next slide, please.

And as you may recall the IO Workgroup recommended that we remove...that we not allow these going forward and our arguments were, we had a couple of different arguments for that, one was that we felt that, and still feel, that this was sort of a disproportionate advantage to large integrated delivery

networks, it essentially allowed them to send an e-mail to themselves and get Meaningful Use credit rather than extending themselves outside of their network to make sure that they are making electronic interactions that they have with organizations outside of their IDN.

There is an exclusion on the bottom end of this so that if you were recommending an exclusion that the exclusion be reinstated for organizations that have fewer than 100. So, you know, there certainly are cases where an IDN literally may have 95% of everything that happens is within that IDN and in that case they could qualify for an exclusion if they had so few of those that it didn't make sense for them to enable an electronic function for very few transactions.

On the other hand, if you're above that minimum threshold this would, you know, sort of push you to move outside of your IDN to make sure that you're electronically enabling that as well. That was, you know, sort of the primary argument, the other was that we didn't believe that it added anything to the quality of care either from a patient perspective, that there was no other information that was being conveyed in that.

And the third point was that it was creating a perverse incentive for organizations to do things or have their technology vendors do things that are not the best way of doing them. If an alerting was, you know, what was trying to be accomplished then there are much better ways to handle alerting within the EHR system rather than telling people the way you ought to do this is to e-mail yourself.

So, we asked three questions of the group as we looked at this. We asked, do selfies enhance care coordination by acting as an alerting function?

Second, does allowing this encourage vendors and providers toward a suboptimal technical approach, which is the sending an e-mail to yourself?

And then finally, does allowing it have positive spillover effects for exchange with other trading partners where this would be, you know, that well if I enabled the Direct messaging to myself maybe then I'll be more inclined to Direct message others as well because I've enabled the function, so it sort of, you know, the opposite of the spillover or of the concern of I'm not extending outward, this was, you know, sort of saying, well, maybe there is a positive way of looking at this that if I enable it for myself I'll use it for others. Next slide, please.

After considering these three in some fairly engaged conversation we came back to a universal view, a unanimous view of the Workgroup that selfies really don't support the intent of objective seven, you know, across the board both vendors and providers on the Workgroup felt that they don't add any additional value, you know, in the vast majority of cases. There is no additional clinical information being passed.

The provider's view was that there is no real alerting function that they are aware of that gets performed by this and furthermore that the likelihood that a provider would actually look at the C-CDA rather than just going into the record was, you know, very, very low. In part it was just because it's a very cumbersome channel rather than just looking at the record itself and also because of the issues that we've dealt with in other places of C-CDA bloat to the extent that C-CDAs have, you know, sort of very circumscribed usability to begin with providers aren't inclined to jump at that as the first opportunity to find out about the patient.

So, we come back, you know, we have considered it, we had an engaged conversation, we took back the feedback from the Policy Committee but we have come back with a unanimous recommendation that the selfies not be allowed.

And I know Troy is a member of the Workgroup, there are others on the Policy Committee who are members of the Workgroup, please add any additional comments that you might have.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente

I think you explained it very well. Thank you.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Thanks.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

And impressively rapid, thank you, Micky, that's really great.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente

That was quick.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Yeah that was terrific. Thank you guys and thank you for the clarification. I'm going to open it up to the committee if there are questions or comments that you would like to make? Okay, hearing none then I think we can proceed with voting on the recommendations that you all have.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Okay. Did you want to do these one by one or did you want to do all of them, however, you wanted to do it, I know there are a couple of others here.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Yeah, please let's do them all at once, I'm sorry, I thought we had reached the last one.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Okay.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

You guys...

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Yes, okay, let's go to the next one and this next one will take...this is the only other one that we'll spend a little bit of time on, but this was...now so you may recall that objective six had a...and objective six is patient engagement and measure three had a requirement, a proposed requirement for patient

generated health data or data from a non-clinical setting is incorporated into the certified EHR technology for more than 15% of all unique patients.

And the Consumer Workgroup recommended that this be broken out actually into unique patients as one category and non-clinical settings as a separate category. They recommended a 10% threshold for information from all unique patients and then suggested peeling off the non-clinical setting requirement and moving that over to objective seven. The Policy Committee approved that so we were asked, you know, to handle that within our recommendations. So, next slide, please.

These aren't easy or straightforward to reconcile and the reason is they...there are a couple of different things that are going on here, one is, in terms of applicability the patient engagement measure...so what I have is one column on the patient engagement measure, the next one is on the IO Workgroup recommendation for measure two so it's a little bit different than the measure two recommendation.

And just to refresh everyone's memory HIE recommendation two was that for 25% of my transitions of cares or referrals that I consume information from another entity. So, it's a different denominator which is the first row there. So, the denominator on patient engagement is all unique patients seen. The denominator on measure two was for encounters for transitions, referrals or new patients.

The thresholds are different, the NPRM had 15%, obviously the Consumer Workgroup knocked it down to 10 but that was only for patients. We are recommending 25% on the qualifying encounters. The payload requirement is different as well. The patient engagement measure said "any type of data or document" whereas the measure two had electronic summary of care record, C-CDA with CCDS components.

The transport requirement there was none specified in the patient engagement measure so it could have happened anyway. In the measure two recommendation there is a floor that has to be electronic means. It wasn't specifying what electronic means but it had to be electronic means.

And then finally, there is the question of the source providers, any provider who is not an EP, EH or CAH as defined by the MU program was the source provider for the patient engagement measure, whereas in the measure two it was constrained to...it could be any provider but it could only be those...but the universe would be those who are making a transition or a referral, or identified by a new patient.

And then finally, there were no exclusions in the patient engagement measure, we were recommending some inclusions, some exclusions on measure two.

So, there was a lot of stuff to reconcile here on the next slide and we didn't come to a firm consensus on this, we just didn't have time, because as we started looking at it we realized this is a lot more complex than just folding one into the other.

So, instead what we are recommending is a set of principles that we did get consensus on, even though we didn't get to a final conclusion, that would say it should be "x" percent of this "y" percent of that. So, the principles are first we do agree with merging it. We think that it should be folded into measure two.

So, measure two on objective seven should really be the baseline for it not, you know, going the other way. It shouldn't be that measure two should be considered to be merged in the baseline of the objective six measure.

Second, we believe that we should not be separating targets for so called non-clinical providers. So, you can imagine saying something like, well we should have a separate measure, you know, for...a separate measure or...which would say for non-clinical providers you should do 5% which would be the remaining from the original 15% or that you should do “x” percent for all providers, “y” percent for non-clinical providers which is an unfortunate term we think that should be changed, but we think that this didn’t make sense at all, it was too difficult for a receiving provider to be able to sort out who is non-clinical, who is not and then setting these sub-targets for that.

The third was in, sorry, my computer just went to sleep here, here we go, the third was we believe that we should be setting some kind of two-tier objective where you have a higher threshold that allows greater content format flexibility which would allow the flexibility to take in information from the so called non-clinical providers because most of them are not going to be on CEHRT. And then have a lower threshold based on C-CDAs. So, you know, C-CDAs are important but you need to have a higher threshold that allows any kind of format.

So, for example, you could have incorporate any type and format of clinically relevant information from 25%, I mean, again this is picking a number of ToCs and referrals, and then a tighter threshold or a lower threshold for a tighter requirements that would say 15% have to be C-CDAs.

Fourth, we do think that you need to...that we need to narrow the denominator. So, the denominator coming over from the patient engagement measure was all unique patients seen during that period. That presents a real problem when you start to set a high threshold around this stuff because if you think about that a providers may not know any place that a patient has gone and particularly a non-clinical setting and so we felt that it needs to be constrained somehow to a universe that a provider would be expected to have some ability to see or to know that the patient has actually gone to another place so that’s why we were recommending that the denominator from the original measure be used which is the retaining on the ToCs, referrals plus never before encountered, plus the electronic query as the denominator.

We do recommend requiring electronic means of transmission and that would allow and a corresponding exclusion for those who cannot do it via electronic means. We don’t think that it makes sense to say you can send paper, you can send faxes and all of that needs to be incorporated as part of a, you know, a specific percent threshold because that’s a very cumbersome, you know, kind of thing to try to automate.

And then finally, this is a carryover from our previous recommendation, allowing the incorporation of electronically queried information outside of specific episodes of care. And then clearly defining the meaning of incorporate and that’s even more of a point here as we think about non-C-CDA information coming in as well as C-CDA, what does it mean to incorporate the language says “incorporate” but we need some clear definitions around that.

So, this is the end of this recommendation and then the next slide just has those remaining four which, as I said, if we don’t get to them I think they’re relatively self-explanatory in terms of our responses. The first one we weren’t able to determine any additional criteria for specialties that could be excluded from information reconciliation requirements.

We also believe that for the question of can reconciliations happen prior to the patient visit, we believe that the measure doesn’t address the timing of that so we request that CMS provide clarity on that. We

think that is how it's happening though. We have heard from providers and vendors that this is being counted and the way they're doing it.

How are transfers, referrals counted, it's based on encounters, so if the patient doesn't show up it won't get counted that's the way that it's working on the ground.

And then finally, we did discuss, but we really don't see any specific impacts from the addition of data segmentation to certification on the recommended approach here to this HIE objective so we weren't able to provide any more information on that.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Well, excellent. Thank you, Micky and Chris in absentia, and the committee. Are there questions for Micky about any of these recommendations since the last time that you all saw them and the changes that they had made?

Okay, can we then go ahead and proceed with a vote on the recommendations that have come from committee? Everyone in favor of advancing these please say "aye."

Multiple

Aye.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Everyone opposed? Any abstaining, that would be me. And Michelle I should have been clear, I abstained on the last one also.

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

Thank you.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Okay, well thank you guys very much.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Okay.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

And again, thank you Micky for keeping us on time...

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Thank you.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Really appreciate that. Okay, so, I believe Michelle that we have a couple of announcements I don't know if you want to do those now or if you move right to public comment and then make the announcements at the end?

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

Let's open up to public comment, make the announcements and see if anybody comes in to make a comment if that makes sense.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Perfect, that's great I'm going to turn it over to you.

Public Comment

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

Okay, thank you. Lonnie can you please open the line?

Lonnie Moore – Meetings Coordinator – Altarum Institute

Yes, if you are listening via your computer speakers you may dial 1-877-705-6006 and press *1 to be placed in the comment queue. If you are on the telephone and would like to make a public comment, please press *1 at this time.

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

Thank you, Lonnie, Karen I don't know, do you want me to make the announcements I'm happy to mention them.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

Yeah, that would be fine.

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

Okay, thank you. We just formed or we are in the process of forming a Quality Measurement Task Force, they are going to be responding to two NPRMs that were released by CMS. It will be a fairly rapid time to turn them around but we will do our best to get that done by possibly the June meeting at least for the first set of responses to the NPRM.

The second is that we have an Advanced Health Models meeting on June 2nd and 3rd and then the next Policy Committee meeting is on June 9th and will be in person so we'll see you all again fairly soon and get to talk fairly soon.

And with that we do have a comment that was put into the comment box and it is from David Tao from ICSA Labs. His comment, and we'll also send this around to the group, is I agree with the IO Workgroups

recommendations to disallow selfies. While there is benefit in an alert to a provider even if they are using the same EHR instance I don't think that sending a summary of care record via Direct is a good approach.

Alerting can be done a variety of ways within the EHR. If there is no alert built into the EHR then a secure message saying "check the latest encounter in the record without a C-CDA attachment" would be a better option. So, I agree with the Workgroup's conclusion that selfies would be suboptimal and should not count towards the ToC objective.

And it looks like that is our only comment so we'll share that with the group.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

All right, well, thank you. So, I think...boy that's a really great keeping on time everybody, much appreciated and Michelle when is our next meeting?

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

June 9th.

Karen B. DeSalvo, MD, MPH, MSc – National Coordinator – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services

June 9th, okay, very good, well we will...that's right, next...it's in person, June 9th see everybody then. Thanks and have a great Memorial Day weekend.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Thank you.

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

Thanks Karen. Thank you everyone.

M

Thank you.

Gayle B. Harrell, MA – Florida State Representative – Florida State Legislature

Thank you, Karen.

Public Comment Received During the Meeting

1. I agree with the IOWG's recommendation to disallow selfies. While there is benefit in an "alert" to a provider even if they are using the same EHR instance, I don't think that sending a Summary of Care Record via Direct is a good approach. Alerting can be done a variety of ways within the EHR. If there is no alert built into the EHR, then a secure message saying "check the latest encounter in the record" WITHOUT a CCD attachment would be a better option. So I agree with the workgroup's conclusion that "selfies" would be suboptimal and should not count toward the ToC objective.

Meeting Attendance								
Name	05/22/15	05/12/15	04/07/15	03/10/15	02/10/15	02/10/15	01/13/15	12/09/14
Alicia Staley				X				X
Anjum Khurshid	X	X	X	X	X	X	X	X
Aury Nagy								X
Brent Snyder	X	X						
Chesley Richards			X	X			X	
Christoph U. Lehmann		X	X	X			X	
David Kotz			X	X	X	X	X	
David Lansky	X	X	X	X	X	X	X	X
Deven McGraw	X	X	X	X	X	X	X	X
Devin Mann				X	X	X	X	X
Donna Cryer	X	X						
Gayle B. Harrell	X	X	X	X	X	X	X	X
Karen Desalvo	X	X		X	X	X	X	X
Kathleen Blake	X	X						
Kim Schofield	X		X		X	X	X	X
Madhulika Agarwal			X					
Neal Patterson		X	X		X	X		X
Patrick Conway								
Paul Egerman	X	X	X	X	X	X	X	
Paul Tang	X	X	X	X	X	X	X	X
Scott Gottlieb	X		X		X	X		
Thomas W. Greig			X	X			X	
Troy Seagondollar	X	X	X	X	X	X	X	X
Total Attendees	13	14	16	17	17	17	17	14