

HIT Policy Committee Transcript August 14, 2009

Presentation

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

I want to first of all mention that there may be some members calling in: Dixie Baker, Latanya Sweeney, David Bates, Janet Corrigan, Floyd Eisenberg and Charles Kennedy.

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

Yes, this is Dixie Baker.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

All right. Have they joined us yet, please?

David Bates - Brigham and Women's Hospital - Chief, Div. Internal Medicine

This is David Bates. I'm on the line.

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

Dixie Baker, I'm on the line.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

They are online? Good, wonderful. Thank you. Okay. First action item would be to approve the minutes from July the 16th. Are there any amendments? Christine?

Christine Bechtel - National Partnership for Women & Families - VP

I just have one, on page five, just to clarify under action item two. It says that the committee adopted the Meaningful Use Workgroup's recommendations matrix by consensus, noting for inclusion in the final version a number of specific suggestions that used to say, and a reservation about its aggressive time frame, and I don't think that reflects – "the entire committee" certainly doesn't reflect me, so if that could be changed to one member or a few members, depending on what folks would like, I'd appreciate it. And I'll give that to Judy.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Okay. Any other amendments? I'll entertain a motion to approve, then.

Unidentified Male Speaker

So moved.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Okay. And a second?

Unidentified Male Speaker

Second.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Any objections? Great, thank you very much. Okay, our first point of business is to get an update from the Meaningful Use Workgroup, and George Hripcsak is going to present. I'm the other party, but I'll sit over here in my substitute job while George presents

George Hripcsak - Columbia University - Chair, Dept. of Biomedical Informatics

All right, thank you, Paul. Thank you to the Committee for the opportunity to present our progress since our last meeting. I'll do the presentation today, which is fair, because last month I got off easy and didn't have to do the presentation, but it's only three slides long.

The workgroup did, before I joined, an incredible job creating the 2011 measures, a consistent set, in a very short time frame. Working with ONC, we realized that the 2013 measures are probably due approximately one year from now, July or August time frame. Therefore, we have time to adopt a more reasonable paced process, gather information and work through it. So what we've done in our last two phone meetings is mainly work through the process and the time line. Our draft time line is shown here on the slide and I'll just go through it briefly.

In this quarter, third quarter of 2009, we'll be developing the process for updating the Meaningful Use objectives and measures. This includes – let me go on and then I'll come back to that. In the fourth quarter, one thing we need to do is gather more information, so in the fourth quarter this fall we plan to conduct informational hearings to inform the 2013 and 2015 criteria development, and I have a slide on that so I'll come back to that.

Then in the first quarter of next year we'll be working hard on those objectives and measures. Then around the second quarter, we'll be ready to start working with the HIT standards committee – or not start working, perhaps, but work hard with the HIT standards committee to ascertain the availability of relevant standards for Meaningful Use. Then by the third quarter, we'll be refining the 2013 Meaningful Use criteria to hand over to ONC to then in turn hand over to CMS.

Then in the fourth quarter we think they'll then have experience and data in the industry to assess industry preparedness for meeting the 2011 and initial 2013 Meaningful Use criteria. Placing that in the fourth quarter doesn't mean we're going to ignore industry for the next year; it just means we think that's when it will be a good time to collect a lot of data. And I'll be covering this a little bit in the next slide, but remember at our last Policy Committee meeting, how we deal with specialties and how Meaningful Use relates to them with a very important topic, and we're approaching that in a parallel path, and one of the things we'd like to do in this quarter actually is to tag the 2011 measures as being relevant to specific specialties, so that's why that's on a time line there. But we're going to do other things, and I'll show that in a minute.

Here is our draft process for creating the objectives and measures. For one thing, our choice of the National Priorities Partnership framework went over very well we think with the public, and we want to continue to use that framework for our Meaningful Use criteria. However, the one thing we discussed on the phone is that we're the Meaningful Use workgroup, not the United States Health Policy workgroup; therefore, there are people who are working hard on setting the national priorities for healthcare and we want to work with those people rather than reinventing the wheel.

So NPP is one good source, and the other that comes about is the Healthy People 2020, which is right now in the midst of defining its objectives, most of them quantitative measures. So we'd invited some presentations from both groups at our last phone call and we're looking forward to working with both of them to identify HIT-sensitive objectives and measures that are appropriate for the Meaningful Use criteria in 2013 and 2015, so we see it as a collaboration.

As I said, we need more information, so we want to gather public input on identified gaps in measures. Some examples – and I'm going to have a slide on this to follow, so just quickly – specialists, smaller practices, smaller hospitals, safety net providers, and patient-supplied information are areas that we identified that we need more information. We want to be able to assess industry initial response to the 2011 Meaningful Use program. We're, of course, going to be refining our Meaningful Use criteria that were published. In other words, the part that was published in the matrix are not our final answers on '13 or '15. And we're going to over time address barriers to EHR adoption and suggest mitigation strategies.

So we're hoping to have an informational hearing on Meaningful Use criteria in October of this year, so the beginning of the fourth quarter, to address those gaps, and for that meeting we're looking forward to dividing the meeting into two parts: the first part to cover this critical issue of specialists, the use of measures that are relevant to specialists, whether we can use national registries as a way to gauge meaningful use of EHR's for specialists, and assessing what needs to be developed in terms of new measures, so perhaps a half day on that.

Then the other half day – now, there are several topics, some I mentioned on the previous slide, that we want to gather information on, and we thought for the first meeting we would go broadly and specifically look for feedback and new ideas from provider organizations from that meeting. So the spectrum of physician practices, the spectrum of hospitals, and specifically safety net providers, to inform us on not just how we're doing, but what we're not doing that needs to be done. And I'll take any questions.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thank you, George. Any questions from the community, please? Gayle?

Gayle Harrell - Florida - Former State Legislator

Thank you, Paul, and I wanted to first commend you for actually listening to some of the comments, and I'm delighted that you're going to be meeting with the specialties and understanding the impact of the Meaningful Use criteria on them. I want to clarify something on the Meaningful Use definitions and measures that are put in place for 2011. There are measures that are going to be required. Two questions. Number one: Does the 10% that was relative to hospitals also apply to physicians on CPOE? And also, is CMS going to be able to accept those measures and the documentation? Are they in a position to be able to do that? So if we have established measures and you're going to be evaluated on it, are they going to be able to do anything with it?

George Hripcsak - Columbia University - Chair, Dept. of Biomedical Informatics

First of all, let me say that all my answers are just about our intention, because now it's in CMS's hands. Our intention for CPOE was that for hospitals, would achieve 10%, but that eligible providers would achieve 100%, that we did not intend the 10% to apply to them. Because our feeling was, if you're going to install an EHR in your practice, what are you doing except for documentation and orders? That is the workflow, whereas in hospitals, it works a little bit differently. CMS can now judge the feasibility of that as far as doctors accomplishing that, but that was our intention.

On whether CMS can accept that, CMS has a range of options for how to – from anything from attestation to actual data that the thing is being done correctly. So CMS will have to decide how it should best prove it. Paul, do you have –

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

I think I'll defer to Tony Trenkle, a member of the Committee on CMS.

Tony Trenkle - CMS - Director of OESS

Are you talking in terms of accepting in terms of the reg, or in terms of whether we'd be accepting them in terms of receiving the measures?

Gayle Harrell - Florida - Former State Legislator

I'm just quite familiar with the difficulty many practices are having with PQRI and I'm wondering, are you going to be able to – is your system built and able to accept data on things such as – it's structured and as what we're seeing in Meaningful Use? Are you going to – what is your system going to be? A lot of question as that you're not going to be ready to do that.

Tony Trenkle - CMS - Director of OESS

We're not going to propose in the rule or accept in the final rule anything that our systems can't accept, so if you have something in there that we don't feel that our systems can accept in 2011, then we won't propose it as part of the final rule.

Gayle Harrell - Florida - Former State Legislator

Follow-up: So you're saying basically at this point attestation might be adequate if you're not there?

Tony Trenkle - CMS - Director of OESS

We will propose in the NPRM – we're looking at our systems now and looking at possibilities, and we have our regulation and clearance that will address that issue, and I don't want to discuss it at this point because we're in a clearance process with the rule. But it will be discussed in the rule how we intend to do that. And then of course you have the public comment period where you can receive comments. But we're also looking from a variety of ways to have our systems will currently and in the future be able to accept data. So whether we can do it in 2011 or later is something that we'll propose in the NPRM that will be out in December.

Gayle Harrell - Florida - Former State Legislator

Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Any other questions? Mark?

Mark Leavitt - CCHIT - Chairman

Just a quick question. As I looked at the matrix – and I'm kind of going backwards so I'm sorry, and we may not be able to do anything about it – but I didn't notice that there was any documentation, the ability to store documents and associate that with some kind of LOINC code. That seems to be a missing piece that we might want to have in the Meaningful Use criteria. Like I said, it might be too late, but did I miss that, or – if somebody can just clarify it, I guess.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

When you mention documentation and you mention LOINC codes, are you – go ahead.

Mark Leavitt - CCHIT - Chairman

No, I – there are going to be scanned documents in any medical record that people are going to keep, and whether you associate that to a LOINC code so that you can bring it up in the context, or you associate it with something else, I don't suppose that matters. But you do need to have the ability to store documents, and I just didn't see that in the matrix and I didn't know if that was important.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Okay. As you know, from the matrix point of view we took the approach, do we do the 500 criteria for what an EHR, certified EHR would have, or do we look at things that could somehow be exemplars that a comprehensive EHR is being used and it's being used meaningfully. So it didn't come to the forefront as far as being one of the exemplars that we may need to do. We certainly are open to reexamining that in the 2013-2015 measures. Thanks. David?

David Bates - Brigham and Women's Hospital - Chief, Div. Internal Medicine

Thank you, Paul. I have a couple of questions, two of which maybe come to Tony. For clarification, as we do the continuing Meaningful Use work, we talked a little bit last time about the challenge of beginning to encompass all the different dimensions of American medicine. And two in particular I'm interested in what CMS can tell us about. One is the statute says that there are hospital-based physicians who are not subject to the Meaningful Use incentive program in the same – at least in this category, through the Medicare funds. We want to address specialists. Is there any clarification yet, Tony, of what the boundary is between the specialists who we should be developing measures for as part of the agenda that George described, versus those who are going to be treated separately because of the statutory language? That's one question.

The second one I'll throw you as well. At the state level we've been discussing whether the Medicaid Meaningful Use provisions are determined by CMS, or they are determined at the state level, or is there a relationship between federal requirements for the Medicaid Meaningful Use incentives and the opportunity of the state to modify or add to those?

Tony Trenkle - CMS - Director of OESS

Okay. And both of these issues will be addressed in the regulation. The first one, we've gotten a lot of feedback from different communities in terms of what is a hospital-based eligible professional. And we have some language in the regulation. As I say, it's in clearance now, so I don't feel comfortable about speaking to that.

The second is yes, as much as possible we want to harmonize the Meaningful Use between the Medicare and Medicaid programs. One option would be to have the Medicare program Meaningful Use objectives as a floor, and then the states, if they want to add additional to that, could go beyond that. But we don't want the state Meaningful Use objectives or measures to be below what the federal is, so if you can think of it that way. That's the direction we're looking at. But as much as possible, we would harmonize it, recognize – and of course there are some differences between the federal and Medicare and Medicaid programs as well as who is eligible for both programs.

The other issue with the Medicaid is, for the first year the eligible professional is not required to meet Meaningful Use, so that's another little wrinkle in that.

Mark Leavitt - CCHIT - Chairman

One more quick point. One is, I have a continuing concern about the measures pipeline, and that I think the Meaningful Use Subcommittee should give some attention to 2015, early, in order to provide direction to NQF or other – or measurement development bodies, so that we have the measures available to us as soon as possible to implement the directions we're going in. There are several categories like the patient engagement category and the outcomes areas where the pipeline is not very robust yet, and I think by us declaring ourselves on those directions, we can incent measures development and testing now. I think we've been a little bit handicapped by having to use measures that were developed five and ten years ago to judge the aspirations we have.

And the very last thing is – it wasn't mentioned in George's report – the Subcommittee has talked about having also a hearing on patient-supplied data sources as part of the strategy, and I continue to hope we do that soon, because I think that's part of this longer-term pipeline.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Just to comment on both of those: One, the importance of signaling early what kinds of measures we're looking for, so both the industry and NQF who endorses measures early can have that advance warning. You'll hear later in today's proceedings that NQF is already working on the 2011 measures, so the message is loud and clear, and actually it's a direction of NQF, so those are good things. But notwithstanding, we should be working on it and will be working on the 2015 as well.

The other point is, as George mentioned, the patient-supplied or patient-provided data is on the agenda for trying to get more information on as soon as we can. We have some other priorities, or ONC has other priorities that we need to act on as quickly – everything we have to act on as quickly as possible and yesterday – but, so it's definitely in the queue. Thank you, David.

George Hripcsak - Columbia University - Chair, Dept. of Biomedical Informatics

I'm sorry it got a little buried, but we did make sure to go into the public record on that slide. That was the purpose, is to make sure people knew that.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Other comments, questions? Gayle?

Gayle Harrell - Florida - Former State Legislator

One more question, if you don't mind, Paul. I want to follow up on the Medicaid, because of course as you know, every state has – their Medicaid program is unique to that state, and are you anticipating that CMS will allow states to set Meaningful Use criteria that – perhaps dealing with children? For instance, in Florida, 75% of our Medicaid recipients are children – that perhaps address specific needs in Florida relative to our specific Medicaid program? Or do you anticipate there just being blanket rules set for Medicaid across the board?

Tony Trenkle - CMS - Director of OESS

I think it's a little premature at this point. Certainly what we're doing now is communicating with the states to find out what some of their needs and requirements are, and we'll take them into account as we develop the rules for the incentives program, so that's about what I can say. I do know that we're actively working with the states and also with ONC and looking at some of the issues that are related to the state programs, and particularly in Medicaid, as you mentioned, the children's and the pediatric requirements are things that we're looking at very closely.

Gayle Harrell - Florida - Former State Legislator

One more follow-up on that: I believe the statute requires that you do 20% of Medicaid in order to be eligible. Is that accurate, and is there a way that that can be interpreted to include SCHIP? Because we have many providers who don't reach the threshold of 20%, especially pediatricians, and are not eligible under Medicare, but they certainly need to be part of EHR, and it's very important that we incentivize them to do it; whereas SCHIP, many practitioners, it's pretty broad. Most practitioners take SCHIP.

Tony Trenkle - CMS - Director of OESS

Yes, the law is pretty specific in who would qualify under Medicaid. I mean, as you said, they have specific percentages. So we're going to basically go by what the law says in terms of qualifying for the program.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Are there any committee members on the phone that would like to make a comment? Okay. Any final comments by members of the committee here? Okay, Mr. Chair, we've finished up with the first item, which is the update from the Meaningful Use workgroup.

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

Thank you all, I'm sorry to be late. I think we're going to move on to the Certification and Adoption workgroup. I guess I should first say hello, thank you, welcome. I don't want you to think that we live here at the Holiday Inn, but sometimes it feels that way. Could I ask Paul and Marc to share their thoughts with us?

Marc Probst - Intermountain Healthcare - CIO

Paul has all the thoughts today, but I get to tee it up.

Paul Eggerman, CEO, eScription

You have the jokes.

Marc Probst - Intermountain Healthcare - CIO

I don't even have any good jokes. At least I had some last time. You've seen the workgroup before. I just want to reiterate what a tremendous group it is and how much work they're putting in. Every call, every meeting, they are very well engaged. And also, Paul. His leadership has just been tremendous. Over the last month it's been a little busy for me personally and he's really taken the load, so I appreciate that.

Nothing on this definition has changed. This is still what we believe certification is, that it's focused very much on Meaningful Use, and that this is not intended to be the seal of approval process. So as we go through the recommendations that are very similar to the last ones, although we did hear the comments from last time, we're still basing it on this same definition. So these are the recommendations, and as I said, Paul will go through each of these. Our hope is that we can go through these quickly. We have fairly high-level bullets on this. And then we can get into discussion around certification.

Paul Eggerman - eScription - CEO

Thank you very much. I'm Paul Eggerman and I'm the Co-Host with Marc Probst on this group. What I am going to do is take you through each of the five recommendations. I want to make sure I explain why we're here at all this morning. Basically, to refresh everyone's memory, we presented last month at the meeting and the five recommendations that Marc just went through were approved in general, but we were sent back to say, provide some more information on the detailed recommendations, and also to consider the feedback that you and a number of other people gave us. So we're back today saying we have done all those things, and we have refined and changed our recommendations based on your comments and based on other comments that we've received. So I'm going to take you through the five recommendations.

Now, what you see on the screen is sort of like a summary of each of the five recommendations where we sort of put down three major headlines or bullets on each of the recommendations. If you look at the appendix in your materials, there is a lot more detail on each one of these, and so that is also where, if you haven't already done so, I recommend you read through all of that detail in terms of how this all works.

The first recommendation is to focus on Meaningful Use. That basically what we are saying with the certification process is that it needs to be driven by the Meaningful Use objectives, that fundamentally we want to have what I would call an outcomes-oriented system of certification. So the first sort of bullet that you see there is a new certification process, focused on Meaningful Use objectives – and it's sort of like the key word there actually is "objectives"; we're not talking about just the measurements; it's the objectives and the measurements – and to do it at a high level with less specificity. So that means that we are not trying to say specifically how these systems will work. We are not trying to say that if you have an alert, this is how you have to do an alert if you get an abnormal value. We're simply saying that you have to have an alert.

We're also saying you have to focus on the objectives, so for example, there's an objective that says that you have to have a drug organ with drug/drug interactions, that's what you have to do. So even though it's at a high level, that doesn't mean that you still don't have to complete – have software that somehow completes all of the objectives, and to treat the objectives in Meaningful Use as fundamentally the roadmap of what we are trying to accomplish. So that's what we're saying with the first item, which is actually saying a lot.

The second item is pre-specificity on interoperability, and I'm going to talk about that more in a minute, but that's actually saying almost the exact opposite. In the first thing we're saying do everything at a high level. We're sort of saying less is more. When it comes to interoperability, we're saying more is more. We want more detail, more specificity and more activity.

The third concept here that's very important is that the current kinds of certifications that occur should continue to occur as what we call optional certifications, that the marketplace might see to place value on. And in terms of something that's happened since the last meeting is, I was fortunate to have an opportunity to speak with and communicate with Mark Leavitt, the CEO of CCHIT, and he told me that he intends to continue to offer the same kinds of comprehensive certification processes that he does offer. So to the extent the marketplace values that, that's terrific. That will still be offered. And I even got the sense that the process is already starting to work, because he seemed to indicate a lot of ideas as to how he was going to be innovative and how he might be able to do that, to respond to various elements of our community. So that is our first recommendation.

The second recommendation really calls out the idea that fundamentally, certification is like a really powerful tool that we have. This is this really powerful public policy tool, and since we have this powerful tool, we should use it to address important public policy issues. And the two issues that we list out here that are critically important, the first one of course is privacy. And this is an area, compared to the meeting last month we did – provide a little bit more detail and describe this a little bit broader, but basically what we're saying is that when it comes to privacy issues, privacy really relates a lot to policies, as to how you do things, and how different people interact with each other.

But there are also some things that the software itself has to do to enable a physician or a hospital to implement a policy. And an HHS certified system must have the capability, so that a physician or a hospital can fulfill all of the requirements of the statutes. So that's everything in HIPAA, everything in ARRA. It includes things like audit trails and consents. Those are all critically important. It's sort of like, to me it's stating the obvious, though ultimately if our patients don't have trust in these systems, then probably nothing else we do matters. So this is a very strong statement that this should be a priority for certification.

The second issue we're going to hear a little bit more about this afternoon as it relates to exchanges, but basically we're saying to aggressively establish new and very specific requirements for interoperability and data exchange. Fundamentally, I think we all know that data exchange currently doesn't exist where

we would want it to be, and there has been some significant work that's gone on in HITSP, and target teams have done great work, but it's time to sort of like kick that into second gear, is what we're saying, that fundamentally there needs to be more work done in this area and we need to go beyond just harmonizing standards. So there's more information about that in the detail.

The third concept is to create these things called test harnesses, which really is just a way for basically users to test their systems themselves, to make sure that the systems really comply with the standards and perhaps indicate that something did not get accidentally broken.

Now, the third recommendation is where there's been I'd say the most interesting feedback in terms of discussion. So what we're saying that we want to do is make sure that we create – it's better to say a more objective and transparent process. And basically there are three comments here, but this should not in any way be viewed as any kind of criticism of CCHIT, it's just simply a recognition that there's a lot of money involved here, there's a lot of people involved here. We're sort of raising everything to a higher level, and so the entire process of monitoring and oversight also has to be raised to a higher level. So there are three concepts here.

The first one is to separate the definition of the certification criteria from – the testing organization from the testing process. There should not be one organization that autonomously is able to do both. This is actually not that shocking of a recommendation. It actually repeats in effect something that's in the legislation in ARRA. The national coordinator really does determine the certification criteria.

The second concept where there's also been some discussion is to permit multiple certification organizations to have a competition; and the third concept is to work with NIST, the National Institute of Standards and Technology, to establish an accreditation organization and process.

Now, as we went through this, I also want to say that we did take into consideration the comments that were made last month, especially a comment by Neil, Neil Calman, who said that, there's a lot of change in the marketplace and how is this all going to get communicated. And that is a very important issue, and when you go through the detail on the recommendations, you'll see that we did address that by recommending that there be a communicates plan and an outreach plan, because there is a lot of information here that – not only is there change, but information that people need to understand in terms of what it means to be HSS-certified, and there have been some suggestions as to how to change that to avoid confusion – perhaps call it HHS-qualified, make sure that people understand that this is really just qualification for the incentive payment, it's not a government seal of approval for the product – to make sure that that is very, very clear.

The fourth recommendation relates to flexible software sources. Basically right now, purchasers – physicians and hospitals – sort of have like a menu of things they can choose from. They can purchase everything from a single vendor, they can try to do what's called best of breed, get things from multiple vendors. They can develop themselves. And our concept here was to make sure the certification process didn't alter that choice, that they still have the exact same choices, and can do that and still qualify for the incentives.

In these recommendations, we respond to the comments that we heard last month, particularly the comment from Judy Faulkner to clarify how this will all work. So you see in this first comment here, it says, "Ensure all systems are certified against identical criteria regardless of source." That's basically an argument of a level playing field, that there can be multiple sources, there'd be vendor and non-vendor systems, but they all have to be certified against the same criteria. So this is like a very American statement of the equality.

The second concept is that while there's the same concept of criteria, that there can be flexibility in the actual processes themselves. So again, I'm going to go through the detail. You'll see there are things that we did to make things a little bit easier for the Open Source community in terms of something called the lockdown, which sounds very exciting, but it doesn't quite live up to its name. But to make that easier for the Open Source people.

And to make a side comment about the Open Source people, in talking to them, these are people who are unbelievably enthusiastic about their work. I mean, we're really fortunate to have people like that in our community. We really love their work, and they're building on the very good work that's been done at the VA, so we want to make sure that they could participate in this process.

The third concept here is this concept of what we call components of the system. So the idea here is that it should be possible for a purchaser to obtain systems and not have to buy it all from one source. So you could buy your e-prescribing system from one vendor if you want to, or if your hospital – maybe there's somebody who has a special emergency department system that you really like, and so you can buy that and buy everything else from somebody else, or maybe you're going to develop one section yourself and you're going to buy things from someplace else. So this gives you a way to do that, that as long as you still follow the first rule, that everything has to be – you have to meet all the criteria, you can get the different components from various sources. So that's the fourth recommendation.

The fifth issue relates to the short-term transition, and this is probably the area that is like most different, and we have the most amount of additional information from last month, and this is responding to questions that you had, Gayle, and Neil, and a number of other people, which is sort of like, how is this all going to work in terms of schedule and time? You're putting forward a totally new process. You're putting forward a lot of the new information. We have a lot of stuff to do. How is this all going to filter out, how long is it going to take? So we've got a lot more information to address that.

First I'll take you through the major concepts of what we have here. There are three major concepts that actually – the first one is actually a very simple concept. It says, "To leverage the existing certification work whenever possible." The issue here is, you look at all the Meaningful Use objectives and a fair percentage of that there's already certification criteria written for it. So if there's already certification criteria written for it, at least in the short term the concept is, why not use it. There's no reason to reinvent something if there's stuff available that you can use. So that's the first concept.

The second concept is a little tricky to explain, because first you have to understand, what is HHS certification. But HHS certification again just qualifies you for the incentive payments, so now we're introducing the concept that we call preliminary HHS certification. So what is preliminary HHS certification?

The way to explain this is to realize that fundamentally, software can't be certified until we really know for sure what Meaningful Use is. But we don't know for sure what Meaningful Use is until it passes its way through this whole sort of regulatory process, and we don't know how long that will take. But sort of taking a guess, it will be early in 2010 before that gets done. So rather than just wait until that happens, the suggestion is to establish something we call preliminary certification. It's based on the assumption that vendors will be willing to take a gamble, to take the reasonable risk that what has been proposed through the regulatory process is probably pretty close to what's going to come out the other side. It's hard to know if it's going to be – if it's 90% or 95% or 98%, but presumably or hopefully it's pretty close, and the suggestion is that vendors should prepare their software according to those objectives. And also the suggestion is that we begin certifying against those, and we call that preliminary certification, which doesn't really have any standing in the statute.

But the purpose of doing that is when the regulatory process is completed, hopefully there's going to be only a very small adjustment needed, but there will be some adjustment. It's hard to know what that is. But that will be some small additional piece that we can tack on, so as rapidly as the regulatory process is done, we can be in a position to have HHS-certified or qualified products in the marketplace. So that's the intention for preliminary certification. So that's the second concept there.

Then the third concept is – like you have to really inhale to make sure you understand this – is, we're talking about the 2008 certification gap criteria. So what in the world is that? The best way I can describe that is, you think about what I just said: There are a lot of vendors who did a lot of work and got themselves certified against the 2008 criteria from CCHIT. So those vendors are going to be saying, gee, I did all this work, I already got myself certified, and I don't want to have to do that work all over again. It's not fair.

And our answer to that is, you're right, it's not fair, and we're not going to make you do that. So the concept is, to the extent that the 2008 certification applied to, say, half, three-quarters, some percentage of Meaningful Use, that part doesn't have to be repeated. You just have to certify yourself to the parts that you haven't done yet, and that's sort of like the gap certification.

So those are the three basic concepts in the transition plan. Again, if you go through the appendix, there's a lot more detail. Now, when you read through the appendix you have to understand that to do this, we need to get the actual criteria from the CCHIT. We have to go through a whole process where the standards committee reviews that criteria. And in the detail, our workgroup suggested that we ask to see if we can get CCHIT to submit a proposal by September. And I have to tell you that we were just extremely pleased with the way Mark Leavitt and CCHIT responded to all this. They couldn't have been more diligent and helpful, and they actually already completed that work.

So in the e-mails that you all received yesterday afternoon, there is a complete detailed analysis of all the Meaningful Use objectives and measurements, mapped back to the 2008 CCHIT certification process, indication where there are gaps. So we now have – and proposals as to how to fill those gaps, even a rating of the intensity of the gaps. So we now have all of the detail we need to put this sort of preliminary plan in place. So that detail then, the hope is that that can be submitted to the standards committee next week – I understand they're meeting on August 20th – and through the months of August and September, can go through whatever public comment and reaction period we need to finalize those criteria, so that starting in October, we can be in a place of starting to do testing for preliminary HHS certification, which is actually very exciting.

So to try to summarize all this, because I've given you a lot of detail and there's a lot of slides with a lot of words on them, but basically we're looking at a new certification process. I could describe it as outcomes oriented at a high level, really driven by what's a Meaningful Use. I would tell you it has a lot of focus on privacy, and focus on interoperability, and we have a detailed plan.

What we are asking for from the policy committee is for your approval today of these detailed recommendations, because if we can have the detailed recommendations approved and get started on the process, I think we can offer something that we haven't been able to offer before, which is clarity – clarity on where Meaningful Use is going, clarity on how the software products can be certified. So that's our presentation. Do we have any comments or questions?

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

I want to thank Paul and Marc and the other members of the Certification and Adoption group. And this goes for all of our members and all of our working groups: There is no way we could buy the kind of incredible effort and clarity of thought and commitment that all these working group members have shown, and the wisdom that they've brought to bear, so – it's been remarkable for me as a new public servant to see how much public service is provided by the public, and it's very gratifying. So thank you personally, and also on behalf of the committee. Any thoughts or comments?

I'm sure you were reminded beforehand that this committee is a body that provides advice to the national coordinator, but does not determine policy. Deven?

Deven McGraw, Director, Center for Democracy & Technology

Thanks, that was a great presentation. I have a couple of questions. One, I want to make sure that I understand the – I wouldn't call it a qualification, but your further explanation on certification for privacy and security. It sounded to me like you said you're not looking for a substitute for policymaking, but instead, looking to certify what I'll refer to as the functionalities that are necessary for the technology to be able to in fact implement some of these legal changes. It's just that often people talk about, we're going to certify for privacy and security, and for many folks that has a much more expanded role for certification than I know I would like to see. I don't think it's possible to do that when you're looking at functionality and technology, and that's what I thought I heard from you, but I'm sort of looking to be validated.

Paul Egerman - eScription - CEO

That's what I intended. You said it much better than I could have, but that's certainly what I intended.

Deven McGraw - Center for Democracy & Technology - Director

Okay. Then my second question is, with respect to – and I don't know if you guys – I haven't had a chance to look at the work that Dr. Leavitt sent in where he listed the criteria that CCHIT has already developed, that – that Meaningful Use. But I'm wondering if they meet these sort of overarching recommendations that you all set forth, which was a high level with respect to the standards, so they're not dictating a particular way that something gets addressed, except more specificity with respect to interoperability, so we know we have criteria that will actually facilitate the exchange of data.

I'm not a technologist, so I look at these criteria and some of them look fairly general and some of them look fairly specific. I'm wondering if we – I mean, that will be something I think that will need to be assessed, because personally I agree that you don't want to have the criteria be so specific that they're hardwiring in necessarily a particular approach to addressing an issue unless it needs to happen in order to facilitate the interoperability and the ability to exchange data. That wasn't necessarily a specific set of instructions that went to CCHIT under the old regime, and so I'm just curious if the criteria have been evaluated under that new standard.

Marc Probst - Intermountain Healthcare - CIO

I think CCHIT had what they had, which was the Meaningful Use matrix and their current processes, and I think they've done a good job in trying to understand how the two align. As I went through it, I thought some of them were kind of detailed, more so than the intent of what we were talking about relative to certification, but given what they've had to date, they've done an excellent job I think.

Deven McGraw - Center for Democracy & Technology - Director

Right. It wasn't meant to be a normative comment about the work in the past, but just wondering how the list of criteria that they have, that they've identified as meaning Meaningful Use, to what extent do they need this additional recommendation that you all are making today about higher level with respect to some criteria and more specificity with respect to others.

Marc Probst - Intermountain Healthcare - CIO

Right.

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

Gayle?

Gayle Harrell - Florida - Former State Legislator

Thank you. In looking at HHS certification, is that going to be done specifically by HHS? Do they have the manpower to do it? Are they going to set the specific criteria or – and will you have to be HHS certified – will that be the definition, HHS certification? To meet certification requirements, if you're already CCHIT and you get a gap certification, do you also need an HHS certification?

Also, is NIST going to be the accrediting body that accredits other certifiers?

Paul Eggerman - eScription - CEO

I think that was more than one question, but I'm going to do my best with it. So if I leave something out, I suspect you'll remind me. First, on the issue of NIST: NIST is not going to be the accreditation organization because when we spoke with NIST, we learned they don't do that. What NIST will be doing is NIST will be working with ONC to identify an accreditation organization and to also establish what a good process is for monitoring and surveillance and how all of that should work. So that was one of your questions.

The other one is, to go back to what this means to be HHS certified, again, what probably will happen is somebody will come up with a different name for that or a better way to name it, but that is – if you look at the definition, that is simply limited to what a hospital or physician needs to do in order to receive the incentive payments. In other words, they have to have a certified system, plus they have to demonstrate Meaningful Use, so they have to either purchase out or get certified that they have it. That's the purpose of the certification.

You asked the question about the existing CCHIT certification. That's done for a number of purposes, but one of those is this thing called the Stark exception. The Stark exception is one of these things that is like too complicated to understand how it all works, but if you read through the detail recommendations, what we said about that was – which we just said in consultation with the ONC staff – is that it should be possible and it will be possible that there will be one process that does both the HHS certification and also creates the Stark exception if that's necessary.

So did I answer most of your questions? I'm unsure I got it all.

Gayle Harrell - Florida - Former State Legislator

I specifically wanted clarification as to what the process would be. You would have to meet HHS certification – if CCHIT continues to be the certifying body, you still have to have a certified product. So you also have to have HHS certification, so you have two levels that you have to have? Or are you combining them –

Paul Eggerman - eScription - CEO

You only have to have one.

Gayle Harrell - Florida - Former State Legislator

You will only have one.

Paul Egerman - eScription - CEO

The only requirement – first of all, you don't have to have anything if you don't want to, but –

Gayle Harrell - Florida - Former State Legislator

If you want incentive payment.

Paul Egerman - eScription - CEO

-- but if you want to sell a product, or if you want to obtain the incentive payments, you have to have one. The idea of the optional CCHIT certification is if vendors choose to, they can continue to do that. And it's sort of like, it's optional. It's like having, I don't know, it's like having a merit badge or a ribbon or a credential that's added to the vendor's marketing campaign. This is something that they have achieved. But that's an optional thing that they are not required to do. To get the incentive payments, you only need to do this one thing.

Gayle Harrell - Florida - Former State Legislator

So the HHS certification basically would take the place of the CCHIT certification?

Paul Egerman - eScription - CEO

I don't want to say it takes the place of it, because they're different things. I mean, CCHIT will continue to offer – I understand will continue to offer what they call comprehensive certifications, and that's their choice to do that. And that will continue to happen. HHS certification is something that is new. It's required to get the incentive payments, so it doesn't necessarily replace it. And it's certainly not the intention to replace it in terms of how the marketplace views the value of it.

Gayle Harrell - Florida - Former State Legislator

And is HHS going to be – are they going to delegate that out? Are they going to accredit bodies who are going to do that? How is that process – how do you envision that process happening? And does HHS have the ability to do that at this point? Do they have time to write the regs to make that all happen, and do they have the money? Do they have the allocation to do that?

Paul Egerman - eScription - CEO

I'll try my best at some of the questions –

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

Will all the ONC people in the audience please stand up, to ensure everyone that we have the staff?

Paul Egerman - eScription - CEO

Right, right. For people listening in, there's about 400 people standing up behind me right now. But basically – actually, there's nobody standing up. Basically what we envision happening during the transition period is that once the criteria is approved by the standards committee, and the very issue that you raised, Deven, has to be addressed to make sure that this criteria relates to the process, that CCHIT will start offering this preliminary certification in October. Then once the regulatory process is completed, what we envision happening is that the national coordinator will then do whatever the national coordinator does to say that preliminary certifications are now final, that that's how it all works.

On the issue of, then, until we get the accreditation organization placed, we envision that that transitioning process will occur. Once the accreditation organization is in place, the accreditation organization will monitor the process. The criteria will probably go through some evolution, but then there will be one or more certification organizations like CCHIT that will continue to do all of the work, and the national

coordinator will somehow do whatever paperwork or process – I have this picture that you have some giant stamp, and you like stamp it down really hard, and it says “approved” on it or something. That’s the process.

You asked questions whether or not they have the money or the people power to do that, and I have to defer to them. I don’t know that. It doesn’t seem like they have a ton of people over there, but I don’t know.

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

So Judy and then Neil.

Judy Sparrow – Office of the National Coordinator – Executive Director

Just a quick question: Sometimes when I was reading the Meaningful Use stuff with the measurements versus the topics of Meaningful Use themselves, it struck me that the actual topics of Meaningful Use were much broader and deeper than the measurements. Are we going to worry about studying for the test, basically?

Paul Eggerman - eScription - CEO

Again – it’s a great question, Judy. When you look at both the summary recommendations and the detail, what we were very clear on is that the certification process can’t be just on the measurements, it’s got to be on the objectives. And it’s for that very reason. We didn’t want to have systems where somebody just has like a spreadsheet and then tells you the percentage of people that do CPOE, and it just is able to split out ten measurements. The reason the measurements exist is to make sure that the objectives are occurring, so that’s the requirement.

Judith Faulkner - Epic Systems Corporation

Can there be maybe changes in the measurements now and then? Things thrown in to say, let’s look for this, as well?

Paul Eggerman - eScription - CEO

I – that’s not our issue. I mean, we put together a framework for doing this, and if the measurements change – if we did the right job in certifying the objectives, it should be possible to change the measurements without a huge amount of effort. But that’s an issue I think either for the – for the prior workgroup.

Judith Faulkner - Epic Systems Corporation

For any individual group being tested to have a few wildcard measurements that go in with various questions to just check the depth and breadth, rather than just the specific report or other issue being examined.

Paul Eggerman - eScription - CEO

Again, I think that’s not our workgroup, but it’s a good suggestion. I mean, the second issue is, can the CMS system handle that. I mean, that’s – you’re adding some complexity there in terms of how they’re going to handle the payment process. But it’s certainly a reasonable idea.

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

We’ll take both comments under consideration. Neil?

Neil Calman - Institute for Family Health - President & Cofounder

Thank you. First I want to say thanks for focusing on the privacy and security issue and also on the educational issue, which I think is incredibly important, and make a couple of comments. One of them is to ask whether or not you've considered the idea of limiting the number of accrediting agencies that we will allow to sort of enter this marketplace. Because what I – I still fear enormous confusion that's going to be created by this process. So imagine that you have the CCHIT group that's going to have a gap sort of process in place, but meanwhile we're going to have new organizations coming up, thinking this is a great business to get into; I'm going to get into the accreditation business.

So they create processes to certify this HHS-certified process, and there could be five, seven, ten of these. If we just say anybody that can show that they're able to certify an electronic health record system to meet these could sort of enter the game. We could end up with a lot of these, and then all of them could develop HHS-plus products. So just like CCHIT is going to have the HHS basic model and then they're going to have their wraparound, all of these other organizations could say, yes, we have multiple levels of certification. Organization A could come out with a five-level certification program or – like NCQA did with Medical Home, three levels of certification – and I think we just have to be really careful, because we're dealing with a marketplace – we're trying to drive adoption, and we're trying to get people who haven't entered to enter this in a simple and as understandable a process as possible.

I think that making sure that we simplify this is going to be important, so one thought would be to limit the number, to say yes, it's not just CCHIT, but it's going to be no more than three, and we're going to have some sort of competition. I don't even know what the process would be by which that would happen, but that there would only be three and they would be contracted or something to do this process, or are we going to have a completely open marketplace and there could be 10 or 12 different accrediting agencies popping up all over, all of them saying and being certified – all of them being accredited to certify EHR's, that they meet the HHS criteria.

Marc Probst - Intermountain Healthcare - CIO

We actually did not talk about limiting the number of accrediting organizations, and that's certainly something I think ONC could look at as they go through the process. We saw NIST as the organization obviously that's going to help – if they follow this recommendation – to go through and determine who could be the CCHIT-type organizations or the accrediting or certifying organizations.

As we talked about it – and it may be a bad analogy – but you can get your car, get its annual inspection done at any number of garages, if they've defined what it is that that car has to do – what it has to pass, whether it's emissions or whether it's brakes or whatever it might be. And if that criteria is well defined, it seems to me that it could be a broader range of people, and that's specifically why we focused on that criteria needs to be identical and it needs to be very specific. But no, we didn't talk about a limiting at this point.

Neil Calman - Institute for Family Health - President & Cofounder

Just a quick follow-up: I think the car analogy is a good one, but it probably oversimplifies.

Marc Probst - Intermountain Healthcare – CIO

Probably.

Neil Calman - Institute for Family Health - President & Cofounder

I think what the process is for this other stuff – I mean, people understand whether their headlights are out a lot better than they're going to understand whether their EHR meets privacy requirements and which organization is better doing it.

I think the other thing that we need to be careful of is that there's a good flow through this process so that it doesn't become a roadblock for people –

Marc Probst - Intermountain Healthcare - CIO

Absolutely.

Neil Calman - Institute for Family Health - President & Cofounder

-- and as this process gets rolled up and organizations are gearing up to do this, we just need to make sure that we balance that. Those are my comments.

Marc Probst - Intermountain Healthcare - CIO

Thanks.

Paul Eggerman - eScription - CEO

I actually want to make an observation. I think those comments are really excellent. I'd just tell you, one of the things we learned as we did this work is this certification thing isn't easy to do. In other words – I mean, I understand the fear or the concern that you're raising, but I have a concern that maybe nobody else will really want to do it when they realize how hard it is to do. So it's really hard to know how that happens. The role of the accreditation organization is to make sure that, whether it's one or two or ten, that they do their jobs right. That's the role of the accreditation organization, based on guidance that they get from ONC and also from NIST. It's hard to know – there is certainly some risk there. It's hard to know how that will work out.

David, can I just ask a question about that?

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

Sure.

Paul Eggerman - eScription - CEO

Is the Office of the National Coordinator going to be the one responsible for organizing the educational process around this, and outreach, or does that go somewhere else?

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

We are – everything is in process, but yes, we take it as our responsibility to communicate with providers and the public about this, and we are thinking actively about how to do that right now.

Just by way of perspective, there's another fairly complicated product that gets accredited and certified, and that's called the Medical Education. So we have a single accrediting organization that accredits medical schools, and it's actually run by the AAMC and the American Medical Association and seems to have worked pretty well. But it's not clear – and maybe this body could give some more thought – how a national coordinator would set a limit, and what the optimal limit would be, and how a federal rule would justify some number, as opposed to another number. Is two the right number, or is 20, or is 50?

Marc Probst - Intermountain Healthcare - CIO

I guess with medical schools, the answer was one was the right number. Maybe we're back to thinking that one is the right number.

Neil Calman - Institute for Family Health - President & Cofounder

One's the right number for the accreditation organization. Again, the difference between the accreditation organization and the certification –

Unidentified Male Speaker

Right.

Unidentified Male Speaker

Thank you for the presentation. As I look through the criteria, the candidate criteria, the emphasis you can see in privacy and security, and there are about 35 of those listed, there are only about five in the area of interoperability. And as the Meaningful Use workgroup gets back together to look at 2015 and 2013, I wondered if you had any recommendations for our group about how it might make it a little clearer for you, because you say here, “aggressively establish new and very specific requirements.” Have we given you enough detail yet in the Meaningful Use around interoperability?

Paul Egerman - eScription - CEO

That’s an excellent observation, because within Meaningful Use, similar to what we said about certification, we want to do things at a high level. As it relates to what you called the candidates for the criteria, those items are just that, they’re candidates, and it’s given to you really for informational purposes. This committee doesn’t really make those decisions or make any recommendations on that; it really goes to the standards committee. So it could very well be, though, that there should be more interoperability requirements put into that concept of a preliminary certification. I don’t know. But that’s a valuable observation.

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

Christine?

Christine Bechtel - National Partnership for Women & Families - VP

I have a question and a comment. My question is about interoperability, and I’m wondering if you can talk more about what you mean by interoperability standards. If we’re really focusing on how data moves, and therefore standards around the movement of data versus the content, and exactly what you put in that which moves. I’m a little bit concerned about the latter because I think that’s a little bit how we kind of got down this rabbit hole in the first place, but could you just talk more about what you envision in interoperability?

Paul Egerman - eScription - CEO

I’ll do my best. I was really talking about the standards themselves for the data exchange –

Christine Bechtel - National Partnership for Women & Families - VP

Does that mean, though, like the movement or the content, I think is what I’m –

Paul Egerman - eScription - CEO

It’s sort of like – the best way to describe it, it’s the details. It almost tells you what sequence the data needs to be put in, and where you can find a piece of information in a stream of data. The fundamental problem that we have right now is that the existing standards have too much flexibility. There’s like wiggle room, and different vendors put different data in different places. So when you go to do a – to exchange data from one place to another, you have to ask the vendor, where is this piece of information? Where can I find it? And you shouldn’t have to do that, so that’s one problem we have.

Another problem we have is there’s not uniform acceptance. Some systems just don’t follow what the current standards are, and so – and it has a huge impact on the marketplace. I could tell you as an entrepreneur, my second company, eScription, one of the challenges we always had when we went to install systems is, would the other system be able to interface through our system. Did they do interfaces according to standard, because the standard existed? If they used the standard, did they adhere to the

standard? This was like an obstacle to get people to use the system, and so it's a very mechanical process in terms of how it all works. So I don't know if I explained it correctly, and –

Marc Probst - Intermountain Healthcare - CIO

I just think – but our recommendation really stemmed from the fact that it's – there's such a lack of interoperability out there in the market, and I don't think we focused so much on was it the content of the message or the format of the message, but it was the fact that we need more focus, whether that's through Meaningful Use or whatever, to improve interoperability between systems. And I don't think – we didn't really dive into what would the actual criteria be to do that; just that we would like to see greater focus in that area.

Christine Bechtel - National Partnership for Women & Families - VP

I think what I'm suggesting is, based on your answers, is that we might think about, in the same vein that we have said sort of a principle for certification needs to be that it's not at the in-the-weeds level, that it is simple, it is cleanly tied to Meaningful – at that sort of principle level, we might also think about certainly – most immediately from a patient perspective, if we could facilitate the movement of data, regardless of sort of what the data is at a basic level, but getting data to just follow me, period, whether it's in a pdf or whatever. I mean, that's enormous, and we really – so I'm just worried that people will think about interoperability but dive down into describing what's on the piece of paper, so to speak, as opposed to, just get the piece of paper to go with me everywhere.

Marc Probst - Intermountain Healthcare - CIO

Yes, I think – and standards obviously is going to look at the real content of what's there, and I think we're going to spend this afternoon talking about the overall HIO's and what they're doing. But that's a great point.

Christine Bechtel - National Partnership for Women & Families - VP

Okay, and then I'll just make my quick comment, is: On the proposed definition of HHS certification, I'm not sure how the definition will be used, so this may be overly semantic. But I would just say there's this line that says that the system is able to produce the Meaningful Use results the government expects, and I think that one rubbed me a little bit the wrong way because I think it's really about the interaction between the clinician and the patient and the system producing the results. So you might just want to say something like, the system is able to support the Meaningful Use care goals and objectives.

Paul Eggerman - eScription - CEO

That's correct. I mean, when we talk about Meaningful Use, we're talking about things about patients and outcomes. When we talk about certification, we're talking about software. So when we say the system will be able to do it, we're really saying the software will have the capability to do it. It's similar to Deven's comment about privacy: If the system has the capability to implement privacy policy, that doesn't mean that you have privacy. It just means the ability to do it, right? And so the same is true of Meaningful Use.

What we're certifying is the product. It doesn't mean that if you buy the product, you automatically get Meaningful Use. It just means you have a system that would let you do it, would let you do whatever it is – the CPOE, for example. So that's a good point.

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

Roger, then David, then Judy.

Roger Baker - Department of Veterans Affairs - CIO

I'll dive in on interoperability here for a second, and pardon me for being late. If anything I'm about to say doesn't jibe with what we've discussed earlier, just ignore it. DOD and VA have at this point a tremendous amount of experience with the issue of defining what interoperability means. We are under a law that requires us to have interoperability between our systems by September, and we're spending an inordinate amount of time figuring out what – agreeing with the Hill what they meant when they said interoperability.

I think we did a very smart thing and had the clinicians define that. What does it mean for systems to be interoperable in such a way that it provides the clinicians what they need at the point of service. So I'd say lesson learned, number one, from what DOD and VA had is, as we define interoperability, it comes back to what's really going to be useful. And maybe diving down that path a little bit, what we found on the medical side is that for the most part, visibility into what's in the other medical record system is what's needed. PDF's work pretty well, with the exception of certain things like lab data, pharmacy information, and things that we've demonstrated, if you have any computable form, you can save lives. So from that standpoint I would encourage – and certainly we can lend all the help and all the expertise we've learned over the last ten years in doing interoperability between big health systems, for what things need to be computable and what things just need to be viewable. But I go back to, we had a clinician's committee do that definition for us, and I think that's probably the smartest move that we made along the path.

Unidentified Male Speaker

Very well put.

Unidentified Male Speaker

On this side, we would concur completely going down that road. And it's the end of September, not the beginning of September –

Unidentified Male Speaker

We'll just note that it's September 32nd.

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

Are we back in Y2K here? David and then Judy.

David Lansky - Pacific Business Group on Health - President & CEO

I think what you're all doing is really important, and I think we should be sober about how important this is. This is a policy process that you're undertaking, and you're putting in place or advising us to put in place durable long-term mechanisms that will affect a hopefully significant market. So the question of the federal role and the private role in certification is a really important one that I totally – I appreciate the approach you're taking, I think it's right.

But the questions Christine and others have raised about where the level of specificity should be, that comes out of a federal process as opposed to the specificity that may be generated through market behavior and valuation of different functions, is a very sensitive matter, and I – it's funny because Christine's edit to the committee charge is exactly the same word that I edited myself, which suggests to me that one thing we may want to do fairly soon is go all the way back to the beginning and write some kind of a short document out of the ONC process that lays out what is the policy structure we are advocating, now that we've plodded through as best we can, that says here's what we think the federal role is in this market, here's what the private role is, here's the role of certification. And the terms of whether it's support, the word here is "produce."

I think the Meaningful Use mechanism is a good way to address outcomes, but certification probably isn't an outcomes-oriented process. I think whatever the right answer is, we have to be more precise as we finish this phase of our thinking, and then articulate that to the public and to the market as to what the different roles will be. And I appreciate the subcommittee's conservatism in saying privacy, security and interoperability are the domains of the public role. But even in the interoperability space, because – an outcomes-oriented approach says, if I can access and use the document, I'm done. I don't need to stipulate a lot of processes internally to that at the federal public process level.

The market will continue to innovate ways to achieve the desired outcome, and so that's both a caution in terms of our process, but also a request I guess, that we come full circle fairly soon and try to write down what the policy direction is that has evolved from this discussion.

Marc Probst - Intermountain Healthcare - CIO

David, do you feel like the recommendations as they now – as they've been now formulated are a reasonable place to start, though, that discussion?

David Lansky - Pacific Business Group on Health - President & CEO

Yes, I appreciate them very much. I do have some interest in what we end up meaning by aggressive specification of interoperability, so – three times I think in the packet we have this phrase about being more specific on the interoperability criteria, and that's I think appropriate and important, but very unspecified as yet as to what that means. So that's the one I think where the action is.

I would just say, since you asked, throughout our whole day's agenda today, I think what has emerged to me is that interoperability is the place we really have to give a lot of attention in a crosscutting way. It's not actually siloed in these different subcommittees, it's a crosscutting challenge that we have to maybe rethink how we tackle it as a committee.

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

Ok. Judy?

Judith Faulkner - Epic Systems Corporation

Suggestion will be taken under consideration. When you look at certifying, and you're looking at what the system will let you do, suddenly I realized that when people look at software, different rating bodies look at software, some of them look at what the software will do. Some of them will look at whether anyone actually can use it that way. Those are really two different levels.

And just to throw out that although the certification may show that the software can do it, you might find that in fact that particular piece of software is never used that way because it's really not able to do it well enough. So I'm just throwing that out as a thought that, at a higher level some time we should look back on not only can it do it, but is it being used.

Paul Egerman - eScription - CEO

Excellent comment. I would make two observations. One is, when you go through the detail on recommendation No. 1, there is a recommendation that ONC examine possible ways to evaluate usability of these systems, so this is not something we felt we could address right now, but we think that it's an interesting issue.

I'd also make the observation, there was a reason why we limited ourselves to the Meaningful Use criteria, because presumably the measurements indicate whether or not the software really is able to do whatever it does. I mean, whatever it's supposed to do. I think your point is, you don't necessarily know, just because they passed the certification, whether or not –

Judith Faulkner - Epic Systems Corporation

Right, and that might be actually back when someone has assumed that it would be able to.

Paul Egerman - eScription - CEO

Yes. That's a good point.

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

We have Charles Kennedy on the phone, who would like to ask a question.

Charles Kennedy - WellPoint - VP for Health IT

Yes, thank you, David. This is just a follow-up comment on David – I think it was David Lansky's comment regarding interoperability. We're introducing this notion of modular certification which by definition increases our dependency on effective interoperability as well as vulnerability too. During the subcommittee we received testimony that two CCHIT fully-certified applications from leading vendors were not able to be made to interoperate despite a significant amount of resources, motivation, etc. So just to kind of follow up on David Lansky's comment, I think we need to kind of address interoperability in a bit more of a broader way. I don't think pdf's are a good technical foundation for us moving forward, and I think this notion of data liquidity or being able to separate the data from the application from the algorithms is something we need to take a closer and more focused look at.

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

I think that we're discussing issues that we'll probably be getting to this afternoon in more detail. I also would recall for everyone that we're not recommending a process that will be fixed in time, but one that presumably can change over time, and that something that we might consider interoperability in 2011 might not be considered interoperability in 2013.

Charles Kennedy - WellPoint - VP for Health IT

Fair point. I just want to ensure as we do that, we don't create blockages to getting toward that evolved state.

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

Yes. Connie?

Connie Delaney - University of Minnesota School of Nursing - Dean

Yes, thank you, David. Thank you for your report, Marc and Paul, and I too would like to follow up on the comment that was just made and originally introduced by Roger, the view computable options, and encourage us to keep in mind the evolution of the science of health and medicine, etc., and our ability to meet and measure our Meaningful Use criteria will be a moving target, and that has major implications for what we then consider acceptable as viewable, and of course we know we're increasingly empowered to accommodate more computable data.

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

Good point. Neil?

Neil Calman - Institute for Family Health - President & Cofounder

I wanted to just go back a little bit on one of the thoughts about the certification piece, which is that we're – and I think this also follows up on David's point about sort of the policy issues. I mean, what we've really been talking about are the policies that relate to people who want to get incentive payments, but I'm wondering what protections there are for a consumer that would go to a healthcare provider that has

chosen not to get incentive payments and who is using an interoperating – a system that has no certification or anything and no privacy and security. How would the consumer even know about that? So I think there's an educational piece – as long as we're only talking about incentive payments, we have two problems: One is we're only talking about policies that apply to people that want incentive payments; and the second is that our incentives payment system is going to expire in four years, and then absent any new legislation that comes down the road that sort of fills this gap, we end up in sort of a free-for-all where people aren't really protected in any way from being engaged in some sort of interoperable systems that don't meet those requirements.

Those are sort of – we have a now problem and we have a future problem, and I'm wondering how – what our thoughts are about those, or if we've had any yet. Maybe we need to have some.

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

Just as a matter of fact, there's a penalty clause that goes into effect in 2015, so the extent of financial effect actually extends until 2018. Gayle?

Gayle Harrell - Florida - Former State Legislator

As kind of a closing comment – I know we've kind of beaten this horse a bit – but the one closing comment I'd like to make is, what are the realistic time frames to achieve all this? Can we realistically expect HHS to come up with an HHS certification? Do we have the dollars to implement that? Are the rules and regs going to be written so that a vendor can be out there in 2010 or 2010.5, and have a product that people will be able to buy and implement in their facilities and practices to receive that incentive payment in 2011? Is this attainable?

Paul Egerman - eScription - CEO

I guess we think with our transition plan, we've answered that question. We've put forward a plan to do exactly what you're asking about. There is a group that can do the certification. There are vendors who are able to be certified. What's holding us back right now is waiting for the regulatory process to get completed.

Gayle Harrell - Florida - Former State Legislator

However, there are vendors – there are specialties that don't have certified software out there specific to them. And that presents a real problem for a lot of specialties who want to get into this, and there's not a product to buy, even with gap certification. Will there be a product for them to buy?

Paul Egerman - eScription - CEO

The answer is yes. The product to buy that will have the basic capabilities for things like drug/drug interactions and CPOE. Whether or not it will have those things that are specific to their specialty, I can't answer that. Again, the basic concept of what we're trying to do is be driven by the Meaningful Use criteria and say that is what we need to do. In this morning's presentation, I got the sense that the Meaningful Use group is going to start to address measurements related to specialties, and I think that how our Meaningful Use group addresses that, the ... relative to the specialties, will drive the certification process. That's how I would envision that occurring.

Marc Probst - Intermountain Healthcare - CIO

Yes, Gayle, and I think with the preliminary certification that we put out there, it gives you a lot of good material. And being from an organization where we develop our own software and we're not certified, and we know we have to get there, it has not been that big of a challenge to take what we understand today – even though it's a moving target – and align it and understand what we have to do to be certified.

So I think it's a very doable plan that we've put out there. Now, I can't answer whether ONC has the staff and those types of answers, but I think the process we're recommending is a doable process.

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

Yes, Rick?

Rick Chapman - Kindred Healthcare - Chief Administrative Officer/CIO/EVP

As a member of the committee, the only thing I want to keep reminding our group of, it was our intent not to endorse any specific criteria that CCHIT has in place today, but rather, to talk policy-wide about how we might go about this, and that we specifically separated the criteria from the certification, and we recommended that ONC then be the final authority, via the statute, to determine if that criteria was appropriate, and that for ONC and this process to be informed by this process.

And one specifically on interoperability, we're saying that once we understand more about what Health Information Exchange seeks to set as objectives, that then the standards committee then could be more specific. And we're asking and recommending that the standards committee be more specific in the area of interoperability, both on how the technical interconnectivity worked and the content, but only after they're more informed by this discussion. What we're moreover asking is that ONC then oversee with NIST assistance seeking an accreditor of the certifiers that would ensure a level playing field and consistent application of the criteria.

Now, the criticism that we received that we spent a lot of time talking about was, well, gee, it's going to take a while until we can get to that point, so can we give those who have participated in the process maybe a leg up to get started toward what will eventually be but only one certification, regardless of the transition period? Only HHS certification when it is available to be applied. In the meanwhile, this is trying to get as close to it as we can, to speak to the very issue that Gayle talked about, which is, for those people who do have systems available to cover their component or specialty group, that they can get started to meet the aggressive time frame, realizing some people and hopefully the marketplace will respond to the opportunity by those specialties that do not have systems to choose from. I hope that adds some clarification.

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

Christine?

Christine Bechtel - National Partnership for Women & Families - VP

Building on that, a couple things. One is, the Meaningful Use workgroup certainly, and I think the policy committee at large, has always recognized the need for every provider type to be able to see themselves in this sort of arena as much as possible, and I think we're getting there. I think we've taken great strides. I don't think it's okay to hold up the entire process because we can't be there right now for every single specialty.

I think you're right, Rick the market is evolving, it will keep evolving. But I also want to note that I think – and I'll probably have 10,000 e-mails after I say this, but that's okay, it won't be the first time – I think that specialists and primary care practitioners operate in a different pay environment. There is a broader payment environment in play here that does tend to reward specialists in a different way than primary care physicians; that's why the high-tech legislation prioritized primary care safety net providers and those who serve the under-served in the technical assistance element of the law. So I think we have to keep accelerating the progress that we're making to drive a market and support adoption by particularly those provider populations.

We have to keep our eye on specialties, we have to get there. We're doing the half-day hearing. But I think we are getting there, and I just want to caution that I don't think we can slow down just because we can't quite get to every population or subpopulation.

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

Paul?

Paul Eggerman - eScripton - CEO

Maybe to build on some of the previous messages, everyone recognizes that it's been an extraordinarily fast time line, and we're operating under constraints. I'd also like to observe, just as this workgroup has done, that all the workgroups have been very responsive I think to both public comment and comments within this committee.

To address some of the comments you made, Gayle, I think one of the things that came out of Meaningful Use recommendations was to use an adoption year, to try to help with the time pressures that all of the industry will face.

A second point is to reiterate what George said this morning, which is, the Meaningful Use criteria is under evolution. So for example, 2013 and 2015 and the vision for 2015 are being discussed now, and built into the process is, after the final rule comes out, to sort of reassess where the industry is. So in other words, the program is not baked in concrete; it is something that will evolve and will continue to be responsive not only to the comments, but what's happening to the industry. Because what we're trying to do is get the things out and use meaningfully, and we'll try to adjust the program as we go along to achieve those objectives, those overriding objectives.

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

If I could just draw people's attention back to the comments that Gayle made about the transitional period, I think that's where you were focusing a lot of your attention – what do we do now? How do we make sure this market continues to function while we're waiting for the federal government to go through a rule-making process.

I'd like to know if there are – and I think that the working group has given us a very thoughtful potential solution. I can't tell you whether it's workable or not because I'm not a lawyer, and this would all have to go through the scrutiny of our general counsel to see if we can in fact – if the federal government could do, even if it chose to do, what had been suggested. But let's leave that aside for the moment.

Do you see, Gayle, any particular problems with the suggestions that have been made as far as a gap or the interim certification approach? Do you think there is something in addition that should be done to try to meet the short-term needs that you've identified?

Gayle Harrell - Florida - Former State Legislator

I think that it's absolutely necessary to have a short-term solution. I think that solution has got to address just meaningful use criteria, whether you call it an HHS certification or whatever, so that individuals out there who have standalone systems, homegrown systems or whatever, can become part of this if they meet that very specific criteria.

My very deep concern is that we are not going to be able to do that, given the regulatory process. First of all, who is going to do that certifying? Is HHS ONC going to certify, going to accredit CCHIT to do that? They're going to have to stop what they're doing and focus on that, because every system out there and lots of other systems who want to get on board are going to have to go through that process. So there's a

whole process that, first of all the regulations have to be written to do. Then you have to have the body to do it. Then there's going to be a huge upsurge in the market. People are going to want to get into this market, and I think that's great. There should be good products out there for people to buy.

But then there's a whole decision-making process that people have to see what the market has for sale, gather the resources to buy it, and then implement it. Is it tenable to do this and have those products in place in 2011? So those regulations and that gap certification need to be as specific as possible.

So, those regulations and that gap certification need to be as specific and as simple as possible. That's contradictory perhaps, but the process of getting there needs to happen very, very rapidly.

If HHS is the accreditor at that point to CCHIT or whoever, that needs to be established that they're doing that. You have to realize the rest of the market is going to stop until that happens. And, vendors out there, smaller vendors in particular, have deep concerns about that I would think.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Any other comments? Are there any particular aspects of these recommendations that people would like to change, amend, qualify? We hear several general comments - the need for a definition of interoperability, the need for policy context, as David suggested; Gayle's concern, not ill-advised, about the ability to execute on a short-term transitional process. We can note all those. Except, perhaps, Neil's suggestion to limit the number of accreditors, I haven't heard any specific suggestions about changes in the recommendations that were presented to us.

Judy Sparrow – Office of the National Coordinator – Executive Director

There was the one suggested change to the definition of certification by Christine and David. There was a one word change that I heard.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

Could we repeat that just so we're all are aware of what it is?

Christine Bechtel – National Partnership for Women & Families - VP

(Inaudible) that the system is able to support the meaningful use results that the government expects.

Unidentified Female Speaker

So, changing the word "produce" is important.

Unidentified Male Speaker

But, I heard another language, that the system will have the capability to achieve.

Unidentified Female Speaker

...Interaction. So, it's to support...

Unidentified Male Speaker

So, you would change the word "system"?

Unidentified Female Speaker

No, "produce."

Unidentified Male Speaker

So, you would like it to read, "HHS certification means that a system is able to support the minimum."

Gayle Harrell - Former State Legislator - Florida

I put issue with “support.” “Support” is a different kind of word. It doesn’t give the impact that “achieve meaningful use.” Do you want the achievement of meaningful use? Supporting is very different than achieving.

Christine Bechtel – National Partnership for Women & Families - VP

Just to be clear, I think my point, Gayle, was just that it’s not the system that achieves it. It’s the provider, clinician, patient. And so, that’s all I’m ramping to is we might say that the system is able to support their results, but the results should come from, in my view anyway, the clinician and the patient working together with the system to get to the results.

Mark Leavitt – CCHIT - Chairman

So, let me wordsmith and suggest a compromise. What we’re specifically saying is the system should be able to support the achievement of the meaningful use results the government expects.

Unidentified Male Speaker

That’s in very simple terms what we were trying to imply is that the system could do it. Whether or not you did it is up to you, but the system could do it. So, however we want to change those words. That was the intent and we weren’t trying to imply people in it.

Unidentified Male Speaker

Yes, you made a comment as your first activity in the public federal government as opposed to my first one and always interested in how much attention is sometimes spent on this one or two words. But, I do understand that these documents have importance and people read them very carefully.

Picking up on what Mark said; certainly our intention was simply that the software is capable and perhaps that would be the solution. Where it says “is able to produce,” we ought to say “it’s capable of producing the meaningful use” or “achieving the meaningful use.”

Unidentified Male Speaker

Or “capable of achieving.”

Unidentified Male Speaker

“Capable of achieving.”

David Blumenthal – Depart of HHS - National Coordinator for Health IT

Yes, David.

David Lansky – Pacific Business Group on health – President & CEO

I don’t have a wordsmithing contribution, but I have a question. The first phrase of this kind of addresses the government requirements for security, privacy, and interoperability. The second phrase addresses the meaningful use results. It doesn’t limit that to the first three categories, subsets if you like of meaningful use. My concern is that I don’t think we’ve said here- I don’t think the subcommittee has recommended we address certification of the functional capacities to address all the meaningful use criteria. That is, you’re not recommending government to certify the ability to report HbA1c of 8% as a particular output, even though that’s in the meaningful use criteria.

So, without doing the wordsmithing here, I think we want to—

Unidentified Male Speaker

Everything but the 8% we would want to certify.

Unidentified Male Speaker

...Capable to do that.

Unidentified Male Speaker

Right.

Unidentified Male Speaker

That's different from this statement about security, privacy, and interoperability. What I'd like to clarify here is whether the charge to this committee and for certification as a process, to Mark's point, does address all of the meaningful use objectives, or just those that pertain to security, privacy, and interoperability.

Unidentified Male Speaker

It's all.

Unidentified Male Speaker

The idea was there are two things. Security, privacy, and interoperability is one thought. Meaningful use is the second thought. Those are the two things that the system has to be capable of doing.

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

So did we have agreement on language that said "A system," Jodi, did you write down that, "is able to support the achievement"? I think that seems to be— Is that okay?

Jodi Daniel - Office of Policy & Research - Director

It's the second phrase. I have the "System is capable of achieving the meaningful use results."

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

I think Roger's language was—

Roger Baker – Department of Veterans Affairs - CIO

"Support the achievement."

Jodi Daniel - Office of Policy & Research - Director

"Support the achievement of"

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

"Support the achievement."

Roger Baker - Department of Veterans Affairs - CIO

"Support the achievement of meaningful use."

Jodi Daniel - Office of Policy & Research - Director

Okay. I had both written down.

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

With that amendment, "Is able to support the achievement," unless there are other comments, I'd like to move that the Committee accept the recommendations of the working group on certification of adoption. Paul?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CIO

I apologize, but the first phrase “system is able to achieve should it fulfill the requirements.” Systems don’t achieve. The people do. It’s the same kind of point.

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

I think the language is “able to support the achievement.”

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CIO

So, is that in the first phrase too, the first line - “Is able to support this”?

Jodi Daniel - Office of Policy & Research - Director

Yes.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CIO

Okay. So, you’ve replaced both of those.

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

Yes. So without objection, the Committee will adopt those recommendations. Thank you very much. Good work.

Okay. We’re actually running a little ahead of schedule and what I’m going to suggest is that we start our break early and come back earlier. I’m sure that everyone would like to work late into the Friday afternoon, but I’m not going to let us fall prey to that desire. So, assuming lunch is 30 minutes; so back here at 12:15.

All right. Ladies and gentlemen, can we reconvene. Sorry we’re running a little late. So, we have another in our stellar group of workgroups and every one of these issues is really hard. Every one of them takes us to the edge of what we know and sort of let’s us peer into the future and requires that people leave their comfort zones and think about a future state that is full of uncertainty. But, all we can expect in that context is that people think really hard and carefully and give us their best advice. There’s no question that all the working groups have been doing that and the federal government and the American people are deeply indebted to them.

Deven and Micky, you met with us last time or you reported to us last time and we gave you some thoughts. I know you’ve been working hard on those. So, we’re looking forward to your report.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Thank you to the Committee. Let me just begin by thanking the workgroup who have been working very hard and also, let me give a special thanks to my co-chair, Deven, who managed a difficult process through some tight time constraints while I was traipsing around Montana on two weeks vacation. So, let me give a special thanks to Deven for managing that.

Deven McGraw - Center for Democracy & Technology - Director

I’m going next week.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

So, this is the workgroup and as I said, I’d like thank all of the members of the workgroup who have been hard at work at helping us sort of thrash through some of these issues.

Let me begin by just telling you what our recommendations are going to be, and I’ll do it just very, very quickly to orient us and then what I would do is walk through some of the considerations that we made

along the way to those recommendations and then hand it over to Deven who will go in detail into the recommendations.

So, we have four recommendations very quickly. One is that there ought to be health exchange requirements related to meaningful use criteria that require Health Exchange. So, that's number one - that we believe that there ought to be Health Exchange requirements related to that.

Number two, we believe that there is a core set of requirements that they need to meet in the areas of interoperability, privacy, and security. It's very consistent with what you heard from Paul Eggerman and Mark's group. We are completely aligned on that, but we believe that that would be the case.

Third, we believe that there ought to be certification of interoperability components to demonstrate that they are meeting those requirements. So, that would be EHRs that have interoperability components, as well as introducing the possibility of other product sets that can meet from a component perspective the interoperability requirements.

And then fourth, we believe very strongly that we need to have alignment between the federal and state requirements. Generally, this would be true around meaningful use, but specifically related to Health Information Exchange so that we don't have disconnects between meaningful use requirements related to Health Exchange for Medicare, from the federal level, and then have state Medicaid requirements that are in conflict with that.

So in a nutshell, those are the four recommendations that we're going to come to. Let me know walk through some of the background, some of the backdrop and some of the considerations we made along the way and then I'll turn it over to Deven, as I said, to elaborate on those.

So first, just speaking about the state of Health Information Exchange today, I won't go through every word of every slide here except on this point to just say that Health Information Exchange occurs in the market today, but penetration is extremely low and non-uniform. I think we've covered that point in the last meeting. So, unless there are any questions I won't sort of belabor the point except to just reiterate - I think it is worth reiterating that it does indeed happen today and we are making slow progress, but it is very, very slow progress. Even in the areas where it happens the most, like ePrescribing, the penetration nationally is something on the order of 4% of eligible prescriptions, according to Surescripts, were transmitted electronically from roughly 12% of potential prescribers.

So even in the areas where we think we're doing well, we're actually not doing that well.

Unidentified Male Speaker

Sorry. Just make one exception - that's outside the federal marketplace.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Yes, absolutely.

Unidentified Male Speaker

The statistics are vastly different between the federal organizations at this time.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Yes. I wouldn't disagree with that. So, what are the barriers that are preventing the market from moving forward on Health Exchange? The main barriers to Exchange today, and these are not in any priority order here. We're just listing these, but there is certainly around legal and liability issues as it relates to

Exchange. There are a lot of things to figure out with respect to privacy, security, and things like that; a lot of variation across the states as we know, which makes that a significant barrier.

Too little business and clinical imperative to exchange more information. There does not appear to be enough at the point-of-purchase, enough perceived value among those who would have to conduct health exchange to go through the pain of doing it.

Then finally on the benefit side, finally on the cost side; too much technical and organizational difficulty of setting it up and maintaining business and clinically relevant electronic exchange related to standards, certification, a wide variety of things that we talked about.

So, it's our sense that getting over these barriers require some combination of incentives and penalties to help increase business demand, a set of actionable standards, which is somewhat aligned with what we've been talking about earlier around stricter standards around interoperability and then finally, monitoring and enforcing mechanisms to ensure adherence to standards.

We haven't talked that much, I think, today about that and we're not going to talk that much in the presentation about that because I think that's probably something we need to give further consideration too, but I think an ongoing concern that I would have is that standards aren't enough around things like— You can have standards. You can have certifications, but at the end of the day, being able to monitor that those transactions are actually happening according the standards in a routine way I think is fundamental to their happening.

In the stream of the workflow on a day-to-day basis being able to monitor that a particular institution or a particular system is out of standard I think is fundamental. I would just point to administrative transactions right now which are enforced by Medicare, for example - ICD9, CPTs. Every single day, they get millions and millions of these transactions and they will in a second report any code that is in violation of standard codification.

Now, take a look at lab results delivery, most of which happen from community hospitals. There is no entity, monitoring entity that is in the stream of lab results delivery from a community hospital to a physician. How would we even know that an HL7 transaction was modified in some way to accommodate some unique local need let alone being able to sort of monitor it and enforce something going forward? So, I think that would be a big concern. But as I said, we're not going to cover that here. Huge important concern.

So, that just leads us to the point that if implemented judiciously, we as a workgroup believe that our funding can help create a value proposition for Health Exchange, which I think is fundamental to this. How do we get a value proposition for Health Exchange that's not only about just meeting requirements?

I think Neil's comments earlier sort of are fundamental here as well, that we don't want to have a system where people are doing things just for the time period that they're getting an incentive and only the ones who are getting a particular incentive are doing it. What we want to be able to do is create something that's more fundamental and foundational that will have the entire market move towards the types of things that we're talking about here.

So, some combination of lowering the technical organizational legal costs as depicted here, and/or raising the clinical and business imperative for more exchange is sort of what we would see as being the orchestration of some of the levers that AARA provides to ONC and to the federal government to be able to sort of accomplish here.

Obviously, in looking at that cost benefit, sort of stylized representation there, right now, we would argue that there are too many institutions that see the costs as outweighing the benefits there, which is why we haven't moved forward for too many of those institutions.

So, when you think about the levers that are available to the federal government, certainly things like certification, grants to states, Regional Health IT Extension Center funding, and NIH governance are all examples of things that can help to lower the difficulty of Health Exchange and in effect, kind of lower the cost of being able to exchange.

While on the other hand, the incentive payments for meaningful use in AARA are an opportunity to raise the business imperative for it either because there's a sense that it's a business need - it's essentially a cost of doing business going forward - or also because of the opportunity of real incentive coming to someone - being paid a rather substantial amount of money to do what we're talking about here.

So of these tools that we just talked about, it's certainly our sense that the meaningful use incentives are the most powerful lever of change that we have here and it's certainly in part because of the huge disproportion in the amount of money that we're talking about here. In the incentives category, it's \$45 billion roughly of the \$47 billion that are now estimated to be a part of the HIT spending here.

The other point is that it directly affects the value proposition at the point of purchase to the extent that these are incentives that are applied right down at the physician level. So, you're talking about decision making at the point of purchase, which is the strongest leverage you can get.

Now obviously, ONC doesn't have the ultimate decision making on incentive criteria, but they can create enablers for robust incentive criteria that would allow CMS to create more powerful incentive rules, which is where we would see sort of the orchestration around some of the things that ONC does have some of the discretion over that can help and enable CMS to have sort of a stronger set of incentives and stronger rule making around this than they might otherwise be able to do if that foundation wasn't there.

So as we look then at those meaningful use criteria, having sort of decided that meaningful use criteria are really where the levers are going to be, we've called out from the meaningful use matrix just a representation. We may have missed one or two here, but tried to call out which are those requirements that have Health Information Exchange as fundamental to there being a requirement that we would talk about as something that could be fulfilled.

As you'll see, when you think about what's going to happen in 2011, 2013, 2015 as the matrix is currently constituted, starting in 2011, there's an appropriate ramp up obviously because we need to have a ramp up. If we were going to characterize the 2011 requirements, they're essentially about increasing the volume of transactions that are most commonly happening today. So, ePrescribing certainly happens today. Lab results delivery certainly happens today. Claims eligibility check certainly happens today. So, the incentives are around trying to put more through the pipes that are already essentially there.

But, once you get to 2013, there's a substantial step up and that's where we're really starting to talk about a fundamental change in the way we talk about healthcare delivery because it's essentially saying that we need to have not only lab-to-provider, but provider-to-lab and clinical entity-to-clinical entity for clinical summary exchange. As patients go through a continual of care, making sure that the records are starting to follow them all the way through, which I think in a sort of viscerally you can image that if we're able to accomplish even some subset of that by 2013 would really change the complexion of healthcare delivery.

If we were able to accomplish a lot of that, from a patient perspective, they would see a difference. They would really see a difference.

Then finally, 2015 is really getting to the anyone-to-anyone, starting to assume that maybe we have almost a platform or a tipping point where you can start to assume that exchange is happening and now we just want to make it more and more rich.

As we think about the work ahead for our workgroup, the consensus among the workgroup is that the work ahead is now about providing policy direction around the requirements for each one of these transactions. That's the work ahead. We're dependent on, obviously, the Meaningful Use workgroup to define what those are. And so now for the work ahead, it's for us to provide that detailed policy direction; some of what Christine was alluding to in the earlier conversation about when do we get to those details and how we're going to define those details. That is the work ahead.

Obviously, we'll start with 2011. You saw Paul and George's time line for when meaningful use is going to be sort of contemplated in their work plan, and we're really going to be following that. So in third quarter of 2011, really starting to focus in on the 2011 requirement in addition to privacy and security because those are going to be fundamental and there's long lead around that. There's a lot of conversation that we're going to have to have around consent, other aspects of privacy, as well as security. So, those will start.

But then, around 2013 and 2015, drilling down into those, we'll essentially be following the path of the Meaningful Use workgroup, which as you saw in the fourth quarter of this year and the first quarter of next year is when they'll be digging in to provide more specificity around those and we'll essentially be tracking that as those start coming on that committee.

The final slide here in terms of the backdrop, before I turn this over to Deven, was a consideration. So, we've kind of walked through what is the state of Health Information Exchange today, what are the barriers that are preventing us from moving forward, what are the levers available to the government to try to increase demand for Health Exchange; walk through a little bit of how the incentives seem to be the most powerful ones and how we would propose that we have to drill down a little bit into those, but recognizing that that's really where the action ought to be and then finally, a consideration of how deep do you go. How do we think about the government's role in the market and what is that appropriate balance?

You'll see here at Spectrum, and we have, of course, been savvy enough to make sure that we define the extremes so that our reasonable sort of recommendation is in the middle there. But, there's a spectrum of government intervention in all seriousness. On the left hand side, you can imagine that meaningful use right now as it's currently defined in a way does sort of set the floor in that it is kind of requiring specific transactions. It is essentially saying that by 2013, what you need to exchange among entities and essentially from whom to whom. It's saying that hospitals have to send information to physicians; physicians have to send information to hospitals. You have to send it to the next point of care. It is specifying that. It's saying what has to happen.

So then, the next question is how far do you want to get into how that has to happen, which is, I think, what our workgroup is about. So, the next step up would be for each one of those transactions that have already been defined, what might be the standards for communication, content, privacy, security; just to jump ahead for a second. That is what we would define as the categories of the core requirements. Obviously, we then drill down into specificity around that, but that's what we define as the categories.

You could take it another step to then say that the requirements are also going to be about specific technologies or specific architectures or specific organization forums by which this would have to happen. So for example, saying that these transactions, in order to meet meaningful use requirements, have to happen through a specific HIO or have to happen through a NHIN node, for example, would be the example of that kind of taking this one step further.

It was our sense that the balance that we want to strike here is certainly not to have too little structure because we believe that that wouldn't resolve some of the significant barriers that we've already pointed out are barriers and that we can't really live with today.

On the other hand, the workgroup feels very strongly that too much structure will absolutely stifle innovation by locking in what exists today and also by artificially channeling product development towards specific technologies and architecture, which is exactly what we don't want to do, particularly in such a fast moving area as technology.

So with that as backdrop and as thinking of the workgroup, let me then turn it over to Deven to elaborate on the recommendations.

Deven McGraw - Center for Democracy & Technology - Director

Okay. Thanks, Micky. I appreciate it. Micky went over these really quickly before, but now they're actually in front of you. You'll recognize many of them. I know we started to introduce these concepts really when we were before you last month, but there were a lot of questions that were raised at that time and there was a need just to go back, continue to think about this, answer the question of how much federal intervention is needed and why, and maybe to provide a little bit more detail to the extent that we could in the time allotted.

And so, essentially, here is where we are and here's what we hope the policy committee will endorse today and that there needs to be core information exchange requirements that are technology and architecture neutral that are going to apply to all participants who are seeking to demonstrate meaningful use to CMS.

Consistent with the recommendations of the certification workgroup, these core requirements should be focused on the capability to achieve meaningful use subject to whatever wordsmithing we came up with before. We'll take a friendly amendment on that one; capability to achieve meaningful use and include interoperability, privacy, and security. Again, there are some common themes being set forth here where because we're the exchange workgroup, we sort of focused a bit more on those, but certainly to achieve capability for meaningful use there's going to have to be other requirements in place too.

Federal government should certify electronic health records and health information exchange components on these core requirements to ease the burden on the eligible professionals in hospitals for meeting and demonstrating adherence with the meaningful use requirements. Again, there's, thank goodness, a consistent thread of what we're saying here among the workgroups.

Then the last point is that federal and state government approaches should be complementary and any grants to states that come through, of course, the grant program, and we'll get into some details about Medicaid that are aligning really well with Tony's comments. So, we're pretty happy about that.

It should require alignment with federal meaningful use objectives and measures. Of course, with the caveat that nothing is official until it's official. Okay. We got it. Just taking it under advisement.

Unidentified Male Speaker

Even then, it's not....

Deven McGraw - Center for Democracy & Technology - Director

Fair enough. And so, what follows in these slides is just a little bit more detail on these recommendations, why we think they make sense. Really, if you're going to set criteria that all systems and components have to meet, then your doctors, your other eligible professionals and hospitals will then have a choice about what model of exchange they want to use while they're still qualifying for their meaningful use incentives.

So, if they want to buy a complete EHR from a vendor and rely on some form of direct exchange or whether they are looking to participate with their local organized exchange - RHIO, HIO, HIE, however you want to refer to them - or through some sort of national network such as the ePrescribing network. Again, if there are a consistent set of standards that all of the component parts and systems need to meet, then that choice will be there and we won't be locking in specific architectures. Again, these would be the same standards applying throughout, at least with respect to some core exchange criteria.

Systems that don't need to be certified or are not seeking to be certified would still have a tremendous market incentive to adopt those standards because they will want to be able to exchange data with entities that do have to meet certification as well as; there's a certain limit to where these policies, even powerful policy tools go. To the extent that we can cover a substantial part of the market through what we have in our hands, the rest of it will follow because they'll need to do that.

And again, consistent with where the certification workgroup recommendations came out that we endorsed today, it really needs to be tied to the capability to exchange, to meet, or achieve or support meaningful use criteria in 2011, again, with a clear pathway to more robust exchange in 2013 and 2015.

Again, I think as Micky pointed out, while the actual exchange requirements might be fairly minimal in 2011, we're talking about ramping them up considerably in the very near future, that systems that the providers get today are going to really need to have the capability to support that over a very short period of time.

Again, these core requirements really need to be focused on what is the exchange that's required to meet meaningful use, and that, of course, includes interoperability, privacy, and security. As Micky pointed out, again, the next step really is to take those meaningful use criteria and figure out what is really required to make sure that the data can be exchanged.

So, what do we mean when we say "interoperability?" I think people probably have very different definitions as to how expansive that definition is. But certainly, what we agree on, at least at this particular phase, is that it's a basic level of, you can call them either transport standards or communication and then the sort of package that has to go around the data, and then, of course, whatever content standards are necessary to ensure that exchange can occur to be capable of meeting meaningful use.

So certainly, a top priority ought to be the transport piece of this because the idea is if you're going to create technologically and architecturally neutral exchange requirements, the ability at a minimum to be able to move human readable, at a minimum, data between points of care has absolutely got to be a top priority.

Similarly, taking a look at the measure definitions and whatever semantic standards are going to need to be required for the clinical data that has to go with the reporting that's required in 2011, as well as on the

perform side. And, this gets to the point that Micky made in a much more articulate way earlier about if you're going to set these criteria, you really need to start with the outcome that we're trying to achieve and work backwards and figure out what is needed.

But at a minimum, what is consistent is transport. Data is to be able to move from point A to point B in a way that people can actually read. Computability, whether it needs to be structured data, in what circumstances do you need it to be structured I think is a whole additional set of issues that I think the Policy Committee really ought to weigh in on and give guidance to standards so that then those can be developed.

Before I leave this slide, meeting the requirements of current law with respect to privacy and security, and those that are enacted in AARA that will soon be current law - those should definitely be a priority, as well as, and we didn't say this on the slide, but I'll take the time to say it now, what Dixie Baker refers to as the AARA-8 - the sort of priorities for standards that have to be addressed by ONC before the end of the calendar year that have policy implications embedded within them that will need to be resolved before specific standards could move forward.

Okay. On this issue of the federal and state interplay, it is our feeling that states have the authority to impose state-level requirement on information exchange to establish any state level meaningful use definition. But, any such requirements should be complementary to federal efforts.

To qualify for meaningful use, again, information exchange that occurs within a state, of course, needs to meet the federal requirements. They shouldn't be allowed to fall below that with respect to their own requirements, but certainly with respect to whatever discretion they're given by CMS with respect to the Medicaid criteria. That's discretion that we would support. Again, this is a decision that CMS will make, but our concern was that whatever the state do promulgate, that it be consistent with what's at the federal level, that it not be conflicting.

We actually made this line of this slide, Tony, before you even suggested that perhaps one way to think about this might be that the federal definitions would create a floor that then the states could go above with respect to whatever additional requirements they're going to put on their state Medicaid incentive recipients, but certainly not fall below.

So, I will; oh, I forgot about this part, and this is very important. We got a lot of feedback from folks who had some confusion about some things that we said about certification and HIOs, RHIOs, sort of organized health information networks and we wanted to take this opportunity to clarify what our recommendations are with respect to that.

We are not recommending a separate certification pathway for HIOs with separate HIO standards. We are, however, recommending as we said, and as the certification workgroup has also recommended that health information exchange components be certified, again, using the same standards that are applicable across the board regardless of the format, whether it's a comprehensive EHR or a collection of components brought together by the provider.

So, one role that HIOs have played in the past and may continue to play in the future as well as other technologies - those supplied by EHR vendors and even new technologies that probably we can't imagine here at this table, but there are probably some folks in the back of us that are making them up right now as we speak - is the ability to provide the components that will actually enable this heterogeneous system that we have that is not like the federal government where it's sort of more under one roof to be able to actually exchange data. Now, I think we are done.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

I'll just note there that the federal government is very heterogeneous.

Deven McGraw - Center for Democracy & Technology - Director

Okay. Well, it might feel heterogeneous to you all who are in it, but it looks awfully homogenous to those of us who live in the private world.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

I think we define "heterogeneous."

Unidentified Male Speaker

We wanted to give you the benefit of the doubt.

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

Thank you. Like all our presentations, these are a model of clarity of thought and expression. So, thank you very much. Questions? Comments? Yes, Rick?

Rick Chapman - Kindred Healthcare - Chief Administrative Officer/CIO/EVP

Once again, a great presentation by your workgroup and lots of good work. It's a very challenging area. One point of clarification I'd like to have is given the fact that you have combined the verb and the noun definition of health information exchange and stated very articulately, one set of standards for information exchange should exist.

As you made the comment pertaining; the deliberation you had between government role and how much two structured versus none and this balance you're trying to seek, one of the things I'd like to understand your thinking on is, is it your assumption that every access or trigger to authorize an exchange of an individual patient's record is given by the patient via HIPAA regulations? I mean what triggers and what tells an institution to exchange data, and my understanding and our implication seems to be from HIPAA. Is that your thinking?

Deven McGraw - Center for Democracy & Technology - Director

The next thing that we will take up are details around privacy and security. I'll answer you on what is the state of the law today with respect to patient authorization.

Certainly with respect to what HIPAA requires, it does not require patient consent before data can be accessed, used and disclosed for treatment, payment, and a list of activities called healthcare operations. That's regardless of the format in which that data is moving, but it's not limited to paper. In fact, it was promulgated to enable electronic exchange of data for claims payment purposes.

So having said that, there are state laws that are not preempted by HIPAA and a number of states do require some form of patient consent before data can be accessed, used, disclosed. Sometimes it's based on the type of data. Particularly sensitive data tends to merit some special treatment and the SAMSA folks will kill me if I don't say this. Of course, at the federal level, and with respect to federally funded substance abuse treatment facilities, there are some very specific authorization requirements with respect to that data. I think it underscores the challenges that we need to consider with respect to moving forward in this space.

The other thing is in addition to the law, there are voluntary policies that institutions and some of these networks have established that have to do with building the trust of the patients in their communities. So,

a number of them, for example, that I'm aware of have adopted policies whereby the patient has to opt in to having their data exchanged through a formalized network, or the patient has the ability to opt out. This is the classic opt in or opt out debate. There isn't a set federal policy along those lines, although folks from ONC may add. I know there was some work done on this with respect to the NHIN grantees and some continuing work going on in that basis.

So, a long-winded answer to say that there's a place where the law is today where except where the state law requires it federal law doesn't necessarily require patient consent for each and every movement of data. However, again, it's an issue that people raise frequently. It's one that we really ought to consider, especially with respect to whether there's an enhanced role for it and what should that look like as we're increasingly interconnecting these systems in a really robust way. Jodi, I don't know if you want to add any—

Jodi Daniel – Office of Policy & Research - Director

I think Deven did a fabulous job of articulating the state of play. This is an area where also, I think, Deven articulated where the state of the law is. This is an area that NCBHS has recommended that HHS look at policies regarding opt in/opt out or some hybrid of that. It is something that we are planning to take a look at and that we would hope to talk with the HIE workgroup about in thinking through some policies.

Unidentified Male Speaker

I would just add as a matter of process, we're also talking about that, as I said, starting right after this, privacy will be sort of one of those things that we're going to really dig in on and bringing the latest state of the HISPIC was around that and possibly having gone through the workgroup to get formal approval at the workgroup of this. But, we almost certainly, I think, have public hearings around this as well. I'm sure it'll be very spirited.

Unidentified Male Speaker

I wanted to have a follow-up to say that only to the aspect of your presentation that did that deliberation about how much government intervening can require interoperability and I just wanted to know, I guess, from the workgroup standpoint if our workgroup or your workgroup is going to take that on and recommend somehow implicit in that will be what triggers and what authorizes an institution or a provider to share data with another.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

So, to recommend federal preemption, for example? Is that what you're asking?

Unidentified Male Speaker

Well, I mean my point was you said you were deliberating that and it's going to have to be rationalized or harmonized with the privacy laws. One thing I wanted to make sure is that as we go forward, we kind of say what we in our policy committee can kind of address and what has to be in the realm of the rest of other groups to deal with outside it. We don't want to be in conflict with it.

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

Adam was waiting and then Gayle.

Adam Clark - Lance Armstrong Foundation - Director for Health Policy

It actually follows-up a lot on that. Kind of what stuck out to me and first, thank you, all, again, for putting this together. This workgroup, I think, out of the three is probably the closest to the patient. It did kind of stick out that patient control, what wasn't; it's in here a little bit, but I don't think it's pulled out as a unique point. When I say "patient control," I look at that as different from privacy and security.

As we're looking at 2013 and 2015 when we're starting to get exchanges with the patients, particularly 2015 where it may be patient-to-patient— I think, at least in my opinion, we need to start in 2011 with at least in the core requirements getting some recommendations from the workgroup to the policy committee about what patient control is going to be for their own electronic medical records outside of physician-to-physician or hospital-to-hospital.

So again, just to get it in the minutes and encourage the workgroup to really think about this one. Thank you.

Unidentified Male Speaker

Can I stop— Adam, is that a comment about the meaningful use criteria not addressing that, or about whether we addressed how we're going to address the meaningful use criteria around patient results.

Adam Clark - Lance Armstrong Foundation - Director for Health Policy

I think probably the latter. As I would see it, HIE and patient control should go into what meaningful use is. Part of meaningful use probably should be patient control over this information, but I look to the workgroup to try to develop the policies, the recommendations under some of those core requirements.

Deven McGraw - Center for Democracy & Technology - Director

Yes, I'm curious why you think it's somehow distinct from privacy, but you've definitely put your finger some really hot button issues and ones that we'll deal with. We would welcome your input.

Adam Clark - Lance Armstrong Foundation - Director for Health Policy

Okay. Did you want me to answer that?

Deven McGraw - Center for Democracy & Technology - Director

Let's leave it for - yes.

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

Gayle, we're trying to get to you.

Gayle Harrell – Florida - Former State Legislator

Yes, trying to get through. I want to go back to the basic issue under all of this. It comes down to that privacy and security and the patient's concern about privacy. I think that is probably the core issue here that we have not talked that much about. I really believe that in the long run, in order for us to be successful as a policy committee and to have what we feel is very, very important, that every patient in this country has electronic health records, you have to engage patients.

This is where I talked with David about this and we've talked with our group about it. This is where I think we must hold some public hearings in order to really, really get down to this core issue and that is, how secure is a patient going to be in that interchange, that exchange of their private information. I think it's essential that we listen to the public, we listen to the patients on this, and I've made that recommendation and I hope we're going to follow through on that.

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

Neil?

Neil Calman - Institute for Family Health - President & Cofounder

Could you put back the slide, your cost and benefits slide? I want to make a specific recommendation about that.

To me, we're always weighing cost and benefits, right? The opposite side for me of the privacy and security concerns is the extent to which consumers see a benefit in the exchange of information. I think in your green bar, we ought to have in there the consumer imperative, which is the extent to which there is some consumer-facing, consumer useful piece to the exchange. That's part of the benefit. I think that's the piece of the benefit that balances partially the privacy and security thing.

So, people are worried about privacy and security because we haven't really sold them on what the benefits are of this exchange to them. I think a very huge piece of this that I've mentioned before is their ability to see everything that's being exchanged, their ability to vet that information to make sure it's accurate. I think that's some of the stuff that Adam was talking about.

It does go beyond just the privacy of the information. Is it accurate? Is it relevant to the care? Is it relevant for this individual provider who I'm seeing right now? Do they need to see everything, or do I only want to share a part of what I'm sharing? I mean there's a lot of complexity around this, but I think we should add that into the green part because I think that's a big part of what we need to be pushing in order to sort of move this forward.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

I don't disagree, Neil. Just so you don't think that we're ignoring or neglecting that, this was particularly about what it looks like from the perspective of an individual physician or practice who was making the determination tomorrow how much do I want to invest in exchange, not about the societal benefit or cost of that.

Neil Calman - Institute for Family Health - President & Cofounder

When you say "value proposition," to me that has a much broader sense. The value proposition of exchange goes beyond that. That's why I think it's relevant. But, I don't need to edit this slide. It's just a point. I think it's something we don't pay enough attention to as one of the things that could beneficially drive this.

For example, in the database model, one of the things that I've been reading about is the extent to which the consumers really value this. They actually provide some of the ongoing business value and contribute to the cost of the continuing exchange. And so, if we're just looking for the business model of it, one of the business models would be to sell it to consumers and make it so valuable that people would give a couple of bucks a month to have their data securely stored somewhere where they would have control over it, access to it, and all of the other pieces. So, I think that that's just part of the discussion.

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

Jim and then Roger.

Jim Walker - Geisinger Health Systems - Chief Health Information Officer

Yes ... Micky. I want to congratulate you for what I think is a really good prioritization of these three issues in terms of interoperability, security, and privacy because, the fact is, until we can interoperate, the concerns surrounding security and privacy are minimized. You know, typically we're dealing with a one-to-one rather than a one-to-many situation.

And I would also say that in terms of identifying standards as the key to interoperability in terms of the transport and the content because until we have meaningful data to share, we have not achieved meaningful use. So again, I think there's a lot of work that needs to be done. I'll point to Roger's comment earlier this morning in terms of allowing the clinicians to determine what data is meaningful to

them in terms of coordinating care and managing transitions in care, and then turning that information over to the standards body, so both the standards committee, as well as the standards panels to identify specifically what data.

But, again, as a final comment, I will say that your point that whatever interoperability standards are established, that they should be architecture neutral and technology neutral, I think is one that will facilitate adoption and will facilitate interoperability. It will also complicate governance.

Roger Baker - Department of Veterans Affairs - CIO

I have a question that's kind of a concern, and a couple times today we've talked about certified and uncertified systems. And in this, we're talking about HIOs and potentially uncertified system, and certification including security and privacy certification.

My worry in the information exchange network sort of world is that right now when we exchange information with someone in EHRs, we have an information exchange agreement. We know what we're going to exchange and how they're going to protect it. And in fact, right now we're wrestling through with a lot of our partners, issues with getting them to agree to the security constraints VA must have on information we provide to them about our patients.

In the many-to-many world, if you're going to provide information to the Net on the patient, you have to know that whoever is receiving it is authorized to receive it and will protect it in such a way that you're conveying your responsibilities in that world. And so when we talk about uncertified systems in a health information exchange environment, I become very worried from the standpoint of what can I let go of and what can I not let go of from an information exchange standpoint. To say it very bluntly, if I don't know that everybody on that network is approved and will protect the information to the extent that I'm required to protect it, I can't participate.

Deven McGraw - Center for Democracy & Technology - Director

You know, I mean, here's the thing. We have policy levers that we can apply to some of the actors in the system, but we don't have the magic wand that says everybody must be certified. I mean, we just don't. I mean, at a minimum, everybody has to comply with the law, but we know that the law gives some flexibility with respect to particularly security requirements in some areas, and you all have very specific security requirements that you have to meet.

The point we were making there with – you know, there's a limit to how far we can get with some of what we're recommending because these policy tools don't apply. Labs is one of the examples that has come up in our discussion. You want the labs to be able to at least accept the same standards, but we're not certifying labs. They're not eligible for financial incentives.

However, all of the providers that want the financial incentives and who want to be able to exchange, receive the lab data and move it on to another provider, where that's appropriate, are going to want the labs to do that. So some of that is going to have to be resolved with data use agreements, and some of that we can resolve with the law, but we do have a limit with respect to what – and that's all we were illustrating there. We were not necessarily suggesting that that was an ideal set of circumstances, but just a recognition of limitations.

Roger Baker - Department of Veterans Affairs - CIO

Maybe really the comment really is as we look at the broader information network to make certain that we have standards about what data protections have to be agreed to by every member of a network before the network can join the network of networks, or something along those lines.

Deven McGraw - Center for Democracy & Technology - Director

Well that's, you know, there are other tools beyond certification that ONC has in the toolbox.

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

David Lansky, then Judy.

David Lansky - Pacific Business Group on Health - President & CEO

Again, I really appreciate the direction we're going in. I took two lessons from what you said today that may apply to other work we're doing, such as the meaningful use piece. I think the recognition that no matter what we do with standards and certification, data won't move until the users want it. Until I want to receive data from someone over there, it's not going to move.

And that really goes back to the question of the incentive structure that we can stimulate to create more pull across the network, which will actually make some of the other things easier to do, like certification will be easier if there's a huge demand to set standards and achieve goals. And the incentive money, we have some influence over, by itself may not be visible enough to create that pull at the moment. Part of what I'm thinking we should take back to our subcommittee is how do we – I really like the slide you did that took out the three, 2011, 2013, 2015 measures that so far create that draw across the network.

Can you go to that one? And in looking at that, it makes me think we perhaps haven't done as much work as we need to in 2013 and 2015 to amplify the signal to the market on the interoperability and data exchange issue. And as I was thinking about things like readmission rates and duplicate test reduction and so on, which really call for data sharing across parties. I hope we will take your report back to our subgroup and think harder about what are the opportunities there to increase the incentives is what I keep thinking. How can we do that?

And the second thought along those lines is what opportunity do we have or does ONC have to communicate to the private payer market a set of signals to amplify that message again, so in California where there's an IHA pay for performance system, for example, which has a lot of influence over some medical group behavior, and we could go back to groups like that and say, how do we marry the signals that are on a chart like this to other pay for performance systems so that we really get the value out there to everybody to start sharing information with each other for the patient's benefit. Otherwise, everything else we're doing here may just kind of lie fallow.

The third thing I just want to mention just is really a question to you. How have you thought about the role of your subgroup and us as a whole in communicating to states HIE strategic direction? I'm thinking of it because Paul and I are both working in California on the structure of the HIE in support of the ARRA funding. And the many, many issues we're wrestling with, without a lot of guidance coming from outside. And I don't know whether there's an opportunity in our process here to take some of the discussions you're having and propagate them to the states so that they can build whatever they're going to build in a way, which facilitates effective adoption of this over time.

Micky Trapathi - Massachusetts eHealth Collaborative - President & CEO

When you say HIE, do you mean HIO?

David Lansky - Pacific Business Group on Health - President & CEO

Well, I won't...

Deven McGraw - Center for Democracy & Technology - Director

They've adopted our ... terminology here.

David Lansky - Pacific Business Group on Health - President & CEO

I don't mean HIO. I mean HIE facilitated by HIOs.

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

Jodi.

Jodi Daniel - Office of Policy & Research - Director

Since this is an advisory committee to ONC, we obviously will be administering state grants regarding health information exchange, and we'll be having a couple of mechanisms for providing guidance to states with respect to those grants. So I think we can take some of that input and that suggestion from you, David, and to the extent there are some issues that you all think we need to bring to the states, we can use one of those mechanisms to do that. We currently have ... for eHealth that the National Governance Association is managing for us, and that's a vehicle that is ongoing now that we could use as a lever if there's some input that's coming to us from this committee that we think will be valuable to the states to have a forum to bring that issue up.

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

Two microphones away from you is Tony Trenkle from CMS, and CMS is going to be writing regs with respect to meaningful use and Medicaid, so there are a lot of ears perking up.

Tony Trenkle - CMS - Director of OESS

That's right.

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

Judy.

Judy Faulkner - Epic Systems - Founder

Yes. I have three topics. The first is the incentive money. What we're finding around the country is that it doesn't matter what the incentive money is. The real barrier is the legal concerns, and our customers are not who are not jumping on. They're sort of doing it because their lawyers and their other advisors are much more worried about legal, and I don't think the money matters as much. And so, I think, first, we have to make sure that we do get those privacy laws figured out because then, as long as they know them and can follow them, they'll be in much better legal shape.

Also, along with that, I think with the incentives, we do have to look at what is sustainable over time because if we start up now and support systems, they need to be sustainable, or we're going to leave people in the lurch, or we're going to have huge government funding to sustain things if we don't figure that out ahead of time. There are a lot of different technologies out there. If we settle on one, and it isn't sustainable, we've got a problem down the road. That was one.

Two is on states. If we say that what we're doing now is the floor, and the states are welcome to add things to that floor, if we end up with states with contradictory state laws, we will have a huge problem with interstate interoperability, and we have to be careful of that.

The third thing goes to what you were saying, Neil, and that is that you're saying the patient's ability to see the information being shared and decide what's relevant. I know of someone who fiddled with his PHR that he could send to his physician, and he changed some of his lab values. Now what does that mean to the physician who can't tell that that was changed? Will the physician make bad decisions in the

person's treatment because that was done? What does withholding or misleading do to that record and to the physician and healthcare organization treating that patient?

And the other side is, what does it do to the patient who wants to be able to say, please hide the fact that I have diabetes or that I have MS or that I have congestive heart failure, and so you hide the diagnosis, but you, as a physician, know that you can see simply by the tests that were ordered what they're looking for. You can see by the results, the meds. What do we do with an allergy if information is hidden? And we know that there's going to be a drug/drug interaction that's going to harm that patient. What do we do then?

Do we violate the privacy and say, don't give this? You're going to hurt the patient. Or do we not violate the privacy and let the patient be hurt? So I think those are deep questions that go into that patient's ability to do things, both on – you may really jeopardize your care. And, two, we may not be able to do it anyway. There's so much that's threaded throughout that record.

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

Yes. Christine.

Christine Bechtel - National Partnership for Women & Families - VP

That's a huge issue, and I can't begin to address that in a comment, but I will say I'm looking forward to the hearing that we'll on patient supplied information because I think it does touch those things. But I actually also want to come back to what Neil said, and I want to reinforce what he said, and also just ask that as we go forward with these recommendations, which are terrific, that we bring in the perspective of patients and families.

One of the things that sort of jogged that for me was the recommendation phrasing that talks about having standards apply to all participants seeking to demonstrate meaningful use to CMS, so it's very provider centric, which is appropriate. But what's interesting to me is we completed a series of focus groups with patients and caregivers this week, and we asked them to talk about their pain points in the healthcare system. And everything we talked about was about information and about coordination, and it was things like, I have trouble remembering all the prescriptions that I'm on, and how do I make sure one doctor knows what the other one is doing? All the stuff we hear about.

We threw at them a number of solutions, all the solutions du jour: ACOs, Medical Home, HIT, and HIT was the one that I think they most clearly grasped and understood. And the reason I think they saw the most value in it, and this was the most interesting to me is that when they talked about the information and coordination challenges that they experience in the healthcare system, these patients didn't see it as a failure of the system. They saw it as a failure of themselves. That's enormous. And so as we think about information exchange, and the potential for patients to be part of the solution and better managing their own data, I just want to make sure that we're always coming with that perspective of the utility of information exchange to patients, of course with all the privacy and security protections, which is part of what makes it meaningful to patients, but that's an important perspective, and so I just want to be on the soapbox here for a minute and remind folks.

Deven McGraw - Center for Democracy & Technology - Director

We definitely had that in mind. They look more provider centric in the slides because, in fact, the incentives don't go to the patients. They only go to the providers, but that's why we were clear that the meaningful use criteria and the capability of meaning, and so to the extent that we're pushing very hard to have meaningful use also include that patient loop and that patient perspective, that then drives how the

criteria will allow that to happen because the provider is such a central part of that, and is the one getting paid.

Christine Bechtel - National Partnership for Women & Families - VP

That's right. I agree, and I think we've done a good job overall really making sure that the patient and families are center and that we use the meaningful use incentives, which are absolutely geared toward providers for obvious reasons, as a mechanism to drive patient and family engagement, and that's critical here.

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

I think, Neil and then Rick.

Neil Calman - Institute for Family Health - President & Cofounder

I just wanted to mention another part of sort of the pull, and one of the things that I've been concerned about is the clinical utility of the data that's presented to providers and how we're going to create the intelligence around making useful clinical data out of an increasingly large portfolio of what could be PDFs and all kinds of years of accumulated clinical stuff.

Then you have a gastroenterologist who is about to do a colonoscopy who just needs a very limited summary of stuff, and that view is different than the dermatologist who is looking at a rash, and that view is different than a cardiologist who is about to do some invasive cardiac procedure, and that there's some real intelligence there. And one of my concerns is that while we're talking a lot about sort of the mechanics of the exchange and how that happens, we really haven't engaged in the discussion of whose responsibility it's going to be to make useful information out of the data.

And so when I speak to Judy, Judy says, you know, well, the – and I don't want to put words in your mouth, but that the EHR vendors have some responsibility as they pull this in to create some intelligence around that, and that might be, but that might not be universally what's happening. So while I think we've been worrying about passing this stuff back and forth, what I'm worried about is we're going to pass it back and forth, and somebody is not going to – people just aren't going to use it because the extent to which that information, the amount of that information that's going to be relevant in any given clinical encounter is going to be small, and somewhere the intelligence has to be built to go through that extreme library of information and make something useful out of it. So that's one point.

And I guess the question around that is who are we contemplating is going to actually engage in that activity, and how might that happen, because I think that's part of your value proposition was clinical, and the clinical utility is really going to be how closely we can get a representation of that data for a particular provider.

Then the second point I wanted to make was just around that state and national models. To me, if we're saying that one of our values that we're subscribing to at a national level is that we're not being technology specific, then I would put into our requirements, or I would suggest that CMS put in their requirements that that be brought down to the state level because I think to the extent that a state adopts a single model, in effect, they're violating our federal guidelines that basically say that we believe that multiple models should flourish.

For example, if patients in a particular neighborhood don't think that the particular exchange that's in their neighborhood is providing value to them, they ought to be able to go outside of that, go outside of the state, do whatever they want to do to somehow enter into a national exchange of information, but not necessarily be locked into one place. So I guess the question is, are we subscribing to that not being

prescriptive about the technology as a national policy recommendation? And if so, then I think we need to drive that down to the state level, so we don't end up saying at a national level, we believe there should be lots of choices. But it's okay if a state subscribes to only one particular model, and everybody in that state, therefore, has to be part of that model.

Micky Trapathi - Massachusetts eHealth Collaborative - President & CEO

Well, I guess, I would just say that nothing that we've recommended would preclude a state from deciding that, for example, for California deciding that meaningful use around interoperability, as it relates to interoperability has to be conducted through this network in our state because that's our state network, as long as the state network met the interoperability requirements that we're talking about, which I think is—

Deven McGraw - Center for Democracy & Technology - Director

For MediCal, for Medicaid.

Micky Trapathi - Massachusetts eHealth Collaborative - President & CEO

Well, right, for Medicaid, exactly. And nothing that we've said would preclude that. I think it's a fair point for you to raise as a point of discussion, but we didn't specifically preclude that.

Neil Calman - Institute for Family Health - President & Cofounder

I guess I'm suggesting that we might want to consider precluding that because, in a sense, it does go against both on the provider side and on the patient side, a possible choice of wanting their information exchanged through a different technology that they might either feel is more secure or might be more patient friendly, and so that's the reason I brought it up, so for your consideration.

Deven McGraw - Center for Democracy & Technology - Director

I want to respond to a point that you made earlier about the sort of what I'll call the gobbleby book of information. I think this is a process where we're not going to be able to dictate it down to the extreme level of detail when we get started. I mean, as it is, far too – we have too few instances of at least the data moving, even in a less than perfect content format.

Certainly, hence why we wanted to make sure one of the top priorities was at least allow the data to move, even if, in some cases, in a lot of cases it's not as structured as we'd want to be. Then we ought to be progressing to a system, as it evolves and it innovates, to one where the physicians and other professionals are getting the data that they need to actually make the treatment decision really in a quick manner.

But the content standard aspect of this is one that is, you know, I've heard it described as Holly War. I've heard – you know, lots of people have really strong opinions about it, and I think that there are some difficult decisions that will have to be made about when do we need specific content, because I think it's like to differ with different types of transactions, and when are we not quite ready for that because to do so would in fact violate our principal of being sort of technologically and architecturally neutral to allow for innovation and some margin.

We didn't spend a lot of time talking a lot about standards content, so I don't want to go too far down this road in terms of where the workgroup was able to get with what is presented in our presentation today. But acknowledging that a lot more work has to be done in this area. There's a role for the policy committee to play. There's an extremely high interest among the members of our workgroup because we had a really robust discussion about it at our last meeting in trying to be more helpful on this issue, but I suspect we're not the only ones.

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

Rick?

Rick Chapman - Kindred Healthcare - Chief Administrative Officer/CIO/EVP

Yes. I'd just like for a minute maybe to revisit the decision to combine the definition of health information exchange in the verb definition and in the noun definition because it seems to me, as we've had – as I've listened to the discussion around the table that we've interchangeably talked about a state health information organization and interchange between providers and mixed the discussion. And it seems to me that it's somewhat confusing.

Micky Trapathi - Massachusetts eHealth Collaborative - President & CEO

Can I just...? Because I know you've said it before, and I wanted to just make sure I understand. Are you saying that it's your interpretation that we have combined those?

Rick Chapman - Kindred Healthcare - Chief Administrative Officer/CIO/EVP

Yes.

Micky Trapathi - Massachusetts eHealth Collaborative - President & CEO

Because we haven't. We've actually broken them apart.

Deven McGraw - Center for Democracy & Technology - Director

When we say health information exchange, we mean the verb. The only time we mean an organized structure, we use the term HIO. In all of our recommendations, the specific ones we've laid out today have to do with exchange as a verb.

Rick Chapman - Kindred Healthcare - Chief Administrative Officer/CIO/EVP

Okay. Then in your, I think your last page of recommendations was that you're not saying that you like to have ... have a separate certification criteria. Was that right?

Deven McGraw - Center for Democracy & Technology - Director

That's right, and that was more to clarify some misunderstanding from our last presentation where folks thought that that was indeed what we were suggesting.

Rick Chapman - Kindred Healthcare - Chief Administrative Officer/CIO/EVP

Again, I would just....

Deven McGraw - Center for Democracy & Technology - Director

You're not the only one. Don't worry, Rick.

Rick Chapman - Kindred Healthcare - Chief Administrative Officer/CIO/EVP

Endorse that because it's confusing in the discussion, and I guess I would just endorse that concept and validate it for you, and then as we might, maybe a suggestion as we go forward, as we seek more public comment and segregate the discussion, it might help to clarify some of these questions, I think, that we're hearing.

Deven McGraw - Center for Democracy & Technology - Director

Yes.

Rick Chapman - Kindred Healthcare - Chief Administrative Officer/CIO/EVP

That would be my observation.

Deven McGraw - Center for Democracy & Technology - Director

I started using the little v and the little n.

Rick Chapman - Kindred Healthcare - Chief Administrative Officer/CIO/EVP

Right. Thank you.

Micky Trpathi - Massachusetts eHealth Collaborative - President & CEO

Yes. Just to clarify, we're not – so in saying that, by breaking it apart, the recommendation applies to the verb and not the noun. That doesn't mean that we are recommending that the government not do that. We're just saying that we are not here recommending that the government do that.

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

Paul and then Roger.

Paul Egerman - eScription - CEO

Thanks for a very articulate presentation. Let me ask, as part of HIE, we've been talking a lot about the technical data exchange standard and certifying the technical exchange components. My question then is, should we also be considering interoperable policies and potentially be more prescriptive because, as part of your definition, you said we're going to allow direct exchange, allow vendor hubs, etc., and have them be compliant with these technical data exchange standards.

It bears a little bit on what Roger asked. If I'm going to join, or I'm going to encourage my patients or share my patients' data on this in this exchange, don't we need to, in addition to protecting and securing the exchange of data, don't we need to protect the data as it flows around? So I guess, how can we say should we join as a provider group, a supplier of data, and how safe is it to join if we do not have interoperable policies? Should that be part of the mix? Should we be more prescriptive on the interoperable policies as part of HIE?

Micky Trpathi - Massachusetts eHealth Collaborative - President & CEO

Yes. It's certainly worthy of more conversation, and we had conversation about that within the committee, and I think where we started to sort of step to the line and then pulled ourselves back was where those very quickly get into architecture, specific architecture considerations. So if you look at that sort of spectrum, I think there was the sense that, as you start moving there, you start to dictate architectures, and so we backed off a little bit. Now that may not necessarily be true. As I said, it may certainly warrant further conversation, and we'd love your input and others on that.

Deven McGraw - Center for Democracy & Technology - Director

The other thing that we talked about was whether certification, which looks at technical functionality, is the right vehicle for enforcing what are essentially policy requirements, and we ultimately came to the conclusion that certification is not a great vehicle for enforcing what should be good policies for networks as a noun to use, much less even exchange that occurs in a direct way.

We do know that there are some other tools that ONC has to use to set up some sort of overarching policy and business considerations that have to be taken into account. One is through the grant program, and the other could be through any criteria that they might establish with respect to ongoing work with NHIN, as well as law.

Paul Egerman - eScription - CEO

To clarify, but policy interoperability, you mean setting policies that are required of organizations in order to exchange information or be licensed or whatever the lever is.

Micky Trapathi - Massachusetts eHealth Collaborative - President & CEO

Yes, and the analogy would be what Tony said about the federal being the floor. So if you think of how NHIN will go out, and how it's governed, and the policies, those might be the floor for any HIE regardless....

Paul Egerman - eScription - CEO

I just would cautious us against HIT semantic imperialism. If we start talking about the reconciliation of policy as making them interoperable, we're going to leave most of the political science behind, so we're talking about setting policy. Is that what we mean?

Micky Trapathi - Massachusetts eHealth Collaborative - President & CEO

Yes.

Paul Egerman - eScription - CEO

Yes. Okay.

Micky Trapathi - Massachusetts eHealth Collaborative - President & CEO

But it may be that as we consider those other levels, that ... governance would be when the workgroup takes that up as an area of recommendation that that's where that would come up.

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

Did you want to say something else, Paul? Okay. Roger.

Roger Baker - Department of Veterans Affairs - CIO

Back to Neil's comment here for a second: I'd like reinforce, Deven, to start with, what you were saying with a very simple phrase, which is, the perfect is the enemy of the good. Scanned images flowing today between users would be wonderful. I know when I go to see my doctor because of past history, and I've seen the same doctor for a long time, he's got something like this. I doubt he reads every page of it, you know, when he looks at the thing, and so we're going to make small improvements as we go along.

The second thing is, from long experience, one of the things that I think is interesting, and we need to remember, is that it's important to separate the data from the presentation. If we do that, we leave a lot of room for innovation by the EHR vendors for what they could do exactly to Neil's point, to make that presentation very, very useful. And so one of the things we need to remember is that what we do will have a tremendous impact on a lot of things we have no concept of relative to innovation. And we want to make certain that we don't preclude innovation by something that's very prescriptive in the beginning, and so from that standpoint, and from a vast amount of experience, I would say, make certain we separate the data exchange from the presentation that's there, and we'll let innovation really flourish from that standpoint.

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

Yes, Gayle.

Gayle Harrell - Florida - Former State Legislator

I also want to follow that thread and say the same thing happens with how that exchange happens, not just the data. We don't want to preclude innovation in how exchange happens, and that's why being architecturally neutral is very, very important, whether it is through the noun HIOs. We want to make sure that the verb HIE happens however it happens, if it happens that way. Whether it's a state kind of entity, whether it's an individual RHIO, or a hub through a vendor or something like that. I think we want to keep

everything as neutral and as open as possible to facilitate as much of that and innovation within those systems to take place.

We don't want states to set a whole lot of rules that preclude various things. We don't want the federal government to set those rules and be prescriptive. We want to allow open innovation.

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

Arthur.

Art Davidson – Denver Public Health

Yes. I want to follow on to what Paul was mentioning before about these policies that need to exist to assure an environment of trust for exchange. And you mentioned earlier in the presentation about the work of HISPC, and I wondered. Maybe you could comment a little more about that.

Then, Deven, when you said that maybe certification is the proper method, I mean, we talk about certification of interoperability to components. Might we say somewhere along this certification that you have policies that are supporting that interoperability and maybe even the meaningful use group needs to go back and figure out how to assure that level of trust in one of the measurements that we make, that an HIE is responsible for that and insuring that the partners within an HIE are adhering to that over time.

Deven McGraw - Center for Democracy & Technology - Director

Yes. I hadn't even thought about whether there was room within meaningful use to make this happen. It's just, you know, what we did discuss was whether certification, which again looks at technical functionalities that exist in either EHRs or components, and again, their capability to allow for the exchange that is required by meaningful use and all of the other functionalities that are required to accomplish meaningful use, that that can actually happen, as we've discussed a fair amount today whether it actually does or not. It's dependent on some of these other variables that can't be addressed by exchange.

We'll have to give some more thought to whether meaningful use is the way to do it or whether there's some other vehicle for doing so, but I think we all recognize that you're just checking off one of many boxes when you say, well, the technical pieces are in place.

Art Davidson – Denver Public Health

Right. I think the components are just not really enough here for us to say, we've got an environment where people are willing to share their information. Mick, maybe you could comment back on the HISPC reference you made.

Deven McGraw - Center for Democracy & Technology - Director

Yes. No, we actually want to hear from – our workgroup is going to get more information from that group, who has been working, over several years, to look at barriers that might exist within state law to exchange of data, and that project has been ongoing for quite some time, and I think we just need to get up to speed on sort of where their work is and what they've been doing, so I can't really comment in detail on it, only to give a nod to that effort and to say we need to incorporate it in what we're doing. Jodi can give more detail.

Jodi Daniel - Office of Policy & Research - Director

...the person who has been responsible for that effort in ONC.

Deven McGraw - Center for Democracy & Technology - Director

I should have let you answer the question.

Jodi Daniel - Office of Policy & Research - Director

It's okay. We've had, I think, now 42 states and territories who have been looking at privacy and security policies and laws, and the variability on how those laws and the variability might affect health information exchange within the state, as well as across states. The last phase that we had of this project was actually pulling states together to come up with some common approaches and solutions and suggestions for how to deal with some of these issues, some of which have started to be implemented, and some of which still need some more work.

There was a lot of discussion. There were actually two workgroups, two collaboratives, I'm sorry, that were focused on consent issues, one of them looking at the variability across states, and we actually will be coming out with a report soon that does the 50-state loss survey on all of the different consent laws across the states and shows where there's some commonality on where the differences are, which we'll have on our Web site. I don't know exactly when, but in the next couple of months probably, if not sooner.

And then another group that was looking at how do you deal with the fact that there is variation. Congress has not made any decisions to preempt state law, so we do have a federal floor with state variability on top of that and how we might be able to bridge that. They came up with some – they listed a couple of different approaches, model laws, compacts. I've heard some discussions about having HIEs in regions working together. There's a couple of different interesting ideas about how you might bridge some of that variation, and so I think there's a lot of good thinking, some suggestions, and some things that may be further along than that that could help in your thinking.

Art Davidson – Denver Public Health

Thank you.

Jim Borland - SSA - Special Advisor for Health IT, Office of the Commissioner

Jodi, if I could follow up on that comment. At Social Security, obviously we have interactions with each and every state, and facilities, healthcare facilities in other states, and I'll also mention, not to get too granular, but there are 148 healthcare facilities around the country that have their own release and clearance forms processes that go beyond even the state requirements. So that's a challenge that we deal with every day, and so harmonizing the state rules will get us so far, but ultimately and, Arthur, I think this was your point is that to create an environment of trust, we must develop guidelines that everyone can live with, even the healthcare attorneys.

Jodi Daniel - Office of Policy & Research - Director

Good luck with that one.

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

Let me ask again whether anyone would seek to modify any of these recommendations at this point. If not, whether there'd be any objection to accepting them as recommendations to the Health Information Technology Policy Committee. I think that's a ringing lack of dissent.

Deven McGraw - Center for Democracy & Technology - Director

We'll take it.

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

Thank you very much, and we anticipate your continued work on the issues that have been raised here.

Deven McGraw - Center for Democracy & Technology - Director

When I get back from vacation.

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

Yes. It's not Montana though, is it?

Deven McGraw - Center for Democracy & Technology - Director

No, it's not Montana.

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

We're ahead of schedule. I don't know what's wrong, but I don't know if we have people here from the standards committee. Pardon?

Judy Sparrow - Office of the National Coordinator - Executive Director

Jamie is in the room, and I think the other three are on the telephone.

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

Okay. If I can get a hold of my agenda here, Jamie is the first up, so thank you, Jamie. We're now going to get comments from the standards committee, and obviously we've been adding to your workload here, or anticipating what you're going to be doing anyway. Maybe that's better.

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

Right. Exactly. Hello. I'm Jamie Ferguson. I have a relatively brief presentation here, and should serve to further keep you ahead of schedule, I think.

What I'm going to do is I want to review the standards. We talked about this last time that we presented. This is a different, probably more easily understandable summary format of our standards recommendations that we're making for the standards required for the 2011 measures, both for certification and certification according to these standards could enable applicants to achieve meaningful use from the use of these capabilities in their systems.

I'm going to talk about our primary standards and then the framework within which we're making these recommendations. I'll just do a very brief review. Generally, we found that many of the standards that have been harmonized and specified by HITSP are useful for the 2011 meaningful use measures. In particular, the clinical document architecture of HL-7 is very useful for structured documents. Also HL-7 version 2.5.1 is very useful for the more traditional messaging where that's needed.

We found that the continuity of care document was appropriate for summary records, and then NCPDP Script for prescriptions, X-12 for the administrative transactions. I don't think there are any real surprises here.

Moving to the vocabulary recommendations, we find that for clinical problems and procedures, SNOMED CT is our primary recommendation for drugs. RxNorm, UNI, the unique ingredient identifier for allergies, with the exception of medication allergies. Lab tests would be identified by LOINC with uniform units of measure through the UCUM and administrative terminology through the implementations of the HIPAA standards.

The key concept that I really want to talk about though is that it's going to take longer than between now and 2011 for many applicants to implement and to get to the full use of these standards. Therefore, we're recommending these standards for definitive implementation for the 2011 measures in 2013. We're also

then recommending a specific number of alternatives that should be allowed for 2011 meaningful use, and examples of that are unstructured documents, free text or PDFs, so long as they have the appropriate CDA, XML header on them.

We've also found that there are a number of legacy implementations, and so there are a couple of primary reasons for really needing to consider this delay. In the first place, we've discussed in the workgroup that we don't want to place an undo burden on any implementer and, in fact, there are implementers who have implemented some of these legacy standards who have yet to get value from their implementations, and so we felt it would pose an undo burden for them to make a switch after having just implemented something else. And that they could meet the intent of the 2011 meaningful use measures by using their current implementations while taking longer time to transition to the standards.

Then, at the same time, many IT projects just simply take longer than two years in order to provide – to be cost effective and so as not to interrupt or disrupt operations, clinical operations. And so for all of these reasons, we felt that the 2013 definitive implementation of these standards for the 2011 measures was a recommendation that would not provide – not place an undo burden on any applicant.

We do have a couple of remaining issues. We found that a couple of the standards that we wanted to recommend weren't quite ready yet, and for one of them, we have an alternative that we're recommending for the quality measure submissions. We find that the XML standard that's being used for PQRI reporting to CMS through registries is a recommendation that's in process right now. We're still vetting that. We expect to be able to recommend that. And then we're still working on the public health data exchange recommendation where the CDC – CDC's method called GIPSE, we found was not quite ready to be recommended.

Our next steps with the standards committee are to move forward with this revised documentation of our recommendations, which we think is a lot clearer. We got a lot of input saying that it was hard to understand what we were saying, and so we think we've written it better. But the recommendations fundamentally have not changed.

We've also gone through with the help of the clinical quality workgroup. We've identified the individual data elements that are in each of the measures for the quality reporting in 2011, and we've recommended standards for those. So those are the basic things that we're still working on, and I'd be happy to take any questions.

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

Roger.

Roger Baker - Department of Veterans Affairs - CIO

...I didn't understand, so just to clarify. On slide four, we're talking about things from the 2011 standard not allowed, but in 2013 including free text PDF images, documents.

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

Right.

Roger Baker - Department of Veterans Affairs - CIO

That's a limitation we've got wrestle around, or that's a plan that we're thinking is going to--?

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

The plan is to use structured documents in the CDA format as the standard. But we found that – we thought it would place an undo burden on implementers to require that immediately for 2011, and we found that there are these alternatives where people could produce images of documents and exchange them and so forth, and put a CDA header on it that would be acceptable for 2011.

Roger Baker - Department of Veterans Affairs - CIO

And 2013?

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

And not for 2013, so we felt that the standard that we're recommending is CDA structured documents, period. But because we found that it would place an undo burden on implementers to get to that standard by 2011, we're recommending that these alternatives be allowed temporarily only.

Roger Baker - Department of Veterans Affairs - CIO

Do we – in the committee, do you have general agreement that people can get away from free text PDF and other images by 2013?

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

That is our feeling, yes, by 2013.

Roger Baker - Department of Veterans Affairs - CIO

Wow. I would disagree with that. I think that's very, very, very aggressive.

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

Well, the gist of our conversations and our consensus in the committee are that if we say now that this is a 2013 requirement, we feel it's reasonable and does not place an undo burden to get there.

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

So we're not – we don't have to take a position on these right now, just for everyone's information. The standards committees will make recommendations, and the ONC will then have to react to them. Gayle?

Gayle Harrell - Florida - Former State Legislator

Yes. On the medication, the units of measure on medications, are you taking into account pediatrics? When you do your dosages, and you're handling dosages on a weight basis of the child, do you have the capability? Does this standard, the unit of measure, have the ability to do that?

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

Yes, absolutely.

Gayle Harrell - Florida - Former State Legislator

Because I know that has been a real concern for a lot of our pediatric folks. And also, I wanted to know on the summary when you're talking about the meaningful use requirement of an encounter summary or a patient summary, you're going to use – your recommendation is to use the continuity of care document?

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

Yes.

Gayle Harrell - Florida - Former State Legislator

This opens the door on the whole meaningful use conversation that we've had many times when we've come to what is a clinical summary. We have to be very careful about what that definition is because that

– what a summary in normal terms when you think of a summary, you’re thinking of a complete clinical summary of what has gone on for that patient, including history. Whereas for an individual practitioner, if you’re seeing – if an ophthalmologist is seeing a patient, it’s a very different summary, so that continuity of care, would that be specific to the specialty as opposed to the general clinical summary?

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

Is your question asking whether we are going to have different summaries for different specialties? Is that what the--?

Gayle Harrell - Florida - Former State Legislator

What is the summary, as opposed to there’s a real difference in what that summary is depending on the specialty.

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

Jamie?

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

Well, I would say that certainly there can be different content. This is a specification that has sections for, for example, medications, allergies, immunizations, and so the content of each of those sections may be different for the different specialties, but the basic structure of the standard and the vocabularies that would be used would be the same.

Gayle Harrell - Florida - Former State Legislator

The structure would be the same, but how it is applied, for instance, I don’t know many podiatrists that really make sure if you’ve had your mammogram, you know, in your clinical summary.

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

Well, that’s true, so whether that part of the summary is populated or not and is required or not is a policy that would be out of our purview.

Gayle Harrell - Florida - Former State Legislator

I see. Thank you.

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

Paul, then Arthur.

Paul Egerman - eScription - CEO

Yes. Jamie, I have a question. I guess it’s on slide three where you’re recommending SNOMED. My question is, for billing purposes, you really have to use ICD-9 and soon ICD-10 and CPT. So won’t everything have to be coded twice if you do SNOMED?

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

Well, okay, so there are existing cross maps that can be used from SNOMED to ICD for billing purposes for ICD-9, and part of our recommendations, I actually omitted, accidentally omitted ICD-10 from the slide, but that is one of our recommendations for 2013. It is in our detailed documentation. It’s just not on the slide here, and I did say these are our primary standards. But SNOMED CT is recommended for clinical documentation.

ICD-9 and later ICD-10 obviously is required for administrative classification purposes for billing and other financial transactions, so we do anticipate that a standard, and we know that a standard mapping from

SNOMED to ICD for that exact purpose is being provided by the National Library of Medicine. We do, for purposes of quality measurement where the ICD codes are required, we do recommend them for both 2011 being ICD-9 and for 2013 and beyond in ICD-10. But we do envision and we recommend as a general direction that clinical documentation should move to SNOMED CT.

Paul Egerman - eScription - CEO

But isn't it confusing to have two coding systems? I mean, basically if this recommendation is carried out, every healthcare organization is going to have to have both coding systems, both SNOMED and ICD-10.

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

What's going to be required is that, for purposes of interoperability outside the boundaries of an organization, that you be able to map into the specified standards. It doesn't say how you have to code things internally or how you have to store data internally, but it does say that for interoperability purposes, you have to be able to represent your information in terms of the specified standards, and that's true for all of them, not just SNOMED.

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

Judy, did you have a comment on that point?

Judy Faulkner - Epic Systems - Founder

Just a quick on ... Neil. Isn't there a lot of argument about SNOMED versus some other things such as IMO? Am I right in that, or am I remembering wrong?

Neil Calman - Institute for Family Health - President & Cofounder

SNOMED is the international standard and it's supported by the international standard organization.

Judy Faulkner - Epic Systems - Founder

I thought there was a lot of disagreement about from the physicians as to which one they preferred. Am I correct on that, or am I misremembering?

Neil Calman - Institute for Family Health - President & Cofounder

I don't think so. I don't think there's been a lot of exposure up to now with SNOMED, but I think it is clearly the recognized standard....

Judy Faulkner - Epic Systems - Founder

Yes, I know. I just thought there was disagreements....

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

Arthur?

Art Davidson – Denver Public Health

Yes. Thank you, Jamie. I see on slide two that there's an emphasis on NCPDP for e-prescribing. And e-prescribing, as you know, is placed in 2011 as one of our key objectives. Then you also have RxNorm on slide three, but then I want to understand a little bit about this third bullet on the fourth slide. So if I'm a provider, and I fax and scan a script to the pharmacy, and I actually structure that in such a way that it has a CDA header that says it's a faxed script, does that qualify as e-prescribing?

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

That would not be our recommendation for prescriptions, no.

Art Davidson – Denver Public Health

Right, but what does the third bullet mean if someone did that? is that not ... I want to understand....

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

This is a problem of taking a summary statement and applying it to a detailed case. There are particular cases where we are recommending that, for example, images of documents should be allowed for 2011 with a CDA header. Prescribing is not one of those, if you look at our detailed matrix.

Art Davidson – Denver Public Health

Okay. Thank you.

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

Sorry. Actually, just some additional detail because I did want to make a summarized presentation and not go through all the detail. In addition to NCPDP Script, we are recommending HL-7 version 2.5.1 prescriptions for inpatient, but not for ambulatory, and that's consistent with the rules.

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

Tony.

Tony Trenkle - CMS - Director of OESS

Yes. Just on page two, Jamie, of course in 2013, it'll be for eligibility benefits, and referrals will be 5010, not 4010.

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

Yes, and that's also noted in our detailed documentation. It does have version 5010. it also has ICD-10 instead of 9.

Tony Trenkle - CMS - Director of OESS

Okay.

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

Christine.

Christine Bechtel - National Partnership for Women & Families - VP

I don't think there's any danger that people will confuse me with the standards experts, so you just bear with me to make sure I'm getting it over here. On slide four, so is what you're saying here that – I think I'm missing sort of the bigger context. So is what you're saying here that, for example, images of documents. If we were to go back to Deven and Micky's slide where they listed the meaningful use objectives that require health information exchange, that for those areas, if you're going to do lab results delivery, you can't do it via a PDF or an image of a document. But that's not, you're not saying that your recommendation is that, you know, electronic health records never include PDFs or images of documents.

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

No. What we're recommending is that for the coordination of care purposes and patient and family engagement measures of 2011, that those kinds of alternative, unstructured documents should be allowed in 2011, but that by the time we get to 2013, for those particular purposes, the exchange of clinical information in those kinds of summaries and those kinds of documents should use CDA, CCD, and structured documents generally.

Christine Bechtel - National Partnership for Women & Families - VP

So if a patient comes from a specialist who is not part of this, you know, doesn't have a record or doesn't have a record that meets the criteria and, therefore, can't interoperate, but what that specialist does, smartly, is print out a care summary so that the patient can take it to their primary care doc, and the primary doctor now has a piece of paper that they've got to deal with. They can still scan it in and store it in their piece, right? It's just that the specialist from before isn't going to get credit for meaningful use, which is fine.

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

I think that's correct. Sure. I mean, I don't think there would be an prohibition on that, but what we're saying is that for the next encounter, I guess, if that scanned document were imported, then that would not be part of the structured document after 2013 that would be provided to the patient after that.

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

Well, I think there's no question that you've got an interested audience here, and that we could keep you here a while longer. But we do appreciate your coming, reporting, and you're meeting next week, I expect, and that a lot of these recommendations will be presented, and that hopefully some or all adopted, and then we can think about how we might want to give our input into those if the committee wants to do that.

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

Thank you.

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

You think?

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

I second that....

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

Thank you, Jamie. Our next presenters are Janet Corrigan and Floyd Eisenberg, who are present by phone. Is that correct?

Janet Corrigan - National Quality Forum - President & CEO

I'm here. This is Janet.

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

Hello, Janet.

Floyd Eisenberg - Siemens Medical Solutions - Physician Consultant

I'm here as well.

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

Great. Thank you. We have your slides up.

Janet Corrigan - National Quality Forum - President & CEO

Wonderful. Thank you. Let's go to the first one, and I should say by background, these recommendations haven't been delivered to the standards committee yet, and this is a work in process, and they need to be reconciled across the various workgroups and the standards committee overall needs to weigh in on these. But we wanted to give you the latest information and a progress report from the clinical quality workgroup.

What we've been doing is to really a four-step process to identify the appropriate standardized performance measures that correspond to the policy committee's 2011 measures. Second, review the performance measures and develop guidance for measure retooling because virtually all of these performance measures have to be respecified to be able to run off of EHRs. Third, to identify the underlying data types and elements that must be captured in EHRs and PHRs to produce the performance measures and then essentially we hand off to Jamie's workgroup, the clinical operations group, to identify the specific IT standards, which you've just heard about actually.

The next slide, please. We started with the recommended set of 30 performance measures that the policy committee came forward with or provided to us. Out of those, there currently exist, for 23 of them, NQF endorsed measures that are pretty close, frankly, to the performance measures the policy committee requested. About 18 of those can be produced from EHRs once the measures have been retooled, but 5 of them will have to be produced in the near term for 2011 through attestation.

The next slide: One of the key issues that we grappled with, which affects virtually all or almost all of these performance measures has to do with the capture of diagnoses through a problem list of some sort, generally. As Jamie indicated, we're anticipating that there will be some use of ICD-9 and then ICD-10 and SNOMED CT. What our workgroup thought would be appropriate is for 2011 to have two versions of the performance measures: one, which uses ICD-9, and then another is SNOMED CT. Then in 2013, the goal would be to have a version of the measure for ICD-10, another version using SNOMED CT. In 2015, everyone would be required to use the measure, which is a SNOMED CT specification.

And we thought it was appropriate to probably have multiple versions of the measures during these early years because for those organizations that already have the ability to use SNOMED CT, the last thing you'd want to do is ask them to turn around and kind of go backwards and have to produce the measure that is ICD-9 or ICD-10 in these earlier years. Now I just wanted to point out, and I think this just came up in the prior discussion, it's certainly anticipated that for many organizations, they would use their internal codes and obtain some SNOMED CT expertise to map those over to SNOMED. It's also recommended by our group that EHR certification should immediately start to require the existence of a problem list.

Next slide, please. Now one of the things that will be important is we do need to make sure that NLMs, SNOMED CT CORE subset, which is what we expect would be used in the near term in terms of the problem list, that it is adequate to be able to produce ... includes the appropriate terminology to be able to produce the measures that are going to be used in 2011 and beyond. I think we will likely need a more defined process going forward to be able to map over and make sure that as the performance measures continue to evolve, that SNOMED CT also continues to evolve to include the appropriate terminology and that CORE subset for problem lists that are needed. So we'd recommend actually that a more comprehensive assessment of the adequacy of NLMs subset be done sooner, rather than later, so that we're prepared going forward.

The next slide, please, the sixth slide. The workgroup also developed some guidance for the measure retooling that has to do with the exclusion. In general, measures have developed over the years with very long lists of exclusions, and I think there's probably been a tendency to want the measures to be perfect for every single case that's included in it to be accurate 100%. Going forward, we think that what we could do is to encourage only those exclusions that really relate to contraindications and start to move away from what is generally called decimal dust in the performance measure community.

For 2011, attestation would likely be necessary. We don't see how one could really jump to obtaining the exclusions from the EHR by 2011. That would be for 2013. And in 2011, there is currently a CPT-2 code

that is used right now for many measures that has three levels. It indicates whether there was a medical reason for excluding the case from the denominator from the performance measure, whether it was a personal reason or a system reason, so that's one what providers could readily adapt to because many are already using it.

Next slide, please. Now our overall goal in getting these measures retooled is to move towards what we call patient centered measures. Essentially what we'd like to see are all of the measures, whether they apply to acute care settings or ambulatory settings or even long-term care settings that they have similar denominators; denominators that are specified to apply to any setting that the patient may be in. And also, that they use consistent protocols for the various age groups. And, in general, what we want to stride towards is harmonization of not only the measures, but the data types and the data elements across all settings.

And I should mention that we realize that, in the near term, the meaningful use incentives really aren't going to be applying to long-term care facilities, but one of the members of our workgroup, John Derr, who comes from the long-term care community, has really been working very closely with us to try to make sure that we keep in mind applications to long-term care settings, whether they're nursing homes or home health or assisted living kinds of areas, because somewhere in the future we do want all of this to be harmonized across all of those settings.

The next slide, please. We also took a look at some of these measures, and in some cases there is more than one measure listed in the grid that you have as a handout, as it applies to particular policy committee measures, and that's because we also think that there's going to need to be some staging of measures over the year. Let me give you a few examples here. The first one, body mass index; for 2011, probably what we want is a measure that just indicates whether or not there's documentation of BMI or not. But by 2013, we'd want a more sophisticated measure, one that actually is capable of identifying the BMI percentile, and also whether not counseling was provided if that's recommended for the particular patient.

You see a similar thing with asthma medications. In 2011, we recommend use of a measure, which is appropriate meds for patients with asthma. But in 2013, a more refined measure that looks at whether the medications are appropriate for the patient's particular stage of asthma.

Then on readmissions, a third example here, in 2011 it would probably be nice to have a measure that looked at whether or not the provider can calculate readmissions to their own facility. But by 2013, would certainly want to be able to see some ability to look at readmissions across settings, but perhaps not the entire community. But by 2015, then looking for the ability to calculate readmissions community wide.

Then the last slide here, we also wanted to mention this whole area of patient engagement because this is one where we, frankly, don't have many measures, and we think it's really critical down the road. So some work does need to be done fairly immediately to begin to generate some measures of whether the patients understand the treatment options, and would also need to begin to develop measures, as well as underlining HIT standards for the comfort care measures, appropriate standardized methods of capturing do not resuscitate to do not intubate orders, and things of that nature.

Then the last comment I would make is that there's clearly a lot of moving parts here. We have to have measures that are ready to go, and that involves the measure development and the measure stewards that develop these measures. There has to be an appropriate timetable laid out for rulemaking, and we have to identify all the HIT standards, and our workgroup thinks that it will really be very, very helpful and strongly urges the policy and standards committee really to work together to develop a very detailed timetable and get some very serious thought and discussion to this that reflects the rulemaking process,

and that it covers really the next five to seven year. And then to do some careful messaging around this to help everybody understand that, in 2011, it is going to be tough. There isn't much time. In 2013, it's probably going to be a bit of a compromise, and there's going to be some very tight timeframes for most EHR vendors, as well as the measure developers, and everyone involved in the process. But by 2015, we really hope that we've got everything in synch and there is adequate timetables for various organizations and groups that have to participate in this rather complicated effort to get their work done appropriately.

Now let me hand this over to Floyd. Floyd has put together a matrix, which I believe you have as a handout, and he wants to make some comments on that.

Floyd Eisenberg - Siemens Medical Solutions - Physician Consultant

Sure. Thank you, Janet. I actually won't be going through every measure on the matrix. You do have that in front of you just to give an explanation of what that shows. We took the recommended list from your policy committee, identified the corresponding measures that we currently have as endorsed NQF measures, and using the framework that was established by the Health IT Expert Panel, HITEP, which Paul Tang helped to chair, we identified all of the individual data elements for each of those measures in the appropriate column so that we could work with Jamie's workgroup on operations for then to identify standards to represent those elements that the standards, of course, if they looked at, included the terminology, as well as the standards for interoperability.

You'll see in some of those one specifically that's a little more complex on BTE where we also entered some comments and concerns that things, data such as the antithrombotic devices, as opposed to medications, the devices themselves may be harder to identify, especially identification that they've been used. In most of them, the data elements, except for the exclusions, as Janet already mentioned, are fairly well defined. So that's just a brief overview. I don't want to take a lot of time on it, but would be happy to answer any questions.

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

Thank you, Janet and Floyd. Questions from the committee? I have a question. You gave us a summary of, I think it was 30 measures, of which 23 had current standards, and 18 needed retooling, and 5 would be done through attestation. Am I recalling that correctly?

Janet Corrigan - National Quality Forum - President & CEO

Yes, that's correct.

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

Can you translate that into 2011 and 2013 and 2015 terms in terms of the availability of standards for measuring the quality metrics that were included in our meaningful use matrix? Is that what you're – are you saying in effect that 23 of the 30 measures would have standards that you would recommend, though 5 of them would have to be documented through attestation?

Janet Corrigan - National Quality Forum - President & CEO

That's correct, so for 7 of the 30, there are no existing measures, and I can kind of quickly tell you what those are. Percent of orders entered by physicians in CPOE ... you know, percent of meds entered for CPEO. Percent of patients access to personal health information electronically. That's just a sample of them, but for seven of them, we don't have a measure constructed yet. Work would have to be done.

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

For all that you have a measure, you think that you can specify measures with sufficient precision so we can develop standards for them.

Janet Corrigan - National Quality Forum - President & CEO

Eighteen of the 23 that we have measures for, yes, we believe that those can be generated from the EHR and that Jamie's workgroup is well along the road to identifying the HIT standards that are needed to do that. The remaining five, which in 2011 would have to be by attestation, the goal would be for those to be generated from the EHR directly by 2013.

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

Okay. One last question: One of the decisions that we've been discussing or issues we've been discussing is the issue of specialty specific measures. If we go beyond the primary care domain, which is where most of our measures have been concentrated, to specialty specific measures, what is the implication of that for the availability of standards within the 2011 framework?

Janet Corrigan - National Quality Forum - President & CEO

Floyd, you identified four additional specialty specific measures that actually could even be done in 2011, correct? Do you want to speak to those?

Floyd Eisenberg - Siemens Medical Solutions - Physician Consultant

Yes. Actually, the reason you see asthma on the list is to address some specialty and also pediatrics. You'll see one toward the end of the grid about for stroke and atrial fibrillation and providing anticoagulation, which was, one, to add a hospital measure, but also to address specialty. So we did address specialties based on a review of existing measures around specialties, and there are standards to deal with those, so that was what we were trying to do by addressing some specialties.

Janet Corrigan - National Quality Forum - President & CEO

Yes, and the one other thing, David, is that our workgroup did have a call earlier this week, and we started to focus on measures for 2013. We are trying to identify sort of what's in the pipeline. Many of those are specialty specific measures. But, overall, I would say it's pretty slim pickings. We're talking about maybe a half a dozen to six to ten additional measures that currently exist. So we need to start sooner rather than later to identify these specific types of measures that are needed, so there's adequate time for measure development and endorsement to take place.

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

Okay. Other questions? Paul?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

So to address a couple of your questions, David, one on the specialist, so the meaningful use workgroup will go identify some of the existing measures that are in the 2011 stats, and some would apply to some specialists, let's say endocrinology, cardiology, etc. And, as Janet mentioned, NQF has a call out to try to grab some more specialty specific measures.

In answer to the seven measures, well, purported measures that do not have an NQF endorsed measure, some of them actually weren't intended to be one of these NQF endorsed measures like the percent of patients with access to the personal health information electronically. It's almost an attestation. Do you make that available to all of your patients? That kind of measure wasn't intended to be something you would actually measure out of the EHR system.

Another example is the HIPAA, compliance with HIPAA. That wouldn't be a quality measure that NQF would typically endorse. Even the percent reportable labs submitted electronically, it's almost, you have

interfaces to certain lab test result systems and not others, and you would measure which one – what percent do you have that are electronic ... so some of those things would never probably go to NQF endorsement.

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

Yes, David?

David Lansky - Pacific Business Group on Health - President & CEO

Thanks, Janet and Floyd. Janet, I have a question that's sort of an NQF process developmental question, I guess. As you say, the pipeline may be thin in some areas that will be important to us in 2015 or 2013, so I guess I see, and correct me if this isn't accurate, I see this process as, in a sense, a customer of NQF, and you have a number of customers, people who define needs for measures, policies, policymaking and other purposes. And in some sense, NQF and the pipeline that supports NQF is being stimulated by a variety of demands from across the country. I'm sure CMS and PQRI is one of those, and we may be one of those.

What should we do or how can we go about stimulating the process of measure development to support the needs we anticipate for 2015 given the range of other users of measures that are out there? I really want to avoid this situation of us looking under the lamppost two and four years from now for the things we can use to measure IT effective meaningful use of information in care. And I'm also worried – the other pincer is whether we're not really the appropriate body to set the national priorities for measure development, broadly speaking. But there isn't one.

We have these various voluntary coalitions and advisory groups, all of whom express themselves, but we don't really have a mechanism to create national policy around these areas of emphasis. But we are contributing to that ourselves, so in the meaningful use discussions we're about to have in the next few months, as Paul described, I think we need some cooperative discussion around, Janet, your other users to make sure we can synch up the pipeline of developers in the right direction.

Janet Corrigan - National Quality Forum - President & CEO

It's a very good point. And I think we actually are a little closer to having kind of a multi-stakeholder, national process for identifying the priorities for measure development and endorsement going forward. Let me just tell you where we're at with it.

We have had a very extensive process in setting the six major national priorities, which I know the policy committee used to a great extent in developing its initial 2011 measures. Those are the major cost cutting areas, whether it's care coordinator, or it's overuse, or it's palliative care, things of that nature, the six major cost cutting areas.

NQF now has a major piece of work that's under development with a contract from HHS that is prioritizing the top 20 conditions using a set of criteria, not only about incidence prevalence, burden, ability to impact quality, evidence of equality gaps, gaps, things of that nature. But prioritizing those top conditions, and we will have that work in, in the next about eight weeks or so from now. That gives us what we kind of call a two-dimensional framework.

We're also going to be working, once we have those top 20 conditions, we'll identify what surgical procedures are embedded in them because we also want to make sure that we have a portfolio of measures that covers all the leading surgical procedures as well, and if they didn't get reflected in the top 20 conditions, and there are others that bubble up, we'll probably supplement that list in one way or

another so that we're covering the really high ... or high priority, both conditions/surgical procedures, as well as those cost cutting areas, which you've already got.

That matrix and work is now underway to map over the measures that we currently have in the NQF portfolio to the cells in that matrix, and we will see where there are gaps. And where there are gaps, that then gets translated into a set of priorities for measure development. And that work will be completed by the end of this calendar year. We already have pieces of it that a good deal of progress has been made.

For example, for the six major national priorities, NQF has projects up and running that are already reaching out and trying to obtain any other potential measures that are out there, and ... measure development field has been on notice since about seven, eight months when those priorities were released that these were going to be a big area of emphasis, so a good deal of measure development is already underway in those areas. But that's the vision going forward, and we're very close to having that two-dimensional matrix and to having the high list of priorities for measure development, as well as future endorsement projects.

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

Thank you.

Janet Corrigan - National Quality Forum - President & CEO

I think that will meet your needs to a great extent, but if it doesn't, provide that input, and we will figure out how to make sure that they get reflected in this process as well.

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

Thank you, Janet. I think we're going to, at this point, move along. We are just getting reports here, and Janet and Floyd, terrific work. We look forward to doing that collaborative work that you've discussed. It seems very important that our meaningful use and the standards development groups be continually coordinated, so appreciate your presentation.

Jodi Daniel - Office of Policy & Research - Director

One thing, and it's actually in response to something that Paul said because I wanted to clarify, given CMS is in the room, our favorite audience today, and that was about the percent of patients with access to health information electronically. And we talked about in the workgroup that we knew that was going to be an attestation process, but what I heard, and maybe I misheard you, Paul. What I heard you say was different. This was, I think, designed to be an attestation of in fact the percent of patients, and not whether you just provide access, yes or no. And that was important because it took us to thinking about, is it being used, not that we would establish a minimum or a max percent, but we would want the percent reported as opposed to a yes or no, so I just want to be clear. Thanks.

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

Right ... noted for the record. Is Dixie Baker on the phone?

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

I am.

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

Terrific. Welcome, and thank you for being here.

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

Yes, this has been really interesting. What I'm presenting today, as Janet mentioned in her introduction, this is really a summary of what I'll be presenting next week at the full standards committee meeting, and I would encourage you to come to that standards committee meeting, but I hopefully will give you enough of a feel for what we're doing that you'll feel comfortable that we're making good progress.

Next slide, please. The privacy and security workgroup has adopted a three-step approach for developing criteria, measures, and identifying standards, and the first step was that we identify the privacy and security capabilities that were needed for what Deven referred to a while ago as the ARRA XIII priority areas of focus that are enumerated in the American Recovery and Reinvestment Act. Then using those as our kind of key areas that we needed to focus on, we mapped them into the standards that were available for product certification, and then we identified measures that could be used for demonstrating that a certified product was being used meaningfully.

Last month, at the July meeting, we presented our recommendations for EHR product certification, the specific security and privacy services that needed to be provided by the product, as well as the standards that were available. And we gave the standards a readiness rating. That work was accepted by the standards committee last month, but since that, we've discovered a couple standards that we wanted to add.

We also discovered a couple of the readiness ratings that we wanted to change. So we're going to be giving an update at next week's meeting. It's not a significant, no significant changes, but we plan to give that update next week. Secondly, we have developed – we've been developing privacy and security measures, and these are measures for demonstrating that the certified EHR product is being used meaningfully, and we'll be presenting that work next week as well.

Okay. Next slide: So this is kind of a summary of the standards update. Last month, we presented the readiness in terms of a rank of a rating one to four. This month, we've added the 2011, 2013, 2015 readiness. We've added a bit more detail about the source references. Last month, we just identified this came from a HITSP construct, this month, this update, and we got questions about that, and so we added the specific references to constructs.

We identified the International Common Criteria for trusted system evaluation as one of the standards, and we got a question at the meeting about that. although it was accepted, we concluded that really the assurance measures themselves should be included as certification criteria and that the EAL, evaluation assurance levels, that are identified in the common criteria should be used as a model, but that the government really shouldn't impose the entire common criteria on this process.

We added to standards, the Web services security and the IHE cross-enterprise document reliable interchange, particularly for reliability of exchanges. We added three HITSP capabilities. We didn't have the – we hadn't identified any of these capabilities at the last meeting, and so we've added three. 143 is the managed consumer preferences ... in fact, all three of these capabilities have to do with managing consumer, well, having to do with consumer services. 143 is the managed consumer preferences and consent. 120 is communicate unstructured document, and 119 is communicate structured document.

And for both 119 and 120, we specified that this would be using either the portable media or the system-to-system topology that are specified in those capabilities, so these would be used for providing the consumer an electronic copy of their EHR in either an unstructured document, which would be acceptable in 2011, and then by 2013, it would be a structured document. And the reason we included the system-to-system topology, as well as the portable media, is for the case in which a provider might provide that electronic copy to a PHR.

We had quite a bit of discussion about the REST, which is a much simpler messaging approach that's used for service oriented architecture solutions, and it's being used more and more. It really is not a new standard. It uses traditional HTTP and universal location indicators. And so we put a note. We added a note that will allow the use of REST as an alternative to SOAP for service oriented architecture messaging.

Then, finally, we changed two readiness levels, and one of my arrows is in the wrong direction. In the case of SAML, we changed it from a readiness level of one to two because it's probably 1.5. It's certainly a mature standard, but it's probably not used by 20% or more of people who have used security assertions.

An PWP, which is personnel white pages, and it basically uses LDAP and domain name service, and so we changed it, consistent with those two standards. We changed it from three to a two, not two to three. My arrow is going in the wrong direction.

The next slide, and the detailed update, by the way, will be distributed. A new handout will be distributed next week when I present these. But most of next week's discussion is really going to focus on defining the meaningful use measures. And since our objective was from the policy committee, I thought that you should know some of the challenges that we found that we discovered in identifying what these measures should be.

First of all, the only objective that was identified is HIPAA compliance. And I understand the reasoning behind that. But the truth is that all of the applicants are already required by law to operate in compliance with the HIPAA privacy and security rules, and so the question is, can we impose any additional measures without prescribing new law or new regulations. That was a challenge for us.

We also had the new ARRA provisions, and it wasn't clear exactly how we should handle those, so for now we are including the ARRA provisions specifically in the measures we identified.

We also didn't want to appear to be subsetting HIPAA. We thought about, well, maybe there are some standards or implementation specifications in the security and privacy rules that we would specifically identify and say, well, you have to demonstrate these, these following five. But then, you know, you're coming across as saying, well, these five are much more important than all the others. Or that you really don't need full HIPAA compliance; you really need to just address these five, so that was kind of out of the question there.

But bottom line is, there is a strong recognition that I've heard reflected over and over in today's discussion that meaningful use of EHR technology unquestionably brings new privacy and security risks to the provider organization and to consumers. And that affectively addressing these risks is absolutely critical to the ultimate objective of furthering adoption and proliferation of interoperable EHRs and health information exchanges.

The next slide, please. Our recommendations that we'll be presenting next week includes three basic types of measures. The first are measures that represent a value that EHR adoption is contributing to the organization's challenge of remaining HIPAA compliant. So if they have to audit accesses – I'll give you an example. If they have to audit accesses to information, then the fact that an EHR product gives them an automated way to do that gives them an additional value. It's not a new requirement, but the EHR steps up and plays a role in their HIPAA compliance.

The second kind of measures that we'll be recommending are those that represent a fundamental change in an organization's approach to maintaining HIPAA compliance as a result of their having adopted an EHR product. In other words, these are like countermeasures to new risks that they didn't have before, so they didn't have the countermeasures. And also, the configuration of security and privacy capabilities that are inherent in the product, I recall at the last meeting, a few meetings that I presented, I mentioned the fact that a product might be certified to have say an encryption capability, but the fact that it's certified to have that capability says nothing about how the organization uses that capability, so that would be another type of measure that we intend to present.

Then finally, measures that can be objectively assessed, and I know that you've been talking about this today, as well as the other two workgroups from the standards committee. We need to be able to figure out or somebody needs to be able to figure out how you're going to objectively assess how they meet those measures. I'm not going to present the details today. It would steal my thunder for next week, but I would encourage you to come to our meeting next week, and are there any questions?

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

Questions? Deven.

Deven McGraw - Center for Democracy & Technology - Director

Hello, Dixie. It's Deven. Thanks for that presentation. Unfortunately, I'm not going to be here next week, so I'm going to miss the meat of your discussion, but I look forward to catching up with you later.

We said a fair amount today as a policy committee, although certainly not the definitive word on standards, but a couple of things that we have agreed on include that the standards be technologically and architecturally neutral, and that there be CCHIT criteria for certification be really aimed at meaningful use and not necessarily a sort of greater list of criteria that products might be sort of given a Good Housekeeping seal of approval, but they're not necessarily part of certification for getting your meaningful use incentive.

Since part of what has been done to date has been looking at existing CCHIT criteria and mapping them, given that we're sort of putting some new shape on what the criteria ought to look like with meaningful use, do you have any plans to sort of go back and look at those and assess whether they address some of the sort of overarching principals that we discussed today?

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

Well, I think we are fortunate that we had really good guidance from the ONC early on, and we initially looked at all of the CCHIT criteria that they used to certify products, and we looked at the HITSP standards. And we ultimately ended up going to the ARRA XIII, and instead of really using the CCHIT criteria as a major input into our analysis, we've really used the ARRA XIII and the HITSP standards as our major inputs into the process.

As a result of that, everything that we are recommending can be traced back to either and potentially both the eight priority areas identified in the ARRA law itself and/or to the HITSP standards or constructs that really support the security and privacy services required for the ARRA XIII priority areas. I also want to, just to clarify, you won't see in the standards that we recommend, you won't see any HITSP constructs listed, but we used the HITSP constructs. We looked at the standards that those constructs referenced, and those standards are the ones that we measured their readiness and ultimately ended up recommending.

No, I don't see any need for us to go back because that's – we went the right direction to begin with.

Deven McGraw - Center for Democracy & Technology - Director

I'm not sure I agree that that addresses the question, but we can take it up later because these are new criteria that we talked about today, so it would be unreasonable to expect, but I think it's something that we need to think about.

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

Yes, let's talk about that. Yes, because I haven't heard anything that would cause me to change what we are recommending today, but I would love to follow up with you on that.

Deven McGraw - Center for Democracy & Technology - Director

Okay.

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

I think that we're questioned out, Dixie, so thank you so much. This is such important work. We really appreciate you and your workgroup's activities. We're now going to move to public comment period, and usually at this point I turn it over to Judy.

Judy Sparrow - Office of the National Coordinator - Executive Director

...audience to make public comment to the committee, as well as anybody on the telephone. The operator can give you the instructions on making your phone line accessible to the committee. I think we'll begin with people in the audience. But just a reminder, we're capping your comments at two minutes, so there's a two-minute limit on your comments to the committee. Thank you. Sir?

M

My name is.... Is that understandable? In the paper on page eight, my name is written as ... Moyer. There's no such person on the globe and, by the way, it is ... how important identification is ... operation ... information healthcare information technology. It is ridiculous that you did not discuss this at all. And so, because you interrupted me the previous time, I sent a letter to Dr. Blumenthal, who is written my comments, which was interrupted, and I ask you to put this letter on the record.

Number two, as I mentioned – how many time I have?

Judy Sparrow - Office of the National Coordinator - Executive Director

Please continue.

M

Okay. If you don't know, I will count. So it's very important task of verification identity, as illustrated very well. You cannot damage public records. It's – I don't know the term how to explain this.

The second point, I don't understand why you don't consider at all the issue of telemedicine because without – and telemedicine is exactly information technology, application for medicine, medical needs. So I may be use my two minutes, but I need to say to you, I have ... with me. Everyone who has computer, I can demonstrate how to solve the problem of verification identity and telemedicine, efficiently and effectively. Thank you very much.

Judy Sparrow - Office of the National Coordinator - Executive Director

Thank you. We'll take the next comment.

Lynn Scheps - SRSsoft - Vice President of Government Affairs

Hello. Good afternoon. I'm Lynn Scheps. I'm the vice president of government affairs with SRSsoft. I've been listening to your past meetings via Web cast, but I felt it was important to be here today to personally deliver this book, which you received this morning. *The Voice of the Physician* contains a petition asking you to listen to private practice physicians on whose participation the success of this program depends. These are the physicians who will have to achieve what their EHRs only have to be capable of achieving, as you said this morning. They implore you to consider the daily realities of medical practice as you move forward.

The fact that a relatively small company like ours would receive such a response in just a few weeks with minimal outreach efforts is an indication of the deep level of concern pervading the physician community. Two things are clear. Physicians feel that their voice is not being heard, and they perceive that the government's expectations are overly burdensome from a practical perspective.

The signers of this petition are not all SRS clients. Other providers have reached out to us and asked that we stand up for them as well. SRS users or not, they are passionate about EHRs, and they speak from positive and negative experience with a variety of products.

Three fundamental themes dominated. Physicians will not adopt technology that compromises their productivity. They will not become data entry clerks, and they will not jeopardize the physician/patient relationship. No financial penalties will persuade these – financial incentives or penalties will persuade these physicians to take actions they deem detrimental or not valuable to their practices.

One hundred and fifty of the signers of this petition were so concerned that they took the time to compose their own supplemental comments for you to consider, and they're in this book. I hope that you will take the time to read through even a portion of them. They're tone, intensity, and content provide valuable insight into what will be necessary to successfully encourage widespread EHR adoption. Thank you.

Judy Sparrow - Office of the National Coordinator - Executive Director

Thank you, and we'll take the next gentleman, please.

Mike Kappel - McKesson - SVP of Strategic Planning & Customer Strategies

Thank you very much. Mike Kappel with McKesson. First of all, I'd like to express appreciation to all the members of the committee. Obviously you've spent a lot of time. You've spent a lot of hours dealing with some really tough issues. It's gratifying to see the level of commitment you have both to HIT and improving health outcomes.

However, in spite, sometimes of all the hours expended and certainly the best of intentions, sometimes your actions can have unintended consequences. I'd like to just point out one of those that could distract from the credibility of your efforts as a whole.

In your transition strategy for certification process, I think the current strategy that you laid out and that you approved today has a serious flaw, and I believe this flaw to be unintentional, but it's significant because it has market implications, and it distorts the market. With the 2008 CCHIT plus gap approach, and I think while it works very well in the ambulatory setting, since more than 70 vendors have already been approved for the 2008 CCHIT. When you turn to the inpatient, in the spirit of the level playing field that you talked about, in the hospital segment there is only one vendor that can currently achieve HIT certification for 2008. And this is true because many of the vendors couldn't address the 12-month time period for increases. And so, they went to or planned on applying for the 2009 criteria, which was more stringent.

However, and I would also like to point out, 2008 certification is no longer available. So your approval of the 2008 plus gaps appears to favor one company and one company only in the hospital space, and that company unfortunately happens to be the only one who is represented on this panel. And I think this is unfortunate because it reflects, inadvertently, I believe, but an unintended consequence that has the potential of, we'll say, distorting the market in the hospital space. So I'd ask if either the National Coordinator in considering the recommendations that you've made, knowing it's recommendations, or Mr. Trenkle in the development in the regs, would consider is there, we'll say, a review process that would prevent such things and the unintended consequences from happening.

Judy Sparrow - Office of the National Coordinator - Executive Director

Thank you. And I believe we have one comment from the telephone.

Moderator

Our first comment comes from Chester Ramsey with Covenant Health.

Judy Sparrow - Office of the National Coordinator - Executive Director

Let's go to Ms. Perot, please.

Ruth Perot - SHIRE - Cofounder & Executive Director

Good afternoon. My name is Ruth Perot. I'm representing the National Health IT Collaborative for the Underserved. I want to start by acknowledging with appreciation three features of the current meaningful use draft. We certainly applaud the lifting up with high priority, the addressing of health disparities in your first priority. We also want to commend the panel for including the importance, addressing the importance of the collection of race, ethnic, and primary language data in the first year of adoption. We also celebrate and commend you for the patient centered focus of the entire document. Seventy percent of patients in California say they want their doctors to have HIT. Patients are clearly important to be at the table.

Having said that, I have some recommendations to enhance your fine work – 29, actually. I won't talk about all of them, obviously – maybe three. The first recommendation would be to look at the concept of safety net providers and expand it. There are nearly as many free clinics as there are federally qualified health centers. Sixty-three percent of racial and ethnic minorities seek their primary care from individual physicians.

We have to talk about the broadened safety net, and if you do, you have to acknowledge the fact that safety net providers are going to need more than access to an incentive. They need upfront dollars to acquire the necessary infrastructure. They need decision support. They need technical assistance, so think about the safety net, but broadly.

The second recommendation, you may recall, I do, the CMS outreach campaign to get beneficiaries of Medicare to adopt prescription drugs, the whole Part D campaign. We spent lots of resources. We think this effort is as important as that in terms of reaching providers and consumers about the opportunities of HITECH, the penalties associated, and the benefits, and we think there needs to be that kind of investment by ONC, CMS, both of you, all of you, to make certain that that word gets out, because if it doesn't get out, we're going to have a participation disparity that is going to aggravate the health disparities we already see.

The third thing we would recommend is that the ONC plan to monitor, as of 2011, the participation of safety net providers, making certain that they are indeed included. It would be terrible to wake up in 2015

or 2014 and find that they aren't there, that we've spent four or five years, and they have not been included. It's too late. It would keep them away from the table, exacerbate again health disparities.

And one final point: I said three, but I misrepresented myself. Reducing health disparity as wonderful. Eliminating health disparity is what we need. Thank you.

Judy Sparrow - Office of the National Coordinator - Executive Director

Thank you, Ms. Perot. Mr. Eaton?

Richard Eaton - Medical Imaging & Technology Alliance - Industry Manager

Thank you. I'm Richard Eaton. I'm with the Medical Imaging and Technology Alliance. We are the medical division of the National Electrical Manufacturers Association, which is the largest U.S. trade association, representing the electrical industry.

I had been at a number of these meetings now, but at this meeting, I was struck by how often the difficult issue of interoperability has come up. For example, I've heard aggressively establish new, very specific requirements for interoperability and data exchange. That was one of the recommendations that was made. Interoperability is a crosscutting challenge – another subject that was discussed.

We all know, and I don't need to remind you that interoperability is at the heart of this whole system, and there's no interoperability without interoperability standards. That's where our organization comes in. We have over 80+ years of standards development and testing experience. Our members work in DICOM, and you all know what the DICOM standard is. In IHE, integrating the healthcare enterprise, and in HL-7, these are all interoperability standards, and our members work on this every day. We were the leader in development of the DICOM standard, and that's over 28 years ago.

You are in a crunch time. I have a great deal of sympathy. Your job is very, very difficult, and you have a time crunch on top of it. I'm offering our services, our expertise, our knowledge in interoperability standards testing and development if you need us to testify, if you need us to write a white paper. I'm very encouraged by that October hearing that I understand we'll be dealing with this subject matter. All you have to do is let us know what you need, and we will put the horsepower and the guts and the oomph behind it, and we'll get it done for you. So please use us. We all are in the same boat here. We all support the same goal of the NHIN, so I urge you to take advantage of our expertise.

Judy Sparrow - Office of the National Coordinator - Executive Director

Thank you. And do we have somebody on the telephone for a comment?

Moderator

Yes. We have Christine Wright.

Judy Sparrow - Office of the National Coordinator - Executive Director

Let's go to Robin Raiford, please.

Robin Raiford - Eclipsys - Director of Government Initiatives

Hello. I'm Robin Raiford from Eclipsys. In my day job, I volunteer a lot for HITSP and the HITSP Tiger Teams. I just have a comment about one that was made about having more detail about interfaces and interoperability, and I just wanted to point out, in the new work that came out in IS-107, the EHR centric, if you dig deep, deep, deep in the weeds in that document, there are 79 interfaces and 443 transactions linked to 7,000 pages of documentation. I would hope that's enough, but just wanted to point that out.

And I also, just in the perspective of talking about HIOs and HIE, whatever, and it's not really clear to me. I'm not a JD, so I can't really say. Section 13405 of ARRA where it starts talking about as of February 2010 where the individual has the right to request, do not disclose if you didn't pay, if the health insurance company did not pay for this. The scenario when somebody comes in for a routine physical or whatever and says, oh, by the way, can you check and see if I have herpes. They don't want that to go out, and they didn't pay for it. They did fee for service. It sets up the situation where they have to make a separate encounter, so that now I don't want to disclose this because if the situation comes up where someone can start cherry picking from a patient level, don't disclose this and this and this. You have an electronic healthcare record nightmare maintenance on your hand or mutiny going on in the HIM department.

And I just wanted to point out one other thing. I also noticed, because there is one enterprise certified product for 2008, and that the CEO of Epic is on this committee, that it's because just one vendor made it that CCHIT has even broadened their Web site to, so you know that there is more than one vendor out there that you can actually filter out and say 2007, 2008. Two others are, just for the record, premarket, which means they don't have a live site yet. I just want to point that out.

Judy Sparrow - Office of the National Coordinator - Executive Director

Thank you. We have time for two more comments. Dr. Peel.

Deborah Peel – Patient Privacy Rights – Founder

Hello. I thought I'd come in person today because I've tried to comment before on the phone, and I know many of you, but not all of you. I'm a practicing physician, and I had and founded Patient Privacy Rights as a volunteer. I'm still a volunteer, and I'm unpaid.

Patient privacy rights has over 10,000 members in all 50 states, and I also lead the bipartisan coalition for patient privacy, which represents 10 million Americans. We have sent you all two detailed letters, very detailed comments about meaningful use, which I'm not sure the meaningful use workgroup has ever seen or heard from, and we're very concerned because the process is happening, and we're trying to participate. We're trying to send you letters, but there's no evidence that they're going anywhere. In the October hearing, for example, there's no place for consumers to be heard.

But the main thing that consumers want, the main thing that they want for EHRs to be meaningful and useful, is the ability to control the disclosure of their information. Anyway, we sent a detailed letter recommending both federal policy be used for meaningful use standards, the federal policy that's in 42 CFR part 2, which has worked for quite a long time to insure the privacy and trust for the exchange of sensitive mental health and addiction records for many years. And we recommended an open source consent, robust consent management system that's been in use for eight years, and it has enabled the exchange of four million patient records in eight states very effectively that complies with the standards in 42 CFR. This was developed by the National Data Information Infrastructure Consortium, NDIIC. I have to think about acronyms.

We think that there are very robust solutions to health information exchange, and to getting the benefits of health information technology with privacy. We're also really concerned that there were several votes today and have been votes every day on documents that we don't see until we get here. The problem, again, for public input, and for us trying to be a part of the process, is we really can't when we get documents the same day as votes. We can't be involved in the planning processes, and we have offered our organization, and the members of our coalition, including the Electronic Privacy Information Center, ACLU, consumer action and others. We would be happy to provide expertise and comments at the workgroup level.

Again, another concern of ours is, of course, privacy. The word privacy is used in all of these presentations and documents. We would urge you to adopt a definition of privacy because, to consumers and in the legal sense, the term means control over personal information. But because HHS and ONC have yet to adopt a definition, the proposals really can be very confusing and the meaning of them is not clear without an actual definition.

The problem of the legal concerns over health information exchange that Judy mentioned could all be solved. We don't have to do agreements. Don't have to do legal contracts, business agreements to exchange data, if you simply get informed, robust patient consent. You don't need all these agreements from stakeholders because the person who can move the data immediately where it belongs for care and for research really is the consumer, is the patient. So we would recommend that to you again.

And then listening to the comments about quality, I would expect that the top 20 conditions would certainly include depression that have the greatest prevalence, morbidity, mortality, and cost. Certainly depression would very likely be one of the top 20. I'm a psychiatrist. I know that depression is the second most common disease in the world, but I would have to caution you. If we have a system of electronic records that does not allow trust and segmentation of mental health information, we will never get that data.

We know from HHS's own findings that two million people a year refuse to get treatment for mental illnesses because they know it's not private. Six hundred thousand refuse early diagnosis and treatment of cancer because they know that the data is not private. If we don't have privacy, we won't get the data to find what is comparatively effective in my field. I would really like to know that. We will never get the data about psychoanalysis, psychotherapy, all the kinds of treatment that people get.

Probably a third of the patients with mental illnesses are off the grid. They pay someone privately like me, or they go to NA or AA, and we really have to think about this. If we design a system that doesn't allow segmentation in privacy, we'll get erroneous and missing data, and that would be a shame.

Judy Sparrow - Office of the National Coordinator - Executive Director

I'm sorry. Could we just have...?

Deborah Peel – Patient Privacy Rights – Founder

Yes, and the last thing that I would say is the comments that the woman made before me about how you shouldn't have to – patients shouldn't be able to block the transfer of data when they've paid out of pocket. That's actually a new right that HITECH conferred on American citizens. That's an important new right. If you pay for treatment, you should be able to decide who it goes to for purposes beyond such as healthcare operations. Thank you.

Judy Sparrow - Office of the National Coordinator - Executive Director

Thank you. And last, a short comment from Tom Leary.

Tom Leary - HIMSS - Staff Coordinator

Judy, I'll spare you the story of when I presented to the HIMSS board, and the bulb went out. I think Judy Faulkner was there. I think this has been a very valuable discussion today, particularly around the health information exchange activities. Whether it's DoD and VA having to share data outside their systems with 50% of their care going downtown or whatever, this committee is addressing then policy issues. You're not shying away from the policy issues that need to be addressed, so continue moving forward. Your

predecessor organization tended to often, sometimes backed away from the policy discussion, so keep moving forward.

Secondly, National Health IT Week is September 21st through 25th. We're going to have a Senate proclamation, House proclamation, and we're hoping that because it's in September, not in May or June, we're not going to be drowned out by Mother's Day or Father's Day this year. One hundred organizations have signed up, including 25 nonprofits or not-for-profits, so please pay attention. These are the folks; this is the activity that this policy committee is a result of, and we're looking for more and more organizations to be part of it. Thank you, and I'll stop before I lose my voice here. Thank you.

Judy Sparrow - Office of the National Coordinator - Executive Director

Thank you. I'll turn it back to Dr. Tang.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thank you, and thanks to the whole committee for all the work that's been going on, and to the members of the workgroup who aren't on the committee. Thank you to the public here and on the Web for listening in, and we will see you in September. Thanks.

August 14, 2009 HIT Policy Committee: Public Comments

1. I am just wondering if there is a group of attendees who were invited because of their expertise or relevance to the industry
2. Another item for parking lot- SNOMED - ICD-10 mapping by NLM
3. How do we get a copy of the data elements mentioned by Jayson?
4. Has any thought been given to the amount of time needed for installation and conversion of these new systems
5. Given all that I have heard, it seems that the timeline is too aggressive. Pick a few points that can be successful, like CPOE and limit initial effort to that. IHE specifications for Data and Image transfer cover this area but need much more testing before they can be used effectively.
6. Maybe I missed it, but might the committee consider HIO receiving accreditation from the federal government?
7. Who will be setting the criteria of what human readable data is? Discussion focuses on transport of data but for this to be effective, the actual data points need to have substance.
8. Q for Deven: In the context of HIE and privacy, the exchange must, either through CDA or some other mechanism, pass the permissions/consent given by the patient to the sending provider. Is that in your roadmap?
9. IS THERE ANY FUNDING AVAILABLE TO VENDORS TO RAMP UP TO MEET THE DEMAND REQUIREMENTS OF MEANINGFUL USE?
10. We supply an EHR, full Practice Management system. We have many systems in the market place. Our qualifying provider doctors have expressed their desire for the incentive payments for their time, cost and effort implementing EHR for improving health of all Americans. The impending bottleneck for EHR certification must be addressed. The current proposed system of accrediting certifiers, then certifying EHR's will slow adoption to a snail's pace. This is counter to

stated objectives. Provider attestation to certification based on established criteria, with subsequent audit, is a viable solution that should be considered.

11. Is there a reason why the committee chose 2008 CCHIT criteria to do the gap analysis against? I'm asking because only 3 companies have attained 2008 CCHIT certification at this point so therefore the committee should be aware of the massive amount of work to be done by the vendor community by October of this year not to mention how is CCHIT going to handle the volume?
12. Will criteria have public review? If so when and how?
13. Is the 2008 certification requirement for ambulatory ehr systems or hospital systems as well? Hospital systems certified in 2007 already meet meaningful use with the exception of interoperability. In this case interoperability should be the "gap" that needs to be certified. Hospital vendors should be in good shape with 2007 plus interoperability.
14. Is it prudent to figure out meaningful use before the certifying body is determined?
15. Committee appears to be not directly addressing the issue of measuring meaningful use vs. certification of a system to be capable of MU. A situation to be avoided is a provider's buying a certified system and sitting it on the shelf. How is it proposed to measure actual use?
16. For the parking lot- we should be thinking about the needs of "process interoperability" as well as data interoperability- i.e. the information needed to support workflow integration between different parts of the health care system- ref. From Tasks To Processes: The Case For Changing Health Information Technology To Improve Health Care James M. Walker and Pascale Carayon
17. Please expand on, if you can, the gap criteria development. Most inpatient vendors are 2007 criteria certified and most Ambulatory vendors are 2008 criteria certified. Will it be a prerequisite to have 2008 CCHIT certification to apply for the HHS interim certification for both inpatient and ambulatory vendors?
18. What is the recommended cost for vendors to get "preliminary certification"?
19. Thank you very much for all of your work. I was wondering if the Committee was considering advanced and/or technological platforms for providers that would mitigate medical identity theft?
20. We are concerned about the effects to our hospital because we are a 52-bed children-only mental health hospital with 80% state supported children (Medicaid/CHIP). Our uniqueness continues to be missed throughout this process. Please remember the demographic versus the specialty. Thank you.
21. While the HIE discussion was enlightening and well presented, the Committee did not directly address the additional costs a HIE places upon the clinician. There is common agreement that there is a disconnect between who receives the value and who pays for the services of an HIE. It is hoped that the cost issue will be addressed and that HIE will not just be one more cost that must be borne by the provider community.
22. The 2011 reporting requirements for physicians should reward those that have implemented EMRs that are capable of capturing the data needed, rather than require the actual reporting; defer actual reporting to 2013; by doing this, physicians will have time to redesign their processes and work flows to better accommodate the reporting requirement; the effort and time to implement the EMR is a great enough stretch for 2011
23. Am I correct in that there will be several certifying bodies focused on just MU certification?

24. Will the HHS MU criteria be a Superset of the CCHIT 2009 criteria?
25. How many of the board members have a provider who uses an EMR now?
26. Under the current fee-for-service payment model, providers don't seem to see much of a benefit from either sharing their data, or using somebody else's data. Which means that there is little push on their part towards HIE, and the market simply doesn't exist. But HIE is absolutely crucial with regard to public health, biosurveillance, early epidemics discovery and collecting diagnosis-treatment-outcome statistics. I believe the Government will have to be the driving force behind HIE.
27. certification based on MU criteria is great, however why should there be a second "comprehensive" certification -- it costly and distracting
28. Does that mean that the new HHS criteria will be a SUPERSET of the current CCHIT criterion? Or a different set
29. The only way you will solve HIE is by mandating 1 master IHE per state - in a standard format - those HIEs out there now would actually like this b/c since they collect the data already they could then just transmit it to the state exchange. Every provider subject to meaningful use should be on the hook to comply with transmitting the data to (1) either a middleman already collecting the data who could charge a fee or (2) directly to the exchange. This would encourage innovation & the free market. Plus you can then, from a national level, run queries showing people at risk of heart attacks and make sure they are on meds. This will lower overall medical / hospital costs.
30. How would we do medical network connectivity for care coordination, medical homes, multi entity registries and other multi path communications to support new way medicine if we go to MARKET Based solutions or proprietary approaches of labs and pharmacies? The claims clearing houses are way different than HIO/HIEs. The claims transactions must be delivered from individual providers to ONE end point, a claims processor in order to get paid! This does not exist with clinical data in any way, does it? The big barrier is that competitors in a market do not want to collaborate and share , but to compete on a most wired, most advanced, and gaining physician lock in basis.
31. Do the penalties for 2015 remain in place for 2015 to occur in 2015 for both hospitals and docs or are they pushed back under meaningful use recom?
32. What do we do if we approach this exchange at the transaction level of orders and results how do we keep from fragmentation which makes consolidating a patients record for a patient centric view? The market based approach may result in aggregation of data and control of patient level data like we have today where insurers, claims clearing houses, insurance, drug company, drug store companies and lab companies have their hold on the data, with everyone else has he data except the patient and the provider in a consolidated form. The current consolidation of data in the insurers hands does not serve the country or the patient well today at all, do they?
33. On HIE what about Edge Server model, how will patient be uniquely identified? Name and DOB not sufficient. Address not reliable. SSN forbidden.
34. What does the opt-out refer to opt out of the inclusion of their information in the entities EMR/EHR, or that orders or results cannot be communicated electronically (exchange) through inter entity communication, or that their history would not be included in any multi entity CDR, or registry without their consent. Of course there are many other areas or environments; however one should document and explore each of them relative to a patient's ability or option to opt out. The answers to these types of questions will or would have tremendous implications to the whole effort. An example might include a patient's ability to opt out of the HIE HealthBridge for all orders and result delivery of transactions directed by the patients physicians with the patients

implied consent. Will the eRX Surescripts connect to and through EHRs hubs, through state wide hubs and or through regional HIOs or HIEs? If so under what circumstances?

35. I would like to echo the comments from Mr. Kappel regarding the certification level for hospital systems to adhere to the 2008 criteria level. Most hospitals would end up in an update process that would stop production of deployment especially to meet Meaningful Use CPOE criteria. We urge you to consider hospital certification level at 2007 plus interoperability and Meaningful Use gaps. This will assist hospitals to continue the momentum of deployment of these advanced clinical features and not take resources away to re-update their systems.