

**HIT Standards Committee
Draft Transcript
February 24, 2010**

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you very much. Good morning, everybody, and welcome to the tenth meeting of the HIT Standards Committee. This is a federal advisory committee, which means there will be opportunity at the close of the meeting for the public to make comments. In addition if members of the committee could please remember to identify yourselves for those members of the public who are listening on the phone or on the Webcast. With that I'll begin with introductions around the table. On my right we have—

Jodi Daniel – ONC – Director Office of Policy & Research

Jodi Daniel, ONC.

John Klimek – NCPDP – VP Industry Information Technology

John Klimek, NCPDP.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

David McCallie, Cerner.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Liz Johnson, Tenet.

Kevin Hutchinson – Prematics, Inc. – CEO

Kevin Hutchinson, Prematics.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Stan Huff with Intermountain Healthcare and the University of Utah.

John Derr – Golden Living LLC – Chief Technology Strategic Officer

John Derr, Golden Living.

Cris Ross – MinuteClinic – CIO

Cris Ross, CVS MinuteClinic.

Janet Corrigan – National Quality Forum – President & CEO

Janet Corrigan, National Quality Forum.

John Halamka – Harvard Medical School – Chief Information Officer

John Halamka, Harvard Medical School.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Jon Perlin, HCA.

David Blumenthal – Department of HHS – National Coordinator for Health IT

David Blumenthal, Office of the National Coordinator.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Dixie Baker, Science Applications International.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Chris Chute, Mayo Clinic.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Carol Diamond, Markle.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

Jim Walker, Geisinger.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect

Anne Castro, BlueCross and BlueShield of South Carolina.

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

Jamie Ferguson, Kaiser Permanente.

Judy Murphy – Aurora Healthcare – Vice President of Applications

Judy Murphy, Aurora Healthcare.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Wes Rishel, Gartner.

Jim Bialick – Genetic Alliance

Jim Bialick, Genetic Alliance.

Judy Sparrow – Office of the National Coordinator – Executive Director

Do we have any members of the committee on the telephone?

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services

Karen Trudel, CMS.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you, Karen. Martin Harris is here as well. He's just taking his seat, and with that I'll turn it over to Dr. Blumenthal.

David Blumenthal – Department of HHS – National Coordinator for Health IT

I'd like to add my welcome. Ten meetings in less than ten months is a lot, and thanks again for all your work. I wish I could say it was coming to a close, but it's if anything accelerating, and we will look forward to hearing your thoughts about the interim final rule, which I hope you can appreciate that it was heavily influenced by your thoughts and advice, but it can be I'm sure improved still, and we look forward to hearing your thoughts about that.

We have been extremely busy on many fronts, not just on the rule-writing front, but also on the grant-making front, and you will continue to hear over the next five weeks and following that additional announcements about programs that are designed to support the provider and patient community to make the best meaningful use of health information technology and to build on the foundation of standards and certification criteria that you've helped us to develop. We are hard at work as we speak on the NPRM, the notice of proposed rulemaking, for a certification process. I don't want you to hold your breath because I'm not sure we get this out in time for you to sustain that breath-holding, but I promise you it will be soon. Having said that, I would just again thank you for your work and turn over the gavel to our very able chair and co-chair, the two Johns.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you, David, and good morning, everybody. Thank you pretty much for all of your hard work. I appreciate the public's input into this process and the staff in ONC and the opportunity to have input initially and to recommend standards done through the process going on over the last month since the IFR, interim final rule, was published, the opportunity again to come back and have influence into the process. I know, David, that you're getting a lot of input, and that is fact, I was thinking about this meeting. It's chartered as a federal advisory committee. This is the democratic process in action. I can imagine that there are many more expeditious ways to conduct business, but there are no more open ways than to have an ongoing dialogue. These dialogues are helpful in terms of getting the best input from a broad cross-section, so particularly appreciate all of the public comments that are coming in during the comment period certainly associated not only with the interim final rule which for those I'll often say IFR today, that date is what we're referring to, and similarly, the Office of the National Coordinator has been taking input on the notice of proposed rulemaking or CMS more specifically on the meaningful use. This creates a lot of work, but it also creates the best end product.

It really brings to mind the great quote from Winston Churchill that democracy is the worst form of government except for all the others that are tried from time to time, and point of fact, it is a process. What he was saying in reflecting on experiences with democracy is that it is not as expeditious, but it's much richer in terms of getting good input and coming out with the best product that suits the broadest variety of needs that will reflect on the aspirations to improve healthcare, improve access to information, and to care broadly in the value of that healthcare and the underpinning health IT. It's hard to think of a better way to get there as challenging as it can be.

With that as preamble, I want to thank each of the workgroups for really tackling this difficult but critical process which we'll review in our workgroup co-chair discussions today, all of that input and recommendations to ... the next part of our body of work. It is that period of time where the world is looking to move from policy to action. After we go through the clinical operations, clinical quality, privacy and security, we will talk about some of the forthcoming ideas in terms of implementation. This is becoming much more time-sensitive, and we appreciate that as well.

Before I go around to ask all the members of the committee to take a look at the minutes, but before we actually come to consensus on that, let me turn to the other John, John Halamka, for any opening comments that you might like to offer.

John Halamka – Harvard Medical School – Chief Information Officer

Sure, so today we're going to focus on reviewing that interim final rule and as I think about the difference between the interim final rule and the notice of proposed rulemaking, the notice of proposed rulemaking talks about stages. You've got stage one, two, and three. That is, there's going to be quantized 2011, 2013, and 2015 criteria. Well, the IFR I think is in an evolving document. That is, we as a group will be providing continuous guidance and refinement.

There's going to be a tension that we'll always have to face of when to be specific and when not, and I think you'll see that in the testimony today because on the one hand if you provide a little specificity it allows the time for the industry to settle on its own standards, sort of the HD DVD versus Blu-Ray kind of issue, but if you provide no specificity, well, you could have a thousand wildflowers blooming, and before you know it every city is building train tracks between Boston and New York all of a different gauge. I think as a team we have to decide where are we specific and where are we not, so I think that'll come out in each of our discussions today because it's interesting when you look at Jamie's and Dixie's testimony, sometimes they've actually said be more specific, and sometimes they said be less specific, so it'll be a fascinating balance.

I look forward to our rich discussion today in this regard, although I think as we look at the next six months, there's clear work that's coming out of our workgroups and taskforces, the vocabulary, subsets, the implementation starter kit that we'll hear about to accelerate, but I think we'll hear from ONC about RFPs that are being issued about the standards process itself. We've already seen the first RFP if folks have not seen that for standards harmonization. That was just issued a few days ago, so this is call it the replacement of the kind of function that HITSP did in the past, and there's a whole framework that is described in that RFP. It's a new framework using the NIEM framework which has been used quite successfully in government and DOJ. A number of government agencies are interacting using structures for describing content with vocabularies outside of the healthcare domain.

What I hope we can do over the next six months is not only continue to provide this ongoing guidance and refinement that supports the continuous evolution of the IFR, but also be an advisor to this process and all the RFPs that are going to be coming out and active participants. I see that RFP as both a bottom-up and a top-down process, so it's actually very well done, and I know more RFPs are to come and I think will be a very good sounding board for all the work you're doing, so look forward to the day.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thank you for that, John. With that I hope people have had a chance to review the minutes of the last meeting. Any amendments, changes that you recommend on that? Okay, hearing none, then we will assume consensus on that and move into our formal agenda. First up today is the clinical operations workgroup and look forward to your comments and discussion of IFR. For that we have Jamie Ferguson and John Halamka leading the discussion.

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

Thank you, good morning. Before we go through the comments that we're here to present on these slides, I just wanted to note for those members of the committee who were not able to attend our session yesterday, we did have a public hearing here in this hotel yesterday of the clinical operations workgroup's vocabulary taskforce. The subject of the hearing was rules of the road for governing the subsets and value sets of the adopted vocabularies that are needed by implementers of EHR technology, and so this includes the governance of the starter sets that are needed for the adopted vocabularies.

We had three panels yesterday. We heard from EHR vendors who described their requirements in terms of how these things should be governed. We heard from the terminology service providers, and we also heard from the content exchange standards development organizations that use these adopted vocabularies in the interim final rule, so we plan to continue this work through March. We had planned actually a government panel as well for the government EHR providers yesterday. I believe they weren't able to get clearance on their testimony in time, and so we're going to continue that through March and continue this discussion, but I wanted to make folks aware of that. The materials I believe will be made available on the Web site, and so look forward to perhaps a future, and maybe at our next meeting we can have an update on that work in this forum.

Moving into our comments and discussion of the IFR and the clinical operations workgroup, we've had a series of calls on this topic, and we have a few recommendations to discuss here with the committee. The first one that we really finalized and came to this version of describing on a call just last week is the recommendation to broaden the adopted standards for content exchange to families of standards. We discussed the fact that implementation guidance in fact with the example of the lab implementation guide for HL7 2.5.1, the implementation guidance actually changes less frequently than the releases of the underlying base standard. Since that lab guide was balloted, HL7 has gotten NC approval on its next major release of version 2 messaging which is 2.6, and yet the lab guide itself has not changed.

We thought that one way to address this issue would be to broaden the adopted standards in the interim final rule for content exchange to HL7 version 2 period and then provide the implementation guidance both on the dot release version as well as the very specific implementation guides through alternative mechanisms, such as advisory letters, guidance letters, circulars, as well as in the testing and certification program and not necessarily to have that in the interim final rule itself. Specifically, we would recommend that the families of standards should be the NCPDP script family, the HL7 version 2 family, the HL7 clinical document architecture family, and I didn't put a comprehensive list on the slide just for space, but the other would also include the X124010 family and the 5010 family. It would also include standards that don't really have families, but that are adopted in the rules, such as the CCR and some of the vocabulary standards. Then in this scheme the implementation guidance would have to be provided to implementers at the same time as the final rule is promulgated through these various mechanisms, and that's where the dot release version as well as the specific implementation guides, whether it's a HITSP guide or some other guide, a balloted guide from HL7 as an example, could be published.

John Halamka – Harvard Medical School – Chief Information Officer

Just a couple of comments here, so here's the challenge is that we've been told that regulation is hard to change, and that is you run the risk by providing very specific guidance in regulation that it's cast in concrete and the industry can't move. Well, the IFR as currently written says HL7 2.5.1 with no implementation guidance, and in some ways that's the worst of both worlds because it provides no details of implementation, but it's declared a specific version, and in fact, as Jamie has said, the specific versions of HL7 actually change faster than the implementation guidance. To say, well, we will declare in regulation it will be this family, but then immediately have detailed implementation guidance which can then evolve outside of the regulation monthly if you feel like it, whatever pace the industry can tolerate, and we as a federal advisory committee continually can look at the usage of implementation guides and make recommendations to ONC of HL7 has now come up with 2.6, and it looks like there's an implementation guide that's getting traction, probably issue a letter of guidance for this, that, or the other kind of implementation detail.

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

I think the same thing then would apply to the particular release versions of the adopted vocabulary standards where there are different releases on different dates, and so the particular release would be essentially mandated through alternative mechanisms outside of the regulation to be adopted through testing certification programs and other guidance mechanisms.

At the bottom of this page is a bullet that says consider minimum implementation guides in the final rule. What that means is that we've observed that vendors seem to have no problem supporting many, many different implementation guides in the different implementations of their EHR technology around the country, and in fact, most implementers simultaneously support multiple implementation guides. There doesn't seem to be a problem having multiple implementations in an actual implementation of these technologies, and so as a minimum one of the things we discussed in our workgroup was having a single implementation guide, fully specific, removing all the optionality as a minimum requirement that would be actually in the regulation.

We did not come to complete consensus on this which is why it says consider this, and we wanted to have a discussion on this point with the committee, but we did think that having a single implementation guide, and I'll go back to the lab example where there's a well-established implementation guide for interoperability that's been recognized by the secretary for HL7 2.5.1 that could be an example of such an implementation guide that could be adopted in the rule, and then the advancement to other forms of

laboratory interoperability for HL7 2.6, 2.7, and future versions then could come out through these additional guidance mechanisms.

John Halamka – Harvard Medical School – Chief Information Officer

The intent here was to set a floor. We don't want to ossify a technology and say it must be this one implementation guide, but to, again, we didn't have consensus on this one, so this is definitely certainly something we want to discuss, but to say it's the family HL7 2 and the floor is HL7 2.5.1 implementation guide. Here it is in glorious detail, and as it evolves, that's okay because this is just a floor. This is consistent with the HIT policy committee. What they did was they said we want to declare an implementation guide plus. Start somewhere and then allow evolution on top of that. You can see the challenge we have which is either we in the reg provide implementation specificity, say here's the one way to do it, or we provide a family with a floor, and that seems to offer us the capacity to evolve pretty rapidly.

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

I'd love to get comments and thoughts and discussion from the committee members on this.

Jonathan Perlin – Hospital Corporation of America – CMO & President

For discussion on this topic, I think Carol Diamond had her card up first. Let me ask each person for the benefit of those on the Webcast to identify yourself as you speak. It's much, much easier to follow that way, so let's start with Carol Diamond.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Usually it's at least 20 minutes into the meeting before my card falls off the end of the table, sorry. Thanks for that presentation and discussion of issues. I want to make a framing comment about I think all of the considerations that we're going to deliberate today, and I think it certainly applies to this workgroup's recommendations and that is that we take the lessons learned, the top ten principles or whatever it is that we got out of the implementation hearing when we heard from lots of different people about what's needed to really drive implementation and have standards get used. We developed those keep it simple and focus on the little guy and make sure that you don't let the perfect be the enemy of the good, and actually, one of the principles was specifically on implementation guides. It was I think the last one about making sure that they're human readable, that there's testing available, that there's even an open source reference implementation for some of these. I think all of this would be helpful.

The only point I want to make is that those principles drive us away from being governed by a timeline that's dictated by releases of new standards and more by a timeline that's dictated by implementation and adoption and experience. I think as long as we have that as an umbrella view, I have no opinion. I don't know whether 2.5.1 for lab versus 2.6 is really where the market's headed. I'd be curious to know if you know how much adoption there's been of 2.6. We certainly over the years have learned of a lot of adoption of 2.5.1, albeit maybe inconsistent, but I just think that the release of new versions is of interest, but the recommendations that we make as a committee should be sort of guided by those framing principles that we uncovered in the implementation hearing.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks, Carol. We're going to go around the table clockwise, so we'll go to Chris Chute and then Stan Huff, Kevin Hutchinson, and then Wes Rishel.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Thank you very much. I appreciate the framework that you're proposing, and I do see wisdom in the view of having opportunity for growth and evolution and not being as you say ossified into regulation. This

need be balanced I would submit with what I would hope is a shared goal of maintaining the practical nature of interoperability, and you said as much in terms of the implementation guide; however, one of the old jokes about HL7 v2 is if you've seen one implementation, you've seen one implementation. If we are not very careful, I think having a family of underspecified issues or for that matter even implementation guides that are neither required or at worst under specified is not going to achieve the kinds of goals that I think many of us hope this opportunity, this once in a generation opportunity can afford. The advent of meaningful secondary use, if I could paraphrase that, where we have the opportunity to do genuinely effective sharable and scalable decision support, for example, enormously improving the quality and safety of healthcare and reducing its cost arguably is not going to materialize absent clarity and specificity about interoperability.

One of the few standards that are successful in the United States today is ICD-9 simply because it's implemented reasonably consistently, and I think part of the reason for that is you've got to do it. It's required, and furthermore, you have to maintain currency with revision cycles and the like that are very clearly specified. We could quibble about whether they're optimal or not, but they are consistent. By the same measure, I think having in regulation clarity about what is expected would actually be welcome by the industry. I know it would be welcome by our organization, and we cannot compromise the goals of interoperability with underspecified recommendations.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks, Chris. ... Stan Huff.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

I like the idea of having more flexibility, so I think that's a good idea. My thoughts were similar to Chris'. I guess the thought is if we allow that flexibility and inversion to standards I wonder what that implies about the certification or other kinds of conformance testing that we would do. It probably implies some flexibility there as well, and I wonder if another thought along these lines would be that at any given time the exact version is known as well as the implementation guide, and so at any point in time somebody who's working to become certified knows an exact target, but that from the broader perspective that there's sort of an old version, the current version, and a planned future version that could be the target, and that way at any given point in time you have an exact target, but if you look at sort of the spectrum over time, you would have people that are implementing at different stages, all of which are compliant, but were just step-wise improvements if you will in this. My thoughts go how do we do conformance and how at any particular point in time do we have an exact target and at the same time allow this flexibility which I think is a really good idea.

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

I'd like to just react to that and say that that was exactly some of the consideration that we had in making this recommendation, and it was based on some of the feedback and information that we've heard about the reasoning behind the current interim final rule and some of the experience with HIPAA that we discussed of regulations being hard to change that we were seeking alternative mechanisms for getting those exact targets within a framework that allowed advancement of the exact targets.

John Halamka – Harvard Medical School – Chief Information Officer

Let me just reflect on Medicare part D where maybe you have some experience to share with this where you had a regulation that said you will use NCPDP script 5. Oh my God, the whole industry is now moving to 8, but the regulation is not consistent with where the industry is going, and now there's this new version 10, and so you have this challenge of how does the industry and the regulation dovetail as the versions go from 5 to 8 to 10? Any experience that you would offer in that regard?

Kevin Hutchinson – Prematics, Inc. – CEO

Yes, that's exactly what I was going to bring up. We have a little bit of experience in this. We were thrilled when the Medicare Modernization Act put in the NCPDP script standard. We were less than thrilled when it was determining the actual version only because of the rule-making process and the legislative process you have to go through to actually get that updated, but it did create a minimum, and I'm thinking if we maybe can build on that where I see HL7 version 2 is like a minimum that says we need to be at least here. I wonder if there's not a process by which we say and any future versions so long as they backwards compatible or don't create complex with interoperability, that gives us an opportunity. I know we're going to review, at some point say should we now make the minimum version 5, but it gives you a longer time period to be able to do that so long as there is compatibility and backwards compatibility with the interoperability and exchange of that information. That might be a way to address it. I'm not a fan of putting versions in there that we end up having to get through rule making before we can actually implement, but I am a fan of putting a minimum standard so that we all stay on a certain level.

John Halamka – Harvard Medical School – Chief Information Officer

To your point it would say in the IFR the family called NCPDP script is to be used for e-Prescribing, and the floor is version 8, but all future versions or implementation guides are fine. That will evolve in guidance outside the regulation.

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

But it does bring up an interesting for that one particular standard that maybe David will have to address is that does this put us in somewhat of a conflict with the Medicare Modernization Act which is very specific on the version for that particular standard?

David Blumenthal – Department of HHS – National Coordinator for Health IT

I hate to interrupt the flow of conversation, but I think there is a fundamental question of regulatory process underlying this discussion. I think the suggestion you've made is an ingenious one. My conversion to a bureaucrat is incomplete, and I feel that I don't yet understand the regulatory process, but I thought Jodi might be able to give us some background on how much flexibility you can write into these regulations and how much we can depend on guidance. To the extent that guidance functions essentially as regulation, there may be Administrative Procedure Act problems with using guidance for those purposes. Anyway, Jodi?

Jodi Daniel – ONC – Director Office of Policy & Research

Well, I have been a bureaucrat a little bit longer, but I've not necessarily absorbed every bureaucratic policy and law yet. There are limitations on what we can adopt and how we can sort of allow flexibility without getting comments on a later version that comes out. There are some creative approaches that we may be able to try to implement to do that. We'll have to go back and talk with folks in our general counsel's office about how much we can do through guidance versus through statute.

There are issues with being vague about what the standard is and then having later adopted standards actually be incorporated into the regulatory scheme, but there are some creative ways of doing it, and we just probably have to work through how we might be able to do that and where we might be able to push some things into guidance. I can't tell you at this point what we can and can't do. We'll have to walk through a couple of different options and see what we can do. It's something that has come up in HIPAA and MMA, and we have tried to do some creative things in the past. Sometimes we're allowed to do those at some point in time and then we get told later on that we shouldn't have let you do that in the first place, so again, I think it's an interesting approach, and we just have to see what we can do within the scope of the Administrative Procedures Act.

John Halamka – Harvard Medical School – Chief Information Officer

Because if you tell us that specificity is required and therefore we are only as specific as to state the floor, okay, this is a specific version number, but it's a floor. Might that be the best of both worlds?

Jodi Daniel – ONC – Director Office of Policy & Research

Yes, that may be a way of making it work. Again, we'll have to check, but that might be a way of making it work.

David Blumenthal – Department of HHS – National Coordinator for Health IT

The general principle here, it's taken me a while to understand this, but the general principle is to prevent us bureaucrats from being arbitrary, so the rule-making process is designed to make sure that everyone in the world gets a chance to comment on things before anyone is compelled to do them. If we have a lot of discretion around guidance without having to go through the kind of thing we went through for the IFR or the NPRM, then people can sue us for being arbitrary and not going through the rigorous process of rule making that we are in effect doing without calling it rule making, so that's the line we're trying to tread here. I think you're trying to from a policy standpoint do what makes a lot of sense which is build in flexibility with a minimum, and that makes a lot of sense. It's just that we operate within this accreted body of law over what's acceptable to do through administrative processes.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks, David. That's very helpful. I think there is a sense of a set of specifications that frankly is specific enough to not be viewed as arbitrary and capricious, but forward compatible to allow future functionalities and a sort of family of compatibility to occur. To Jodi's coming back with policy guidance, then we have a number of other cards up, so we'll go to Wes Rishel first and then John Klimek ... then Janet Corrigan.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Thank you, Jonathan. I think that people who have known me for awhile in standards have detected a move from the right wing to the left wing. I think it had little to do with the elections of the year 2000, and by what I mean by that is one of my favorite aphorisms was that optionality is a four-letter word meaning that whenever you write a spec with options in it, then either one of the parties is obligated to do all of the options or you really don't have strong interoperability and that without effectively coming as close as possible to plug-and-play interoperability we have huge scalability problems rolling out interoperability across the country.

Having lived through the HIPAA implementation, I was very much aware that the burdens of the regulatory process are both, it's a heavy process, and it's a process that has to be prioritized in terms of internal resources in the administration. Year in and year out those go up and down, but the need to continually update standards doesn't. I had big hopes for the process that was executive order and HITSP and so forth, found difficulties in that which I don't think were just difficulties in trying to implement too quickly.

I think that fundamentally I have come to believe that the implicit philosophy in the NPRM and the IFR should be made explicit which is that certification is precise and tells you what accretive software can do, but the emphasis on the implementer is to get the job done. If they can use those certified interfaces, so much the better. They probably saved money. They probably got the job done faster and so forth, but at the end of the day, if they're still using HL7 2.0 and they're getting the job done, there's no need to change. If their way of getting the job done is to adopt a vendor product that pads rather than requires them to go to a standard, that's fine too, and I think that is the only way we can deal with the need to be

updating standards continuously, adapting them to variations on the use cases and yet still be supported by a regulatory process.

I think the issue is a little different with vocabulary than it is with transport and format standards. I just wanted to add to Chris' comment on ICD-9 another point and say if we could get this into the regulations, then we could probably get better plug-and-play interoperability. If you use ICD-9 wrong, you can go to jail, so if we can get that level of enforcement into the use of SNOMED, then I would say we'd be in good shape. Short of that—

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... friends don't let friends use HL7 version 2.2?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Well, I was talking here about codes. I think that we recognize one of the things that has worked acceptably well in the HIPAA world, and a lot in the paper world that preceded HIPAA is a shorter type frame public process for updating codes. There are committees that meet all year and once a year, announce new revisions to ICD-9 codes. We have a lot of opportunity to improve those processes now because we have the Internet as a way of facilitating that coming to consensus, but I think that we need a lightweight, acceptably public, delegated process for codes and perhaps for recommended other standards where there is no regulatory consequence for failing to meet the recommendation, but in general, if something is working, if the vendors have been able to go to it and test it, then it becomes an easier option than doing something else. I just wanted to make those points. Thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I just want to make sure I captured the kernel of what you're saying. If I've heard you correctly because I think this needs to be translated into policy putting aside the vocabulary comments you made and the need for a more rapid cycle transparent process that there is no interoperability without a tight enough specification. In essence, you're saying narrow enough for interoperability, but broad enough for I guess future compatibility. Is that, or—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

No, there is no interoperability without a very specific and detailed specification.

Jonathan Perlin – Hospital Corporation of America – CMO & President

You're extremely specified on the—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Well, I think that that is the end game where I'm suggesting a regulatory approach is around how you use that specification, and the first part of that is to say you use very specific, fairly rapidly evolving standards, more rapid than the regulatory process, for certification. You find some public process for achieving consensus on that that is short of the regulatory process but still public for that, but that you don't translate that into an imperative for the hospital to use that standard in order to get the job done. You take the position that if you're certifying the products as they evolve, they will find it easier to use the standard approach, but you don't require them to change something they're doing that gets 50% of their lab results in structured format or whatever the meaningful use criterion is.

Jonathan Perlin – Hospital Corporation of America – CMO & President

That's very aspirational, just going to have to go back to Jodi's thinking, and maybe next time we gather work particularly on the clinical operations workgroup to consider what the policy ramifications are. If I

again re-paraphrase, near enough for interoperability but with an adequate revision time cycle so that it doesn't pose constraint to future functionality.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

More than that, it's establishing a process for certification without making the leap to say that using the certified interface is the required means of achieving the meaningful use criterion.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay, but that's a slightly different framing because it's not self-contained within the guidance that's here. It's an evolutionary process. I think that's something that'll have to be considered, but I think it's aspirational. I think we'll have to consider how one actually operationalizes—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I'm trying to figure whether aspirational is good or bad.

Jonathan Perlin – Hospital Corporation of America – CMO & President

It's a stretch. It's an ideal. I'm wondering as we offer guidance to the National Coordinator what they can actually do to I think it's an important notion, and so one framing has been that the specifications recommended are tight enough that there's interoperability, but that there is nothing that excludes forward compatibility and additional functionality assuming a sort of floor. On the other hand you're saying that's great, but a way of getting there is to set the floor and the type of specification for interoperability, but add on a process that allows that future decision making be transparent and rapid cycle which I think is terrific. I just think it's also challenging to operationalize, and so I think we have to take that to the next level and say if this is an idea around which there's enthusiasm and I mean aspirational really in the best sense, we still owe a practical articulation of how that would happen, and not only practical, but politic in terms of what's in the realm of bureaucratic possibility.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I just need to first of all comment that this whole process has been a big lesson on the facts of life. We've learned the facts of life about what are requirements for regulation. We're trying to speed skeet through a slalom where the pylons are cement walls instead of flexible pieces of plastic, and the other fact of life that we have to accept just as much as we accept the regulatory facts of life is that standards at the high degree of specificity end up being used for very narrow cases and not everything people need to do.

There was a big lesson that I learned in the brouhaha in HITSP about lab versions, and I didn't learn it until last week. Up until then I had a complete misapprehension of what was going on there which is that we were in effect asking the lab vendors for the reason to get the 2.5 from 2.3 to change the administrative processes around their systems, to carry data that they didn't need to carry for a business reason in order to be able to comply with the standard. Well, that's a big deal, and that's the kind of thing we'll never get to enforce the standards to have that

One, we need to find some process for allowing standards to evolve and adapt, but two, we need to decouple that from the way that hospitals and practices achieve their business goals and our goals for quality and safety to the max extent possible. I wouldn't suggest that we say you can code problems using whatever code you want. We don't care whether it's ICD-10 or SNOMED, but I would suggest that you can find several ways to get that data together for a community and send it together, and if the community is doing it and they don't happen to be using the latest version of spec we don't care as long as you get the job done.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Well, we appreciate the threads. I think, again, we're going to have to ... the notions or actually operationalize them. I wonder ... feels as strongly about that decoupling aspect. I understand it's an unnatural act for an organization to take on administrative overhead for things that don't serve for basic value case. I think that's something we need to be sensitive to both in terms of innovation and acceptance. On the other hand, to get to that first state of interoperability around certain sorts of activities, that's a little bit challenging to reconcile. We've got a number of cards up, obviously very provocative set of thoughts. Got John Klimek next and then Janet Corrigan. We'll go around to Cris and Kevin. Am I leaving someone out, and David McCallie.

John Klimek – NCPDP – VP Industry Information Technology

Thank you. Basically, my comments are very similar to what Kevin had mentioned across the room about versions. In the NCPDP world of versions, to our members it means that there's some additional functionality that we're giving them. It's meeting some industry needs that we have out there, but in moving to newer versions, then there's a fear like Kevin mentioned that somebody thinks of it and puts it into a law, and all of a sudden everybody's got to move to the new version, and then there's a cost associated with that version change. As much as we love version changes and it gives us additional functionality, we're somewhat fearful of that hard brick wall in front of us saying that we need to move to it.

Right now pharmacy is moving in the telecom world to version D.0 which everybody's out there working on in the pharmacy world of transmitting claims between pharmacies and payers. We have an end date to make that happen, and that's a big financial burden right now for pharmacies and payers. Again, my fear is, again, sticking to a version or naming a version, but then I'm fearful also of losing that interoperability, too, as well. If we don't then, especially in the pharmacy world, we depend on interoperability. There are no two ways around that.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Terrific comments, appreciate it. ... Janet Corrigan.

Janet Corrigan – National Quality Forum – President & CEO

I think this is a really important discussion, and I think it probably in the near term here is a good idea and the regs to include a floor and provide some degree of flexibility, but there are really inherent problems in that approach over the long term because the field can move along, and frankly, there is a big difference between ICD-9, ICD-10, and SNOMED and what you can do with those in terms of quality measurement, public reporting, paper performance, all of those important application areas that we really want to try to support. You don't get comparable data. You can't construct performance measures in ways that you then get the clinically richest information, measure the most important aspects, and get comparable data to people who are using different standards ... of one example.

I think we need to focus particular attention on the ongoing process for promulgating standards and for raising the floor and deciding how much flexibility is going to be there. Towards that end I think we might want to consider exploring some nonregulatory, but quasi-regulatory kinds of processes for promulgating standards that the government can accept, and I would encourage the ONC staff to work with the general council to think a little bit about the how to use private sector standard setting organizations that are under the National Technology Transfer and Advancement Act, and once standards have been promulgated there or the whole schedule for how the standards are set for when the floor is raised I think could be done through private sector organizations. If they follow the rules of NTTAA, they go through a very transparent process ... for public comment, all the same kind of things you see in a regulatory process, and then the government has a great deal of flexibility, indeed a mandate to use those kinds of

standards or schedules. I wonder if there isn't a way to think about a process that can be done in a very transparent and open way but has a degree of flexibility providing for input.

The other thing I think we should think about in the context of that process is whether or not we want to identify some best practices and how that process would take place. For example, we need to know from the field what proportion of providers are ready to move the floor up or would be able to deal with the floor moving up. Often times in regulatory processes, the 25% of laggards who aren't coming along tend to wag the dog, so maybe we need some guidelines or rules for if 50% of the field is there able to make the leap, let's go. Now it's time to do it, and that's a judgment call, but you can study that and identify best practices for doing it.

The other thing I guess would be on account, and I think the Wes approach of thinking about lodging the standards to the product certification is a very intriguing one, but I wonder if it doesn't need to be both product certification as well as at some point clear promulgation of the standard because you can have a great product at a high level, but so much of this depends on organizational behavior and indicates, for example, of those ICD-9, the willingness of the clinicians to code at the level of clinical specificity or record information at that level of clinical specificity to enable moving to the higher level standards. Thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Yes, Wes, go ahead.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

One, I think the treatment has to be different for codes, but two, I have no problem with saying that data must be provided using a certain coding system. For the clinical quality measures, it absolutely should be the case that everybody who submits, submits with the same coding system; otherwise, you have no way to compare the data. My problem would be in saying that you must get to that code by the same route back in the skunk works in the hospital.

Janet Corrigan – National Quality Forum – President & CEO

Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Go to Cris Ross next.

Cris Ross – MinuteClinic – CIO

I appreciate the comments and the approach that you brought to this. It seems to make sense to me. I understand all the pros and cons about families versus nonfamilies, but I think Jon's comment of 2.5.1 is the worst of all possible worlds, it's specific, but it doesn't give you guidance. It's hard for me to imagine (I understand the limitations to the regulatory process) how you could do anything other than what you guys have recommended.

I think the other issue here is I think we should warn ourselves against the seduction that we're going to be able to leap to codification in one jump. We live in a chaotic and early stage enough environment that trying to get it all right in sort of one fell swoop seems completely impractical to me, and we're going to have to be thinking about how to narrow specifications as we go forward as opposed to get it all right all at once.

The other issue I want to raise a little bit is the limitation that we potentially run into in thinking that somehow we've got everything right, even within the category of NCPDP or HL7 regulation. I think about,

for example, about 12 years ago we codified on a set of standards that made the Internet possible, and they're now all cracking. Everyone would think TCPIP and HTML should be sufficient to carry us forward essentially forever and all we have to worry about is getting HTML more and more right, but now we have BlackBerrys and iPhones and Kindles and all sorts of other ways to display standards that even groups like W3C are really struggling with that. I think the regulatory framework needs to be thinking about not just codification within the set of standards that we already have, but be adaptable to new things as they come along. I just don't think we've invested all the HIT we're ever going to want to or need to invent.

I guess the last question that I would raise to some degree is if we are going to engage in this idea of counting on HL7, for example, to guide us towards more and more specificity, the question that I would ask is did NCPDP, for example, behave differently once the Medicaid Modernization Act came into place once there was increased adoption of the e-Prescribing throughout the system, and I think the answer is clearly yes, but the other answer is the pharmacy world has a more homogeneous set of stakeholders and a closer set of stakeholders than HL7 does. I don't mean to be going on at great length here, but it feels to me as though if we're going to go down this path we need to have some ideas and prediction around what do we, how do we think HL7 would react to this? If we were to say we want you to accomplish this goal of starting with this floor set of standards and move us forward, what guidance would we give to HL7? I like Janet's comments about how we need to leverage private sector organizations. Again, how would we influence things so as to have that private organization head in the direction that we want them to go to? I think that's sort of a general question that I don't have any answer to because I'm not involved in HL7.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks, Cris. I think that's a great segue to Kevin and any guidance from experience. We'd certainly most appreciate it.

Kevin Hutchinson – Prematics, Inc. – CEO

Well, I was going to mention the, someone had mentioned how we operationalize some of this is just to share a few stories, and I'm actually thrilled that we're having this conversation because I think this is broader than the clinical workgroup about processes that Janet brought up with respect to how we're going to refresh these standards as we go forward. There are several hundred EHR vendors, e-Prescribing vendors that are on the Surescripts network, and in any one point in time there are anywhere between three to five versions of NCPDP running through that network. Some pharmacies are on different levels and the EHR vendors are on different levels, but I want to assure everyone that those different levels are not causing conflict in being able to allow transactions to flow.

Now, from a process standpoint there's almost like a refresh where this is allowed for a period of time, and then there is a notice that goes out that says we are moving the network to the following minimum standard if you will, and there's a period of time that people know that they have to then build toward that next standard. I think as a standards committee I could see where we would allow a floor for a period of time, and then there's a notice that says now we're moving at this point in time to that standard, but in between those periods, we've had some vendors that every time a new version comes out they want to stay up to speed. We have others that stay way back until they're told that they need to move to the next version. Even though there could be five different versions between it, in many instances these standards are very subtle differences between 8.5.4. and 9.1 where it sounds like a brand new version and this is very difficult. You could have three data fields difference between those varied standards, but I think that if we have a process by which there's a minimum and there's a period of time you will have multiple vendors on multiple standards, and then we refresh the minimum, notice goes out, and you move forward. It works very well.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks, Kevin. That's very instructive. David McCallie.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, this is David. I like the notion that Janet and Cris propose, and I like Wes' notion of aspirational, or I guess it's Jon's assessment of Wes' aspirational, but I want to go even beyond aspirational and question that what we ought to be regulating is the desired outcome rather than the process to get there. The regulation ought to define what does interoperability mean rather than what's the standard that we should use today that approximates this vague notion of interoperability. I realize that's really idealistic, but in a sense ten years from now when we look back we'll say I can't believe we thought XML was the way to do these things, or I can't believe we thought that HL7 family X was the way to do these things. We were so naive about what was possible.

If we define what interoperability means, then regulate that and then stand aside and let the industry figure out how to get there. You could do that through a variety of means like certification. The certification bodies could be given the authority to define the minimum standard as of for the next X stages of meaningful use for example, or it could be that public/private entities like HITSP could be given that role. It could be that in some cases industry just gets together and figures it out on its own, but the regulation should focus on the desired outcome rather than on the process.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Well, thanks. I think this discussion is extraordinarily rich, and it's proposing really in the best sense the desired goal to help the commerce with health information, but in no way retard innovation or pose really excessive business overhead. Thus said, if you don't mind, Jodi, because what's being proposed for a number of different approaches towards us, let's take ... and then come back to you because you've heard a lot about a number of approaches. I'd be interested in your comments and sort of broad summary to all, so let's take ... and then go to you for the—

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

Just as my rule as timekeeper for this section, I want to note we've got about ten minutes left, and we do have three more slides to cover. This is just the first slide. ...

W

But I agree. I think this is a very rich discussion, and it's probably the very topic we should be discussing. I wanted to just both support Janet's point that the NTTAA gives a lot of capabilities to the government in choosing and supporting different kinds of standards and speaking to how they're going to use them and adopting privately sector developed standards is critical. I also wanted to, what David just said. I think getting to the, defining what interoperability, what the result is, is far more a way to be specific than to how you're going to do that because things will change, and I think Cris made that point. I'm actually supporting three of you. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Jodi.

Jodi Daniel – ONC – Director Office of Policy & Research

I actually had a question, not the summary statement, but I'll do both. I think we hear the suggestion from the broad group that there be some flexibility so that we're not locking standards ... about regulatory processes which is something that we struggled with for many years and that is not something we want to do. The question is how we do it. My question, and then I'll do a little more summary, is when we're talking about versions if there's a possibility that if you set a floor and then you have a version that comes

out that has significant change on the prior version or two prior versions, if you have an interoperability problem or ... backwards compatible and how, I just want to know what we might be stepping into base on the recommendation.

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

Well, this is one of the exact reasons why we didn't come to complete consensus on the recommendation to have a minimum specific implementation guide in the final rule, and that is that at times some of the field level data elements are deprecated or basically discontinued in version updates, and so there is, although there's a goal of backwards compatibility, there is not necessarily complete backwards compatibility to the extent that might be required. That's one of the considerations that we had in essentially not coming to consensus, but wanting to consider that recommendation.

Jodi Daniel – ONC – Director Office of Policy & Research

I think in summary I think that the goal that folks are stating here I think is legitimate, and I think it's one that we share to allow for flexibility and not lock in standards. The question is, is how we do that. We are required by the statute to regulate and adopt standards through regulation, so there are some statutory limitations on what we do. The question is what we can do through guidance. Then the certification process, we have to certify that products meet standards, so the question is, is whether or not we have any flexibility within the certification process for allowing for newer versions to still meet certification or if the statute would lock us in, and that's another question.

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

One of the things in that regard I wanted to point out here is that we're trying to differentiate between what I would call major releases and dot releases or minor releases on the standards where there may be a balloted or an NC or an accepted standard that is what I would call a major release like an HL7 version 2, and then there are dot releases, 2.5, 2.5.1, 2.6, 2.7, and so forth that have minor field level changes, but that fall within the broad construct of the previous adopted standards. Our hope was that the standard could be that the broad base of the major release and then have the minor release or the dot releases be done through the guidance or potentially through certification under mechanisms.

One other thing in this regard just to clarify is, and this is not exact, so therefore it's wrong, but my way of thinking about it is that the version numbering of NCPDP is roughly equivalent to the dot release versions of HL7, so when you talk about a version of NCPDP, it has a different meaning than a version of HL7. HL7 version 2 versus version 3 is a major big deal whereas the NCPDP version 5 to version 8 is probably similar in terms of the degree of change as the difference between HL7 version 2.3 to 2.5.

Jodi Daniel – ONC – Director Office of Policy & Research

Then one other summary comment is that, and I think somebody mentioned this is that we need to in thinking this through think about how it interacts with our other regulatory standards like the MMA standards and the HIPAA standards to make sure that those are aligned so that folks who are trying to comply with all these regulatory schemes can do so without too much difficulty. I've already had some exchange with CMS and ONC folks to try to tee up the issue and get some more clarity.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I think this discussion is so central. I really appreciate all the comments because it's really the operating paradigm for the standards forward. I can't think of anything that's more central. I hope it is aspirational, Wes. I mean that in the best sense. We may have a little work to do before it's inspirational, but aspirational is a pretty tall order for now. Jamie, we're going to get back on track here.

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

Okay, we do have as I said a few more slides to cover here. One other thing that we wanted to request clarification on, and this was something that did come up in the discussion we just had is we wanted to request clarification in the rule on what's required inside the EHR versus what's required for exchange or the borders. For example, we know the problem list is required to be captured in ICD or in SNOMED, but there's not a similar degree of specificity of what needs to be done inside the EHR versus only for interfacing or interoperability purposes in all cases.

John Halamka – Harvard Medical School – Chief Information Officer

I'll give you an example. In 1989 the ... created a problem list vocabulary called BI89, and we contributed that to the metathesaurus. It's now part of the National Library of Medicine whole nomenclature that crosswalks a variety of vocabularies. It's therefore mapped to SNOMED, so my doctors can specify one of the codes that is proprietary to our institution and perfectly express a SNOMED code when submitting a quality measure. Is that okay or not? What is the from the IFRs perspective when it says thou must use SNOMED, ICD-9, IND-10, is that in data exchange, between borders? Is that in every system inside the organization? Is it what the doctor sees? We're just simply requesting clarification.

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

Then also supporting the discussion we just had about obtaining guidance through the certification testing mechanisms and other mechanisms outside the regulation, we would recommend that minimum vocabulary subsets for each of the adopted vocabularies should be required through certification. This would not be the complete list of all lab test results by test name, for example, but it might be the 95% most frequently ordered tests that would be required in the certification program. Subsets of this kind would form a floor which probably most implementers would have to exceed that floor for the particular medications or the particular lab tests that they use, but that there would be some broad minimum that would be set through the certification and testing process.

John Halamka – Harvard Medical School – Chief Information Officer

Certainly, in the workgroup, the taskforce, and vocabularies, and we've heard many, many stakeholders say we would love to have freely available starter sets for vocabularies on commonly ordered lab tests, the problem list for SNOMED CT for example, and so this is just suggesting that just as we are trying to provide a floor on content that we provide some kind of floor on vocabulary.

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

Okay, a couple of comments on that.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Dixie Baker.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Yes, what comes to mind to me is the IFR scheme of certifying EHR modules. If I present my EHR module and I go and I use Dixie's favorite coding 101 and I assume that this other module's going to do the translation into the standard module, can I get my module certified? I think that's where you would run into problems because people would state it as an assumption. Is somebody else going to do it?

John Halamka – Harvard Medical School – Chief Information Officer

I think one of the interesting issues here is I think this is because it's with David McCallie's point which is if the intent is to be able to achieve quality measurement and through the combination of Dixie's favorite vocabulary connected to the Dixie to SNOMED translator we can actually achieve the intent. From a policy perspective, David's happy. From a doctor's perspective, I can use the tools that are available to

me. It doesn't require a huge amount of change. Is that a win for everybody, or is it suggesting actually Dixie's favorite vocabulary has to be removed from your iPhone, you can't use it anymore?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

No, I'm saying that I assume, not that I send it to Dixie's favorite translator, but I assume that Wes' translator is there. I don't think you'd have a problem if somebody submitted two modules that did translation. I think where you'd have a problem is if you assumed that some other module did the magic.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay, let's take one more direct and brief comment. Kevin, particularly appreciate any insights from the practical experience.

Kevin Hutchinson – Prematics, Inc. – CEO

Real briefly, I'm not suggesting this is the right way to do it, and Jodi, keep me honest here, but in the implementation of NCPDP and the Medicare Modernization Act, it actually excluded closed networks from the requirements, so when it left, take a Kaiser as an example. Kaiser could do what it needed to do internally, but when it left Kaiser to go to the pharmacy or if it left the organization, then it had to comply with those standards, but within the organization or within what was considered and defined as a closed network or closed system, I think is what it was called, then it didn't necessarily have to comply with that. Again, I'm not endorsing whether that's the right approach or not right approach, but it was handled that way in the Medicare Modernization Act.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks, very instructive. Did you want to comment on that, Jodi, or did you have, no, okay. Then let's come around. We've got Wes then Anne and then Stan Huff then.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I think that, Dixie, you can correct me if I'm wrong, but I think she was actually asking a question about certification of modules and that though I just wrote a published note for clients that said there is absolutely nothing in the certification process, it assures that two modules work together to meet your meaningful use requirement. You are responsible for figuring that out yourself. I would say that the answer to your question is if you will depend on how the certifying agency defines a module, and we don't have any guidance on that in the IFR either expect the very broad guidance that a module has to help with at least one meaningful use criteria. It's possible that you can shout for a certain certification agency and find one that would say producing in Dixie's vocabulary is okay, but that would really, I don't see there's anything in the regulation that guides us in that direction.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

The one who bought that would be none the wiser.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

That's why I think, this is why I keep going back to meaningful use. Certification is a modest benefit required by the law, but the real money comes for finding a way to get the job done as opposed to using certified pieces of software.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Anne Castro next.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect

Thank you. From everything that's been said today, I quickly go to there are two things we're talking about. One is certifying an EHR. Another one is certifying interoperability. It's not necessarily all one thing, and I think prior to today I've been thinking about it as all one thing and getting frustrated with the balance talk back and forth, and the opportunity here is that EHRs are certified for what we really want them to provide at the patient level, but that standard, standard interfaces are certified to provide the interoperability so that Dixie has to at least get her coding scheme to at least one of the recognized standard interfaces that I think we should provide.

That's an RFP opportunity for ONC to get those interfaces created and made available to people to use so that it meets Wes' aspiration which may get to inspiration now to not impact the office internally. John doesn't have to change everything that he's put millions and millions of dollars into, but only on the outside borders to they have to communicate at a very standard level, but you can have more than one. You would work with the entities that manage those coding schemes so that you were prepared for big changes, major changes like ICD-9 to ICD-10 instead of just the interim years of just code changes. That is an ongoing process that should be supported, so it's in my mind coming down to certification of two things. I feel very comfortable all of a sudden not having to put the two together. I offer that as something that we talk about and consider.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks for that. I think this gets to a very central issue, the issue of the border management in the last slide that you just discussed and with the implications the certifications are in terms of interoperability and finally what the implications of interactivity between certified and potentially noncertified elements of information systems that have that products relates both internally and beyond the border when used in an interoperable context. These are fundamental and that's why I think the last slide you presented was so critical in terms seeking that further guidance as to the exact requirements. Okay, Carol Diamond and then we'll go to Stan Huff.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I think Stan was before me.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

My understanding, I think all of our previous discussion in the committees was that we were leaving it as an opportunity for people to do the best that they could inside of their own system and that interoperability was at the borders when you were communicating outside of the system. I would speak very strongly in favor of that, not the least reason being that the standards we're specifying in fact fall short of covering all the things that you need to do in a real system, so all of our experience and even being a co-chair of the LOINC committee, I can say that our institution, there's about 15% of what we send between our lab system on our EHR that's not covered by LOINC, and I kind of have an inside with that group. Similar statistics for problem lists in SNOMED, there are things that we need to say, and I hope we never get in a situation where we say we can't record in the EHR what needs to be done to take care of patients because that code doesn't yet exist in one of the standard code systems. I would speak very strongly that we normalize at the borders and allow a lot of creativity and expansiveness in what you can do within your own system because that's where we can provide and in fact have to provide the patient safety and the ability to always say what we need to say clinically to take the best care of patients.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Okay, good point. Let's go to Carol and then to Cris Ross and then we'll go with that. Carol, you're up.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Just for emphasis I'm going to agree with that. I think our business is only at the border, and our business is not inside the organizations. I also want to make, I know that we're going to get to this in the privacy and security comments, but since it was raised here as well, this issue of certifying every module is another thing we have to look at from that perspective. Not every module speaks outside the borders, number one. Number two, as soon as you have 100 modules, the combinatory complexity of certifying what is then 10,000 potential interfaces is impossible to implement. I think we should really focus on both the requirements from a requirement standpoint, from a certification standpoint on just what's required outside of the organization and not get in the business of we have to certify every module and make sure that everyone inside the organization is using the standard exactly the way it needs to be used outside the organization. I don't think it's aspirational, actually. I think Wes' comment or suggestion was realistic.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Cris.

Cris Ross – MinuteClinic – CIO

Carol just made a specific one I wanted to make, but I think also maybe a general point which is I think we're still hearing confusion around what's the difference between meaningful use and certification, and I think Anne's comments indicate where the division is between those, and if that's the case, I think we need to get more clarification on why it is that certification of technology is not the same as a measurement of meaningful use. I think it suggests that certification in some ways is less specific and less binding to some degree if we are going to go down this road of certify at the water's edge or the McCallie rule, maybe we'll use that, which I think makes total sense, and I'm really, really encouraged by the seeming consensus here, but I think if this is the wedge that helps us clarify what is certification and what is meaningful use, I'd be very encouraged.

David Blumenthal – Department of HHS – National Coordinator for Health IT

Let me just respond to that. A lot of the thinking that I hear around the table has in fact animated the IFR and the notice of proposed rulemaking. The certification process or certification criteria will only attest to the presence of a capability. They will not and cannot assure that the capability is used to any extent or to its full extent. In order to create the use, you need to incent people to struggle with the capability to get it to be used, and that motivation comes from the incentives in the meaningful use incentive regulation.

The requirements of interoperability will be, if we are successful, laid out in our meaningful use notice of proposed rulemaking over time. We will have to define what interoperability consists of at the level that's required in order for Medicare and Medicaid which is the only level we have right now to give the provider some extra money or take away some money. If that is the balance that Markle and others have been suggesting to us and others that you set the goal and then to the extent possible certify the technology that can get you there if you can figure out how to use it, but we can't sit with you and the certifiers can't sit with you and get you to be a meaningful user. We are in fact creating regional extension centers and state health information exchange in grants to create an infrastructure to help with that, but the rules can't make that happen.

This conversation is so rich and where we in the federal government and ONC could really use your guidance, and I know you're working to give it to us, is in this question of how specific one needs to be in order to make sure that electronic health records, that the standards built into electronic health records and certified are able to accomplish interoperability that will be hopefully incented by meaningful use. What level of common functioning or what level of functionality and standards capabilities need to be built in, in order to make that happen? Where do we need to be specific and where can we be general?

We've certainly heard from the community a point of view that we need to be much more specific, and then we've also heard from the community don't be too specific. There may be some areas where everyone agrees you need to be very specific. That would be nice to hear. There may be some areas where everyone agrees you should let things kind of evolve and watch. That'd be good to hear, and then if there are the mechanisms that have been proposed for those other areas where people are not quite sure, what is the right mechanism for allowing change over time. I know that we're sharing our problems with you, but that's why you're here, for us to share our problems with you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks, David. Jamie, please.

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

Yes, if I can just react to that, David. From the perspective of our workgroup discussions, I think we're in complete agreement within the workgroup in all of our discussions that you need to get to that complete level of specificity that I think Wes and Cris and others have described here in this discussion to ensure the interoperability to achieve the meaningful use objectives. The question that I think we're struggling with here is how to achieve that level of specificity through regulation versus other means.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Well said. Cris, did you want to weigh in on this? Last comment on this topic, and then we'll move to—

Cris Ross – MinuteClinic – CIO

Very quickly, I think we all agree that the Goldilocks principle has to apply here. What is the right amount, but I submit that part of the reason why you're hearing different opinions as to where that golden rule actually exists is because we come with different use cases, and use cases ultimately drive the level of specificity that we need to adhere to. For some of us who are perseverating about scalable decision support that can be used in almost a plug-and-play modality, we're advocating very high degrees of interoperability. Others for whom essentially information physician-to-physician communication is the extent of it require a more relaxed level of interoperability. Unless we can get agreement as to what our shared use cases actually are, this debate isn't going to go away.

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

That's the perfect segue to this next slide. The good news is our last two slides are small observations rather than questions.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I believe Stan did have his card up for the last point. Is that just up from, okay, sorry.

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

For example, in the IFR the CCR and the CCD are both listed as appropriate for clinical summary transmission, and for that purpose that you point out if it is a clinician who wants to send a problem list, a medication list, and an allergy list from place to place, absolutely. CCR and CCD can both do that. Now, ... on the other hand for quality needs who entered what data, when, for what purpose, in what workflow with a bunch of rich metadata to measure quality, and the CCR wasn't really ever intended for that purpose, so your use case point is that, alas, the specificity and the choice of standards when there are multiple depends upon what you want to use it for. We simply made that as an observation, not making any recommendation.

Similarly, as an observation, and this may get very subtle, in the NPRM there is the note that claims attachments can use CDA revision 2 level 1, 2, or 3, but level 1, level 2 are human-readable only and

provide really no computable interoperability, so not really quite sure what that meant because if the intent here is that we're going to have semantic interoperability inside of claims attachments with codified data elements, you probably don't want a bunch of people just reading unstructured text, just an observation.

John Halamka – Harvard Medical School – Chief Information Officer

In fact, in our workgroup discussions we would support a recommendation to essentially go the same way with CDA that the claim attachments NPRM went which is to allow the level 3 as well.

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

Then final slide I think, no, sorry, two more slides. Next to final slide, I believe we've talked about many of these recommendations in the previous discussion. We did want to recommend that convenient subsets and value sets should be published both starter sets as well as complete quality measure value sets, and I believe the quality workgroup report will get into this in more detail. We felt that a lower priority would be convenient subsets of the vocabularies to be published for medical specialties.

We also had a discussion in our hearing yesterday about the need for coordinating releases of the adopted vocabulary standards, and I think the general consensus is that so long as the schedule is known in advance, it doesn't have to be, in my hypothetical example, on the second Tuesday of every month. We don't need to have that level of integration of released schedules, but the release schedules of vocabulary updates need to be well understood in advance.

We also want to emphasize that while we are recommending publication of convenient subsets that are based on the frequency of use of terms or concepts in the vocabularies that almost every implementer is likely to go beyond those subset, and so EHR users need mechanisms for easily going beyond those minimum subsets. Finally, we did want to make a specific recommendation to include in the final rule the adoption of standards for vital signs being LOINC or SNOMED. Then want to consider the possibility of expanding the medication allergies beyond those that are proposed in the IFR to include not only ingredients, but also clinical drug and drug class medication allergies because really medication allergies are noted at all those different levels.

Final slide, as a reminder, I think technical note, the ... core operating rules really apply only to the current HIPAA transaction standards of 4010A1, but the language in the interim final rule would seem to indicate they should be used also with the 5010 transaction set which they actually don't apply to, so we would request clarification of that. We also had a discussion in the workgroup about the possible inconsistency of some of the current legal compliance requirements of federal contractors and Medicare providers to adopt and actually to implement and use the recognized standards of HITSP essentially under the executive order 13410 being a requirement that could potentially conflict with some of the adopted standards in this rule. We wanted to note that without recommending any particular resolution to it.

John Halamka – Harvard Medical School – Chief Information Officer

As to what we presume, and this becomes a Jodi question, which is if the IFR because there was through the HITSP process or the previous administration the notion of acceptance and recognition and publication in federal register, the VIFR would replace all of those previously recognized standards because there are inconsistencies between the IFR and previously published recognized standards.

Jodi Daniel – ONC – Director Office of Policy & Research

The IFR is a regulation, and regulation does trump any guidance that is published. To the extent that there are any inconsistencies, the regulation is what sets the standard for any products that need to be certified as meeting those standards.

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

Again, just seeking guidance on that point. That's it. You can see two rich slides and then a lot of smaller observations.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Terrific discussion, now, before us we have to affirm consensus to the recommendations just to summarize in briefest terms, Cris, I'm going to adopt your terminology of the Goldilocks principle which really is the basis of our discussion of the degrees of specificity. I think there was great consistency around the point about specificity sufficient for interoperability and for guidance to occur, and I think there was a very excellent point that David made about where there is clarity ... for specificity it may be easier, and there are other areas where it's more formative.

I think the point that was made as well, Cris, about the use cases determining the lens with which different of us come to. That discussion is particularly important. It occurs back to the conversation throughout this discussion, this is really the intersection that we all have in common is that we're looking at this I hope collectively with the lens of how do these standards support the parallel work in terms of meaningful use. That really is that intersection.

I think it's been ... I think once before that we had this, it only makes sense to apply this at the borders, that it be not only unrealistic, but it would be cumbersome and difficult to try to reach into organizations and apply internally. I think there's a consensus of spirit around that. I think to be very clear ...is the need for specificity, I just want to be very clear on that, but that we have not come to resolution in the process for evolving that allows appropriate evolution but doesn't disenfranchise entities that ... speaking to, to participate in that interoperability. That's a piece that I think is still out there.

None of that is inconsistent with any of the recommendations. On the other hand, it does suggest that there is a good bit of work in terms of defining what the policy parameters are that would support that evolution and really helping to realize these recommendations. With that, do I hear a motion for acceptance of this report and recommendations for them? For those on the Web Thank you, any disagreement with it? Terrific. This is obviously going to be a topic of considerable further discussion, and I think our commitment to you, David, has to be that the discussion not be as long as the evolution of the actual intended product, so we have some work to do quickly. Carol.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I just have a question for process clarification. I know that some of the workgroup reports are being presented in slides and some have been written up. What's the process from here to get to a final document for the committee?

Jonathan Perlin – Hospital Corporation of America – CMO & President

Jodi, do you want to comment on that?

Jodi Daniel – ONC – Director Office of Policy & Research

Sure, and feel free, Judy, to jump in, but in order to transmit the recommendations, we will have the co-chairs prepare a recommendation letter and then have the chair and co-chair of the standards committee sign off on that to transmit to David. It's up to the chair and co-chair if they want to circulate that around to the broad group for consensus before sending that forward, but what we'd ask is that the chairs of the

workgroup revise and prepare a recommendation letter based on their recommendations and the discussion that was set forth here and submit it to the chair and co-chair of the full committee for approval and submission to David.

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

I just wanted to note, Carol, I do have about half a dozen pages of notes that I started to type up into a letter essentially as Dixie had done, but figured that it would be more productive to have this discussion with the committee and make sure that we weren't missing any major points or that there weren't major changes to the recommendations before essentially finalizing it in the letter text.

Jodi Daniel – ONC – Director Office of Policy & Research

Let me just say one thing. The letters from the workgroups are recommendations to this full committee, so they're obviously subject to the discussion here and then the agreement by the chair and co-chair before they're submitted. The letter that we have from Dixie's workgroup would still be subject to discussion and revision based on the discussion in this full committee before getting submitted to ONC, and all of those recommendation letters that are submitted to David as the national coordinator we will post up on our Web site.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Okay, so when the question at the ends of these sort of discussions is whether there's support for all of these recommendations, we should assume that the recommendations will get modified or edited based on the discussion?

Jodi Daniel – ONC – Director Office of Policy & Research

Correct.

David Blumenthal – Department of HHS – National Coordinator for Health IT

There's the issue of comment on the regulation as well. Jodi, do you want to say something about that?

Jodi Daniel – ONC – Director Office of Policy & Research

For individuals—

David Blumenthal – Department of HHS – National Coordinator for Health IT

Or for the committee as a whole, sending a letter to me is not the same as entering a comment for the record.

Jodi Daniel – ONC – Director Office of Policy & Research

Sure, so there is a formal comment process on the regulations. They are submitted through reg.gov or through the mail, the regulation specified, the date they have to be in by, and the process for doing that. The committee can formally submit those recommendations through that process as well if they so choose, and any individual or organization that is represented on this committee can also on their own submit their recommendations to further regulations for us to consider. If folks do have their own points they want to make that are not necessarily part of the consensus recommendations of this group, then folks should feel free to submit those as well in their individual capacity or in their organizational capacity.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

But we should not assume that we'll see the revised recommendations again before they're submitted?

John Halamka – Harvard Medical School – Chief Information Officer

From a process standpoint today, we're going to actually see Dixie's full letter which presumably would then be revised. Jamie will finish his full letter, and I presume we would circulate it to all of you, and only when we had incorporated ideas and comments would we then sign it and forward it to David.

Jonathan Perlin – Hospital Corporation of America – CMO & President

That's my working approach to the process. Dixie.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

There was one more thing I'd like you to capture in the notes, and that is that certainly I support that the certification should not necessarily certify everything within an organization. It should focus on the borders. I agree that much, but I would like you to also capture that the model of certifying EHR modules does not support that because there's no certification of the edges of a combination of modules.

David Blumenthal – Department of HHS – National Coordinator for Health IT

Certification actually has a very specific meaning in the law. We certify according to the requirements for meaningful use. That's what certification criteria are related to, and so if a module purports to enable a user to accomplish a meaningful use function, it can be certified for that purpose. That could be an internal purpose. If there's a module for recording a problem list, the certification process will determine that, yes, that module is capable of collecting a problem list using whatever the standards are that are recommended. It won't certify that module as to its interoperability unless the module also asserts that it is capable of interoperability, and then it will certify to whatever level of interoperability is required under meaningful use. I think that this idea you can only certify at the borders is not really fully consistent with what the purpose of certification is which is to assure people who buy whatever it is that you can get to meaningful use or some aspect of it if you use properly the equipment that is being sold.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

To Wes' point, there's no certification that the modules work together, so that's what I'd like you to

Jonathan Perlin – Hospital Corporation of America – CMO & President

Great points. We have three cards up. Let's take those, and then we'll make sure to move on to the clinical quality, and folks tuning in may be seeking a schedule, so let's go to Wes and then Liz and then Jim Walker.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I just want to quote Bertrand Russell who did some great things between his nervous breakdowns. "Everything is vague to a degree which you do not realize until you have tried to make it precise." For all I know that may have contributed to his nervous breakdown, but it's exactly what we're going through here. Every time we think we have a standard for something, what we have found is a new platform to discover new complexities, and that is progress. It just doesn't feel like it. The way we have to meld that into the regulatory process is to find a way to let that discovery happen without it instantly snapping into a regulation.

Sort of the principles that were adopted by the implementation workgroup include adopting things after they've been proven in industry, and yet we're trying to find these new things, trying to solve these new problems. We just have to find a way to say we understand that the meaningful use requirements may be ahead of the standards in some areas and people have to figure out how to solve them. Where we have made it precise and shown it's precise through usage, then we have the option to snap it into a regulation.

I see Janet squirming, and I just want to make a point of distinguishing submissions to the government from these other things that we're talking about. I think that if the government is not precise in what it

requires in a submission, you can't get submissions, so that's a different case than what I'm talking about in general.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Liz.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

... actually for David. I don't know if John Glaser can answer it or not. He spoke to certification of the EHR and the components inside and outside of the borders, but what we haven't talked about at all is attestation. That term has not come up here, and yet, it's in the regs. It would be very nice to hear some conversation, whether it's now or when David returns around that concept, and I don't know if, Jodi, if you could speak to it, but there are two different, we talk about attestation and actually getting to meaningful use. We talk about certification as products, but we're not talking about attestation at all.

Jodi Daniel – ONC – Director Office of Policy & Research

Can I just clarify what you're asking? Attestation of—

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Meaningful use for the organization, so if you look inside of the NPRMs and the IFRs, the notion of attestation exists, and yet we're not speaking to it at all in terms of To talk about, I believe what it infers is that when you believe you have achieved meaningful use beyond the certification of a product or interoperability if we get there, then you have to attest to certain activities.

Jodi Daniel – ONC – Director Office of Policy & Research

Let me see if I can clarify, and then tell me if this addresses your question. I'm not sure if it will. The certification is that the product incorporates the standards and has certain functionality and capabilities, and that has to actually pass the certification test to meet the statutory requirement that an eligible professional or a hospital is using certified EHR technology. The meaningful use is about what the provider or the hospital has to do, so the assumption is that they have the capability. It's then what do they have to do using that capability, and what CMS has said in their proposal (and Karen Trudel is on the phone, so feel free to jump in, Karen, if you have anything to add) is that the eligible professionals and hospitals can attest to meeting some of those requirements that they proposed in the rule for actually doing the things that they have the capability of doing and that CMS is requiring for meaningful use.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Will we see additional guideline as to the format of that attestation?

Jodi Daniel – ONC – Director Office of Policy & Research

Karen, do you want to answer that?

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services

Yes, that's not a matter that we felt we needed to deal with in the regulation itself. Rather what we did was to talk about what the meaningful use criteria were and what the measurement factors were going to be—what's the numerator, what's the denominator, what's the base amount that we're looking for.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks. I hope that's helpful. I get the sense of your question that those things that are certified don't need to be attested to and that there'll be a process for attestation, but maybe we can clarify that in different context, but I appreciate your bringing that up. Let's close this section with one last comment from Jim Walker and move on to quality.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

This is a comment about certification. Granted that it has the narrow meaning that it has, that this module achieves some part of meaningful use, but not that this module will work with anything else in the universe. I think we're going to need to communicate that very clearly to the market because people, it will be very hard to get people past the idea that it's certified to work period.

M

There's already confusion in the market with many vendors making promises that their product is meaningfully use-guaranteed. What does that mean?

Jonathan Perlin – Hospital Corporation of America – CMO & President

I think that brings us right back to the wonderful Bertrand Russell quote that Wes offered. Everything is vague to a degree until you make it precise. This is a little difficult to make that guarantee at the moment. Terrific discussion, right at the heart of evolving standards and their applicability, I greatly appreciate the thoughtfulness of that. Thanks to the co-chairs and to the workgroup for both the presentation and all the work behind it, more to do. We're going to segue now to the clinical quality. We have Janet Corrigan and Floyd Eisenberg to bring us forward, a parallel discussion about meaningful use as it's really on the back of the standards, the desired applications ..., so a great segue from the foundational to the applied. Look forward, Janet Corrigan and Floyd Eisenberg, to your comments and your recommendations at this juncture.

Janet Corrigan – National Quality Forum – President & CEO

Thanks very much, Jonathan. I'm going to give the presentation of the clinical quality workgroup, and to refresh your memory.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I'm sorry, Janet. I have some audio, if I could ask you and Floyd to pull your microphones a little closer so they broadcast well.

Janet Corrigan – National Quality Forum – President & CEO

To refresh your memory, these are the members of the clinical quality workgroup, many of whom are here today and invite to join into this discussion as we go forward. The workgroup really had two specific questions that it discussed in its conference call, and the first was to review the measures that are listed within the NPRM and to identify the extent to which those were consistent with the measures that were recommended by this committee, and I mean the quality measures and then also pertaining to the IFR to review the adequacy of the IFR standards to support the requirements of the full set of measures that is included in the NPRM.

By way of a summary, there are 90 ambulatory measure and 43 hospital measures. The list includes 15 of the 17 measures that were recommended by the standards committee. Two of the measures that we recommended that were not included in the NPRM were the medication reconciliation and then the ability for providers with HIT to receive laboratory data electronically. Those were replaced by EHR metrics that have to do with the reporting and exchange of clinical information, med rec, and summary of care records.

There was some concern about the very large number of measures that was included in the NPRM; however, it's really important to note that when it comes to any individual type of clinician or provider, it's a far limited set of measures that actually applies to that particular clinician or provider, participating provider organization. For the physician level or ambulatory measures, there are three core measures that apply to all specialties, and then there are specific measures that have been added in most cases

that applied to a specific specialty area. In the case of primary care, there would be a rather large number of measures, meaningful use measures, were all of these measures to move forward in the final reg; however, for the other specialties, it's a far more limited number, so there is some need to think a little bit about the volume and the burden associated with that volume of measures were they all to move forward.

Now, the second part of our discussion focused on the implications of these larger numbers of measures and whether or not there were adequate HIT standards that were included in the IFR to be able to support these measures. Let me turn that over to Floyd. You've heard some of this in the prior presentation. I think we're consistent with where Jamie's group came down on the need for some additional specificity with regard to the HIT standards to support the other measures that were here. I should also have added too that our committee did not attempt to go back and weigh in on whether the many new measures that were put forward are appropriate and the best measures for meaningful use because that really falls within the purview of the policy committee. Floyd.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

Sure, thank you. Actually, let me just bring back a statement that Chris Chute made in the earlier conversation that in our discussion about the standards in the IFR, we are looking at the secondary use case, not primarily sending information from provider to provider allowing a human brain filter for the data, but actually, it needs to be computable. In the same context of measurement to be reused or used for clinical decision support concurrently in care, the same standards would apply.

Of our concerns if we can move to the next slide, the first was regarding the allergy list. There really are no standards specified in 2011. A number of the measures have as exclusions for the measure that the patient is allergic, has an adverse reaction in the past, or is intolerant, and without a standard to represent this, it's all based on local use of allergy. Additionally, the UNII codes suggested in stage two as a potential are all at the drug component level, not at the drug level, and in most cases, at least in the near term, all of the specification locally is based on drug level, so that may be somewhat problematic. Recommendation here is that med allergy standards need some specification for 2011, and drug level rather than component level would be suggested.

Next slide, on vital signs no standard was suggested in stage one 2011 CDA template advocate as a candidate for stage two, but as was discussed in Jamie's slides, depending what level of CDA, it would really need to be a level that specified detail and not just a human readable component under vital sign, and a vocabulary for vital signs in findings is therefore needed to compute measures. If we look at some of our measures, body mass index and percentile, it starts with height and weight to calculate the body mass index and percentile. If we look at vital signs, especially blood pressure and some others as we look through our measures that are in the NPRM, those data are required. A vocabulary standard for vital signs and clinical findings would be helpful in 2011.

LOINC had been suggested in the past. I did see in Jamie's slide LOINC or SNOMED. I know in a number of conversations the question comes up if you provide two alternatives it becomes more problematic to implement, not that it can't be done, but it's harder. It would be helpful to have a harmonized decision on which standard for vital signs, for instance.

Next slide was in units of measure, in many cases for the measures, the units are important in order to do the calculation. There was no unit of measure indicated in stage one, UCUM suggested in stage two, and basically the recommendation is it would be very helpful to have consistent units identified in order to calculate quality measures. Again, this would also be very helpful for clinical decision support and other implementations of data.

Another discussion not on the slides was about the PQRI XML and the fact that in the stage one that was recommended for reporting out measures, but in stage two other options might be available. The community did have a discussion that there seemed to be some confusion where people should go if there are two different standards or if something further is expected, but it's not defined what that is. That's a summary of our discussion. I'll leave it for discussion.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Kevin, did you want to say something? First, let me thank you both very for that. These are very crystal recommendations, and I appreciate the delineation between the purview within the standards committee and the policy committee, and we'll just open up if there are any comments or a motion for consensus around these recommendations. Appreciate it, thanks, a motion by Elizabeth Johnson. Any objections? We have two. Let's go to discussion.

M

Floyd, given your concerns about the generality of specifying CDA and specific issues around CCR, if C32 were adopted, would that over-specify, under-specify, or would it be like baby bear just right?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

It would resolve the specificity issues. There are elements within C32 that may not be necessary for the measures, so if that's what you mean by over-specifying, it may, but that would resolve the problems.

M

Sure.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

Okay, thanks.

W

Could you clarify your last statement about PQRI XML and QRDA? Were you saying that PQRI XML is required in stage one, but there is a reference to other standards that might be used later, that that's confusing and that reference should be omitted? Is that what you were saying?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant

No, actually, let me just clarify. I did not mention QRDA specifically. If I did I apologize. I don't think I did, but the second component for stage two was other standards may be selected in the future. The recommendation is not to remove that, but if the direction is to look for another standard, then having something temporarily asks implementers to go in one direction and then change, and that would be problematic, and it was not felt that the PQRI XML was the long-term solution. In other words, there was a direct recommendation to say perhaps PQRI XML should not be listed, but indicate there will be a future decision might be a solution, but that's not, I'm giving my personal opinion here.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks. Any further discussion? Any objections to consensus on the recommendations? Good, with that then we thank you very much for your work and to all of the members of the workgroup for the input on that. Let me turn to Dr. Halamka to introduce the next discussion of privacy and security.

John Halamka – Harvard Medical School – Chief Information Officer

You give me all the long presentations. Dixie and Steve are going to present all of their discussion which you'll find mirrors a lot of the discussion that was had about such things as certification of modules and

where we need more specificity and where we need less specificity if we're going to accomplish the goals of meaningful use, so look forward to your presentation.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

We're going to give our comments and recommendations on the privacy and security sections of the IFR, and we also addressed, we looked at those provisions that had to do with consumer access to their records, we'll have a recommendation in that arena, and we looked at the transport standards as well. The members of our workgroup, the process, knowing that this was an interim final rule, now a final rule, we didn't want to do it line-by-line. We really wanted to focus our review on some key questions and to try to tease out any big concerns that might exist.

We created a set of questions, and each of our workgroup members was asked to respond to these questions. The first question had to do with the overall certification approach. The second focused on the certification criteria, and we asked them to look at the reasonableness, the sufficiency, and the specificity, whether these criteria were specific enough to do a certification of a product. We asked them to look at the adopted standards in terms of their reasonableness and sufficiency, and we looked at specific solicitations that were in the IFR. One specific to us was that there were several standards that we had recommended that the IFR writers had chosen not to include, and they asked us to respond on that, so we had a question about that. We were also solicited comment about the reasonableness and technical feasibility of the accounting for disclosure standard. That was another of our questions, and then the final question, just asked a general do you perceive any gaps in the IFR?

The first topic we're going to talk about is that we noticed, and this was true of just the privacy and security standards, not the content standards or vocabulary standards, was that in the preamble to the IFR, there was a table, table 2B, that listed not only the functional standards, but also after each functional statement was a parenthetical remark that said e.g. All of the standards themselves that we had recommended with one exception had been translated into these functional statements with e.g. We thought that's a good idea.

We agree that that's a good idea because it does support the flexibility to implement these standards in a way that's convenient to the vendor's judgment as the best way to implement it, but then in the body of the regulation itself, the back part of the IFR, these e.g.s did not appear, so we were concerned that there may not be sufficient specificity for either the EHR developers or for the certifiers to be able to certify the compliance with those functional standards. Our recommendation is to include in the certification program that's currently being developed a framework and processes for specifying and maintaining a current list of these e.g.s if you will so that there would be a current list of examples, technical standards that meet the base level functionality that's specified in the functional standards in the IFR.

The second concern had to do with certification of EHR modules, and I must admit this is a concern of mine beyond just privacy and security which was brought up in the previous discussion is that the IFR allows for the certification of EHR modules that meet at least one certification criterion, so this raises some security issues, the first one being if a module meets a security certification criterion but provides no health functions whatsoever, can it be called an EHR module and certified as an EHR module. For example, if it does nothing, but it's an encryption chip, can that encryption chip be certified as an EHR module because it does meet one of the certification criteria? The second concern is what if a module that meets an EHR criterion, a health criterion, but it provides no security capabilities, nor does it call any security services, it just meets a health certification criterion?

Then we thought as a group if every module, every EHR module provides its own security service, then security protection is going to be fragmented across the organization, and it'll be impossible to have an

enterprise level security policy enforcement, but on the other hand if each of the modules provides their own separate security, if each module assumes that somebody else is providing the security, then there could be no security at all, and in fact, a module could undermine any security that might be there. After discussion and contemplation, our recommendation is that the privacy and security criteria be made addressable in the same sense that the implementation specs in HIPAA are addressable for every EHR module that's submitted for certification. If you submit a module, then you have to address how each of the security criteria will be met.

Auditing, the first concern that we had is that it includes audit alerting, and audit alerting is not required by HIPAA or ARRA, and real-time audit alerting is a very difficult thing to provide. Within a product that means real-time processing of your audit log record and some decision support in there that says this is when I alert that something has happened, and if it's a cross-multiple product, it also requires bringing the audit logs together into a single data model and again, the real-time decision support. The second concern was that it says audit data must be recorded when electronic health information is created, modified, deleted, or printed, but it doesn't say when information is accessed, and auditing of printing is difficult for small systems, and it still wouldn't capture the auditing of, like, print screen.

Our recommendations, we believe that the requirements for audit alerting should be deleted. It's not a HIPAA requirement, not an ARRA requirement, and it's difficult to implement. We believe that access should be added to the list of items that are audited. Third, we think that printed should be replaced with exported. Finally, for 2013 we would like consideration to be given to adopting the ASTM E2147 standard which has a list of auditable events and data elements to be collected.

Integrity, data integrity, we felt that the scope of the integrity requirement was somewhat ambiguous, and we request that it be clarified that being able to detect any alteration in data in transit is sufficient for the entire channel which is normally done in systems today and that the integrity of the individual payload that's passed across that system or individual message or individual document, if you will, that that need not be independently verified.

The next concern is authentication. The workgroup recommended that the integrating the healthcare cross-enterprise users assertion profile, XUA, which uses another standard called the security assertion markup language assertion that that be considered as a standard in 2013, but we did not recommend it for 2011. Basically, the XUA profile is a profile for passing an authenticated identity between one organization and another, so I log into Kaiser, and Kaiser passes my identity over to mail. Today, SAML, security assertion markup language, is normally used, it's a standard that's used for single sign on, and quite frankly, it's not widely implemented even within enterprises today for single sign on, and it's virtually, I won't say absolutely, but it's virtually never used between enterprises. We felt that this was beyond what should be required for 2011.

The second concern that goes along with that is that if you look at authenticating systems between organizations, that's really what's needed for 2011, and so the second concern is that the authentication of entities or authentication of organizations to each other before they establish a trusted path between them is not included in there. What we have in the IFR is XUA SAML which is beyond what is reasonable in 2011, and we don't have any kind of authentication of two entities before they establish a trusted path between them.

Our recommendations are to remove the certification criterion standards for cross-enterprise authentication and reconsider in 2013, and we think that this criterion should be revised to really verify the ends of a connection between enterprises, between organizations. The IFR refers to establishing a trusted path to the use of transport layer security, or TLS, or Internet protocol security, or IP sec, for

establishing a trusted path between organizations. It refers to those two in terms of encryption and integrity protection, but those very two same standards are also used to authenticate the end points before they establish that trusted path, so we believe that that should be the replacement for XUA for 2011. Our recommended revision of his function requirement is authentication of entities at each of the protected transmission channel must be implemented.

The encryption trends criterion, the encryption criterion refers to something called user-defined preferences, and in truth the IFR does use the term user to refer to an organization, but we felt that it should be clarified that this isn't person level precluding. It isn't that I decide whether or not I'm going to encrypt something, but that this general criterion should be revised to read encrypt and decrypt electronic health information according to entity-defined preferences in accordance with the standard. In general, an entity establishes the security policy which dictates when information should be encrypted, and we felt that this criterion should be revised to reflect that fact.

The encryption standard, what we recommended was the advanced encryption standard which is the NIST recommended standard for government systems. It was implemented in 2011, so it's been around for quite awhile, and it specifies that symmetric encryption in the IFR specifies this AES in functional terms, so it creates an opportunity. It doesn't say AES. It says it has a functional description of AES or block encryption and block cipher 128-bit string key, etc. The way it's worded in the IFR it specifies that encryption must be symmetric. Symmetric encryption is where both ends use the same encryption key, and they encrypt it with the same key as they decrypt it with. The public key encryption uses one key to encrypt and another one to decrypt, and a lot of email systems use public key encryption, asymmetric encryption, so we felt that the standard should allow for both public key encryption and symmetric encryption. We also thought it was strange that SHA-1, which is the secure hash function, is explicitly required as the standard in the IFR and AES is not, so there seems to be an inconsistency between the two.

The final concern was that the breach notification rule that came out in August, the preamble site FIPS, federal information processing standard, 140-2 as a valid source for acceptable encryption processes to use to encrypt databases so that you don't have to do breach notification if information is disclosed, and the annex A of 142-2 lists a number of encryption algorithms that are deemed acceptable for federal systems. Annex A lists three acceptable symmetric encryption algorithms for kind of giving you a safe harbor against breach notification, one of which is AES. The other one is Triple DES, and the third is Escrowed Encryption, so by specifying just AES, there is some inconsistency with the breach notification rule.

Our recommendation is to do one of two things. Either to recommendation the use of FIPS 140-2 annex A and tell them they can use any of these three for symmetric encryption, or I know there's some concern about prescribing federal standards on the private industry, so if that's not acceptable, we recommend at least to translate that functional standard back into AES so that it's very clear that it's AES we're asking for. We're not asking for a proprietary algorithm that they happen to put together that still meets the functional requirement. Secondly, you notice that we no longer limit encryption to just symmetric encryption. We recommend that the exchange say that the capability to establish a secure communication channel must be implemented.

Accounting for disclosures, the 2011 criteria and the standards seem to be out of sync with the timeline. The meaningful use objective that was recommended by the policy committee targets the accounting for disclosure for 2015, so it's kind of inconsistent to have these certification criterion standards in the 2011 timeframe. The rule isn't due out until 2010, and the secretary has the option to push that date out.

The second concern is that for full accounting with minimal adverse impact to operations and system performance that we need to allow for the generation of that accounting offline. In other words, it doesn't have to be in real-time accounting for disclosures which number one, it could impose a performance impact on the system, requires a lot of additional functionality, and secondly, you could get a better full accounting of disclosures if you did it offline as a post processing. We thought that the criterion should really allow for the generation of this accounting of the disclosure offline in post processing if the vendor chose to do it that way or the organization chose to do it that way. Both should be allowed.

Our recommendations here are to postpone the certification criterion for accounting of disclosures until 2013 or possibly even 2015, to revise the criterion so that it says create a record so it allows for either a real-time accounting or a post processing accounting. Then the third, revision of the wording, both those changes which are underlined are both to really allow for the post processing generation of the accounting. Finally, we again recommend that the ONC consider adopting the data elements identified for basic disclosures in ASTM E2147 as the standard. Okay, Steve.

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst

There was a lot of discussion at the workgroup and in the calls on this issue, and there may be some here as well. This has to do with the language around consumer access and what access is going to be for consumers in terms of electronic versus paper, etc. It focuses on the need for clarification around the words online access to their clinical information. We think that's unclear and that the language is possibly inconsistent with meaningful use objectives of providing patients with timely access to their health information. As we're all aware here, HIPAA of course gives consumers the right to obtain their records, and ARRA gives them the right to an electronic copy, so there's clarification needed we think around the term online access could be interpreted as real-time access.

We don't think that the IFR intended that or that that's what the spirit of the NPRM is all about, but online access may not meet also the HIPAA and ... requirement for electronic copy, so it's not clear whether electronic copy also in the wording of the IFR should be a human or a machine-readable or possibly both. Obviously, that's pretty critical to the intent that I think we all have of having consumers and patrons have access to a meaningful document. There's some discussion going on in ... and other places around consumers being to download very easily a meaningful usable document or something they can download.

Next slide, our recommendation is to change the language. This language may need some more input and some more nuances, but to revise it to read to enable a user to provide consumers with electronic access to their health information, including at a minimum lab tests, etc. and to provide a copy of the consumer's personal health information in electronic format. Again, there were some tortured conversations about the wording there that may need additional work, and we'd welcome any input here. Secondly, we recommend that the committee send David and others comment about establishing as a priority for 2013 the specification of messaging and vocabulary standards for sending and transferring electronic records to a PHR vendor, so clarification needed around that and finally, to publish guidance for developers and eligible professionals and hospitals on how to provide consumers timely electronic access to their health information. In addition to the actual wording, we think that there ought to be over the next few years very specific guidance to folks, the vendor community and the provider community about communicating to patients and consumers how they're going to access their information and making that meaningful and getting that message out.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

The final thing, I believe this is the final one we addressed were the transport standards. This is in section 17202 adopts the simple object access protocol, SOAP, and the representation of state transfer,

REST, principles as standard protocols for electronically exchanging health information formatted in accordance with the standards adopted under 17205, 17205 are the messaging standards. Privacy and security workgroup did recommend that both SOAP and REST be acceptable ways of accessing services, but we didn't recommend that they be the only transport standards that would be allowed. These protocols are commonly used, both of them, but it's unclear to us what value including them in this IFR brings to the industry.

The second concern is that they are in conflict with the section that they reference that they're supposed to support which requires HL7 messaging and CPDP script and X12N transactions. The other concern is that none of the, although there's a standard for SOAP and REST, none of the certification criteria in the IFR incorporate either of these standards directly or by reference, so we recommend that this whole section be removed from the IFR.

The omissions and gaps, the IFR solicits feedback explicitly on the specific omission of DNS, domain name service, the lightweight directory access protocol in consistent time. We have no objection with the omission of those. We think that possibly that consideration should be given to adding some standards for time accuracy in 2013. We think that especially as audit information and accounting for disclosure between organizations becomes a requirement that the timestamps that you put on audit records and the timestamps that you put on accounting for disclosure. It'll become more critical that those timestamps be accurate. We believe that for 2013 perhaps a threshold for time accuracy could be implemented.

The omission of the certification criteria and standard, I've spoken about this, but we believe that the omission of the certification criteria and the standard for authenticating the two organizations that are establishing a trusted path between them is a critical gap, and we think that this gap effects confidentiality, care quality, and patient safety and should be addressed. We don't think it's a big stretch to address it because the standards that are capable of doing that are already in there.

The omission of example standards in the body of the regulations we believe could be perceived as a gap. In fact, we perceive it as a gap initially, but we think that our recommendation of maintaining a perpetual list of acceptable standards as part of the certification program would be a good way to address this potential gap. Lunch.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Perfect. Dixie, if you could just go back one more slide.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

I sort of like that.

John Halamka – Harvard Medical School – Chief Information Officer

Yes, if you go back to the transmission slide, I just wanted to make a point on this one. This gets right to the heart of this specificity versus providing little guidance or vagueness. If we were to ask what is the most common means of sending an HL7 version 2 transaction from place to place today, the answer is a minimal lower level protocol MLLP or TCPIP. Actually, probably, there are a few places using SOAP or REST for HL7 version 2 messages. NCPDP script is I look at what Surescripts does, they use HTTPS POST. It's kind of REST, but not exactly.

You're saying e-Prescribing in the country wouldn't comply, and the X12, well, the CAQH CORE phase 2 which is one point SOAP 1.2. It probably does fit, so here we have this interesting challenge which is you could say I'm going to be real specific, MLLP, TCPIP, HTTPS POST, or CAQH CORE phase 2, or you could just say get it from here to there until the NHIN gives us an implementation service both for the big

guys and the little guys that everyone can use. Until then it's heterogeneity. Your recommendation is until then be moot.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Yes, and I would add that this particular transport layer transmissions, the standards change fairly quickly, and I understand that that's one of the reasons why they didn't want to include the security specific standards in the IFR. Until a year ago SOAP was the going thing. Now, REST is the going thing, so we really don't think that this should be addressed in the IFR at all.

John Halamka – Harvard Medical School – Chief Information Officer

Right, in the sense that it doesn't really help to provide something this vague.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

It doesn't help, exactly.

John Halamka – Harvard Medical School – Chief Information Officer

Let us open it up to questions. Wes, I see your card is up. Is that spring-loaded by the way?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I just wanted to comment that aspiration gets inspiration through perspiration and only after depreciation. I think that there's a lot of wisdom in this recommendation around 170202 because neither really SOAP or REST by itself is a statement that is sufficiently specific to assure the level of confidentiality and endpoint authentication that we really require. We could arguably simply depend on HIPAA regulations which do require encryption on a public network and authentication of the endpoints in the interim. I just wanted to say it would be nice to send a signal to the folks that are impressed with REST that we haven't ruled it out, but it should not be a statement that says any old thing that qualifies by the daily evolving definition of what REST is would automatically be accepted as meeting the requirements.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

I want to make it real clear that whether you use SOAP, REST, TCPIP, HTTP, whatever that this is not in the security section, so we do have, even if you use REST, you still have to authenticate the endpoints over it and encrypt the link over it.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

So all the more reason we don't have to rely on HIPAA, all of our reason for what I was saying.

John Halamka – Harvard Medical School – Chief Information Officer

...

W

I'd like to go back and speak to the encryption standard slide 13. I want to strongly support the recommendation that you do call out AES for several reasons. FIPS that she references gives you a possibility of three, but one of them is DES which has already been broken, and we're going to be moving away from that, so if you just call out AES, it's a strong standard. It's available, and it's a United States standard. If you don't call it out explicitly, you could be open to Japan's or Korea's or Russia's standard because they're all in the same space, and it's the one that everyone's familiar with. In your wireless routers you see it there, so recommend using it when you connect your wireless router. I think calling that out explicitly, which is exactly what they recommended, but I wanted to pick the second one.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Thank you. I appreciate that.

John Halamka – Harvard Medical School – Chief Information Officer

Well, that's what my home wireless router uses. Carol Diamond.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I have a couple of comments to raise, and I tried to think about what about the sort of security requirements wasn't jiving for me, and I think what it comes down to is that if we see security as an attribute of tools that's enforced through certification as opposed to an attribute of processes and practices, then I think we buy ourselves a lot of complexity and maybe not much more protection. I can use a certified system and post my login ID and password on a post-it note on the system and thereby give someone unauthorized access, and it reminds me of the discussion we just had about the role of certification versus meaningful use. What's the parallel to meaningful use in this area? It's not clear to me that I know.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Well, it's clear to me that I know. I can explain, and David's taken a huge step recently. As we did these standards, our standards recommendations, we would often get into conversations that were really policy conversations, and the certification certifies that the capability is there. Encryption is a great example. It doesn't certify that you're using it, but the problem we had is that at the time there was no workgroup in the policy committee which is where what you're talking about needs to come out. The policy attributes of when you encrypt something really is a policy decision. It's not a certification decision. The product needs to be able to encrypt. When you encrypt whether you encrypt your full disk, that's an example that we had a lengthy conversation on. If I've got my EHR on my laptop, you should do full disk encryption. If the clinical repository is in a data center that's physically protected and electronically protected, then you don't, but all of those I think and I was appointed to that new workgroup, and I think those decisions on policy decisions will come out of the policy committee and that privacy and security workgroup that's kind of a twin to ours.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes, so I look forward to that. I would just say that it does get to the issue of some of the other requirements, including the discussion of certifying the modules. My sense is that organizations are going to run these modules on a box, and what we care about is that the information is protected when it goes inside and outside the organization, and if there's a module internally that's helping the EHR do some, I don't know, primary calculation to do a quality measure, but it's not the module that's reporting outside of the organization, why do we care about module-to-module security? In other words, I'm concerned about the absolute here, not taking into account that it's similar really to the interoperability and standards discussion we had that there's a set of policies and practices that need to protect data inside and outside of the organization and that when data moves outside of the organization, there are security requirements that potentially can be looked at in the context of tools, but there's a much bigger component that needs to go along with them in terms of how they're used and how they're implemented.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Right, and that's exactly why we thought the addressable was a good approach because you know what your module is supposed to do. If it's supposed to do an internal calculation, then you addressability is my module does an internal calculation, so we really don't have to be concerned with authentication of users. We don't do authentication of users. We do an internal calculation. We don't need to generate an audit record because we do an internal calculation.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

It would be helpful to clarify that recommendation because I didn't read it that way.

John Halamka – Harvard Medical School – Chief Information Officer

This gets back to the required versus addressable, the ... that was used in HIPAA, and so you're correct. Unless you're a HIPAA speak compliant person, this is basically saying because the use cases are variable and because they are policy based, ... going to have this conversation where I offer EHR services in the cloud, and my laptops have no caching whatsoever. Should I be required to encrypt my laptops? Why? Well, the answer would be it sort of depends on what's your architecture and where's the

data living, and do you allow caching of personal identified information? Then maybe you should, and so that's all addressable. That's what that meant.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I just would think for public consumption, too, that it could be clarified to be—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Clarifies what addressable means.

John Halamka – Harvard Medical School – Chief Information Officer

Right.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Okay.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

And what it doesn't mean.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Okay, we can do that.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

The other issue I wanted to raise is the recommendation on the e.g.s, the four examples. I actually had the opposite reaction to the four examples. I think in some cases they don't create any clarity, and in other cases they might foreshadow a standard that's never going to come to be, but give some sort of a signal or create the opportunity to create certification programs or what have you, but I don't think we really know how this all transpires. The one place where the e.g. I think is not good is on the network security model. There we talk about TLS, SSL, IPv4 with IP sec. You cannot open a secure channel if you're using different ones of those. We really have to choose one, so that's an example of where if ever there's a place where there's one security model that needs to be specified for the network, it's there, so the e.g.s I don't think help there at all.

In other cases, as I said, some of those standards may never meet the criteria that we've talked about here in this committee. They may fall by the wayside or not come to be, and I just think even for candidate standards, we should really have in our recommendations the discipline of making sure that those candidates meet those criteria in some way or that we've sussed it out against those criteria because they could send a signal isn't intended.

I have another area to address which is on the consumer side. One of the things that's come up in our work, but also in the implementation workgroup is the assumption that electronic access, the requirement to provide electronic access is one that the provider actually not only has to create the portal where the consumer can come in and get their information, but support all of what that means in terms of the application and how the patient's going to use it all of that, and that's just not realistic for every data holder that in this very diverse system.

Where we're finding ourselves evolve in our own thinking and certainly where a group of people who are here and who've been participating in the implementation workgroup and other places have been organizing our thinking around is that maybe what's needed right now is the download capability. If things were downloadable, then other services or applications that the consumer may use or want to choose can be used with that downloaded electronic copy, but it takes the provider out of having to be the application provider for the consumer also.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Our recommendation's totally consistent with what you're saying because ARRA does not require online access. It requires an electronic copy. In fact, we saw the Markle recommendations, and we're totally consistent with that.

I would like to address, though, your comment about TLS versus IP sec. There's a fundamental law in security that the lower you implement security, the harder it is to bypass, and the higher you implement, the finer the granularity of control. TLS and IP sec are intended for entirely different purposes. IP sec is perfect in my opinion, a perfect protection for, like, the NHIN gateway because it's at the IP sec, it's at the network level, but it doesn't know about Dixie Baker or Steve Findlay. It knows about the network. TLS is up there at the transport layer, so it knows about the endpoints. It's more when you need a finer level of granularity control, I want to identify this system I'm connecting with or this application I'm connecting with or this person I'm connecting with, and IP sec can't do that, so you really need both of those. We really should not be recommending one or the other.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes, I'm not sure that, or we could talk about this at greater length, but IP sec, for instance, doesn't work with most of the network-addressed translation services that are widely used today, and so it has a lot of—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Yes, gateway-to-gateway, right.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes, and as soon as everyone has a unique IP address which—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

And generally do.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

... over for a long time.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

But we can talk about that offline.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes, that's been over for a long time, though, and that incompatibility I think is a big deal. Anyway, this is more a point about the e.g.s being less is more rather than more is more.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Do you agree with the recommendation that the certification program should maintain a list of acceptable standards that meet the particular functional criterion?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes, I don't think there's any problem with acceptable standards. What I'm worried about is that in the four examples when they're listed that lots of other ricocheted reactions can occur from that for standards that might never come to be, and I just think it's a waste of time. It sends a signal that I'm not sure is valuable. That's it. I don't want to take any more time. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer

Great, Jamie.

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

Thanks. I'd like to come back and touch on the integrity requirements and really two separate comments that really relate to each other. One is that I would like to support the secure hash algorithm, the SHA-1

requirement or higher, but that in the first place whatever the set of integrity protections are, they should I think explicitly apply to data transfer by devices and media as well as messaging and electronic document and health information exchange, and I think that's an important clarification. At the same time, I would support the addition of a digital signature requirement to stage one. This digital signature is a well-established standard that's widely used. My organization believes it would provide important protections for consumers and providers alike and that it would be a reasonable addition to the stage one requirements.

John Halamka – Harvard Medical School – Chief Information Officer

Chris, why don't we go with you.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Carol

John Halamka – Harvard Medical School – Chief Information Officer

Okay.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

It's okay. Take my turn. I'll wait until the end. I have one more issue to raise.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Thank you. I am not really technically familiar with much of the security issues that you've raised, but I did want to address the consumer access question. While I think we're all sympathetic to enabling both providers that may have limited portal capability and users meaningful access to their content, we have to be a little careful if we revise that to say electronic access. The reason I'm saying that is an unreasonable interpretation, but nevertheless an interpretation, could be a month's data dump on a thumb drive. Well, that's electronic access. We've given it to you. Have a nice day. Clearly not what is intended, but technically is an electronic access.

I think the implication that you were seeking is notion of a download format or an export format, but we confront the problem that there really is no publicly-specified shared view of what a PHR export format should look like. I know HITSP has looked at this a little bit, but it's a work in progress. That's my understanding anyhow. We're confronted with what is really going to be in the patient's best interest in terms of providing them with meaningful access to content that they can look at.

My interpretation of online carries with it, and again, this is a person interpretation, the notion of what Carol was characterizing as a portal and some kind of interface and so that it's not just a dump, but it has some kind of navigation capability, a display capability, and so on. That's I think a fair interpretation of online. I understand the limitations of online, and I also understand the challenges, but I think we have to be careful revising that to say just electronic access because in my opinion that has the potential to actually have a lower denominator and a lower level of capability to be technically compliant, but not necessarily helpful.

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst

I don't think we implied that it would only be electronic.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

But the law says electronic.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

Amplifying HIPAA.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

This conversation is exactly the kind of conversations we had within our workgroup, and there are many question marks in this arena which is why we recommended, we finally said after about an hour on the teleconference about this one single topic, we said there are a lot of questions here because ARRA says

also that you have to provide if the patient comes in and says I want you to send this to my PHR, you have to provide that. Well, you don't want to send them a, well, what do you want to send? Do you want to send them a text version? That needs to be explored. That's going to be something different from what you would give the patient to take with them, so we think that there are a lot of issues around here and around this topic, and it's getting more and more attention, and we feel that there really is a need for some guidance and some clarification in this area.

John Halamka – Harvard Medical School – Chief Information Officer

The implementation workgroup has been having similar discussions because as you read through the, oh, you must provide within 48 hours the medical record to the patient. Well, what does that mean? Four thousand pages of everything from 1957 to the present, how I even do that in electronic form, in a CCR or CCD format, or does it mean an abstract of the current problem list, medication list, last discharge summary? How do you package this stuff I think is an open question for all three of the patient engagement criteria.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

The other question we had relates to a conversation this very group had about providing patients online access to their lab reports. Is that real-time access when the updated lab report comes in or the preliminary lab report? Is it online? We don't think it probably is, but these are, again, issues that need to be explored.

John Halamka – Harvard Medical School – Chief Information Officer

Okay. Janet.

Janet Corrigan – National Quality Forum – President & CEO

I have a little bit of a nagging issue that I just wanted to kind of throw out there, and I'll be the first to admit this isn't an area I have a lot of expertise or familiarity with either, but throughout many of the recommendations here there are references to the security and privacy arrangements that pertain to the exchange of information between enterprises or between entities. I think we're going to have to grapple with what defines an enterprise or an entity because in the prior discussion I was very comfortable with the focus of our work being at the boundary and kind of leaving what goes on inside alone.

In this particular area, I'm not comfortable with that at all for a couple of reasons because when I put on my consumer hat I really care about privacy breaches, even if they're within Intermountain Healthcare or within Kaiser Permanente from one part of the organization to another where information shouldn't have been shared and it should've been protected. I care about that, and I think that those kind of breaches could really erode consumer confidence overall in this kind of a system if we aren't particularly careful about them.

The second reason is that we have a tendency when we talk about internal or external to give examples like Kaiser Permanente or Mayo or Intermountain, and we're in a period now where we are anticipating tremendous innovation in the development of new organizational structures, a lot of work going on defining accountable care organizations. They could emerge as some sorts of ... between hospitals and heavy admitters that will then be able to accept bundled payments. Those are sort of loose organizational structures that are a far cry from Kaiser Permanente and have far less ability to protect patient information. We just need to be cognizant of the environment that we're moving in and that these organizations or entities or enterprises differ tremendously in their capabilities internally.

John Halamka – Harvard Medical School – Chief Information Officer

A very good point, so for example, I have an integrated delivery network which is really five completely separate institutions, and our rule is no bite of data ever traverses the public Internet unencrypted, so sort of our definition is we use IP sec tunnels between five different organizations so we effectively appear to be the same closed encrypted network even though we're disparate.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

That's a good point.

M

I wanted to address the issue around modularity. To comment first on Janet's point seems to make an awful lot of sense to me. On the one extreme we don't want to have any of the things she warned us about, but now let's go to the other end of the spectrum which is the modularity piece, and I'm encouraged to hear that the intent is not to create a security and transactional certification of module-to-module within organizations at a high level granularity. Again, I think the ... there are just impossible, so the description and answer to questions that others have raised would be great.

I want to piggyback on that actually by pulling in some of your comments that were in the written document but were not in the presentation here which related to administrative transactions within a modular system. I actually think we have a pretty significant omission here that needs clarification pretty desperately. You describe how there are a number of things we're doing ... that don't fall in scope. That makes complete sense. Your logical conclusion is we recommend that electronic claim submission and eligibility be removed as a meaningful use measure and a certification criterion for EHR technology. That has a certain logic to it, but then when you think about, well, what are we doing when we're submitting clinical data with a claim, for example, when there is an administrative event, but there's also a disease management imperative, and we're providing biometric data to a DM company as part of a commercial transaction. That needs to be picked up somewhere.

I'm really concerned that the idea that the phrase EHR still has not been sufficiently defined, and we still have a problem, well, what do we mean. Does that mean, and I know I'm a broken record on this subject, but do we mean that to mean all of the technology used by a medical practice, or do we mean that to be the clinical component within a broader framework, and I really think we need to get some guidance—

John Halamka – Harvard Medical School – Chief Information Officer

... is not recommendations from Dixie's workgroup. It was comments that happen to be made people as independent participants in the workgroup.

Cris Ross - MinuteClinic

Whoever said it was really smart. Nonetheless, I'm going to take whatever occasion I can I guess to ride this horse and say I think it's really a problem, and I think we're going to have issues where we do want to have an EHR connect to a practice management system in order to submit clinical data to an outside entity, and we need to address that.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Yes, for those of you who haven't seen, we have two letters in there. One of them is really our privacy and security workgroup recommendations about privacy and security, and the other was two recommendations from our workgroup members that we wanted to put forward, but were really not privacy and security. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer

David.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

I wanted to come back to the flexibility versus specificity question and ask Jodi's opinion. Jodi, I want to alert you to pay attention. In the workgroup discussions, I'm a member of this workgroup, and we've had these long discussions about how specific to be around, for example, the encryption standard, whether we should specify AES in particular or whether we should make a more generic reference to FIPS 140-2A and in a sense kind of outsource the definition of the standard. In one case we outsourced it to the FIPS document and in the other case we outsourced it to the certification process. I'm curious to know whether that's acceptable. We went around and around on it.

My concern is that encryption will be broken. DES got broken, so we went to Triple DES. Triple DES is shaky, so everybody's gone to AES. With quantum computing on the horizon, AES will get broken some

day, and we'll have to go to something else, so how do we regulate the highest possible standard encryption without naming it?

Jodi Daniel – ONC – Director Office of Policy & Research

That's a very good question. In drafting the IFR, our concern was that we would lock in a specific standard that could then get broken and that then, in fact, everybody would be required to comply with that standard that the industry has already moved beyond, so that's why we were looking at functional standards rather than specific standards and allowing for the industry to develop better encryption approaches than what we put in the regulation. That's what we tried to do, and that's why we sort of moved away from naming one particular standard.

As far as how we would accomplish what you're saying, I'm not sure how we would best do that, and we obviously would love to hear advice. We have to set a standard in the regulation. The question is how do we make sure that our standard doesn't lock into place something that may become antiquated before we update the regulations.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, and so that's my question to you. As soon as—

John Halamka – Harvard Medical School – Chief Information Officer

We declare AES to be the floor, but—

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, but there really isn't a measure as good as AES. There isn't an encryption goodness standard. You can specify a number of bits in the key and things, but that doesn't necessarily correlate to strength of the algorithm.

John Halamka – Harvard Medical School – Chief Information Officer

... offers the FIPS guidance because we know FIPS is going to continue to evolve.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

Yes, we wanted to reference some group that is keeping up with the current standard, and if that's acceptable, then that's the best way to do it.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

We assume because annex A of FIPS 140-2 is a current list of acceptable standards, so I think and I hope what David's really asking is can we reference FIPS 140-2 annex A and say whatever they recommend as acceptable, but assuming it's going to evolve as quantum encryption comes into, quantum encryption is on the horizon, and it sure doesn't meet the functional requirement we have in here.

John Halamka – Harvard Medical School – Chief Information Officer

David had a comment to add.

David Blumenthal – Department of HHS – National Coordinator for Health IT

There are a lot of tough, naughty questions. We should not forget that somewhere in this place, in this mix will be a certification body that will have to be recognized and will continue to have to prove itself capable of certification. One possibility is that the certification body has some of the discretion that we've been looking for, especially when the standard specifies a functional outcome rather than a specific standard. If a certification body, for example, were certifying against an outdated standard, it might be very attractive to some EHR vendors if it was easier to accomplish that standard, but the question is would it continue to be recognized over time as a certification body if they're consistently certified against an outdated standard.

David McCallie – Cerner Corporation – Vice President of Medical Informatics

That's essentially what we recommended is that the certification bodies define the state of the art that it would be tested against, and presumably that could change as the state of the art evolved. That made sense to us. My question is, is that an acceptable way to write the regulation.

Jodi Daniel – ONC – Director Office of Policy & Research

Again, we're going to have to look into it, but the way you usually adopt a standard is with all of the problems that come along with that. It is a snapshot, and we're trying to figure out how we don't lock that in, and I think that's sort of been a theme here, and there may be some creative solutions with the certification process, or there may be some creative solutions with guidance. We're setting minimums, but it is in fact a snapshot, and I think that's what everybody in this group is struggling with, and it's exactly what we've been struggling with because I think we have the same policy objectives that you all have laid out.

John Halamka – Harvard Medical School – Chief Information Officer

Jodi, did you have your own comment? You had your card up.

Jodi Daniel – ONC – Director Office of Policy & Research

I did. I had a couple of, two comments and one question. On the audit concerns and recommendations, the comment I have, and I guess you can feel free to respond to these, is that at least what's in the IFR there isn't anything that says that the alerts have to be automatic, and it talks about provider alerts based on user-defined events. I didn't know how that since you were talking about providing real-time automatic audit alerting, that seems to be in my mind disconnected with what we had said in the rule, so I just wanted to—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Audit alerting is in my mind by definition near real time. You don't want to receive an alert three days later that somebody is trying to break into a system or alerting and firewalls. Firewalls traditionally have alerting capabilities, and they're near real time so that you can do something about it. It does you no good to learn that a week later that somebody broke through your firewall, and so that even though the IFR did not use the word real time, almost by definition it's near real time or it's of no value.

Now, if we use, somebody brought up that with an ATNA implementation where you have an audit repository where auditing already is transferred, the records are transferred offline and into a standard data model. You could do some level of alerting, but we don't have the requirements for ATNA or audit repository. These products are unlikely to be sending their audit records in real time anyplace. They're more likely to be just kind of keeping them there and somebody comes by periodically and reviews them which is all HIPAA requires.

Jodi Daniel – ONC – Director Office of Policy & Research

Let me just clarify because obviously this is something we could clarify. The concern is with the real-time alerts and the challenge of doing that, or—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Well, what kind of alert would you have that would be of any value at all if it wasn't near real time.

Jodi Daniel – ONC – Director Office of Policy & Research

Well, you were just talking about that you can have this alert repository. I'm just wondering if the concern is with the rule itself or with the interpretation, if there's something that can be clarified that would address your concern.

M

I think the word alert.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Yes, alert.

Jodi Daniel – ONC – Director Office of Policy & Research

The word alert implies a—

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

It implies near real time, yes, within the context of audit. Well, even in the context of an EHR, you don't want to receive an alert two days later that your patient had a drug-drug interaction. Alert the term implies near real time.

Jodi Daniel – ONC – Director Office of Policy & Research

Okay, that's helpful. The second, this is just a point on the accounting for disclosures. I just wanted to clarify because you're talking about the timing of that, that the statute requires compliance for covered entities by January 1, 2011 unless the secretary for people who adopt after 2009, unless the secretary modifies that compliance date, and so without any regulation from OCR which obviously they could defer that date, but the concern was that if we waited until 2013 or 2015 that there would be a problem with the timing in the statute for complying with the accounting requirement and the standards. That was our, just wanted to make sure that that was understood and so just a comment.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

We should pass that comment to the policy committee because they have identified it as a 2015 meaningful use measure.

Jodi Daniel – ONC – Director Office of Policy & Research

Then the last question, and this was on authentication, you talked about (I think it was slide 10) authentication of entities at each end of a protected transmission channel, and my question is, is that if we have a standard that's talking about authenticating at endpoints how we would address that through a certification process that's certifying the EHR technology.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Well, in truth you'd find out whether they support TLS or IP sec because of those standards do that before they establish an encrypted channel. They both start out authenticating one or both ends of the transmission, and whether it's one or both is a policy decision, but the product itself, if it supports either TLS or IP sec, it'll be able to do that.

Jodi Daniel – ONC – Director Office of Policy & Research

Okay, thank you.

John Halamka – Harvard Medical School – Chief Information Officer

Carol.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yes, if you wait long enough, you get another comment to make. Two things I want to clarify. One is the comment that Janet made about the policies internal to the organization, and I think, Janet, this is exactly the point I was addressing with Dixie early on which is to say you can have the certified tool. It's not a function of the tool that they're using inside the organization, so the tool might encrypt data or the tool might offer the capability to have an audit log, but it's the processes and practices inside of that organization that really determine whether or not the information is protected, and that's really the policy conversation I think and the policy requirements that are necessary.

As we know most of the breaches to date in healthcare have been things "that have happened inside of the organization," a piece of hardware gets stolen. It's not moving over the Internet it's just somebody steals a laptop or there's inappropriate lookup of a celebrity or what have you. The ones that have certainly been in the media are about policies and practices that are internal to the organization, and I think that's a really, really important point, but it is insufficient to try to address them through tools or capabilities and tools is a point.

The second is on this accounting and disclosures, and I'm glad Jodi raised because I want to raise it too. I'm nervous for just the point she made that this can somehow delay the rule, and I'm wondering if there is a creative way to at least create some, by the way this is another case of where it's the chicken and egg thing. It's kind of they want the technical standard, but the policy isn't there that says what belongs in the accounting of disclosure and how do we use it and what do we need it for, but I'm wondering if there is a way to at least create some minimal requirement, whether it's data elements or what have you in the absence of a standard that an organization has to keep or account for internally even if it's not a standards based requirement so that the rule can get made I guess is the question.

John Halamka – Harvard Medical School – Chief Information Officer

That's what that ASTM standard really is. It's really a list of what you are going to keep.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Right, but the recommendation is to delay this, and I guess I'm trying to figure out if there's a way not to delay and maybe not to name a specific standard if it's not the right time for it, but at least identify a handful of possibilities or data elements that could be useful in creating the policy.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

I think you need to make that recommendation to the policy committee because I think that a measure being in their list of meaningful use measures is going to set when people implement that, and right now the meaningful use measure for accounting for disclosures is 2015, so if you think it should be closer, I think that you should recommend that to the policy committee because I would bet that that's when it's implemented if that's what they recommend.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

So I should recommend it?

John Halamka – Harvard Medical School – Chief Information Officer

No, we.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

We.

John Halamka – Harvard Medical School – Chief Information Officer

The way that this transmission works is that in the letter that you will revise we will make the recommendation to David, and David will take it to the policy committee. I believe, Judy, isn't that how it works?

Judy Sparrow – Office of the National Coordinator – Executive Director

The recommendations will go to CMS and be part of the recommendations from this advisory body on the regulations. Remember, we have until March 1 to make those recommendations in order to give time for ONC to transmit it to CMS. We've got a few days' grace on that by the way, the March 1 date. Anything else?

Jodi Daniel – ONC – Director Office of Policy & Research

I would just say just capture the issue and say if in fact the policy is to delay this until 2015, then you should delay the standard, but we recommend either ONC directly or through the policy committee, and we'll figure out the best means of making that happen or communicating that.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

I meant one should, I meant one should make that recommendation, not

Jodi Daniel – ONC – Director Office of Policy & Research

... figure out the language on the letter. We'll work with Dixie on the letter to get it right.

John Halamka – Harvard Medical School – Chief Information Officer

Jonathan.

Jonathan Perlin – Hospital Corporation of America – CMO & President

I just want to kind of point out I think this point that both Janet and Carol made is so important. I think we just need to offer one piece of context is that none of this vacate the requirement of HIPAA, and so regardless of what's specified or not as standards, there still exists the requirement with all appropriate penalties enforced to assure that the protection of data and these standards are simply not to specify tools. That point is absolutely critical, and it's part of something, and then we're collectively passionate about establishing that trust fabric that becomes so important.

John Halamka – Harvard Medical School – Chief Information Officer

Okay,

Dixie Baker

... the FIPS 140-2A, we are revising that. It will move past DES and others and expect to do that by 2011, so I really do want to emphasize again that we should specify that standard. If you want to call out the FIPS, fine. If you want to call out AES as a floor, fine, but I think you do need to specify an encryption standard. This one in particular is implemented and accepted worldwide because the world voted on it and helped form it, and the testing labs are out there. I just want to emphasize that that one really needs to be in there.

John Halamka – Harvard Medical School – Chief Information Officer

Great.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

Thank you. We appreciate it.

Jodi Daniel – ONC – Director Office of Policy & Research

We may include you in some of our discussions

W

I'd be happy to do so.

John Halamka – Harvard Medical School – Chief Information Officer

Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Two quick ones, the first one I think that the substance of what has come out of this recommendation solves the concern that I had earlier which is that we seemed to be implying that audit content was a means of accounting for disclosure, and I don't believe that the two are that related, and I think as it's revised, all right, thanks. Then speaking of alerts, I want to try an alert here now, see if I can raise John Glaser's attention. Look at that, all right. David made a comment before he left that one possible approach to dealing with standards was to turn that over to the certifying body, and while we clearly can't know what's being written in the NPRM or who's writing it, it should be clear that if there are more than one certifying bodies then we have a difficulty with relying on the certifying body to set the standards. I just wanted to make that comment.

John Halamka – Harvard Medical School – Chief Information Officer

Jim.

Jim Walker – Geisinger Health Systems – Chief Health Information Officer

I just wanted to jot that down and then bring up something that was written in the additional documents that was presented by Dixie to the group. Crystal brought up the first topic. The second one refers to newborn screening specifically. The reason I wanted to bring this up is I know that's outside the purview of the privacy and security workgroup, but I think it's important to acknowledge the depth in which

newborn screening and that transmission of that information touches the health system overall. Really, it's going to be the first meaningful record that is included in someone's electronic health record, and with the security considerations that need to be made passing that information through the system are very important. I think that if you look at the recommendation that it's important to acknowledge while we're not recommending a specific standard for newborn screening, but a standards base implementation guideline which is based on vocabulary standards that have already really been developed and analyzed by HITSP as well.

I just want to bring this up to say that the IFR would be the recommendation to include some kind of vocabulary guidelines for newborn screenings specifically, but that when we get into the NPRM, there's going to be a need to evaluate newborn screening as an early part of the health record. I think I want to take this opportunity to not only point out that this is here, but that this is what we consider to be a very, very important part of every American's entrance into the health system, and so this is going to be a huge topic moving forward. It may be more on the policy side when it comes to the privacy matters there, but that this is the first opportunity for consent. This is the first opportunity for electronic transmission of that data, so I want to be very clear that that's there.

John Halamka – Harvard Medical School – Chief Information Officer

Great, and so in terms of getting this one transmitted to CMS, I would imagine your organization would do it directly. Jodi, these were the, we had two comments that happen to be made by individual members of the privacy and security workgroup. One refers specifically to NPRM guidance, and so rather than going through the workgroup to the committee to CMS since it's a single individual making an NPRM comment, their organization presumably would communicate this to CMS?

Jodi Daniel – ONC – Director Office of Policy & Research

That would probably be the best approach.

John Halamka – Harvard Medical School – Chief Information Officer

It is of course all circulated to us, but we understand the issue.

Jodi Daniel – ONC – Director Office of Policy & Research

Of course, it's in public conversations, and ONC is listening and CMS is listening, but it would be good for on the record to submit them specifically in the process that is suggested if it is from an individual organization.

John Halamka – Harvard Medical School – Chief Information Officer

Great. Well, final comment on privacy and security? Kevin.

Kevin Hutchinson – Prematics, Inc. – CEO

Very short, I think that this is more of an editorial because it's outside of the purview of this committee, but I think when we're talking about privacy and security, one of the things that we should consider, and I don't know if it can go through ONC to cooperate on this is deterrence. Something David brought up was technology is going to continue to advance, and we're going to break encryption and we're going to do certain things. HIPAA does cover those that are under those covered entities, but it seems to me that we need some level of deterrence, some type of support around legislation making it a felony or illegal to hack into someone's electronic health record that deters. Even though we have this capability, we could put the technology and standards in, but around privacy and security, there's a lot of privacy and security in banks, but banks get robbed, and there are laws against that, and I think we should look at how we work with justice on putting together individual hackers or other type of laws against hacking into someone's electronic health record, again, outside the purview of this committee.

John Halamka – Harvard Medical School – Chief Information Officer

Very good recommendation.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

That's a good point particularly if you think about ARRA has the provisions for breach notification, but those are like penalties on the organizations, not on the individuals, yes, good point.

Jodi Daniel – ONC – Director Office of Policy & Research

There are some laws that justice can use to go after hackers as well as there are criminal penalties under the privacy and security rule, and DOJ has prosecuted those who have improperly used or obtained information, so it's probably something worth looking at. Whether or not whatever is out there is sufficient, I don't have the answer to that. I think another area is also just if there's anything we can be doing particularly with working with OCR on HIPAA security rule to help look at the actual activities and organization ... that might help prevent security breaches beyond just whatever's in the standards that we're trying to incorporate into the technology. Input there would be greatly appreciated as well.

John Halamka – Harvard Medical School – Chief Information Officer

Great. Well, a very rich discussion and as we had a process for our previous discussions, the intent of this is we now had some comments to revise your letter which include expanding on what is the definition of addressable so that's clear and then capturing some of the discussion today. Directionally, based on what we've heard, is there consensus from the group that we accept their recommendations? Of course, once the letter is revised, we will all have a view before it is signed and transmitted. Objections? Okay, well, we will move forward, and in the interest of yes we will end early today, if your biological systems can withstand about three more minutes, we have a very short report from the implementation workgroup really talking about what are our next steps with our March 8 hearing, and so Liz is going to make that for us.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

We have put together four panels. We have a public sector panel that will be really looking at what ONC can bring us, what ... were working very diligently. One of our real challenges is making sure we have leave behinds so that we're able to bring back to this committee and to the public in general real usable tools going forward which is I think part of the goal. Then we'll do two panels on implementation and experiences, and they will be a mixture of a scale of type of providers from the large academic to the very small rule standalone with their vendor partner, and both persons will present to, again, leave us with tools.

We're really focusing on three areas. Meaningful use and what are you doing to address the new areas in meaningful use that you've not addressed before. Two, quality reporting, how are you managing that and where are you going forward with that and then other kind of innovative ideas around interoperability and that sort of thing. The second panel will be physician and HIE-based so that we'll begin to look at those kinds of parameters and again, looking at both the provider, whether it's an eligible provider or the vendor and the kind of ideas they can bring to the table.

Then finally, the final panel will be on innovation, so we're really looking for something we've talked a lot about here. How do we do consumer engagement? How do we really reach out there and look at new ways of bringing patient care information to the site of care, for example. One of our presenters will be an organization out of Houston that has developed an EMR that is for the homeless, so it's healthcare for the homeless, and this EMR is available, and in fact, we're now negotiating to bring that to be a tool that can be used nationwide.

That's the type of information and panels we've put together. I think it's going to be a very productive day, and it's March 8 at some place new, Mayflower Hotel, thank you. That's where we are, and any input or additional information you'd like to share with us I look forward to hearing from you, and thanks to Chris and Judy and John and Carol for all of your help in making this come together, and of course Judy Sparrow. We couldn't do it without Judy Sparrow.

John Halamka – Harvard Medical School – Chief Information Officer

The context for this activity is that the implementation workgroup in one of it's early planning calls said, well, how can we best benefit society to achieve meaningful use by reducing barriers, building accelerators, and so we talked about, well, let's see. Starter kit, that would be one. Two would be this

whole issue of how to transmit data from place to place and all the various ways to do it. We'll probably bring some clarity to that. Three, how to ensure we engage patients and families, and what are some of the novel and emerging technologies to do that. Four, in a quality measurement, how do we reduce the burden? How do we make the glide path a little easier? Five, what about all this vocabulary stuff?

Well, we in looking at those five said this implementation starter kit is really the low-hanging fruit, so you've heard about how we'll do these three initial panels. There'll be I'm sure additional hearings. There'll be the blog that, Chris, you will maintain. There will be a lot of writing and the take-homes, the idea of the leave behinds which we hope we get these tools whether they are open-source technologies that can be shared or guides of best practices so that you could say come here, download your starter kit community, and you will have a whole lot of intellectual property that you can now leverage to get to meaningful use faster.

Chris, since you were involved in all of these calls, any other comments you would?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards

No, I don't think so.

John Halamka – Harvard Medical School – Chief Information Officer

Judy, you led it the last time, anything else to add? Any other comments and questions on March 8 other than we hope it doesn't snow in Washington that day.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

John, you shouldn't say things like that.

John Halamka – Harvard Medical School – Chief Information Officer

Yes, there's actually more snow in Washington than there is in Boston. Can you believe that?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Actually, it's not going to be a problem. Should that occur, John, we'll just take all five panels and do all the speaking. What do you all think?

John Halamka – Harvard Medical School – Chief Information Officer

Well, any other comments or questions? Okay, well, Jonathan, let me turn it back to you for the summary and the wrap up.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks. I think a terrific discussion really right at the heart of our guidance to David, CMS, just appreciate the breadth of expertise that that's brought to bear. I come back to where I started that I suspect that there may be areas where not everyone feels that every last sort of nuance of their concern is answered, but can we provide not only a practical, but the word practicable that is applicable in the real world guidance and in fact the desired outcome. The process is inherently messy and inherently productive because it's ... really seeking of broad input, so thanks for that rich discussion. Along that line we now turn to the public comment to really get that most important piece of the discussion. Before we do that I want to thank Dixie Baker, Steve Findlay up at the podium for your great work and to Liz Johnson, the implementation team which couldn't be here today for their terrific work as well as the other, Jamie Ferguson and John Halamka and Janet and Floyd, terrific reports out today. Judy, if you could give instructions for our public comment period.

Judy Sparrow – Office of the National Coordinator – Executive Director

Indeed. This is the time for public comment. Anybody in the room wishes to make a comment, please come to the microphone, state your name and organization, and a reminder that the comments are limited to three minutes. Those of you on the telephone if you wish to make a comment, press star 1, and those of you on the Web if you wish to comment, please dial 1-877-705-6006. Are there any comments in the room? Do we have anybody on the, we do have one person on the phone. Would you please state your name and organization?

<Q>: Yes, this is Deborah Peel with Patient Privacy Rights. I have a number of comments I'm going to try to organize very quickly. Just so that the group knows, Patient Privacy Rights Coalition, the coalition bipartisan for patient privacy, had a great deal to do with a number of the sections that you've been discussing today when working with Congress and in Congress intent on breach notice, on accounting of disclosures, on audit trails, and on the sections on encryption. I'm afraid with three minutes I probably can't cover anything, and so I would like to register a serious criticism here which is when we can't even read the documents before and when we cannot comment before you take a vote, that really is the exclusion of the public from this process.

Let me talk about the breach notices. There is tremendous intent with the people that worked on this to in the language of the bill to explain what kind of accidental internal access was and that that was very different than internal breaches, and the public and Congress intent was internal breaches, there really is a way to distinguish them from accidental access and ongoing use. Those that are not accidental do need to be reported. That's very, very important.

Then in terms of the audit trails, I can't quite understand all that you have recommended today because it's kind of confusing between what's recommended here and the timetables elsewhere, but we are very, very disappointed that there's any thought of pushing back developing meaningful audit trails and access to them to 2015. All of the things that the public wants most, the protections that we put into high-tech and our coalition was the one that worked for audit trails as well as segmentation and the ban on sales and encryption and so forth. All of these things are pushed off and off, so it's very disappointing to hear that you are I think recommending postponement of the audit trail. Again, I'm a little unclear of exactly what's being recommended because it's hard to read and listen and try to do all of this at once.

In terms of working particularly with Congressman Markey's office on encryption, they never intended a lockdown standard to be encryption. The language of the statute has to do with the information being unreadable and indecipherable because they did in fact anticipate that as many have pointed out that encryption would be broken, and so we would really agree with those that were talking about how to not lock down some kind of technology when we know very well that new and better technologies will come about.

I guess the other thing that I really want to talk about is the audit trails. We absolutely want them. We want them soon, and we want them to say who accessed the record, for what purpose, and what portions of that were seen. We think that delaying this is a huge mistake. It's very, very important for transparency and accountability since consumers at the moment do not have the right to control who sees their information electronically. It's very, very important for us to be able to see exactly who does it, for what purposes, and when, and that should be as Dixie pointed out very close to real time. In fact, we really do feel like that there's a lot of industry stonewalling about being able to do this and provide it in human readable format in real time, so that's very important to us.

Secondly, when you talk about what formats, electronic, of access we're going to have to our electronic records, as patients, patients are really entitled to the record, not some form of the record, but the record. That's what we've had with paper records. If you go to a doctor's office or a hospital and you request a copy of your record, you get everything.

Now, we agree with you that for some people that's confusing or that's too much, but the point would be for patients to have choice, that they could have the actual data that they clearly have a right to as well as data that's been run through some sort of a process to tone it down, make it more understandable, or whatever. There can be different versions that people can be offered, but make no mistake. The public is going to want actual copies of everything which they've pretty much been entitled to with rare exceptions by law.

For example, mental health records, I know in my state, Texas, we're permitted to instead of sending the entire record, we're able to send a summary of certain things because the material is considered pretty sensitive, but for the most part, patients are going to want everything, and I think as E. Dave ... pointed

out when he got the data dumped from Harvard into his Google PHR, it was pretty much everything, and he was able to find massive numbers of errors, and so it's really important that patients don't get some selected, restricted views of things and don't get them way, way later, years later than we want them to happen in the bill.

Again, the kinds of things that I think we have to offer is that we were present in working with Congress on getting many of these key sections, and so far consumers have not really been able to weigh into this process very easily.

Judy Sparrow – Office of the National Coordinator – Executive Director

Dr. Peel, excuse me, could you summarize for us? We have other people.

<Q>: I'll stop now, but I do want to thank Dr. Blumenthal and Jodi and the others that have agreed to set up a one-day conference where we really can pull consumers in for this committee to hear from, not only about these issues, but to also see demonstrations of the kinds of privacy enhancing technologies that we think really should be used as minimum functionality for the NHIN and for health information exchange. Thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you very much, and we have another person on the line, please.

John Halamka – Harvard Medical School – Chief Information Officer

It maybe was a clarification that there was actually no recommendation of a delay in anything related to audit. This was actually a discussion that referenced that that NPRM itself has 2015 as the requirement for disclosure log, so there was nothing about audit delays that we discussed.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you, Dr. Halamka.

Jonathan Perlin – Hospital Corporation of America – CMO & President

As always I think this public process of input is so critically important. We appreciate the comments and also really encourage your submission, everyone who's listening, your submission of comments to the Office of the National Coordinator, CMS, or the other responses to the IFR and NPRM through those channels.

Judy Sparrow – Office of the National Coordinator – Executive Director

We do have one more public comment on the line.

<Q>: My name is ... and I work for ... Healthcare, also serve on the board of directors for ..., and during the discussion today, the challenge was raised that codifying the version of a standard and/or implementation guides through federal rule making increases the risk to lock us into older versions for too long that really could and should reasonably be replaced by more current versions but where the federal rules cannot change fast enough. I support the suggestion that rules can include a minimum base standard for and can help address this challenge, but we should recognize that base standards allow for substantial optionality as they have to consider substantial variations in related use cases whereas implementation guides can significantly reduce implementation variations.

We should also recognize that while we could consider that getting the job done should be sufficient based on minimum source standards, there is substantial risk without adequate implementation guidance that we continue the current level of Babylonian communication rather than reduce it across the continuum of healthcare providers. To get to more widely used consistent communication across healthcare providers, it would be helpful that through federal rule making we formally recognize the sanctioned structure with an open consensus-based decision-making process where the industry stakeholders can come together to agree on most current implementation guidance, agree on reasonable ... target timelines where decisions are well documented, voted on, and with full opportunity for any

stakeholder to participate and voice their perspective. However, the suggestion made to have the certification organization perform double-duty to also write implementation guides incorporating appropriate source standard versions should not be considered good practice, particularly when multiple certifying organizations are in play as Wes Rishel indicated earlier. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you very much. I believe we have one last comment, if you could please state your name and organization.

<Q>: Hi, this is Robin Raiford. Judy, can you hear me?

Judy Sparrow – Office of the National Coordinator – Executive Director

Yes, we can.

<Q>: Hi, I just wanted to just reiterate to the committee and along your theme as talking today when I heard Wes talking about aspiring to do something, but don't forget aspiring can cause aspiration as in choking in the vendor community, that a glide path of where you're going is just so critical. It's going to probably be unknown until later this fall how much of this rapid development to put things in without a lot of notice into products what kind of, for lack of a better term, hot fix hell that is going to create this fall for people not being able to test, not the electronic medical record if that worked, but maybe they hooked it up to 20 different things, and it broke things within their environment that they were using it, that they added it onto that. A glide path is just really critical so that when we are creating things that maybe we're building new pieces in the database and we're building new translation tables within the database itself. How critical it is to know that months ahead of time, not weeks ahead of time to make that and just make that comment on behalf probably of every vendor out there that's struggling to do this right now.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you, Robin. I believe that's all for public comment. I'll turn it back to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Great, if there are no public comments in the room, then I think we have completed the business of the day. We're receiving probably some more guidance from Judy and the office in terms of the form of our responses both to the Office of the National Coordinator and CMS as well as to the IFR and NPRM specifically. As Dr. Blumenthal also invited, those individuals with specific interests that would like to comment in a personal capacity, that is also something that is part of the democratic and open process. Thank you each for all of your efforts. John, anything else on your end?

John Halamka – Harvard Medical School – Chief Information Officer

So, HIMSS is coming up. I will be giving a standards town hall, just describing the work we've all done together over the last year on March 2 from 8:30-9:30, so I may see some of you there. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President

With that, thanks everyone. We stand adjourned.