

HIT Policy Committee Transcript January 13, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director

Good morning, everybody, and welcome to the eighth meeting of the HIT Policy Committee. This is a federal advisory committee, and there will be an opportunity at the close of the meeting for the public to make comments, and minutes of the meeting will be published on the ONC Web site. Just a reminder, please, for members of the committee to please identify yourselves when speaking so those listening on the phone know who is talking. And with that, let me begin on my right, if the members of the committee could please introduce yourselves. Jodi?

Jodi Daniel – ONC – Director Office of Policy & Research

Jodi Daniel, ONC.

Charles Kennedy – WellPoint – VP for Health IT

Charles Kennedy, WellPoint.

Connie Delaney – University of Minnesota School of Nursing – Dean

Connie Delaney, University Minnesota School of Nursing.

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

David Lansky, Pacific Business Group on Health.

Deven McGraw - Center for Democracy & Technology – Director

Deven McGraw, the Center for Democracy and Technology.

Adam Clark – Lance Armstrong Foundation – Director for Health Policy

Adam Clark, Live Strong.

Neil Calman - Institute for Family Health - President & Cofounder

Neil Calman, Institute for Family Health.

Christine Bechtel - National Partnership for Women & Families – VP

Christine Bechtel, National Partnership for Women and Families.

Paul Egerman – eScription – CEO

Paul Egerman, software entrepreneur.

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

Paul Tang, Palo Alto Medical Foundation.

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

David Blumenthal, Office of the National Coordinator.

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

Rick Chapman, Kindred Healthcare.

Gayle Harrell – Florida – Former State Legislator

Gayle Harrell, former state legislator from Florida.

Marc Probst – Intermountain Healthcare – CIO

Marc Probst with Intermountain Healthcare.

Tony Trenkle – CMS – Director of OESS

Tony Trenkle, Centers for Medicare and Medicaid Services.

Scott White – 1199 SEIU – Assistant Director & Technology Project Director

Scott White, 1199 SEIU.

Judy Sparrow – Office of the National Coordinator – Executive Director

And I believe we have Art Davidson on the telephone, and any other committee members, are you there?

Art Davidson - Public Health Informatics at Denver Public Health – Director

Yes. I'm here. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director

Any other committee members? Okay. With that, I'll turn it over to Dr. Blumenthal.

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

Thank you, Judy. Welcome to our committee members. Welcome to the audience and the public that is participating remotely. We are pleased to be able to meet again in the new year. We are at a very, I think, important point in the implementation of HITECH and in the deliberations of this committee.

With the committee's help and that of the standards committee, we have now issued two of the three critical regulations that we were tasked with producing: first, the interim final rule on standards and certification, which had to be issued by December 31st; the second issued by CMS was the notice of proposed rulemaking on meaningful use, which was issued simultaneously. They will actually be published in the federal register on January 13th, at which point a 60-day comment period will begin for both of those regulations, and which will conclude on March 15th. Paul will review with us part of the day today will be devoted to informing the committee about those regulations and to discussing them.

We've also now, just before the Christmas break, ONC has completed its plans for allocating all of the discretionary funds that were appropriated for us under the HITECH Act so that we now have approved spending programs for all those moneys. Very few of the moneys have actually been spent, but the necessary request for applications and a number of the requests for proposals have been published. Actually, virtually all of our proposed grant programs, which account for the great bulk of the funds that we are going to be allocating, \$1.7 billion have been made public. And we are receiving large numbers of letters of intent and applications happily exceeding our expectations in terms of numbers. And, over the next weeks and months, we will be announcing awards. And we're very pleased that the community of not only the health informatics community, but the local governments, state governments, community organizations, nonprofits, academic organizations throughout the country have been responding vigorously to these opportunities.

I think the combination of this work constitutes, I think, an important point of reference and a milestone in a very long journey. I hesitate that we're even at the end of the beginning, but we're certainly at a point where we should, I think the committee should take pride in what its accomplished. And I think you can

see from the notice of proposed rulemaking that you all, your recommendations had a major effect on the thinking of the CMS and the department and the government in formulating that notice of proposed rulemaking, and certainly the standards committee's recommendations had a major influence on the interim final rule. I've said before here that we could not have done this work without you, and I think you can now see evidence of why that is.

Today is an opportunity for us to reflect, particularly on the regulations, and then we will also, in the afternoon, move to forward-looking work, as we always do, exploring some reports that Paul will tell you more about. Just, again, welcome. Thank you for your help, and we look forward to an equally vigorous agenda coming forward in the new year.

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

Great. Thank you very much, David. Thank you for all of the outstanding work that's gone on in the Office and other departments in the Health and Human Services. It's clear that the Office and CMS have been very busy in preparing the almost 700 pages of proposed rules and IFR, and all of the grant RFAs that you've released, and I think the community is very appreciative. And you saw the vigorous response.

Very exciting work, so today's agenda is divided essentially into three sections. A big part of it is going to be the committee's comments on the two proposed, the two documents that have been released. One is the NPRM for the meaningful use criteria, and the second being the IFR for the standards implementation and certification criteria. The second piece is the NHIN workgroup has prepared a series of both findings and recommendations that they'll discuss with us right after lunch. And then we'll conclude with our preliminary sort of ideas in terms of the strategic plan workgroup, as we prepare over the next few months a document to forward onto you as input to your strategic planning process.

With that, any other? I'd also like to get approval of the minutes from December 15th, previously distributed to you. Any motion?

W

So moved.

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

Any second?

M

Second.

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

Any other corrections or discussion? All in favor?

M

Aye.

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

Any opposed? Thank you. We'll turn it over to Tony and Farzad to cover the NPRM for the meaningful use.

Tony Trenkle – CMS – Director of OESS

Good morning, everyone. I want to echo what Dave had said about the work of the committee and how much that contributed to the effort that we had in pulling together this NPRM. Without the work and the

recommendations that the committee to the Office of the National Coordinator, it's quite clear we would not have gotten as good of a product that we did end up with. Obviously a number of people may have some things that they have problems with, with the NPRM, and we'll talk about that. But as we've said before, it is an NPRM. It's a notice of proposed rulemaking, and there will be additional opportunity over the next several months for people to provide comments and to certainly help us, as we get to look at the final regulation that'll be out later this year.

As David said, actually, if you get your copy of the federal register today, the NPRM has been published. It was displayed on December 30th, and it's published today, and the comment period will close the 15th of March, which is the ides of March, and hopefully is not any kind of omen of what will be coming in over the next several months.

Now what's in it? The definition of meaningful use, the definition of a hospital based eligible professional, which many people have a very keen interest in, and of course the incentive programs for Medicare fee for service, Medicare Advantage, and the Medicaid program, as well as the impact analysis and the Paperwork Reduction Act. These were all laid out in various sections of the regulation. Of course, in the ONC regulation, there are the initial specifications, and then, as David mentioned, the establishment of the certification programs and the procedures become a certifying body will be in the future NPRM that ONC comes out with.

I think, looking at this from a very macro viewpoint, I think this NPRM does a number of things that are fairly unique, as well as scaling a program of this across a national scope. Number one, I think the harmonization of the criteria across the CMS programs as much as possible that we've done here, really bring together the Medicare and Medicaid programs when we look at the quality measures and look at some of the other criteria that we used to develop the meaningful use matrix, I think is critical. It's something that will have very interesting ramifications in the coming years. Of course, the states obviously have an opportunity to provide additional comment in terms of meaningful use criteria, but it sets a base that we can build from.

It closely links with ONC's certification and standards IFR. We spent a lot of time with Farzad, Jodi, David, and others from ONC in order to insure that we had as much and as close coordination as possible because we recognize that the definition of a certified EHR is critical in developing the meaningful use criteria for this program. Of course, we mentioned the HIT Policy Committee. We also tried, as much as possible, to coordinate with existing CMS quality initiatives to try to harmonize that and, as you'll see throughout the document, especially in the quality sections, we do refer to the various CMS quality programs.

And then it builds a platform that allows for staged implementation over time. And, as you know, the committee was very vocal in several meetings talking about the need for a staged approach and also for the idea of these stages being geared not only to the years and to the infrastructure, but also when the professions joined the program. So we had taken that all into account, as we did the NPRM. I don't think I need to tell you about this. I think you were all involved in this in a big way, starting with the NCVHS hearings back in April, and moving through the comment period that we had in June, the listening sessions in July, the policy committee recommendations in August, and then finally the clearance process, as we received additional input from the various department operating divisions and the Office of Management and Budget.

This is another familiar picture to all of you, the idea that in the stage one, we're focusing on data capture and sharing, and then moving out to more advanced processes and improved outcomes, as we go through the various stages of meaningful use over the next number of years. The stages, as we've talked

about many times, there'll be three regulations. The one that's out now for comment, we hope to learn from what we've put out this time, the initial stages and years of the program then to begin to build stage two for 2013. Of course, the infrastructure work that ONC has been doing will help us with that, and then stage three, which coincides with the year that Medicare penalties begin to kick in. We hope to have moved on to the stage three, as we defined it in the previous slide, and as we point out in the NPRM.

State one, of course, focuses on the five areas that the policy committee recommended. These were taken from the NQF work from several years ago, and I think it really provides a nice platform. We then took that and have added some additional measures and other information that we'll talk about in a few moments, how we changed from the original policy committee recommendations.

The stages, of course, we have mentioned this. The idea that you can do the escalator approach, as David has talked about numerous times. You come in, in 2011 or 2012 in stage one, and then gradually we move up to stage three by 2015, but allow professions who come in, in the latter years until 2015, to be able to come and to move up in a staged manner. That will be, of course, defined in the latter years.

The meaningful use summary, just quickly, the EP's [eligible professionals] 25 objectives and measures, as much as possible, we wanted to try to require the measures to have a numerator and a denominator. In some cases, it was more of a yes or no, but as much as possible, we did want to require that. The hospital is the same way. Obviously there's more that required a yes and a no in that area. Also with the reporting period, the focus was once again to try to get the stage one of the escalator was to allow a 90-day reporting period of continuous meaningful use in year one, and then for a full year each year subsequently, which we think is a balance, once again, between recognizing the challenges of getting to meaningful use in year one and then ramping up as they go out further.

Quality measures, 2011, we require attestation with a numerator and a denominator, and we also are moving towards requiring electronic submission in 2012. We divided it up into two areas. We have a core group of measures and then a subset of clinical measures, most appropriate to the EP specialty. They're allowed to self-select, and then are required to continue reporting in that specialty. The eligible hospitals are also required to report the ... quality measures.

The core measures, the three core, the tobacco use inquiries, the blood pressure management, and drugs to be avoided by elderly are core quality measures that all EPs are required to report on. And then we developed a number of specialty measures for various specialists. These are ones, for the most part, are NQF endorsed or are used in the PQRI program. So we tried to be consistent with measures that were already being used. And, of course, we know we'll get some feedback on these.

Hospitals are required to report summary data on 43 quality measures. These, of course, are also consistent with a lot of the measures with ... program. And for the hospitals where the measures don't apply, they'll have the option of selecting an alternative set of Medicaid clinical quality measures ... recognize the differences between the programs. This also, of course with the hospitals, they can receive a potential incentive payment for both Medicare and Medicaid, whereas in the EP area, they'd have to choose. They do have one opportunity to change from Medicare to Medicaid, or vice versa, in the EP area. But the hospitals can collect both.

The other issue was the e-prescribing incentive that Medicare has offered under the MIPPA legislation. That will not be able to be received by anyone who signs up for Medicare, but those in the Medicaid EP side will be potentially eligible to get the MIPPA incentive as well. And this is just a quick summary of the differences between the programs. Of course, the incentives in Medicaid are much higher. The bar for becoming eligible is much higher in Medicaid. And, in Medicaid, you can implement, adopt, implement

and upgrade in year one. And, in Medicare, you have to be a meaningful user, so there's an initial payment that is received in the Medicaid area that you don't get in the Medicare. And, of course, in the Medicare area, you have a penalty in 2015. The program payments begin to stop in 2016, whereas in Medicaid, the payments can go all the way up to 2021. And, of course, there are different eligibility requirements in both programs.

This is probably the area that you're most interested in. These are the areas where there were some changes from the HIT Policy Committee recommendations. That's why I brought my colleague, Farzad, here to help explain some of the changes since he was involved.

Farzad Mostashari – ONC

Thanks, Tony.

Tony Trenkle – CMS – Director of OESS

So I wanted to share the hot seat with Farzad. I'm not going to let him get away with – so he wore a bowtie for the occasion. But as you can see, we've made some changes, deletions. I guess the one that most people were concerned about is the documentation of progress notes. Record an advanced directive was one that also drew a lot of interest from a number of people. And providing a summary of care record, that was one of the items that the Social Security Administration, among others, had wanted to see added. Then we did a number of changes in the objectives to reflect what we thought were more indicative of where these objectives should be going in terms of adding growth charts, limiting the smoking status. All these are out for comment, of course, but these were some changes we've made.

In the measures, then we went and fine-tuned to insure that there would be objective, how to measure, added thresholds, calculated some based on unique patients seen, as opposed to office visits because, depending on the measure, there might be some reasons why it would be more appropriate to be unique patient seen. And we made some other changes, as you can see below, that we've asked for comment on. But they were our best shots, as well as getting plenty of help from others within the department and the Office of Management and Budget to help us write some of this.

The timeline, right now we're in the period where we're really beginning to focus within CMS, so making sure we make the implementation dates, making sure our systems are in place. The outreach is out there. The regional extension centers that ONC is working on, making sure that all that is in place so that we can meet these deadlines, which are no sooner than January 2011 for Medicare in the EP area. The hospital is October 2010. Then if you forward that on the three-month timeline for reporting, people can then begin reporting on Medicare EP side at April 2011, and then January 2011 for the hospital side. And then Medicaid, we haven't established a specific date at this point, but some time in 2010, we want to begin making payments for adopting, implementing, or upgrading, so obviously from a systems and process standpoint, even though we don't have the final reg out there, we have a very short timeframe to begin to roll out a national program.

The next steps, we want to hear from you. Paul, I know we'll be talking a lot more about that later with the meaningful use workgroup and some of the comments that are made today. The comment period, as I said, ends in March. We then have a period of time where we review them. We have to pull together a final regulation. We go through a major clearance process, and we hope to get it published in the spring of 2010. And, of course, a lot of that depends on what are the types of comments we get, how extensive they are, and what types of decisions have to be made at the policy level before we reach the final regulation. Farzad, did you have any further comments then? Okay. Well, then I guess I'll open it up to the committee for comments or questions.

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

I think, Paul, you were going to lead the response.

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

Sure. Maybe if we could go to the next set of slides, please. Per Tony's direction, we wanted to make sure that the committee had its opportunity to provide input to the NPRM in time for them to go through their clearance process. So that meant that we had to get the final letter in by March 1st. The way we've organized ourselves is we had a preliminary call before this meeting just to identify some of the topic areas, and so I'll present that to you shortly. And so that says, this is what the workgroup at least is planning to do in terms of flushing out what are the differences and what would the workgroup like to present to the committee as possible comments back to ONC and indirectly to CMS. So that's not a comprehensive list, but this is an example of the topics we felt that at least some of the workgroup members felt were significant to provide feedback on.

We're going to have an all day meeting on January the 28th in order to sort of work on that and get that work accomplished. To remind you, this is a list of the workgroup members, and these meets are open to the public now. We first expressed our appreciation to all of the great work that went on with CMS and ONC in putting together this NPRM, and we also noticed that a lot of the recommendations were incorporated, and so the framework was largely adopted, and we're very grateful for the amount of attention they paid to the work that came out of this committee.

We divided our comments into three sorts of buckets. One might be labeled philosophical policy comments, sort of broader ranging implication. Another might be areas of asking for further clarification, and that could mean some fine tweaking in the final rule. And the third might be actual granular comments on specific elements of the NPRM, so just to give us a way of organizing our thoughts. Where we thought we would spend the most time would be on the first category, the philosophical policy comments and feedback back to ONC and CMS.

Here are some examples that came up. One is in the clinical quality-reporting requirement. A number of times, we tried to propose an approach. You know, when we thought of the two kinds of extremes, one is an exemplar, meaning that if you were able to report on this measure and improve upon it, well, that probably meant that you, one, got a comprehensive, in terminology of the NPRM, a certified EHR that's capable of producing results. The second is you probably implemented it well. You probably trained your users, and your users are effectively using this tool in order to produce results. That's what we meant by an exemplar measure, and we've tried to come up with a few of those.

And the alternative approach, we labeled sort of the 500 measures approach, is to have all the measures you can think of. There are over 500 NQF endorsed measures, for example, and have people pick and choose from it. So whereas we might have recommended more towards the exemplar approach, the NPRM came out more towards the many measures approach, and so that's one thing that we'd like to relook at and discuss and see what kind of comments we might have back.

The other on clinical quality reporting is it's probably a moment in time when we have an opportunity to fundamentally change the kind of quality reporting that is done. So as we all know, we've been tethered in a sense to whatever data is available, and that data typically has been claims and administrative data, so most of the existing NQF endorsed quality measures are based on that kind of data. Well, now that we're trying to accelerate the adoption of EHR, which includes a lot of high quality, rich clinical data, is this the time to more than retool, almost reinvent quality measures, as they now exist? That is something, we wouldn't want to miss that opportunity. In the process of coming out with incentives to report on clinical quality, should we really spend some time, and maybe this is part of the strategic planning

workgroup, of commissioning essentially a redesign of what we now know as quality measures. That's another type of comment that we wanted to explore further.

The second area is the maintenance of up to date information in the EHR. Clearly that is the goal, and the original thought from the workgroup was when we said maintain a problem list, it was every time you see that person. In the NPRM, it's a one time, there must be one or more problems or meds, etc. So that's another area we wanted to discuss.

A third area is the stratification of the quality reports by variables that would indicate disparities in care. So that we noticed was missing, and we wanted to follow up on that. A fourth is this whole notion. It's very important to glide path. One of the reasons of staging it and to start at even putting in placeholders for the out years, the 2013 and 2015, is to give everyone in the industry a chance to start planning. So clearly it takes more than a year to get things going, whether it's on the provider side or the vendor side. We wanted to make sure we got as much information out to the industry as possible to signal the direction, and so that would help both providers and the vendors of these systems in planning.

Tony already mentioned the hospital-based position, and it's a scenario of intense interest. And stage three, we heard a number of comments about the criteria that although there was an adoption of the option year strategy, one of the consequences is by 2015 when the adjustments kick in, you're all of a sudden up at the – it's either the escalator or the cliff. So that's something that we're going to work on further and see if we can't come up with constructive comments back there. In each of these, we were hoping that we would both outline what the differences are, understand the rationale for the NPRM's approach, and if we thought necessary, propose an alternative and its rationale, so that's our commitment back to ONC and CMS.

The missed opportunities, Tony mentioned some of the things that were dropped from the matrix. All of these topics did come back up in our workgroup call. Certain members certainly felt that there was a reluctance to drop to not have these. And I'll just go through a couple of them. Let's say the progress note, the rationale was that it may not contribute to care coordination, and there certainly was a lot of feeling that it may very well. But we'll develop that thought and bring it back as comments. And you see some of the other ones that people thought were missing from the NPRM that were still important.

Areas for further clarification, and this may simply be a fine-tuning of the words when the final rule comes out. Examples are questions like the CPOE by author. Is the CPOE intended to be by the authorizing provider, or is any licensed person able to enter it in? One possibility is on behalf of or for a physician. That would be two different kinds of intent. Maybe these are some of the questions that could come up today.

The whole relevant encounter, and I think the responsibility lies with the workgroup that did not come up with a crisp definition for that. We may want to circle back and help out with that. The denominator for the measurement, some of them may require some manual processes, and the testing of capabilities is test within, is it testing the software in some way, or does it actually mean testing with some recipient of that information. It wasn't necessarily clear.

Finally, granular comments that we'll work on or individuals actually may submit have to do with the care summaries. Is that all transitions, or was that transitioned from one site to another? Timeliness, does the 48 and 96 hours, does that have an impact on weekends, for example? And patient reminders over 50 years old, that was one of the decisions that was made, and there may be comments about, is that a cutoff that might eliminate some of the benefits.

These are the kinds of areas that we've talked about. As I say, as a workgroup, we'll focus in on the philosophical comments and provide a structured way, almost like you laid out the NPRM, of providing comments back to you, so that you have full consideration of the rationale behind them. At this point, maybe what I'll do is open it up to perhaps questions from the full committee to CMS and add input to the workgroup, as it begins its preparation of comments to submit back to the full committee for consideration.

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

Paul, can I just make a couple comments about responding to the NPRM. First of all, thank you for the workgroup's initial input. One thing I just want to make clear, as people do comment, whether here in this venue or as official comments, is what we're looking for is if there are areas that need clarity, we'd like to see them emphasized, you know, what is not clear. If there's something that you think was in there that should not have been in there, or needs to be changed, we need to have not just to say it's a bad idea, but explain why it's a bad idea, and if there's something that would accomplish the same result or a better result.

We need that to be explained. I mean, it's nice for people to say, for example, that a hospital-based EP, as we defined it in the regulation, is wrong, but you have to give us a reason on a national scale what is a better way to do it, and why that's a better way to do it, and back it up with data, if possible, because some of this is done based on existing policies in the Medicare program, and how we've treated, for example, hospital-based professionals in the past. They've been paid at higher rates, for example, if they want a change for this particular program. We certainly looked at the definitions that were in the statute, so some of these are limitations by however defined in the statute.

Others in the quality measures, which I'm sure Farzad can talk about in far more detail than I do, were developed based on input from others within the department and OMB. So if you have concerns about them, you need to be very clear as to why you think that these particular measures are either not appropriate or if they need to be changed in some way. But I just want to make sure that people are clear. You cannot propose things that are not in the NPRM. We can basically take what's in the NPRM and modify it, but if it's not a – and Jodi is the lawyer here. If it's not a logical extension, as is defined by the lawyers, then we cannot change that in the final.

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

Let me ask a question on that then. Of the things that were dropped are no longer eligible to be commented upon?

Jodi Daniel – ONC – Director Office of Policy & Research

There are a couple of answers to that. You can always comment on it.

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

Right, you can always comment.

Jodi Daniel – ONC – Director Office of Policy & Research

We accept all comments and welcome them. The question is whether or not, if there's something that hasn't even been mentioned in the rule itself, then we could be challenged if we put in some new requirements that we didn't provide any notice of in the proposed rule. So if we talk about in the preamble and, you know, we get a lot of comments on it, then arguably we won't have a logical ... there would be enough to give people an indication that that might be a new requirement. If it's completely silent, then there is an issue as to whether or not, if we put in a new requirement, did we give people an opportunity to really provide adequate input on that issue? You're welcome to comment on everything,

but the things that are mentioned in the rule, either in the reg text or the preamble are fair game. If it's something brand new, it would be hard for us to go there in the final rule.

Farzad Mostashari – ONC

Thank you for the IRF also.

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

...specifically made mention of each of the policy committee recommendations, and if we were not taking them or modifying them, we specifically provided rationale for that. And so, I think anything that the policy committee recommended in terms of the objectives and criteria have been, each one has been included in the reg text.

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

That's correct. If they need to be put back in, if there's a rationale, then they're fair game. But if you come up with some brand new objectives and measures that are not mentioned in the regulation, then they can't be put in because there's not – they need to be public comment on them before they could be included in a final regulation.

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

That sounds like the ones that were dropped from the matrix are acceptable and can potentially be changed in the final rule? Is that what you're saying?

Farzad Mostashari – ONC

If there were specific objectives, we discuss each and every objective in the reg text, our rationale, and if there are counterarguments to our rationale, they could be reintroduced, if I understand the administrative procedures.

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

Right. That's correct.

Farzad Mostashari – ONC

There were some measures that were included, not objectives. There were measures that we did not comment. We didn't comment on every measures, and you mentioned two of them there. That's a different story.

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

Okay. So just to be clear, for example, the measure on percent generics that were used, and the measure on indications for high cost imaging were not specifically mentioned in the NPRM, so it would be off the table. Okay.

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

Right. I think so. Yes.

Jodi Daniel – ONC – Director Office of Policy & Research

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

I think, yes, we'd have to get a legal from our general counsel, but I think that's probably a good, fair estimate. Yes.

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

Okay. Open to comments then. Charles Kennedy?

Charles Kennedy – WellPoint – VP for Health IT

I had an opportunity to meet with many of the Blue plans and the BlueCross BlueShield Association, and one of the questions that came up was the proposed meaningful use stage one objectives include check insurance eligibility electronically, submit claims electronically. We certainly support both of those objectives wholeheartedly, but the question came up if a physician already has a practice management system, which is not an electronic health record, simply a practice management system, and can perform both of these functions, does that satisfy or in any contribute to achieving these criteria, or do they have to find an EMR that does the very same function?

Tony Trenkle – CMS – Director of OESS

What we were told by our Office of General Counsel is if it's defined under the umbrella of certified EHR, then it would be part of the meaningful use criteria. Farzad, I don't know if you want to talk more to that.

Farzad Mostashari – ONC

We included every single one of the meaningful use objectives as criteria that need to be met by certified EHR technologies as an aggregate in the IFR, and so it is accurate to say that certified EHR technologies must be able to provide the ability for claims and eligibility checking. The recommendation from the policy committee on certification, and this is now a certification discussion, was and has been that we permit modular systems where a combination of practice management system and an EMR might satisfy that.

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

Right.

Charles Kennedy – WellPoint – VP for Health IT

That's fine. Thank you.

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

Deven?

Deven McGraw - Center for Democracy & Technology – Director

Yes. We had in the second meeting, actually, of our new privacy and security workgroup, and spent a little bit of time talking about both the meaningful use criteria in privacy and security, as well as the certification criteria. This was really just our first bite at this apple, and we'll be discussing it further on our next call and coming up with some more concrete potential recommendations. But on the meaningful use point and the requirement to conduct a security risk assessment, I think, in general, folks thought that was a positive development.

But the one concern that did get raised is that a lot of providers just have no clue how to do one of these. And that one thing that might make this more meaningful is for there to be some guidance or assistance provided to those providers who, while they've always had the requirement to conduct one of these, may in fact never have done one or have done one in a way that isn't really terribly comprehensive. That could come potentially through the RITEC, the regional – I can't remember the acronym – the educational extension centers, or maybe through guidance from OCR in implementing the HIPAA security rules. Then we had more discussion, quite frankly, on some of the criteria in the IFR, which are a lot more specific on the security side, but I'll hold off on talking about those.

We didn't spend a lot of time as a workgroup talking about the fact that the criteria that we specified about HIPAA and sort of being under formal investigation under HIPAA, sort of being a disqualifier until you get that resolved for meaningful use payments, I think we'll talk about that a little more, so I'm now switching into talking personal mode is that I still think – I get the point that the HIPAA criteria, everyone has to abide by them. There's nothing, and so there's a reluctance to sort of put them as more additional meaningful use criteria, but we don't have any as of yet additional privacy requirements as part of meaningful use. All we have is the law. And so to the extent that you've got someone in the situation where they've reached a violation point, the notion that they may have to pay a penalty, and yet still be able to draw down funds from the federal government, I have to say, doesn't sit well with me, but I'm still sort of thinking through what type of comment that I personally might file in that regard, and I'm not sure whether the workgroup is going to agree with me or not, quite frankly, but we'll have more discussion on it.

Tony Trenkle – CMS – Director of OESS

I have a couple comments, but I know, Jodi, you had something you wanted to say.

Jodi Daniel – ONC – Director Office of Policy & Research

I had one on the first point, which was about providing some guidance to small providers. We actually do have a plan underway, and we're actually working on it currently, and would love any input that the privacy and security workgroup has on this. But we are working on trying to come up with some educational materials on security to use through our regional extension centers, and so any guidance or any input that the committee, the workgroup has to share on what might be part of that would be very helpful, but that's something that we've identified as a need and that we're working on and working with our folks in the regional extension center program to do that.

Tony Trenkle – CMS – Director of OESS

Yes, and I also want to point out though, while CMS had the security rule, we published a number of documents, guidance documents, including one for small providers that could be used as part of the education materials that the regional extension centers and others have, so there's a lot of material out there, but I understand the need that the extension centers and others could play in helping educate and help them walk through what's needed in a risk assessment.

In terms of the privacy area, certainly if you can provide some more specific guidance and clarification that would be helpful, as we look at this for the final rule. I think there was just some concern about not only did it already exist, but also in terms of if a complaint is logged against someone, or if it's an entity that a complaint is logged against. It's a complaint that has not been resolved. I mean, what stage do you begin to deny the person or the entity the incentive, so there are some gray areas there that if you can provide some guidance and suggestions, I think that would be helpful in having us look at that.

Farzad Mostashari – ONC

I'll just add to that on the regional extension center front. My personal experience, you're absolutely right. There are many providers who have never done this, although that is probably not unique to the meaningful use. There may be other meaningful use criteria that they've also never done before. And we see the role of the regional extension centers as helping provide the resources to them to be able to successfully achieve that.

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

Christine?

Christine Bechtel - National Partnership for Women & Families – VP

Christine Bechtel with the National Partnership. I have two questions, but first I want to say really well done. I think the collaboration between CMS and ONC was really productive and resulted in a rule that is very good, very strategic, very pragmatic. So I appreciate all the work and thoughtfulness. It's a very thoughtful regulation, so I really appreciate that.

I have two teensy little issues, teensy-weensy, itty-bitty. One has to do with how the data collection regarding race, ethnicity, language, and gender is actually used, and it's probably a technical question. One of the things that the policy committee has recommended was that quality measures be stratified by race, ethnicity, language, and gender. And I believe also that as we ask providers to create lists of patients with specific conditions, that we know that they're able to then look across their demographic populations. That's something I did not see in the rule, and so my first question is sort of a technical one, which is, you have quality measure reports. You have disparities, data collection, and you have condition lists, but there's no sort of use of the data to crosscut those two areas. Fair game for comments, I assume.

Tony Trenkle – CMS – Director of OESS

Absolutely. Yes. I think that's fair game for a comment. I think it gets back to Paul's – some of what he was saying at the beginning. If you show where there should be better coordination as to how we develop these measures and to get towards outcomes, I think that's a fair game for a comment.

Christine Bechtel - National Partnership for Women & Families – VP

Terrific. My second question, Farzad, I'll be you can guess what this is going to be. Did you want to comment on that?

Farzad Mostashari – ONC

Yes. We do preserve the language in the policy committee recommendations, but the objective ... the patients to use for reduction of disparities, among other things.

Christine Bechtel - National Partnership for Women & Families – VP

Which is not a requirement for actually using that. That's the purpose stated.

Farzad Mostashari – ONC

That's right. It's not in the metric itself, although the requirement that they collect that information would certainly permit or motivate providers to do so. On the quality measure stratification, the initial year reporting is by attestation of the summaries, summary counts of the quality measures.

Tony Trenkle – CMS – Director of OESS

Right.

Farzad Mostashari – ONC

And we are hopeful that by 2012, we will have the machinery in place and the standards in place and the IT, health IT systems to a place where that reporting can be done in an automated, electronic way, and the specifications for that could include the stratifications, whether it's by provider or by other measures. That would be very useful as a comment, if you feel like we missed an opportunity there.

Christine Bechtel - National Partnership for Women & Families – VP

Terrific. The second question that I have is about patient education materials, big surprise, so my question is really can you speak to the rationale for the exclusion of that element?

Farzad Mostashari – ONC

A couple things: One was one of the things that we heard was that there are many – it's all good, but the cumulation of these, we've heard a lot of concerns that the cumulation of all the good stuff may be too much. So there was looking, scanning across the matrix of everything that is important saying are there any now that we can look at and objectively say, this may be something that we could try to slim down the measure set, and is not quite ready for primetime in terms of widespread implementation using currently available technologies.

With patient education materials, there was the concern that if we actually scan across what's in the marketplace today, and I recognize, and many of our folks, you know, Neil is sitting right next to you, and he's doing some great work on this. But in terms of the marketplace as a whole, the availability of patient education materials that are at the appropriate health literacy level that are in different languages that are integrated tightly at the appropriate care to provide that information to patients when they need it is still not there. If there is information data that you can provide that says actually we got this wrong, and actually 55% of EHR systems currently do, and according to their readability scale, the average readability scale of the commercially available tools is actually at an appropriate level, then that's certainly information data that would be extremely valuable in helping us make that.

Christine Bechtel - National Partnership for Women & Families – VP

Thank you. That's helpful. I think, as a previous to our comments, what we're hearing from the consumer organizations that we work a lot with is two things. One is, obviously the importance of making information that we give patients access to and copy of, making that information meaningful and actionable, but at the same time, being careful that we don't overwhelm the healthcare system and healthcare providers with lots of questions from patients because they don't understand the information that they're being given access to. And so I would just say, I think we have to be careful not to let the perfect be the enemy of the good. I think there are a lot of other ways that providers can in fact use their electronic information systems to deliver information, patient education information, but that it doesn't necessarily in the first year have to be so stringently tied to generated from the electronic health record, but rather, using the record to generate the right list and then making sure that patients have access to broad resources that they can use to better understand the information that they're being given access to. Can I tag team in Neil, by the way?

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

Is it related to this point?

Neil Calman - Institute for Family Health - President & Cofounder

Yes, and my other....

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

Because there are other people. Okay. Sure.

Neil Calman - Institute for Family Health - President & Cofounder

Just on both Christine's point, I think one of the things that I think all of us are hoping is that the information that we've come out with the NPRM is going to move the industry quickly. And I think a great example of it happened. There was a big press release by one of the big EHR vendors in the last couple of days that announced exactly their capability of linking patient specific and problem specific information, and you wonder why that came out. It came out because we've been talking about this for a while. And I think, you know, it's just a great example of the fact that we have to build upon what can be done, not what necessarily is done now because of the enormous amount of money that's being put out. Is has to be transformational, and I think that there's a good example of that.

The other thing, since you called me out on this, Farzad, the National Library of Medicine is now, because of the prototyping work that some of us have done, now has the ability to link directly up with problems and is doing the same thing with medications and lab testing so that people will be able to link to MedlinePlus through their systems, and that's now available for vendors to work with them to make that interface. These are great examples of motion that has been created by the discussion, and I think that's exactly what we were all praying would happen so that the system could transform. And I guess, since my other point is on a different topic, I'll switch, and then I'll put this back up.

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

Great. Judy, then Gayle.

Judy Faulkner – Epic Systems – Founder

Okay. Two things: One is, I think that the goal was to improve healthcare for the U.S. even more than to have the vendors as teachers. One of the things that I have repeatedly seen over the last couple years, as people talk about the problems of the U.S. and the huge problem of the chronic disease and of how that affects not only our health, but us monetarily, is the correlation that almost every talk gives with obesity and chronic disease. This is something we talked about at one of the very early policy committee meetings, which was prevention of obesity in childhood.

As I look at the three core measures that we're focused on: tobacco use, blood pressure, and drugs for the elderly, we are hitting one for geriatrics. The other two are primarily adults, although certainly tobacco use starts in childhood typically. And I don't know if it's too late, but I was wondering if there could be more emphasis on, I think, protecting the future health of the country through more of a focus on childhood obesity.

Farzad Mostashari – ONC

Let me give a little more information on the quality measure piece, and also address what Paul pointed out about the exemplar versus the 500 measures issue. One thing we heard loud and clear was that the measures should apply to the providers who are applying for the incentive payments, and that the initial set of exemplar measures, if you took all of them, there may be many specialists, including pediatricians, who would say these measures don't apply to me and don't get at what really matters for me. And what we've done as an alternative, we're trying to thread the needle on this has been to say, okay. There are maybe three, and where this is a proposed rule, we're looking for comment on that. There may be three measures that are truly not just measures that matter that are exemplars, but that have the broadest applicability. Again, it doesn't guarantee that every single provider will find these applicable, but they have the best chance of doing those.

And then asking providers to identify another set that meets their practice, and these are grouped currently by specialty. So pediatricians would have the option of looking at, and we're seeking comment, again, on each of these sets saying, tell us which of these measures do you think most applies to your specialty and are measures that matter. And we've listed the NQF endorsed measures for, for example, pediatrics, which includes BMI as the NQF endorsed measure on childhood obesity within it. In addition to appropriate antibiotic use, childhood immunization status, appropriate testing for children with pharyngitis, and so forth. So there is a set of measures that the pediatric community, working with NQF, has said these are the measures that apply to us and for particularly the Medicaid CMSO who had expressed high concern that these measures that we initially talked about were not relevant to the pediatrics population.

Tony Trenkle – CMS – Director of OESS

Right.

Judy Faulkner – Epic Systems – Founder

But what I don't quite understand is we have the two ends of life, peds and the elderly, and one is pediatrics, one is geriatrics. But if we're separating all the specialties, geriatrics is on the core measures, pediatrics isn't. So shouldn't you either take geriatrics off or not use the fact that pediatrics is a specialty as the reason it isn't on?

Farzad Mostashari – ONC

It would be fair. The reason why we have the NQF Measure 22, drugs to be avoided in the elderly, is that medication management and appropriate prescribing and reducing adverse drug events is something that cuts across specialties more than almost anything. So for specialists who prescribe, which nearly every specialty does, there is the risk whether they're prescribing something for ophthalmology or whether they're prescribing something for kidney disease. There are interactions, dangerous interactions, and drugs that are not suitable for the elderly. That was the reason why that measure was thought to be a measure that would be a good, core measure that spans across specialties, not in contradistinction to, and I wouldn't pose it as a contradistinction to pediatrics as a core measure. It's just that there are many specialties who don't see, A, that many children and, B, feel that managing obesity in children is within their scope of practice. If, on the other hand, your proposal be that BMI be added as BMI measurement for all ages.

Judy Faulkner – Epic Systems – Founder

I could do that, yes.

Farzad Mostashari – ONC

Be added as a measure for all providers.

Judy Faulkner – Epic Systems – Founder

I think that would be....

Farzad Mostashari – ONC

That would be, I think, highly appropriate comment.

Judy Faulkner – Epic Systems – Founder

I think I'm coming at this from a different direction, looking at the end goal and working back rather than looking at, we do prescribe drugs. Sometimes they cause interactions. That's bad, and I don't disagree. But if the end goal is better population health, picking those key things that are the most important for better population health and working that back into, then what are our core measures. That was number one.

My second question is very tangential, which is, but very interesting. I've thought about this a bit. There's a certain amount of money to be spent. Has there been an analysis of, with these measures, will be over or under the amount of money to be spent?

Tony Trenkle – CMS – Director of OESS

The amount of money to be spent in terms of what? I'm not sure what you mean. You're paid....

Judy Faulkner – Epic Systems – Founder

The stimulus money.

Tony Trenkle – CMS – Director of OESS

You're paid for meeting the objectives of meaningful use.

Judy Faulkner – Epic Systems – Founder

Yes.

Tony Trenkle – CMS – Director of OESS

Regardless of what we put under that, you're still going to be paid the same amount of money. We don't pay per measure or pay per objective.

Judy Faulkner – Epic Systems – Founder

But if – I'm talking about the total, which is \$38 billion or \$19 billion, or whatever that number is.

Tony Trenkle – CMS – Director of OESS

Well, it's....

Judy Faulkner – Epic Systems – Founder

How is this going to match to the overall budget?

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

I think the point is, it's an entitlement program, Tony.

Tony Trenkle – CMS – Director of OESS

Right.

Judy Faulkner – Epic Systems – Founder

And what does that mean, David?

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

It means, and Tony can correct me, but basically there's no cap on the amount of money.

Tony Trenkle – CMS – Director of OESS

Right.

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

It's all a matter of how many providers, hospitals and eligible professionals meet the meaningful use criteria. If they meet it, they get paid.

Tony Trenkle – CMS – Director of OESS

That's correct.

Judy Faulkner – Epic Systems – Founder

Okay, because I've heard some people worry about that, and so the answer is, it won't stop when you hit the cap.

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

Correct. There's not a cap. When you see these numbers, they are estimated numbers, and you can look at our impact analysis and see that the numbers are based on how we derive some estimates of meaningful use participation or achievement, I should say.

Judy Faulkner – Epic Systems – Founder

Thank you.

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

Gayle?

Gayle Harrell – Florida – Former State Legislator

Thank you very much, and I do want to say thank you for listening to this committee and listening to the public testimony that we have had, especially this discussion, just as the discussion on specialties. I know that was not on people's radar scope to start with, and I appreciate that what you have done, especially in the specialty area. However, as we move forward, and as we start that escalator, there are specialties within specialties.

Tony Trenkle – CMS – Director of OESS

Right.

Gayle Harrell – Florida – Former State Legislator

That at some point you may want to look at retinology versus ophthalmology and various specialties within specialties that those measures are appropriate for each individual specialty and subspecialty within that. So as we move forward, certainly this is a good start in doing that, but I don't think we're finished there.

Tony Trenkle – CMS – Director of OESS

Right, and we've heard some of those comments already from different subspecialties, and I think we'll be seeing a number of comments. I look at this as a beginning that we get out there and get feedback from the community, and we can refine these as the additional stages come in in the future years.

Gayle Harrell – Florida – Former State Legislator

And I also would like to comment on the privacy and security area. Here again, the REC centers, in assisting small physician groups out there, are strictly geared for general practice and family practice and internal medicine, and they will not be small specialty groups who will be able to access assistance from those RECs. So I am very concerned again on how we are going to make sure that the privacy and security that needs to be built into this is adequately handled in those offices as well. So I think perhaps we need to look very specifically at assisting them and making sure that there are the resources there for them to get the education to do those risk assessments.

You know, that the proper policies are put in place to make sure those records are private and secure. That's the number one issue for most patients out there. Are my records secure? Are they private? And when you talk to people on the street, they will, you know, everybody is going to back off from this if you cannot assure them.

Tony Trenkle – CMS – Director of OESS

Right.

Gayle Harrell – Florida – Former State Legislator

So we have to make sure, not just the family practitioner, not just the internist, but also across the board in every area that we have that privacy and security assured. And we also have to, as we start into the exchange of records, and we start from one provider to another and one hospital to another provider, I

see that in the recommendations, in the rule, we're only looking at one test. Is that within an integrated system? Does that meet your qualifications, or is that one test outside an integrated system?

Farzad Mostashari – ONC

Let me take the first one first. You're absolutely right that the need for privacy and security cuts across all providers, and that those in small practices, including specialists, are going to have the greatest difficulty in having the resources and the knowledge to address it consistently. And you're absolutely right that the regional extension center program has a focus on primary care providers.

The point to note is two-fold. One, the resources and materials generated for the regional extension center will be made available to all providers, and we think that there are going to be some very valuable tools, resources, information, easily digestible format, you know, suitable for laminating that will be made available in the public domain and made available as a resource to everybody.

The second point is the regional extension centers are not expected to be the only way that people access health. We think that there's going to be a wide variety of organizations that are going to be helping providers achieve meaningful use, including the societies, the associations, and so forth. But also, for profit entities who will provide consulting services that we're already seeing emerging in the marketplace. We will help you get to meaningful use, and if that includes doing the security assessment, we will help educate you and teach you how to get to meaningful use.

The focus on primary care providers is the recognition that, frankly, they make, they have fewer resources oftentimes, particularly the small primary care providers than the specialists might in being able to access those consulting and other market driven resources for achieving the help they need to get to meaningful use. So the regional extension center program is important. It's going to have positive externalities that others can use, but it's not going to be the only way that people can get the help they need, that they really do need to get to meaningful use broadly, not just in privacy and security.

Tony Trenkle – CMS – Director of OESS

Yes. I think one thing I'd challenge the committee too is an assessment is just that. It's an assessment. What you do with the assessment and how you move beyond that is really much more critical. Obviously you need to have an awareness, and a lot of organizations are not even doing a risk assessment today. But I think the work that Jodi mentioned, the additional educational materials and, as we look at additional stages of meaningful use, we need to think where do we go beyond that. One way, as people have talked about, is tying it to the penalties that come out of the privacy and security complaint system. But other ways might be looking at what you actually do with the assessments and how you use them to improve the security and ultimately the privacy of the information that you're supposed to be protecting.

Now the second question was on the one tests, and I know we've gotten some feedback on that as well. Did you want to tackle that one?

Farzad Mostashari – ONC

Why don't you take that one?

Tony Trenkle – CMS – Director of OESS

I'm trying to – I'll have to go back and take a look at it and see what the – I think the – initially it was to show the capability for 2011. That was the idea that—

Farzad Mostashari – ONC

Yes, so the principle, as Dr. Blumenthal has articulated, is by information exchange, our goal is not that people exchange information within an organization, however large, within a practice, within a vendor community. The goal for information exchange is information that goes where the patient needs it to go, and needed for that patient's care. So the intent certainly is that it has to be information that crosses organizational boundaries.

The information exchange criteria is probably one of the most difficult balancing intentions here. On the one hand, there was plenty of discussion in the meaningful use workgroup and in this committee. The recognition that information exchange is critical, certainly, requirement for better coordination of care and improved health, which is the goal. On the other hand, the recognition that there is a limited availability currently of organizations, as we have currently conceptualized the National Health Information Network, who can provide access to the patient's information wherever the patient needs to be.

The testimony we will hear today from the NHIN workgroup might help unlock that dilemma, but I think this is one of the most difficult of how aggressive to make the information exchange requirement in light, both of its importance, and yet of the realistic capabilities present within communities.

Tony Trenkle – CMS – Director of OESS

But I think the goal was to show that there is an intent do to that exchange of information if the capability is not there is one issue that Farzad mentioned, and that's something that's going to be obviously changing over the next several years. But the idea was that we want to have something in there that at least they make an effort to begin to exchange data, and the question is, does this one test, is that a high enough bar, or is that something that we need to take a bigger look at, as we go to the final regulation. We'd certainly welcome comments that the committee members and others have in terms of how we can achieve that balance, as Farzad said, given the fact that we know the infrastructure today is not in place.

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

If I could just add a comment to that, Farzad summarized it very well. I think the Office of the National Coordinator has an idea of where it wants to go, and that is to have information flow with the patient irrespective of organizational boundaries or practice boundaries or proprietary boundaries. The question is very practically how to signal that and gradually reward it over time, and we want meaningful users who are, in good faith, trying to be meaningful users, but are inhibited by the lack of infrastructure in their community. We want those people to be able to benefit from their efforts. And I think that was part of the rationale of the committee in setting a relatively lower bar for exchange in 2011 in the first stage.

The question is how high to set the bar in 2011 and 2012 and whether the exhortations and comment that come in the preamble and in other messages coming from the Office of the National Coordinator and the federal government, whether that's enough to signal to providers that even if it's a pretty minimal test in 2011, they might as well get working on doing it better because eventually they're going to have to do it better. And we'd welcome comments on what precisely the escalator should look like, how far we should take people at which point along that journey.

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

I think Neil had his second round, and then we'll go to Marc and then David.

Neil Calman - Institute for Family Health - President & Cofounder

Thanks. I guess my comment referred to the section of the NPRM that deals with Medicaid. I think we spend most of our time talking about the Medicare piece, and the glide path on a lot of the pieces of the Medicaid component are considerably different because of the ability to integrate other sources of funds, I guess, into just the incentive payment dollars, the ability to integrate some of the state HIT and EHR

grants and other things so that the glide path could potentially be a lot longer, I guess, is what the point was in the NPRM for Medicaid.

What I'm really concerned about is that if you happen to be a provide in a state that doesn't really have its act together, or a patient, worse yet, a patient in a state whose providers can't access these dollars because the state doesn't have its act together. We end up creating some fairly significant potential disparities between states who are sort of moving in the appropriate direction and those that aren't, and that really sets it apart from the Medicare program, which is sort of rolled out across the country at the same pace.

So worrying about vulnerable populations who are going to be served by providers who are mostly going to qualify under the Medicaid provisions, I worry about what's going to happen to people in those states. I worry about the patients there who are going to potentially get the benefits of electronic technology at a much later point. And I worry about the providers who need those incentive payments the most who are going to potentially be unable to access them because their state plans haven't been approved.

And so do we have a process? I guess my question to you all, and to Dr. Blumenthal, is do we have a process to monitor what's happening in all of the states across the country? And do we have a process in place at the federal level to provide assistance to states that really don't have a history of being involved in health information technology and may not have developed the infrastructure within those states to kind of move in this direction? And what are we going to do? And maybe that exists, and I don't know about it, but what are we doing about that?

Tony Trenkle – CMS – Director of OESS

Yes. I think there are several answers to that. I'll give it from the Medicaid to CMS perspective, and I know Farzad and David have additional comments on the work that ONC is doing.

From the Medicaid perspective, of course, under the law, we can give out dollars to states to help with the development and implementation, development of plans. We've certainly been working closely with ONC in looking across the various states and looking at ways where we can work together with ARRA funding and with ONC's funding to provide the infrastructure there that's needed to support the meaningful use criteria achievement by providers in various states.

We have asked each state, along with ONC, to have a point of contact, a central point of contact in the HIT area. There's a conference in February that the Medicaid folks at CMS are holding that they want to begin publicizing more of the information that's available and funding opportunities. So I think we're building on some of the things we've done in the past, but I think there's going to be – there's a lot more push. Of course, there's the work being done under CHIPRA as well, in the children's area. And there's a renewed emphasis by the Medicaid folks at CMS under this administration that are really focusing on this as well.

And one of the key areas, and then I'll turn it over to Farzad, is the work that ONC is doing that we've been working very closely with, with the exchange dollars and some of the other work with extension centers that ONC has had where we've been really working together to try to make sure we coordinate and leverage funding as much as possible. Farzad?

Farzad Mostashari – ONC

There are state grants from ONC, some \$500 million-plus that we're applying for the purpose of helping establish the infrastructure in states, and we are coordinating closely, as Tony said, with CMS. There is a requirement to have a state HIT coordinator. Every state, I think, will have one, and a state HIT plan.

The focus of the grants is around the health information exchange infrastructure, admittedly, but I think some of the components that are put in place and part of the plans will address the HIT adoption.

The point you raised, though, is a really important one, I think, and I think there's a certain extent to which the federal government can provide resources and technical assistance, as Tony said, in education and guidance and so forth. But there's also, I think, a very valuable role for providers of care to underserved communities and community health centers, I'm sure, will be doing their part in asking for and clamoring for their states to have a plan that can help get them, bring down the resources, not just in terms of the HIT incentive payments, but also in terms of the, as Tony pointed out, the 90% federal match for even the administration of the program.

Neil Calman - Institute for Family Health - President & Cofounder

Can I just ask a followup? I guess, to use an analogy from my practice, what I'm worried about are the people who aren't coming in. So we always answer this with what we're doing for the people who are coming in and applying for those grants and moving this stuff forward. What I really want to know is, is there a process to monitor who is not coming in? Like what's happening in the states that are not coming forward, who aren't identifying people who are functional in those roles, because the innocent victims of that are going to be providers there and the patients in those states. That's what I'm trying to get a sense of. Do we have a grid somewhere or a chart or something? Somebody is following this?

Tony Trenkle – CMS – Director of OESS

Yes.

Neil Calman - Institute for Family Health - President & Cofounder

Great.

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

Marc?

Marc Probst – Intermountain Healthcare – CIO

Thank you. First, thank you for listening to us. I mean, it's just great to see this and see what's come out, and to know you're spending some time doing this. I suppose there are a few things I wish I'd have said a little louder about how quickly the escalator is moving and where it's leading to, but this is really great work.

The question I have is more of a process question, so I come from the mountains where the air is a little thinner, and not quite as appreciative of what the federal process is that we're going through with the comments and all. As well as you have done on this, there still is some ambiguity in the 600+ pages that are out there.

Tony Trenkle – CMS – Director of OESS

Right.

Marc Probst – Intermountain Healthcare – CIO

A specific example might be directly reporting from the EMR or EHR system. Now that wording would suggest that even if you have a certified electronic medical record, if you took that out into a secondary system like an electronic data warehouse, would that still be a valid way of processing, you know, sending in that information? I'm not really looking for that answer. I think there's a whole series of those types of questions. And is the way to get that clarity simply through comments and waiting to hear

response back, or is there any mechanism for clarity in some of the wording that's within those regulations, because I assume there's going to be a fair amount of comment based on what's released?

Tony Trenkle – CMS – Director of OESS

Yes, I would assume there's going to be a fair amount of comments as well. Yes, I think there's several ways, Marc. One is where there's ambiguity in the regulation, particularly when it relates to policies, comments, public comments, comments written as formal comments are welcome if there are certain things that are not clear from that perspective. If there are more operational issues that we need to deal with, we're working on ways to provide that information, either through frequently asked questions, working through the extension centers, or other types of vehicles.

If there's something you see in the regulation that's in there that you think is not clear, then I would certainly make it a comment back to us, and it should be addressed in the final regulation. But if it's something that's more operationally focused, not specifically addressed, then that's something that we can talk about separately that we can provide other vehicles, whether through frequently asked questions on the Web site, through training materials, or other types of ways that we can get the word out on processes and ways to get the effort explained better, I guess for want of a better word.

Neil Calman - Institute for Family Health - President & Cofounder

Thanks.

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

David?

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

Yes, Paul. I want to echo Marc's appreciation for both ONC and CMS having handled this process with so much openness and, I think, real interest in hearing from all of us as to opportunities to improve the rule. The two areas that I have real concerns about and, in the next month or two, will hopefully have a change to work out in more detail, but I was hoping you could share whatever you can about how you came to where you are.

The first is, we had in the original statutory language, and subsequently we've emphasized the cost of healthcare and improving efficiency by virtue of the adoption of EHR and HIT. And the only two real explicit efficiency measures we had were the generic and imaging measures. Then, of course, there were a number of implicitly measures that may lead to improved efficiency in healthcare like care coordination and so on. But the explicit opportunities to really draw the user's attention to improving efficiency are, I think, mostly missing in the measures now.

Since those are both in terms of statutory language and then one of our primary objectives. In fact, our first tagline has the word efficiency in it. Is there anything? I want to find opportunities to make sure then in the final rule that concept is visible and given attention by the users. So ... my first question was, do you have any thoughts in how you deliberated on how to capture that construct in the rule?

Tony Trenkle – CMS – Director of OESS

I guess there are a couple ways, Dave, and I'll ask Farzad to also comment on it. But I think one is certainly how we emphasize that in the preamble, and if we didn't provide enough emphasis on the efficiency area, I think that's something we need to take a look at, as we move towards the final regulation. The other is, of course, getting it into specific criterion objectives. As you said, we do have some, but maybe there's others that, as you mentioned, were not in there either because they were not – they did not come up in the discussions and were not part of the original recommendations, or because

maybe they should have been, but they didn't get in there. The former, as Jodi said, with a logical extension we could probably address. The latter will be much more difficult. But I think part of this may be looking at, okay, what can we signal in 2011, and then what do we need to do in the second stage to make sure that there's a greater emphasis on efficiency or other areas that maybe we didn't have the same emphasis that we needed in, as we did in some of the other areas. Farzad, did you--?

Farzad Mostashari – ONC

Yes. We actually looked very hard for measures, and we included, for example, under oncology, avoidance of overuse of bone scan for staging low risk prostate cancer patients. Under radiology, inappropriate use of – well, probably benign, but the radiology measures in particular that we could find, whether in PQRI or NQF, that addressed some of the overuse issues. Also on the hospital side, there were measures that we could find that had some track record for looking at potentially avoidable events.

But I think this gets to what Paul was talking about in the slides about maybe as part of the strategic planning process, this might be more appropriate as a recommendation to point out that the current quality measurement process, as you're well aware, has not really given us, either in speed, nor in focus, the kinds of measures that are really needed to be able to achieve all the goals that we want. So the tension there, and this was, I would say, with the health information exchange, this is the second most difficult area in balancing is pushing the system into, for example, measures that we think we need to have versus the availability of consensus defined measures that can be implemented in health IT systems and defined in a standard way. Certainly in your role at PBGH, you can do a good deal to help push that. And as part of the strategic planning, I think we look for advice on how that could be accomplished.

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

I think the distinction I would hope we'd look at ... the consensus measures that may be appropriate for quality performance assessment and even quality improvement may not be the only pool to look at for assessing whether IT is being deployed in a way that improves efficiency. And I hope we don't confound one historic process with an urgent need to address healthcare costs in America. And if we deploy all these billions and don't have some evidence that the users are being very serious in addressing unnecessary costs, I'll be very disappointed, and I'm sure it'll really be a challenge to how do we improve this process to get that done.

The second point I wanted to make was just a comment on the advanced directives item that's now not being included in the recommendation and the rule going forward. And I think one thing that I felt at least in advocating for the advanced directives measures was that it was a measure of real patient engagement or stronger patient engagement. Many of our measures that we're able to implement now for patient engagement are actually passive measures. They are pushing data to a patient who may or may not have any engagement with the data, whereas the advanced directive measure at least implies some interaction and a signature at some point, and hopefully a discussion about a very important health issue. And I hope we can find a way to capture that construct again in the battery of measures we put forward, so we don't, so we really show that we're serious about having the patient engagement dimension be reflected in the use of the tools. Thanks.

Farzad Mostashari – ONC

On the advanced directives, we got a fair amount of feedback that pointed out several issues. One was the applicability issue, specialists and others saying, do I really have to just be discussing advanced directives with every patient who comes to see me, and not seeing that as being within their scope. There's also concerns about the appropriateness of, even for primary care, whether every, whatever, 20-year-old that you see, you need to have that conversation with them as part of meaningful use of health

IT. And then there are the absence of standards for documentation of advanced directives and standards of care in terms of how frequently they're to be updated and so forth.

Tony Trenkle – CMS – Director of OESS

...issues as well.

Farzad Mostashari – ONC

As well as state jurisdiction issues and laws, state laws that pertain to that. So there are a number of reasons why that requirement to have a minimum level of advanced directives, we didn't feel comfortable moving forward with that as a requirement and defining a specific metric for that. If there are, I think you're getting at something deeper.

Tony Trenkle – CMS – Director of OESS

Right.

Farzad Mostashari – ONC

And if there are metrics that you can think about or objectives you can think about, that would be great.

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

Thanks.

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

I want to close off this section, and thanks to ONC and CMS again for a really tremendous effort. Thanks for listening to your advisory committee, as far as our input, and also can sense that we're going to have a very vigorous discussion in the meaningful use workgroup in terms of presenting comments, but also in a way that can be useful to you. So the comments, the alternatives, and the rationale for any alternatives we might propose, and we'll get that to you in a timely way. And that'll come before the full committee though for comment before we send that back. So in the next meeting, the February meeting, we'll be presenting the meaningful use workgroup recommendations for you to discuss before we turn around and write that letter. I'll turn that back over to Dr. Blumenthal.

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

Well, I have the pleasures of adjourning us for lunch, and also thanking you again. You all gave us an incredibly wise, thoughtful framework, and I don't think there's any country that has this kind of a framework laid out for its electronic systems, and I hope and expect that the thinking you've done will ramify not only within the United States, but beyond the United States in terms of trying to make concrete what societies can achieve and should expect from the creation of an electronic system of health information. We'll see you in an hour.

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

I think we're going to get going in just 30 seconds.

Judy Sparrow – Office of the National Coordinator – Executive Director

Operator, I guess we can open up the public lines now. We're ready to reconvene.

M

You're live, Judy.

Judy Sparrow – Office of the National Coordinator – Executive Director

Dr. Tang?

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

Welcome back. Dr. Blumenthal had some other business for the first half hour, so he's going to join us a little bit late. And we took the hour from when he said an hour rather than the scheduled time.

We're going to continue now on the other document that was released. This is the IFR on the initial set of standards for implementation, standards implementation specifications and certification criteria for EHRs. We'll begin like we did this morning with a presentation from ONC. This came from ONC this time, and then we'll have comments from the committee that can be considered. I think we have Farzad, Doug, and Jodi.

Farzad Mostashari – ONC

Hello. Since this is the policy committee, not the standards committee, I'll be doing this presentation because certainly if it were the standards committee, I would not stand a chance. For those of you who could switch-hit and also could have served on the standards committee, I have brought Doug Fridsma here who was on the standards committee before we persuaded him to come over to the federal government. We do have spots available for all of you should you choose to seek federal employment. Any technical questions, I'm going to turn immediately to my left, but let me talk from a policy perspective about the principles that under... the certification criteria and standards. And, no surprise, the source for many of these principles was none other than yourselves and the HIT Standards Committee.

In terms of the certification criteria, we took the recommendation that the certification criteria should be minimal and focused on assuring providers that the EHRs they buy can support meaningful use, so the certification criteria do not include many other EHR, basic EHR functionality that are no doubt very important, but are not directly related to the attainment of meaningful use. We also focused on key capabilities that could be tested pretty objectively and simply. And, again, focused on a minimal set, as minimal as we could make it, so that there would be the possibility of innovation in this field.

When it comes to the standards, this is really fascinating from a policy point of view. But recognizing that whatever we do has to be incremental, and to signal the future so people start moving, and yet not push the industry too hard to implement standards that are not yet ready. We thought that it would be very important to just recognize common methods already in place that basically have the market has ruled are the ones that are going to be used for secure transport. And where we do push industry would be to push industry on the vocabulary and terminologies. We've heard a lot that the systems need to be capable of incorporating, for example, LOINC or being able to enable mapping to RxNorm, as we'll hear. Where we did, I think, go a little bit further than the HIT Standards Committee recommendations was on narrowing down and signaling a little strongly that we need to get there on the terminologies.

On the security functionality, while we kept that very strong, we didn't – and there was plenty discussion about this on the standards committee. The concern was that particularly as we came to understand the arcana of regulations, not arcane to you, Jodi, but arcane to me, was that if we had named a specific standard for security, then any evolution in that standard, any advancement or innovation in those that would exceed potentially the security around, say, encryption, I would no longer have been compliant, and we would have run the risk of freezing the market in sub-modern or suboptimal technologies. So the approach that we took there was to define the requirements functionally, while giving examples of current technologies that meet that level of assurance.

That's kind of the overview, and this is in terms of the construct of this. The meaningful use objectives really drove the certification criteria. And then a subset of those certification criteria involved standards that must be implemented within the electronic health records as part of their certification. To give an

example, you have to provide a patient summary record. The certification criteria are the capability to electronically transmit a patient summary record. And then the standards for that include not only that the CCD or the CCR must be used, but also the vocabulary standards for each of the elements, the common elements, whether it's medications, problem list, labs, and so forth within that. That's the structure of our thinking.

I do want to underscore, and this actually wasn't immediately obvious to me, and it may not be to some other folks. But the standards that we're requiring here are requirements that electronic health record systems must be able to have the capability to use those vocabulary standards. It is not, other than, I think, problem lists, Tony, that specifically mentioned vocabularies in terms of SNOMED and ICD. The only one that in the meaningful use that pertains to individuals providers is that standard.

Tony Trenkle – CMS – Director of OESS

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Farzad Mostashari – ONC

For the IFR, which is where the standards were defined, the standards are incumbent on the EHR vendors who seek certification. It is not a requirement on every provider who seeks to achieve meaningful use. I see some furrowed brows, so let me give an example.

Systems must be capable, EHR systems must be capable if a laboratory is sending an electronic lab result with LOINC, they should be able to input. They should be able to accept that lab result with the LOINC code properly and to manipulate that information according to the LOINC code. But if a provider – but there's no requirement that a provider look at all of their lab tests and prove to us that all their lab tests have a LOINC code next to them. So the requirement is on the systems being capable of using those vocabularies, not on the provider having to go out and force everybody else in the ecosystem around them to use standards, which they can't currently assure.

And just to point out that the initial set of standards are in four categories, as recommended. There are the content exchange standards, so those are your standards used to share like the clinical summaries, prescriptions, structured electronic documents. There are the vocabulary standards. There are transport standards and, finally, the privacy and security standards. The interoperability standards are mostly when systems talk to each other, whereas the privacy and security standards cover not only when information goes from system-to-system, but also within systems.

I think that's too small to read, so I'll turn it over to Doug Fridsma for any comments, corrections he'd like to make to my non-technical summary. And now turn it over to the committee for questions.

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

Thank you very much. Maybe I'll give the certification group a chance to make some comments to start us off, if you'd like, Paul and Marc.

Paul Egerman – eScription – CEO

Sure. I'm Paul Egerman. I do have a number of comments. First of all, I just want to say the IFR represents really excellent work, and so I just want to say thank you for a terrific job. It's a complicated topic, and I read through all the textual description, and you're very clear on what you were doing and why you were trying to do it. That textual description is very helpful because the other side of this thing, there's a lot of software developers and vendors who are trying to figure out what to do, and to have it all written down as to what you're doing and why you're doing it, and what the future is, the glide path is helpful.

I'd also say, from the standpoint of those of us who work in the workgroups, it's also gratifying to see that so many of our recommendations were accepted, so that was also very nice to see, and it made sense that not all of them were accepted. Although, I'm sure, like everybody else, I have one, favor one that I wish really had been, but I do understand that.

And I'd say also the IFR does have in it some things that are really, you know, really fundamentally important to our industry. It does include the concept of a modular EHR. It's really called out a major goal, and that concept of the modular EHR, I think, has the potential to provide for a great deal of innovation in our entire industry, and so I think that that's great. And you also have some – you go through a number of technologies that are fairly – that are very recent and modern. I would call the IFR is a document that I would say is fully buzzword compliant. You've really done a terrific job in terms of making sure that you've got the right technology.

The fact that you're talking about a modular EHR, one observation I would make for you is that that means when it comes to exchange or interfaces or interoperability, we also have to think about exchange between applications. So if you have this vision going forward that we are going to have all kinds of different modules made by all kinds of different vendors, there is going to be a need for more and more clinical interfaces, and the IFR really only has two clinical interfaces. One is a laboratory interface, and the other one is e-prescribing. I'd say those are a major step forward to have those two, but in the long-run, we're going to need more clinical interfaces in order to fulfill this vision of this modular system.

But having made that observation, the question I have is I have a couple questions. The first question is really sort of a process-oriented question. I'm trying to understand how this IFR is going to relate to the NPRM, the meaningful use thing that we talked about this morning because the IFR, I understand – I may not understand this right – but it's on like a 30-day track, and at the end of 30 days from today, if it was in the federal register, this becomes law. And so even though there's a 60-day comment period, this is like final right now, and so this is final, and how does that relate to what we discussed this morning with meaningful use? What happens if people make comments to the meaningful use, to CMS, and CMS reads these comments, and they say, yes? We need to add this new something or other, this new capability. What's going to happen to the IFR that's already final?

Jodi Daniel – ONC – Director Office of Policy & Research

It's a great question, and you're exactly right. This is a final rule. It's effective 30 days from the date of publication, which is today. You have the copy hot off the presses. So it is a final rule as opposed to the CMS meaningful use rule, which is a proposed rule and doesn't take affect until they publish, until they get the comments, interpret them, incorporate them, and publish a final rule.

That being said, the word "interim" is in front of the word "final rule" for the very reason that the expectation is that we do accept comments on it and can modify the rule to reflect those comments, or to reflect the comments or any changes that CMS makes in their regulation as well. Obviously there is a desire, since this is a final rule. People will start acting in accordance with the regulation, and so I wouldn't expect that there's going to be a 180-degree shift from what's put out now. But to the extent that there is a change in the meaningful use regulation, we obviously have to coordinate these rules with the CMS rule. And to the extent that there's some new provision in the CMS regulations that require a new certification criteria, for example, that's something that we would work closely with CMS to determine.

We do expect to get comments. We do expect to consider those comments and to incorporate them as appropriate, and then to publish a final rule, and to work closely with CMS to make sure we keep the integrity of the rule that we do have on the books, as well as support their needs for their incentive program.

Farzad Mostashari – ONC

I'll also add that while conceptually you can see it as a real problem, practically speaking, a lot of the potential modifications to the NPRM might have no impact on the criteria, whether it's definition of hospital-based eligible professional. It doesn't affect. It's really important. It doesn't affect the certification criteria.

Whether CPOE can be done by, you know, the denominator is all providers who do it or just the physicians, it doesn't affect the certification criteria. And the number of things that we heard that could be new requirements is severely limited by the Administrative Procedures Act, of what can be added back. So I think it's the problem space is pretty limited to, and I guess the counter is, things could get dropped that might have been in the certification criteria, but the negative consequence of that is relatively limited.

I think you're right that it's a conceptual issue. I'm not sure how much of a practical issue it's going to be. If it does turn out to be an issue that we do need to modify the IFR to reflect the NPRM changes, we have the ability to do that.

Paul Egerman – eScription – CEO

I'm trying to understand what you said, Farzad. To put it differently, if I were a software developer or vendor—

Farzad Mostashari – ONC

Start building.

Paul Egerman – eScription – CEO

That's ... this is the blueprint I should start building, and if there's a change, it's like a one percent change. This is the blueprint I should start building, and it's not going to change by very much. That's the correct message the industry should hear about what this IFR represents.

Farzad Mostashari – ONC

There is very little regret likely for vendors who build to be able to do these things.

Paul Egerman – eScription – CEO

That's very helpful. Thank you very much. I do have some other questions, but let me give other people a chance to ask questions.

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

Other committee members? Deven?

Deven McGraw - Center for Democracy & Technology – Director

Once again, we did have a little discussion in our privacy and security workgroup about the security standards in particular, and a couple things. Again, we sort of just got really our first bite of this apple, and we're going to talk about it more, and we have another meeting scheduled in a couple of weeks. But one of the things that folks noted is that, of course, as you explained, Farzad, these are technical functionalities that need to be in the system for certification. But there's sort of no concomitant obligation to use any of them. So for example if you've got an encryption required to be in the system, but you decide that you won't turn it on, potentially you've got a capability that's underutilized that could advance security.

On the other hand, again, we're still talking about this, but if that requirement was one that could not be turned off, that's one way to write a criteria that actually kind of hardwires it into a system. You know, my own sense is that I'm not sure how workable that is, but for a lot of providers who have never worked with encryption before, I think for some of them it's going to be an adjustment. And whether or not they utilize it is going to be dependent on whether or not, in some respects, they might have to, so we're going to do some thinking.

Again, you know, as always in the privacy and security space, you know, there are more policy levers potentially available than just the meaningful use rule, and I think there's the privacy and security rule under HIPAA, for example, and other sort of levers that ONC has itself. And so we're going to try to respond in a more specific way to this rule per se, and then I think do some harder thinking where we have some more time about how one might get the policies around security to maybe catch up with where we're getting the technical functionality with respect to these records.

Farzad Mostashari – ONC

Can I comment on that?

Deven McGraw - Center for Democracy & Technology – Director

Sure.

Farzad Mostashari – ONC

I would submit that it would not be appropriate for us through certification criteria to be making those policy moves. For us to say the system must have encryption that cannot be turned off is really a backwards way. If that is a policy decision, it should come either in the framework, as you said, of meaningful use, so direct your comments to Tony Trenkle.

Deven McGraw - Center for Democracy & Technology – Director

Right.

Farzad Mostashari – ONC

Or to other....

Deven McGraw - Center for Democracy & Technology – Director

Yes. And, personally, I do not disagree with you, Farzad. But there are certainly, you know, you sort of look at all the tools in your arsenal, and people do start to think creatively.

Jodi Daniel – ONC – Director Office of Policy & Research

Can I also make one comment? I think you hit the nail on the head when you were saying that there may be other levers. And I think that was some of the thinking that went into this that we are required to come up with HIPAA security guide ... under ARRA.

Deven McGraw - Center for Democracy & Technology – Director

Right.

Jodi Daniel – ONC – Director Office of Policy & Research

So there are opportunities there. Obviously we have those regulations. There are things in the HIPAA rules that are addressable. It might tip the calculus if something is addressable and, in fact, you have the technical capability to do it versus before you didn't.

Deven McGraw - Center for Democracy & Technology – Director

Right.

Jodi Daniel – ONC – Director Office of Policy & Research

And so some of those things might be able to be forward through guidance or through the HIPAA security rule itself. And so those are still things that we are thinking about as well, and any input obviously would be very helpful. It wasn't, you know, but some of these are difficult policy issues as to, we heard in the standards committee that encryption is a very important tool, but there are times when it's very useful and actually adds an important layer of security and other times when it's more challenging or when it doesn't necessarily provide the same level of assurance. So there at least seem to be some, you know, it wasn't an all or nothing on some of these, and that was some of what we struggled with when we were talking about these issues.

Deven McGraw - Center for Democracy & Technology – Director

No, I mean, I know we recognized that, and so on the one hand, if we're thinking about the other policy levers that don't have the 60-day comment period, we've got a lot more time, so that's the other thing at issue here.

One thing that we did do, again, a little discussing about, but further flushing out, so on the issue of patient choice, which we are going to take up from a policy standpoint in the very near future. I think start taking up probably within the next month or so. Even if we didn't do another thing on that issue, we still have in certain parts of the law today, whether it's in federal law or state law, a requirement that patient consent be provided first for the data to flow for a certain purpose. Sometimes it's on certain categories of data, etc. Again, if we did nothing else, we still have those laws in place today.

I think I was personally wondering where a technical functionality might be part of certified systems to actually help providers to comply with the law, that in fact they, in many cases, they already have to comply with. So I don't know whether that was part of – I'm curious whether that got talked about at all because it's one of those that isn't really talked about at all in the IFR. And so it doesn't sound like it's necessarily based on previous discussions. We've had a likely candidate in round one, and so I'd be curious to get feedback on any discussion you might have had on that.

Jodi Daniel – ONC – Director Office of Policy & Research

I'm going to look to Doug also as far as where the standards are on consent.

Deven McGraw - Center for Democracy & Technology – Director

They were often called consent management tools, like an ability to allow the equipment to help you meet a legal requirement, which....

Jodi Daniel – ONC – Director Office of Policy & Research

Right, and I think your point is well taken. There are legal requirements that exist for consent. There are also providers that use consent, whether it's legally required or not, and that's helpful. And there's been some work among the standards community on consent management standards, which I'm going to let Doug elaborate on where those are.

Farzad Mostashari – ONC

I don't actually remember if they were part of the standards committee recommendations to ONC.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics

Yes. I don't believe, and I'd have to go back and check, but in terms of the recommendations that came from the standards committee. Certainly there are technologies out there that can be used as a framework to provide electronic means, and that's really what we're talking about, the electronic means to capture and make sure that we have signatures and all the things you would need for patient consent.

I think, with many of the standards that we look at, there was a lot of discussion trying to weigh those things that are out there and available, but not on widespread use, and those things that were really fairly solid and had a fair degree of uptake. And so there was a lot of tension and discussion about where to draw that line or where to put that bar. Clearly this is the first of the IFRs or the standards that will be established, and I'm hopeful that this committee and the standards committee will continue to provide us recommendations about how to incrementally extend these. But that wasn't something that specifically came from the standards committee to discuss.

Deven McGraw - Center for Democracy & Technology – Director

Okay.

Jodi Daniel – ONC – Director Office of Policy & Research

And just to further elaborate on that. To the extent that you all, as a policy committee, think that's an important area for standards and certification criteria, obviously you can set that priority for the standards committee to make recommendations to us on, and we would be glad to hear....

Deven McGraw - Center for Democracy & Technology – Director

Right. Well, as I mentioned, we have it on our draft work plan, so you'll definitely be hearing more from us on this one way or the other.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics

Good.

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

Other comments, questions? Tony?

Tony Trenkle – CMS – Director of OESS

I've just got a couple comments. I think a lot of what Deven was saying too about the different levers that need to be involved here. We've got the DEA rule on the e-prescribing of controlled substances that when that comes out in final will have certain security criteria that need to be integrated in with the other security criteria. Of course, you've got the privacy rules that OCR, the Office of Civil Rights, is coming out with.

We also need to look from our perspective, CMS, not only meeting the requirements of meaningful use, but making sure that there's capability for us to audit and look at meaningful use as being achieved. So its capabilities to assure that they can meet the requirements of meaningful use, but it has to go a little bit further than that as well. But I think what's critical is that you set up a process here that can continue to evolve over time to meet the changes in meaningful use criteria, as well as harmonize with some of the other regulations and standards work that's going on, so that we don't create disincentives or create barriers or other types of unintended consequences, as we move down the road. I think you've started on the right path, but it's obviously something that's going to continually need to be looked at, as we continue to evolve this infrastructure and evolve the criteria for meaningful use.

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

Gayle?

Gayle Harrell – Florida – Former State Legislator

Thank you very much. And I was wondering if perhaps we could have the same kind of crosswalks that we had with the meaningful use criteria as to what is in and what is out, because I understand that there are some things that were not included from our recommendations. If it would be possible to give us kind of a point-by-point as to what our recommendations were, as well as what is in and what is out. If you have a synopsis that maybe verbally you could give us a little bit of what's not there as to what's there....

Farzad Mostashari – ONC

We were planning on going through that in detail at the standards committee. But, Doug, maybe you can give some of the high points.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics

Yes. I think, in general, we tried to incorporate as many of the recommendations as we possibly could, and I think, to Farzad's introduction, we tried to constrain some of the choices when it came to things that were very specific to healthcare. And we tried to make sure that those things that were not unique to healthcare had more functional description to allow innovation to drive that. So as an example, and again, when we speak in front of the standards committee, we'll go through in a little bit more depth.

But when it came to the patient summary data package, that sort of encapsulation, the recommendation there was CCD, CCR, CDA template, or HL-7 2.5.1. So there were about four choices of possibilities. What we incorporated was to include CCD or CCR as the framework. So we eliminated a couple of the recommendations and, in a sense to frame these standards around just two. But we realize that under recommendations from this committee and from the standards that we hope that we will begin to converge on a single standard there, and begin to, again, keep constraining those choices to improve our ability to support interoperability.

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

That's a big one. I believe the initial standards committee recommendation did not include CCR. It included a variety of CDA template with free text or whatever. There were certainly conversations afterwards with the standards committee where the point was made that if we really want to – if we think that sharing of a patient care summary is critical for meaningful use, pushing industry to standardize earlier would be a good thing, and that there are de facto to current care summary documents that are de facto in the marketplace today and that we should, instead of allowing the HL-7 CDA template with free text, that we should really push industry towards greater standardization on one of those two or really on both of those currently, and urge the vision ahead that the strength of both will be integrated over the longer-term. That was a big one in terms of the CCR, CCD discussion.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics

There are probably two others to sort of highlight, and we can go through more if you'd like. With regard to electronic prescribing, one of the differences there is that we recommended or that the rule has elected to have local or proprietary code sets that are used to describe drugs that are mappable into RxNorm, and so the IFR described the subset of vocabulary or terminologies around drug vocabularies that are mappable into RxNorm, and that's a little bit more prescriptive or directive than just using local or proprietary codes, which was the recommendation.

One other area that there was a distinction was around laboratory orders and results. There we again were trying to push forward a little bit more, not so much that internally, and the regulation really doesn't

address internal representations of vocabularies and terminologies. But we wanted a certified EHR technology to be able to receive code sets that were LOINC code sets, and to be able to persist those. So we didn't want meaningful use criteria to be dependent on a lab system sending you that information, but we wanted the certification criteria to say, we need to be able to have that functionality so that we can receive those, if they're available with that.

Then I guess the other kind of broad area had to do around describing security and encryption technology. Rather than specifying a particular kind of security or encryption technology to use, instead taking that technology and describing it functionally, and then putting examples of the kinds of technologies that would support that. Those were some of the highlights, I think. Are there others?

Gayle Harrell – Florida – Former State Legislator

I know in our subcommittee dealing with HIE, and that became a real issue when talking about lab results in particular and which version of HL-7 was going to be used. Did you specify on that?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics

Those, the specifications for some of that exchange, we don't have, and, Farzad, you can correct me if I get this right, but we don't have specific descriptions, and this perhaps goes back to the point made previously about modules and clinical interfaces. We don't describe a particular laboratory, clinical interface. What we do though is that there are some public health reporting requirements for some laboratories, and those specify in HL-7 2.5.1 or 2.3.1 as the way of interacting. It's important to also note, however, that for some public health agencies, there are other state laws and some other restrictions as well that may, that also have to be considered, and the certification criteria included that as an appropriate standard, if your state required a particular way of reporting, that that could be certified there.

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

Any other questions or comments? Paul?

Paul Eggerman – eScription – CEO

Yes. I just had a couple comments. First of all, to follow up on the question that you asked, Gayle, about how the IFR differed from the workgroup recommendations. It seems like what Doug spoke about was very helpful. One of the recommendations in the certification workgroup was that, related to interoperability, that in effect it would be hard edges around all of the specifications, and so that's a very subjective issue. In fact, that's a subjective issue that I think that you have with all of the activities that you did. And so one of the issues that the certification workgroup will look at, and I suspect one area that you will get a lot of comments from a lot of different people on is to what extent you really have hard edges on the specifications. And the comments could be both ways. People might think they should be a little bit more specific, or people might think they should be less specific. There should be more flexibility. That's a tough issue.

The question I have for you, as I look at all this, and I do want to reiterate this is great work, and you have advanced this significantly forward. This work, though, there's one other thing that has to happen. In other words, besides software developers knowing that now they can write their software to this, they need to know how they're going to get it certified, and so there's this other thing called the NPRM that's yet to be released. Can you tell us anything at all? Is that eminent? Can you give us any information at all about that? Are you not allowed, just not allowed to tell us anything?

Jodi Daniel – ONC – Director Office of Policy & Research

It wasn't published in today's federal register.

Paul Egerman – eScription – CEO

That's very helpful. It saves me a lot of time.

Jodi Daniel – ONC – Director Office of Policy & Research

Right. We're working very hard on that, and we are trying to get it moving as quickly as possible. It won't be out today or tomorrow, but we're trying to get it pushed through as soon as we possibly can, so keep your eyes peeled for it. Yes, we don't have a specific date at this point that we can let you know.

Paul Egerman – eScription – CEO

I'm hearing not days, but maybe weeks.

Jodi Daniel – ONC – Director Office of Policy & Research

I will neither confirm nor deny.

Paul Egerman – eScription – CEO

You've got a nice smile.

Tony Trenkle – CMS – Director of OESS

...right now.

Jodi Daniel – ONC – Director Office of Policy & Research

We're just giving you a break. Giving you time to digest Tony's rule.

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

The rule that Tony wrote. Deven?

Deven McGraw - Center for Democracy & Technology – Director

I want to follow up on Gayle's comments, and Paul's earlier on lab certification criteria since we did present a set of recommendations before this workgroup in the last meeting, and some of them were adopted, and some of them were tabled. And then the rule dropped, and we've sort of been – my cochair and I having discussions, what do we do now? So we are trying to schedule a call with the workgroup to discuss what we might recommend formally, but one of the questions that does occur, did occur to Micky and I, and I actually was having a conversation with Paul about this, is that while there are requirements for the certified EHR technology to have the capacity to send lab results to public health agencies using the full complement of standards that we had recommended, but yet we don't have sort of – it's almost as though we stopped one step short of saying, well, hospital labs. As long as you have the capability to send it in this way to public health agencies, why not use that same capability to communicate those results to you customers who order labs from you? Because I think we recognize that one of the issues with standardization in this space is getting the labs to send the results in a standardized format. And we have a bit of limited reach with respect to what we can do because there's, you know, the independent labs in particular are not subject to these criteria, but we do have a lot of lab results being delivered by hospitals. So I'm wondering, you know, how close are we to sort of that next step if we're already requiring the technology to be able to send results to public health agencies using the very standards that we had recommended?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics

A couple thoughts on that: So one is that the certification criteria for hospitals that send lab results to public health comes from, stems from the meaningful use requirements. And there is, again, no meaningful use requirement forwarded by this committee that hospital labs send results, LOINC coded or otherwise, to community physicians for example. So the policy driver wasn't there.

I'd also make the point that there may be other policy levers. We recognize that the meaningful use primarily bears on providers and hospitals, not laboratories. And as your workgroup has recommended, there's a need for the partners, the trading partners of providers to also be able to support the interoperability requirements. There may be other policy levers that would be more effective in meaningful use and the certification criteria tied to it for achieving that.

Finally, as you pointed out, there may be, again, positive externalities. If the hospital laboratories have to be able to support a certain level of HL-7, certain LOINC coding for certain public health reporting features, that maybe a, albeit, weak driver of the increase in capability of laboratory information systems for supporting those mechanisms.

Deven McGraw - Center for Democracy & Technology – Director

I know some folks want to respond to you as well, but I just want to remind and reinforce, remind the committee and reinforce the piece of the recommendations that the IE workgroup made that in fact we did adopt with respect to encouraging greater interpretive guidance from CLIA, the CLIA office within CMS to try to move the labs in a more positive direction. My understanding is that this will be out very soon, and I just want to, again, reinforce how important that is and how much we support getting that out.

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

Thank you. I wonder if I could interject a clarification on the meaningful use. Farzad, you said we didn't, although we don't have any meaningful use for lab, so that wasn't a lever we did have. In our meaningful use matrix, we did say that to get one of the criteria that you receive results in a structured way. So that's, I think, as far as we could go from the meaningful use policy side. And it seems like that would also open the door for certification criteria ... labs or, in this case, you do have some scope over hospitals, in the hospital lab. Anybody else...? All right. Thank you once again for the great work and for spending your time with us.

Art Davidson - Public Health Informatics at Denver Public Health – Director

Paul, this is Art. I had a question.

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

Thank you, Art.

Art Davidson - Public Health Informatics at Denver Public Health – Director

Yes. This is similar to the question, I think, that Neil asked this morning regarding the Medicaid capabilities to receive information from meaningful users in their communities or states. How do we think that states are lined up right now, especially in the public health departments in states, to receive the data that Deven was just describing being sent to the state health departments using specific versions of HL-7? Do we have an idea of what the landscape is like and whether there are states that certainly are advanced, as Neil pointed out, regarding Medicaid and the ability to receive, while other states may not, and actually be somewhat prohibiting improved interoperability in exchange? And if that is an issue, how do we address that?

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

Well, Art, we would ask for your help in working with the state and local public health partners, as well as, we are working with CDC on increasing the capability of public health departments to participate in information exchange. There are funds that have been allocated for this purpose, specifically looking at the meaningful use requirements. The specifics of those will, I hope, be made clear. But in recognition that there may be, and the recognition that there is, and there quite likely will be some jurisdictions that

cannot receive the information currently or do not have an interest in some cases to receive, for example, the ... surveillance information. The meaningful use has ... as well as the NPRM that it's subject to applicable public health agency requirements.

Tony Trenkle – CMS – Director of OESS

As I mentioned this morning, we have a number of planning funding activities going out to the states to take a look at where the gaps are and ways we can address those gaps. As I said, we're also working closely with ONC and looking at how we can leverage the funding from both agencies to address some of these gaps, as they exist, but part of the planning activity is to begin to look at what do we need to get there, recognizing that each state is different, and some are far more advanced than others.

Art Davidson - Public Health Informatics at Denver Public Health – Director

Thank you.

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

Thank you very much to the panel, again, and to the committee for comments. I'll turn it back to Dr. Blumenthal.

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

Thank you, Paul. Thanks to the panel. The next section, and I'm glad we have a few minutes. We're a few minutes ahead of time. One of the questions that's come up, this came up this morning, two questions that came up this morning that bear on this next discussion. One was how we get the states enrolled or involved in information exchange, and they vary in their abilities to participate, so that was sort of one question that came up. Another question that's been circulating is, of course, how much exchange is going to be possible given the infrastructure for exchange, and if we hold meaningful users accountable for moving information around, whatever the standard is, don't we have an obligation to make it feasible for them to do that? You can't create a community at an individual. The community has to take shape around you. It has to be a collective effort.

We have asked a workgroup of the policy committee to help us think about our responsibility to create a backbone for exchange. What is the federal role in that regard? How far and in what form should we push the exchange capability? We have a history that we are both cognizant of and continuing of creating a demonstration program called the Nationwide Health Information Network, which developed in a previous, in a world before HITECH, and had certain characteristics.

And, in effect, what we wanted to know is, is this a sufficient, a necessary and sufficient approach to creating the backbone for interoperability, or should we be thinking more broadly? Strategically, where should we be heading in the interoperability area? How do we support states? How do we support individual physicians? How do we support hospitals? What is, and how does all that relate to making meaningful users capable of meaningful use, not just ten years from now, but a year and a half from now?

So this is a core responsibility, and we're trying to isolate and elaborate on the critical federal role and the role of the department and of the Office of the National Coordinator and CMS in this realm. So we are very appreciative that the workgroup has met and thought a lot, and feels like it's ready to make some recommendations. Depending on the fixed scope of the recommendations and the reception that it receives here, it would be terrific if we could adopt all or some of them. And transmit them as advice to taking off my National Coordinator hat and putting on my policy committee chairman hat, transmit them to the National Coordinator, because this is an area where, given the timeframes to meaningful use, if there are new investments that we have to make, if there are new policies or aspirations we have to verbalize and communicate, we have no time to lose. So we need; we very much value and need your direction,

and that's why we've gotten, asked the workgroup to work as hard and as fast as they have, and present recommendations in the short timeframe that they have.

We appreciate their work, and David Lansky is going to, I think, lead the presentation, and then is someone going to join you? Pardon? Doug also? No. Danny. Oh, Danny. Is Danny here?

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

I don't think Danny is here.

Jodi Daniel – ONC – Director Office of Policy & Research

He wasn't able to make it.

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

Okay. So you're David and Danny for today.

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

That is something I can't do justice to. I'm very fortunate to have Danny as the cochair of this workgroup, and he's phenomenally talented. I'm sorry he's not with us today, but the group as a whole has been a very kind mix of people from this committee and the standards committee, so it's unusual in having both the strong technical and policy emphasis in the way our discussions have proceeded, which is necessary because this is a complex area.

And I think, as David just suggested, it's particularly interesting because it is a place where we are dealing with the reality that it is a very big country, and there are tens and hundreds of thousands of people who need to be accessible to this information exchange process. And we don't know where they all are today, and we don't know how to talk to their EHRs and how to find them and how to feel confidence that those hundreds of thousands of potential users are who they say they are, and that we can successfully manage the communications across this network. So that urgency of solving that problem in order to enable meaningful use has been the thrust of our discussions so far.

We have had two days of testimony. One focused on a question of directors, and one focused on the question of authentication in the last month or so, so we have begun to collect some expert industry and public policy input to what we're doing.

What we wanted to do today was walk you through our thinking up to this point, describe what we'll call findings from our early investigations, including these hearings. Then, as David said, outline several recommendations that we think are timely in order to accelerate the HIE infrastructure, building upon the work of the Nationwide Health Information Network. Let me just go through that.

The workgroup members are listed here. You'll see a number of folks from this committee, and we've also had extraordinarily active support from the staff and consultants, and I want to thank them specifically for doing that and helping shape our discussions. Really, it's interesting that the process has forced to come back to the question of what is the Nationwide Health Information Network, and we actually spent a surprising amount of time on that topic, given how far along we are in this process. And I think it was helpful.

And this definition we put forward today is a reminder that we are not conceptualizing the Nationwide Health Information Network as a thing or as a particular set of servers or wires that are being accessed by hundreds of millions of people. We're conceptualizing it as a set of policies, standards, and services that enable the Internet to be used for secure and meaningful exchange of health information to improve

health and healthcare. This is, we think, a fairly potent descriptor of what we're talking about here, and this will come back, as we proceed, with the question of what can the federal government do to enable meaningful users to exchange information that helps them satisfy the criteria for meaningful use. We think the opportunity lies in this set of policy standards and services, and that's what we want to recommend to you today.

Our workgroup will develop a set of recommendations for both policy and technical frameworks for the NHIN in a way that is open and fosters innovation. That's how we see our charge.

The meaningful use criteria, as we've now seen it in the proposed rule, requires the exchange of health information among providers and with patients to achieve the goals we've described, improving quality, safety, and efficiency, patient engagement, coordination of care, and population health. We are taking, as our starting point, what can we do to help potential meaningful users exchange the information they need to, to satisfy those criteria. So in other words, we are not taking a grandiose, comprehensive view of what is the ultimate Nationwide Health Information Network look like. We're trying to drive our attention to those critical opportunities to enable meaningful use to be successful.

As we look at the stage one criteria that we talked about this morning, we see several elements that involve direct communication of patient data among providers primarily, and secondarily, several cases with patients. Examples include doctor to consultant, lab to doctor, doctor to pharmacy. And in the cases that we are looking at for stage one, for the most part, the exchange is for treatment or payment purposes. The sender and the receiver are already known. Their identities are known. And the sender may or may not have an active prior relationship with the recipient.

These characteristics, if you like, of the early meaningful use criteria, again, they shaped our discussions of the committee up to this point. What can we do in terms of available standards policies and services to help this set of criteria be satisfied, and that's how we have shaped our early focus. You'll notice, obviously, that these are largely HIPAA, already described under HIPAA in terms of the privacy protections that are afforded and the requirements for consent. So this, in a sense, limits the scope of the challenge that we have to take on for this first phase of recommendations.

Here is a recasting of the same glide path we've seen before. And again, if you look at stage one primarily, these are primarily push messages. This is the opportunity for someone who has a packet of patient data to send it to another recipient, and so we tried to scope our task to that particular transaction.

This is our prototypical exchange, and this one, I think, Farzad described this to you at our last meeting. This imagines a doctor over on the left or provider, provider A sending some information to provider B on the right. And we have a number of critical elements that are required to make this a successful translation or transfer. Even in the paper setting, we have to have some vocabulary or document or standards for how to describe and encapsulate the packet of information. We have to find the recipient by whatever technology is available.

We have to certify that this packet is authentic from the point of view of the person sending it. In this case, we imagine a signature on it. There has to be a way to send the packet of information across space to the other recipient. It has to be received and retained in a secure manner. And all the parties have to trust that this set of relationships was executed in a way that gives them confidence that the packet they're receiving is what was meant to be and who it was meant to be sent from.

We then have to translate this set of fixed critical factors into the electronic world with this new, enabled, EHR environment we're discussing today. And we think that the work done under the auspices of a Nationwide Health Information Network provide some of the tools we need, so I won't belabor that.

Our goal is to provide wide participation by both individuals and organizations that want to satisfy meaningful use criteria. We think we need to work incrementally because it is a large and complex problem, given the scope of the country. And, therefore, change will be evolutionary. However, whatever we do in 2011, we don't want to be a dead end, so it must be foundational to building on the long-term information exchange capabilities. And we do want to build upon the Internet and the available and appropriate security protocols to facilitate transport.

Of course, our primary question as an outgrowth of this committee is what is the policy question? How does the government play a role in facilitating this set of transactions? One could imagine an alternative state where we say, well, the incentive money and the criteria are there. The market will supply solutions, and I think we are certainly open to that possibility, but so far our deliberations and in order to meet the aggressive timelines that are provided by the statute, we feel that there's some opportunity for the government to play a role in either enabling or providing key services.

Some of the attributes of those roles the government might play, we want to learn from existing patterns of exchange out on the wider Internet. We want to do a minimal intervention on the part of the government. The government should do as little as is appropriate to facilitate the success of the process. The government can create incentives to stimulate exchange without getting in the way of existing exchanges. We want to foster innovation. And we want to see a long-term expansion of the scope of information exchange.

Our earliest findings, really we're looking at this set of transactional elements, and in order to achieve meaningful use, we think the four critical pieces that we need to give our attention to are secure transport on the Internet, directories that allow us to locate those recipients of those messages, some means to authenticate and demonstrate the identity of the key parties involved in that exchange, and then the larger trust fabric that wraps around all of it, so that all the parties believe that what we're all up to here is a trustworthy enterprise and is safe. The patient information is being used safely.

The first broad category there really is the directories area. We did have a hearing day of directories, and we learned about what's going on in the private sector and in the public agencies. We discovered many provider directories. But each of them was created for its own purposes, and is sustained by a particular business model, and provides value to a particular set of users, which may not map to the requirements that we envisioned for meaningful use and information exchange.

They have different types of data. They use different data definitions. They may not collect the data that we need to enable the kind of information exchange we're talking about for meaningful use. And there are certainly questions across the board on the quality, accuracy, timeliness, maintenance of the data.

In general, the quality of the data in the existing directories around the country depend upon who is in that directory and how much they care about maintaining the accuracy and currency of their data. We certainly foresee – we do not foresee a mega directory. Instead, we foresee that private sector directories and government-based directories will exist, and we want to see them maintained, and we want to take advantage of that existing infrastructure of directory services that's out there.

We had a day hearing last week on authentication, and we have increasingly broken apart our conversation into two categories: identity proofing, the task of verifying that a person is who they say they are and have the appropriate credentials they need, professionally or institutionally. From the issue of authentication, that is attaching significant message to that person or their messages that verifies they are in fact the correct source and authorized source of the message.

The government has published a number of standards to guide authentication across the board, not only in the healthcare space, and we heard testimony from some of the agencies working with those standards, and we came to appreciate that there's a well developed set of procedures for assessing the risk of different kinds of information transactions, and that process of risk analysis has to be executed to determine how stringent the assurances need to be, that the proper identity proofing and authentication is happening. This, in turn, depends upon the context. We spent a lot of time discussing context for healthcare transactions.

As I mentioned, we realized that this assurance process requires both to prove that the carbon-based life form is who it says it is, and to attach the authentication signal to that proof and, in general, that's best done as close to the provider as possible. The implementation of the identity proofing and the implementation of the authentication credential can be done in a variety of ways. And we have not yet really delved into the technical options before us. We're still sorting out who should be doing what. The government has defined standards for both identity proofing and authentication, and mechanisms to procure, identify intermediaries who can do this for us. We'll come back to the intermediaries question soon.

The last area of the trust fabric some of this is just stating the obvious, but it forces us to give some attention to things we don't want to neglect. The information exchange depends upon common trust elements, including rules that all the parties subscribe to. It certainly depends on preexisting personal and business relationships, and we want to take advantage of those, not ignore them. It requires an understanding and expectation of data uses, assurances of some form that the data exchange is taking place as expected, especially around identity, and then some oversight and accountability mechanisms.

The implementation of the trust elements will differ based on the parties to the exchange, and if we don't have a mature policy and technical trust framework, it's going to be a barrier to exchange. People won't trust the infrastructure we put in place. Those are both our context and our findings to this point. We have addressed each of the four areas briefly. Again, I'll remind you of our definition of the Nationwide Health Information Network that it's a set of policy standards and services using the Internet, not a vast new enterprise that can be instantiated in some hardware necessarily.

With regard to meaningful use, our recommendation is that the policy standards and services to the Nationwide Health Information Network should enable the broadest range of providers to exchange information to achieve meaningful use and enable consumers to access their health information and provide support to states and other organizations that are part of this network. Secondly, that the government should focus on the minimum standards policies and services needed for foundational exchange components to further meaningful use in the near term.

I'll just go through all these, and we can come back to them individually if we want. The second recommendation regarding transport versus content, for our purposes we have said the focus should be on private and secure transport over the Internet, and have increased focus on the data content over time. But here we're primarily focusing on the transport itself, not the content. Secondly, that the policy standards and services should be structured so that simple intermediaries can provide the required services for private and secure routing of health information.

The third area of recommendations pertains to the directories. We note that the federal government already maintains provider directories to meet existing federal obligations and it should, therefore, work with the stakeholders to improve upon and leverage the existing directories for the Nationwide Health Information Network. We recognize that the government has a unique role in assuring that authoritative

provider directories are available to accelerate the exchange of information to successfully support and increase the efficiency of meaningful use. And finally, that the government should define a core set of policies for the interoperability of trusted directories.

The fourth area is authentication. We recommend that we build upon existing federal standards policies and practices for authentication and identity proofing, that we determine the level of confidence or assurance appropriate for different exchange scenarios. That is that it's not a one size fits all solution to all health information exchange. Third, that we permit innovation and local autonomy in the method of authentication, so that suggests again that we don't imagine a single national infrastructure to assert proofing or authentication for everybody. Fourth, if intermediaries are involved in the exchange, make sure that certification or independent verification of those intermediaries is done for authentication and identity proofing. Now I'll illustrate this in a moment. Finally, that there should be oversight mechanisms and redress of this authentication service that we're imagining.

Let me give you a visual illustration of this. I'm sure the text is very small to read, and this is a very preliminary. We're calling it a straw case. In other words, this is not a proposal. It's not a plan. It's a way of illustrating a set of concepts that we're all wrestling to better understand. The ultimate way to successfully implement authentication services may look nothing like this. But this illustrates some of the elements that probably somehow have to be addressed.

If we walk around this illustration as if it's a circle going clockwise, starting in the lower left at about 7:00, we imagine provider A wanting to send a message to provider B over on the right. And we'll imagine provider A wants to send a care summary, as we just heard about in the last panel. Provider A, she is using a certified EHR product to package the care summary that she wishes to transmit, and she and her EHR product are attached to what we're calling in that blue bubble at about 9:00 an HSP, which is a health information exchange service provider. This could be a health information organization, regional or otherwise. It could be a vendor and the vendor's network of customers. It could be an integrated delivery system. It could be a health plan. It could be a variety of organizations, which choose to aggregate services to EHR users.

But this HSP is suggested by the hour going up to about 10:00 there, the authorized HSP certifier. This blue HSP has been certified by some process as being one that plays by a set of rules that we are talking about here. That is the HSP, the health information exchange service provider, is competent to verify identities of the users and to attach the appropriate certificates to those verified identity users as they transmit information across the network.

We imagine, therefore, that the messages being transmitted from provider A's EHR, the HSP is verifying that provider A is who she says she is, and is attaching an electronic certificate to her message saying, yes, she is who she says she is. That message is then being routed perhaps through a set of directories, which are illustrated by the phonebook at midnight there on top of the picture, around to another HSP that is supporting the provider B's network of EHRs, who in turn has verified that provider B is who he says he is, as the user on the network, and is the appropriate party to receive this message.

The pieces at the top of this picture suggests that there needs to be a process by which the Nationwide Health Information Network determine who is eligible to issue these certificates, which are, in turn, proofs of identity, as messages are transmitted around the network. So there would need to be a mechanism by which there be a nationwide route certificate authority who in turn designates the various certificate authorities who issue the certificates. This is much as it operates now in the general, commercial Internet space. We are recognizing, given the special sensitivities of health information and identity management that there may be some set of activities that are described by this picture that are specific to the health information network.

The last step in the recommendations, we do not have a recommendation regarding the trust fabric. What we're simply describing to you that we have already come to understand, there are a lot of roles the government could play in asserting greater trust in the network ranging from taking no action to issuing regulations or even dealing with new statutes. At this point, we're not at all prepared to address what those adjustments might need to be, but that'll be on our radar, as we go forward with this process. Let me stop there and see if people have general questions at a high level, and if not, we can go back through the recommendations and take them individually, I think.

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

....

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

Sure, Richard.

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

My question would be in maybe could you expand just a little bit more on the definition of an HSP? That's a new term to me, and what role it might play, and what role? It appears on your chart that there's a certification body, and to what extent would they be certified?

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

Yes. I can expand very minimally because, as I say, this is a conceptual approach, not a proposal for a particular organizational structure. But I will say that there's a general recognition that the health information exchange function broadly with non-capital letters needs to have a number of services enabled to help people find other users and then safely transmit messages to those users. I think what this is just doing is saying whether the mediating organization that does that is you delivery system that you're attached to, your IPA, a vendor's set of relationships with their customers, or a RHIO in the old language we used to use, the health information organization that's regional.

Regardless of what it is that's going to be facilitating your message transmissions, there are some things that have to do consistent with rigorous standards of identity proofing and authentication. Those functions should be verified against those standards by somebody. It's not necessarily that the HSP is a new entity. It's really a label on a number of existing entities, but it asserts that they have met some standards for proofing and authentication.

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

Just one follow-up, please, which would be, is it your concept at least initially in your early discussions, or maybe we can flush it out later in discussion, but are these entities conceptualized to maybe perform the functions of integration or information integration or integration engines where there's translation going on, or just the facilitation of the four areas you were talking about?

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

No, we won't speak to that question at this point. There are probably a lot of ways to address that need, and whether or not those overlap with this set of needs, we haven't talked about at all.

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

Can I just insert a point of information? The committee is not being asked to consider this straw case. It was introduced to be helpful, but it's not definitive. It's preliminary. There are a thousand questions you can ask about this. We could spend days on it actually. It doesn't show up in any of the recommendations. It's not required as if you embrace the recommendations, and it is, as a question of

whether it's going to cloud the picture or clarify the picture, I'm not sure. But there is certainly a danger that it would cloud the picture if we spent a lot of time exploring it because it is just – I only saw this last night. I haven't had a chance to process it. I just want to caution us that we have four recommendations in front of us. I would much prefer that we spend our time thinking about the broad policy issues than thinking about this particular heuristic, which is only meant to illustrate how this might come together in some fantasy of a future world.

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

David, I'm trying to clarify. You said it would be useful to have ... recommendations to further the work on the NHIN. These recommendations are fairly high level.

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

Yes.

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

My brief summary would be authentication of carbon based life forms, being able to find out where they are, and using the Internet to get the information across with the appropriate services and standards. If that's true....

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

Yes, and implicit in all this is that though the NHIN, as we have known it, is compatible with these, might be compatible with these, it does not necessarily encompass all of these. So there's an implicit idea that we need to supplement the traditional NHIN with something else if we're going to get to meaningful use in 2011. Now we had some cards up. Connie, I think, was up first.

Connie Delaney – University of Minnesota School of Nursing – Dean

Thank you, David, and thank you for the summary, David. My question seeking just an additional comment on would probably more belong to recommendation one and two. Can you make any additional comments related to personal health information or the interaction of the information that might logically reside in the PHR, the relationship of that to particularly recommendations one and two?

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

I will say that we have generally not spoken about that issue very much. I think we made an early decision to prioritize the types of transactions for 2011 that were provider-to-provider message sending and, secondarily, provider-to-consumer message sending. But even there, the issue of authenticating, for example, the consumer is one we haven't tackled because it's complex, obviously. In the straw case, we illustrated. We're sure to reflect PHRs as one of the elements we need to address over time, but we haven't really done it at this point.

Connie Delaney – University of Minnesota School of Nursing – Dean

Thank you.

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

Yes, Adam?

Adam Clark – Lance Armstrong Foundation – Director for Health Policy

Thank you. I hope I'm not adding clouds to this issue at all, but I did want, at a high level, to ask just the question about the term Internet and what that actually means. Does it segue into telemedicine approaches? I mean we all have devices up here that are shaking the tables with people communicating with us different ways. And, in particular, for certain communities who may not have access to the

Internet, but may have access to mobile phones as far as getting information back and forth, do these recommendations segue into that area, or is it the intention that the Internet be the firewalls?

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

Well, I think the committee is pretty – they're trying to be technology agnostic in terms of the platforms that are used to move information around. We actually spent a fair amount of time in the authentication proceeding discussing phones, cell phones as a device to provide authentication services and to carry messages and certificates on them, so I think there's a willingness to embrace a variety of ways of getting information around. But I don't think our recommendations have spoken particularly to some of the applications you're raising. As Paul said, more abstract level at this point. And I would think whatever directory functions and authentication functions we describe here, we would want to make sure that they speak to the different technologies that are available to implement them.

Adam Clark – Lance Armstrong Foundation – Director for Health Policy

Thank you.

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

Paul?

Paul Eggerman – eScription – CEO

Thank you. These are very good and reasonable recommendations. I actually just have an observation. Everybody talks about exchange of information. You automatically assume that you're also going to transport data. I believe it is possible, especially if all you're looking at is clinical summaries, to exchange the information without transporting the data. The other way that works is you have directory services and authentication, but you simply allow one physician to have read access to a summary that exists at another site without moving the data. And if you do that, you simplify a lot of things, especially simplify the issue about what happens when it goes from physician A to physician B. What does physician B do to it in terms of retaining it, and what happens to it. If they don't retain it, they can only just look at that clinical summary. And so maybe this observation was a suggestion that perhaps this is like a different straw case, if that's the right terminology for your workgroup to consider.

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

Okay. Gayle?

Gayle Harrell – Florida – Former State Legislator

Thank you. One of the things that concerns me is in the very first recommendation. You're talking about the federal government should focus on minimum standard policies and services needed for foundational exchange components without mentioning that in order to further meaningful use in the near term, but I think every time you talk about meaningful use and furthering that exchange of data, you must always say insuring privacy and security. Any time that has to be foundational in every time we make a recommendation. That is the basis on which things have got to take place. So I would recommend that as you go through these, revamp just making sure any time you say that, you say while insuring privacy and security.

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

Thank you.

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

I actually appreciate that, you saying that, Gayle. For example, in the area of the directories, there is a recognition, but it's not explicit here, and maybe it should be, that directories by themselves expose

information to a variety of potential misuses, and advocating directories sounds good, but making sure that the structure and access to those directories is itself protected in the ways you're describing is equally important.

Gayle Harrell – Florida – Former State Legislator

Absolutely.

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

Judy?

Judy Faulkner – Epic Systems – Founder

A couple things: I do like a lot of things. It's real and practical. In addition, I'd comment a little bit on what you said, Paul. If it is read only, you run into two things that will happen then. One is that you'll not be able to trigger the alerts that might alert the physician that this is a drug/drug interaction because it's going to be an awful lot for that physician to remember. And, secondly, I think we would have to look into what the legal, medical/legal ramifications of that would be because they do need a record of why they made the decision, as they made it. And that also factors into it, so I'm just bringing those two things up. I think it's very good, and my real question is, what are the next steps?

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

Well, I think, under recommendations three and four, both the directories and authentication items imply work to be done. So the bottom point on this one on number three that the government should define a core set of policies for the interoperation of directories. We have informally discussed the importance of getting on with the business of what needs to be in these directories to enable the kinds of message exchange we're talking about and what policies need to guide those directories. How should they be structured, for example? So we haven't gotten into that level of detail yet, but that would be the kind of further analysis we would have to do.

Judy Faulkner – Epic Systems – Founder

When is it going to get to not just the rules by which those go back and forth, but the instructions on how you pick data up? Will it get to that at some point, because that's what's, I know with the interoperability that our group does, that's what stops us from interoperating with another group. We don't have the rules yet for where you go to pick it up.

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

...answer to that level of detail?

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

Do you want to comment, Doug?

Judy Faulkner – Epic Systems – Founder

Am I getting out of the topic?

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

No.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics

I think you raise an important point. The work going forward needs to be grounded in reality.

Judy Faulkner – Epic Systems – Founder

Yes.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics

We need to – we can't make decisions about the standards or those rules for how you would pick up the data in the abstract, and so I think one of the things that we need to think about, as we do this, is to see are there examples. Are there tests that we can do? Are there pilots, other things like that that might help us get to that level of specificity and do it in a way that is reflective of what really is happening with the boots on the ground?

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

I think the intent also is to come back to this group with more specific ideas at a future meeting, perhaps in February, even that soon. So what these are is recommendations that set us on a direction, and then we will sort of fill in with more concrete plans and the ONC will actually try to begin experiments and pilots trying to develop the applications of any implications that fall from these recommendations. Jodi?

Jodi Daniel – ONC – Director Office of Policy & Research

Yes. I had a comment on recommendation number one, and it actually goes to what Connie was raising about it talks about supporting meaningful use in the near term, but only talks about enabling the broadest range of providers. And since, in your arrowed drawing about stage one, it talks about information to consumers, as well as public health reporting. If that limits the scope that you were saying you were trying to accomplish, which is to help exchange to support early stage meaningful use, if we're limiting it just to providers, understanding the challenges of authenticating individuals and that sort of thing, but it also excluded public health authorities, so I just....

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

Let me just make clear. Maybe this isn't worded well. I think our intent is to say that our goal is to enable eligible professionals to satisfy the meaningful use criteria. To do that, they have to communicate messages to other parties who are not only other eligible professionals.

Jodi Daniel – ONC – Director Office of Policy & Research

Correct.

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

So that our discussion, for example, about directories has looked at there are directories of pharmacies. There are directories of labs. There are directories of public health agencies, which would need to be enabled through this network, so we understand that.

Jodi Daniel – ONC – Director Office of Policy & Research

Great. Thank you.

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

Deven?

Deven McGraw - Center for Democracy & Technology – Director

Yes. I just also want to congratulate you on the recommendations and say that I support them. I think they seem like the best sort of set of steps forward toward getting us to where we need to be in a very quick timeframe. I know that the emphasis on the trust and the need for policies and certainly that's part of what we see our duty to do and part of our charge as part of the new privacy and security workgroup, and I think many of the things that we have tentatively put on our agenda for the coming year dovetail quite well with where your headed in the issues that you've identified to be resolved. But we may not, in

fact, have identified some that you have been coming up in your discussions, and so I'd really love to stay in close touch, make sure we're working together in a synergistic way, and to invite you to use us actually to help uncover and resolve some of these issues that are in fact central to the trust building aspect of this.

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

Good. That would be very useful for us to do. I think we realize that we're sort of down in the basement working on the plumbing on some of these issues, and they're not as visible as some of the more exposed issues of privacy, for example. But they will be very important to creating a trustworthy infrastructure. So it would be a great opportunity to work with your group on some of these things.

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

Scott?

Scott White – 1199 SEIU – Assistant Director & Technology Project Director

David, recommendation number four, baring in mind that we're talking about a Nationwide Health Information Network, you make a recommendation for local autonomy in the method of authentication. It seems counterintuitive to a national model as opposed to are we going to have different authentication aspects and having difficulties in those working together?

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

Yes. Let me use the straw case to illustrate at least how I think about that problem. The HSP blue bubbles there, if you imagine one of those as an IPA of doctors, and another one is the VA, and another one is customers of a particular vendor, they may have, consistent with the guidelines issued by the authorized, the yellow box up in the upper left. There may be a set of criteria that are established either in the federal standards I mentioned earlier or new ones that we may come up with, that everyone has to meet some criteria.

But they way they meet them may vary. So one of them says, if you go to your post office and show a passport, you can prove you are who you say you are. If someone else says if you're a doctor on the medical staff of the hospital, and you're working in the emergency room today, you're who you say you are. Those are two different ways of solving the same problem of in person validation of identity.

I think what we're saying by local autonomy is that in different circumstances there may be equally acceptable ways of, for example, proving identity, but that they may be operationalized differently in a certain local situation. So I don't think we mean autonomy outside of the standards that are established by the Nationwide Health Information Network.

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

Paul?

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

Thank you. Let me try to read between the lines and maybe restate and see if I've gotten this correct. I think there may be – we may have had some – we, the community, may have had some preconceived notion of what NHIN is. It may have looked monolithic. It may have looked very intensive in the overhead, etc., and even prescriptive. And I think your set of recommendations really opens up the discussion. It's perhaps enabling. It's permissive, more permissive, and you've tried to identify core services that have to be in place in a best way, and then having communication go over the Internet. The purpose, and I think this goes back to what David said then is if we have to have meaningful use be accomplished and be paid out on, then it has to happen pretty quickly, and a very monolithic,

cumbersome, one size fits all probably isn't going to do that. So what you're saying is there are some things we do have to get right in a robust fashion, and let's have the permission and enabling of going through with those things. Have I got that correct?

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

Very nicely. Thank you.

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

Gayle?

Gayle Harrell – Florida – Former State Legislator

Yes, one more question on the authenticating. That is a critical component of privacy and security, knowing who that person is, that carbon entity is, is to authenticate them. Now in looking at the straw case you've put up there in the authenticating certifier, are you anticipating that the certifier of the certifier is the NIN, or who is going to determine who those certifiers are? That's critical.

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

We agree that's critical, and we have not yet gotten to that, deal with that question. There are other context in other parts of government, for example, where there is a mechanism for the government to say, these ten organizations are all certifiers, and they can go forward, so there are models we can look at, but we haven't done the investigation yet to see which ones make sense here.

Gayle Harrell – Florida – Former State Legislator

You're talking about things such as PKI, things of that sort, or what are you talking about?

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

That's a methodology, but I think the process of who is the certifier as a business process is also something the government has already done.

Gayle Harrell – Florida – Former State Legislator

Okay.

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

We are, as you know, heavily involved in trying to think through a certification process for electronic health records, and we're learning more than I ever knew existed about certification. But the implications of creating this elaboration on the traditional NHIN are still being thought through. And I think the workgroup wants to bring ... more to bring them back to us. Christine?

Christine Bechtel - National Partnership for Women & Families – VP

I just wanted to say that I think these recommendations got to a really good place, and are really reflected of the need to get information moving in a very sensible and secure way, and in a way that's going to benefit both providers and patients. And we were very clear, I think, in talking about the fact that consumer access to their health information is a really important priority. Like many things, we have some work to do to get there, but I just wanted to say, I think this is a terrific set of recommendations that are very practical, and so whenever folks are done with the discussion, I'd be happy to move that we accept them.

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

I heard one comment, a very important comment from Gayle about amending these to insert privacy and security in—

Gayle Harrell – Florida – Former State Legislator

Assuring privacy and security.

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

Assuring privacy and security in – I think recommendation one is what she pointed to, but I think there are other places where it would be pertinent, so it may be that we don't want to wordsmith these right now. It might be that we could modify them. We could accept them conditionally now, modify them, and bring them back to look at again next time, along with some other thoughts that the workgroup may have ready by that time.

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

That'd be fine.

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

Any other additions or changes that people would like to suggest at this point? Any other comments?

Art Davidson - Public Health Informatics at Denver Public Health – Director

David, this is Art.

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

Sure, Art.

Art Davidson - Public Health Informatics at Denver Public Health – Director

David, I really like these recommendations. I want to maybe take something that's in the fourth recommendation, which talks about permitting innovation and local autonomy in the method of authentication. I wonder whether there's anything of value in terms of permitting local autonomy regarding directory services. It seems like the third recommendation focuses entirely on the federal government. How might innovation be valuable at this level as well, as HIEs try to stand up their own directories?

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

I think it's a good suggestion. On the second bullet, the phrase authoritative provider directories points to your question. Most of the authoritative information is local, and it's very difficult to sustain it when it becomes aggregated to a national level, whether by a health plan or the government or anyone else, so it's a good suggestion. We could certainly take it under advisement, as we do, as David just said, come back with some refinements to these. We could entertain that as a possible friendly amendment to the third group here.

Art Davidson - Public Health Informatics at Denver Public Health – Director

Thank you.

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

David, just for my information, could you say a little bit more about what that amendment...?

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

Friendly amendment?

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

Yes, what that friendly amendment might involve.

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

Well, it's consistent with the fourth point that Art mentioned around innovation of local autonomy. We may consider whether innovation and local autonomy is an asset in development and maintenance of directories to insure they're closer to the source and dynamic, in that sense, maintained.

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

So there's clearly a balance here between those who – between the local initiative in creating directories and making sure that the directories can interoperate, and I guess the territory we're exploring here is do we need standards for directories, and is that enough, in effect? Is there an analogy between what we're doing with EHRs and what we are talking about doing with directories? Is that the discussion we're involved in?

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

I think it is, and the word assuring in the second bullet is, I think, the critical one. For the government to assure that authoritative provider directories are available, I think we'll have to deal with the points you just made: what are the standards? What's their content? What's their mechanism for maintenance?

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

Gayle?

Gayle Harrell – Florida – Former State Legislator

I think that's absolutely critical. You have to know who is doing those directories, and there has to be some authentication of those directories. States run medical providers. They license physicians. They license pharmacists. Those kinds of things are very, very valid, and they are done by an agency that you have trust and confidence in. I don't anticipate a local group setting up a directory and then they become part of this entity. That would be very difficult in making sure you're securing the privacy and security of any record that is then allowed to go to that entity.

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

Judy?

Judy Faulkner – Epic Systems – Founder

You really have two entities, don't you? You have the entity of the organizations that are sending information back and forth, and you have the identification of the patient itself, so you're getting into not only the directories and having them work together in identifying their authenticity, but also are you going to be tackling the problem of identifying the patient?

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

No, we're not doing ... patient linkage, for example, and patient identification is something we have not talked about in this workgroup at this stage. I don't like that grimace, Paul. That looked painful.

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

Yes. Do I really want to say that? I don't know how we get away from patient authentication either from a safety or for any of that, so while I certainly understand the issues because we struggle in many, many fora. How do we get away from that?

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

In order to enable meaningful use for 2011, you mean?

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

You have a point, but then it still has to be solved.

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

There are many things on that list. Yes.

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

I'd like to ask if anyone would like to move with that we accept these recommendations, conditional on the two changes that have been suggested: one by Art related to assuring a balance between innovation in the creation of directories, and maintaining the authoritative nature and privacy and security of directories. And the other related to assuring privacy and security as a foundational aspect of any mechanism of information exchange. Any – it's been moved and seconded, so any opposition, I guess I should ask. If I hear no opposition, then I will assume that the recommendations are accepted. Thank you, David, and thank you to the workgroup, Danny Weitzner, thank you in your absence. And we will be back to you with additional, more concrete suggestions, and with modified language for the next workgroup, for the next policy committee meeting.

I think we're now moving to the last item of business, which is the strategic planning exercise that we are required to do under HITECH. And we're going to be hearing from two presenters. One of them is to my left, and the other is Jodi Daniel. Do you want to take it from where you are? We'll just....

Jodi Daniel – ONC – Director Office of Policy & Research

Let Paul.... Do you want to start?

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

Go ahead.

Jodi Daniel – ONC – Director Office of Policy & Research

Okay. We have had two meetings now of our strategic plan workgroup, and we wanted to take this opportunity to update the full committee on some of the thinking of the workgroup. What we're going to talk about today is not set in stone. We wanted to get your input before we go and delve into a little bit more detail, and there is at least a couple of areas where the workgroup is still struggling to kind of get it just right, so your input is very welcome, and we plan to come back and update you all again, as we go into more detail and get this more finalized. So this is really just sort of a check-in, let you know what we've been doing, some of our thinking, and get some of your policy thinking and strategic thinking to weigh in on our discussions.

Here are our workgroup members. We have quite a large group for this one, which was intentional because we wanted to get a lot of different perspectives represented. This is an effort. The strategic plan is an effort that ONC is required to undergo under HITECH, and we are required to give stakeholder input. We wanted to reach out to a variety of different stakeholders, both on the policy and the standards committees, as well as others that are not represented on those committees, and we do also intend to have some public input and have a session where we get more public input into our thinking once we have something that's a more final draft.

This is our process at this point. We are looking for the strategic plan, this workgroup to provide recommendations to the full committee, and develop a strategic framework that will set themes, goals, principles, objectives, and strategies to provide advice to ONC on our strategic plan effort. Those recommendations from the workgroup will come to the policy committee, which will make a recommendation to the National Coordinator on those themes, goals, objectives, and strategies.

Then ONC will go and take that input, just as we have with other input we've gotten from you on the regulations and such, and draft a strategic plan that takes into account all of the hard work that the workgroup and the policy committee puts in, and all of the advice that you all give us. And our hope is to have a strategic plan that we would release in the fall of this year. I'll turn it over to Paul to talk about the vision and themes and to start with theme one.

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

Thank you, Jodi. As we presented to you last time, we broke the workup in four themes. It's not necessarily the way the final document will go in, but these are ways we've chosen to organize ourselves. One of the things we've put as a vision for this whole experience, which is not just what ONC does, but the context, which was laid out even in HITECH, of why are we trying to promote the adoption and effective use of HIT.

The sentence we have up there is that we wanted to create a learning health system that is patient centered and uses information to continuously improve health and healthcare of individuals in the population. So that's the vision that is driving this whole initiative and drives the Office. As I said, it's sort of set out in statute.

We introduced a number of concepts, learning health system, the patient centeredness. We're using information, whatever technology or methods are used to get that before people, and we've sort of blurred the distinction between health and healthcare, so those are elements of that vision that hopefully will show up in the strategic objectives that we present to you.

We'll look at theme one, and in the sort of cyan is the goal. The first theme has to do with meaningful use. The goals are the same goals that we had in creating the meaningful use framework, which is to improve health outcomes, patient engagement, care coordination, and efficiency of the health system while reducing health disparity. We do this through meaningful use, or one of the ways to promote that is through meaningful use of HIT.

The principles there, the draft principles there are really a rearticulation of the thought process behind the creation of the meaningful use framework that was originally proposed by the meaningful use workgroup. And so those focus on health outcomes. They track the national health priorities. These are not priorities that ONC or any of us set, but these are things that, as a group, there's a national consensus of these are the contemporary priorities that we should be focusing attention on. They focus on individual and population health, and fostering and enhancing patient engagement, increasing the efficiency, reducing the burden. You know, increase the efficiency of the health system, and particularly reduce the administrative burden on providers and patients of having to deal with the health system that we have.

Throughout all of this, there's a balance in trying to make sure as many provider organizations, both on the professional side and on the hospital side, can engage and participate in this program possible. Yet, there's still a sense of urgency set out by the President's goal of having all health information in EHRs by 2014. Finally, of course, even though there's an additional set of resources made available, it's still finite, so we need to balance, to prioritize the use of those resources to those with the greatest need. A lot of times that will happen with the smaller organizations.

The draft objectives that derive from those principles are before you. One is we still have the 2014 goal out there. There's a little bit of a twist on the 2014 goal. Instead of saying that all health, all individuals have their health information in the EHR, the sense of prioritization ... the folks that start using the

services of healthcare providers are probably the ones that you're going to involve first. So there's a little bit of a prioritization or a staging built into that sentence.

The second piece is to support team-based coordinated care across the entire health system. The third objective is to support consumers in taking a more active role in their health and healthcare and managing their information. The fourth and fifth are sort of combined to say that we want to use all of the policy levers and all of the resources provided in the ARRA program to emphasize the meaningful use to achieving the improved outcomes. That involves coordinating both the public sector and the private sector to do those.

Then we want to demonstrate and measure the impact that these systems have had on health outcomes and efficiency. And finally, to make sure that we don't forget the public sector, the public health sector, and not only do we report information to the public health agencies, but also look to get information back that would drive and inform the decisions that are made every day on individuals. Those are a set of objectives under this meaningful use.

Jodi Daniel – ONC – Director Office of Policy & Research

Great. If we go to theme two, the policy and technical infrastructure: the goal of the workgroup had come up is to enable management and exchange of electronic health information through the development and support of appropriate policies and technical specifications. This is actually an interesting discussion. Originally it was just focused on exchange of electronic health information, and there was a lot of discussion about how we need appropriate policies and technical specifications, particularly privacy and security requirements that focus on the management of electronic health information, as well as the electronic exchange of health information, so that's all built in that goal.

The draft principles, the first was that policies and technical specifications should, at a minimum, allow providers to achieve meaningful use of health IT. So this isn't a limit, but that is a minimum goal for the policies and technical specifications that the federal government either requires or promotes. The second was that efforts by the federal government in the area of policy and technical infrastructure should leverage market innovation and leverage publicly available information and communication technologies to foster appropriate health information exchange.

Originally, there was a comment on the left panel about Internet. We actually had talked about this being leveraging the Internet, and that actually got broadened to publicly available information and communication technologies. Since this is a five-year strategic plan that we're talking about, to make sure that we're taking advantage of other available technologies, including mobile technologies that may come down the pike or that may become more prominent in the next few years.

The third was effective health information exchange should enable all participants in the exchange to contribute toward improving health and healthcare. This also goes to one of the NHIN recommendations about trying to support all the participants in the exchange to be able to participate, or all folks who may be contributing to health and healthcare to be able to participate in health information exchange.

Next, that policy and technical specifications should be kept as simple as possible and be designed for implementation by all participants. This is actually something that came from the standards committee and their recommendations from their implementation workgroup about trying to keep it simple so that less sophisticated participants may also be able to play a role. Finally, that policies and technical specifications should make possible and promote increased patient engagement and access, so that this is not just limited to provider communication, but that we should also be trying to promote increased

patient engagement and access in electronic health information exchange. Those are the principles that are recommended or that the working principles that the committee has been developing.

For the draft objectives, there are four that we have identified, and I just want to highlight, this was actually one of the areas where we struggled with the most in our last meeting trying to figure out how to articulate these objectives in a way that was both comprehensive, as well as appropriately focused. And so this is sort of probably the most drafty of all the objectives that we have here. Anybody on the workgroup who is looking at these, these are trying to reflect the latest conversation we had on this, but this is still very much a work in progress, this one. But I'll try to explain the concepts behind them so that you understand what some of the thinking is.

The first is: establish policies and technical specifications, including standards and certification criteria, to foster health IT product development that can support meaningful use. Originally we were talking just about standards and certification criteria, and folks were saying, well, there might be other technical specifications or functional specifications that aren't quite as or technical policies that may also need to be included, so this is about standards and certification criteria, as well as technical and other policies that can foster health IT product development and meaningful use. The second is increasing market confidence in health IT products and solutions that support health and healthcare improvement. This incorporated things like the certification process, product safety, those sorts of things to increase market confidence in the health IT products that we were trying to promote adoption and meaningful use of.

The third was increasing the nationwide capability for health information exchange. This is sort of looking at the NHIN activities, as well as other activities to support exchange and the capability for exchange, and some of the infrastructure and technical requirements that might be required for that, that you just heard on the last panel. And the fourth was encouraging participation in health information exchange, and this was really getting at the policies that are necessary to encourage participation in health information exchange. Some of those go to liability concerns that are being raised. Trust, making sure that there's a trust fabric to encourage participation in health information exchange, as well as governance of health information exchange organizations or NHIN. Those were the concepts that were built into or the thinking behind those draft objectives.

On theme three, we have a theme specifically on privacy and security, and I know the question is going to come up, so I'm going to mention it while I'm thinking of it now. There was, in all of the draft principles, some of them we had privacy and security mentioned, and it kept coming up, so we actually, there was a recommendation by the workgroup that at the very beginning of the document there be a general principle that everything has to be done in a way that builds and ensures trust in the information exchange and the technology. While you won't see that in each set of principles, it was something that the group thought was so important that it was going to be moved up to the front as a guiding principle for everything that we're doing, so we do have a special theme, a specific theme on privacy and security, but there will also be messaging at the front end that this is something that's critical in every piece of the strategic plan.

The goal here was build public trust and participation in health IT and electronic health information exchange by incorporating privacy and security solutions in every phase of development, adoption, and use. For the draft principles, there was a long conversation about these. There is – ONC had published a nationwide privacy and security framework for electronic exchange of information in December of 2008, and there are eight principles that are listed here that are based on fair information practices, and there was a discussion and some agreement of the group that rather than reinventing the wheel on some of those principles, that those principles should be incorporated as principles for our strategic framework.

Then there were a couple of other principles in this area that were important. First, that solutions should enhance privacy and security while facilitating the appropriate access, use, and exchange of health information to improve outcomes, and that privacy and security solutions should be flexible to adapt to the evolving technical capabilities over time. This is very consistent with the approach ONC took on the security standards and making sure that the standards were flexible enough to adapt to evolving technical capabilities, so those are the draft principles for theme three. I'll turn it to Paul for theme four.

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

Okay. Theme four, this is sort of the forward-looking.

Jodi Daniel – ONC – Director Office of Policy & Research

I'm sorry. I skipped the objectives. I apologize. Sorry about that. The draft objectives, these are fairly general at this point, and I think a lot of the detail will come out in the strategies. First was identify and prioritize general privacy and security needs for all stakeholders. The second was to develop, promote, and enforce privacy and security laws and appropriate policies for all aspects of health IT and health information exchange. And the third was increase an understanding of policies and practices to protect privacy and security of health information.

So the second one, I think there's a lot packed in there. We still have a lot of discussion to do, and some discussion with the privacy and security workgroup to make sure that we are connected with their efforts and their prioritization, but this is where the privacy rule modifications that are articulated in HITECH fall in, enforcement strategies, breach notification. And the last one, the third one was actually important about making sure that not only do we have the right policies in place, but that they're well understood, that we're communicating them, and some of the strategies that were being discussed was about education campaign, guidance of best practices, and working with the regional extension centers to make sure that they are helping providers to understand privacy and security requirements. I apologize, Paul.

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

No problem. Theme four was the sort of forward-looking. If we put it in stages term, getting out into the stage three and beyond kind of thing. That is, how do we transform what we have today, which is a healthcare delivery system, a transactional one at that, into a system of health and healthcare that is constantly learning? That involves everyone, not only on the professional side, but also the patient side.

The principles would be how do you take this stuff and facilitate the rapid learning? How do you not only enable, but drive the innovation that would change things in diagnosis, in treatment, in decision making, and creating new knowledge. That's really the guiding principle for this particular theme. And how would both the people about which care is about the patient and their professional healthcare team work together to create new evidence-based knowledge? Finally, how would we apply these things that David talked about, the methods, the policies, the services, and help create knowledge from the distributed data sources? That would be the goals or the principles of what we want to accomplish in this theme, so it's really transformational.

The objectives, and these are just our first draft, is can you create knowledge and tools that would help professionals and their patients work together to make the best possible decisions? How do we do that? The second is how do we create learning communities? The professionals in the organizations, let say providers in this case, need to find ways to store and manage and then derive new knowledge in order to advance the practice of medicine. How do we use HIT to do that? That's in bullet two.

Let me jump to bullet four, which is, we talked about providers. We've talked about patients. A lot that goes on in the so-called chronic care model has to do with the communities. As a country, we certainly

don't do a whole lot with communities. Yet, HIT can be very important in making that happen. Can we use HIT to create the partnerships and understand where people live, which is outside of our four walls, outside of the office, outside of the hospitals? They live in schools. They work in employer places. And they attend senior centers. Can we reach out and connect those and create services and knowledge that address the so-called social determinants....

Then, finally, how do we take all this knowledge that we're creating and make it better? So comparative effectiveness research is part of that, drug surveillance, drug monitoring, but also turning that around to use it on how to develop the next set of drugs. All those things would be useful. So these are kinds of objectives to support that vision of the learning health system that we're proposing as drafts. And below each of these that we've talked about, we've talked about goals, and we've talked about strategic objectives. We need to delve into the strategies that would become the sort of practical day-to-day things and program that ONC creates and supports. That's where we are now, and would love to have your feedback because we're on this path.

The next iteration is, one, to update this with your input and, second, to delve into the strategy part, and then we'll be bringing back a final draft document in March before we then have a public sort of comment period. In April, we have a hearing session, I think, is what they're called. Then we'll finally deliver to ONC a set of our recommendations in May, so comments, please.

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

David?

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

Thanks. I really like the emphasis on information, as you did in the fourth bullet. As the glue or the stuff that all this stuff technology is meant to support. I think, to the extent, the thematic emphasis can be on enabling information to be widely available to support better health and healthcare is great. I'm wondering how, and there's nothing at all that you presented that I would disagree with or question as being valuable. So there's nothing to me that strikes a wrong note, but I do still have trouble picturing how we'll get to a vision that sings to the American people and says here's what we're trying to achieve, and here are the major elements that we need to work out to get there. And I do think, at least from my own part, what's still missing, not in this document, but in the country, is a condensing vision of how electronically enabled information flow changes our health.

And I hope that there's a way to answer some questions along the path. For example, what is the government's role in all this? Is the government's role to create incentives for certain behaviors or certain technology products? Some of the language in the draft outlined is so high-minded as not to be very instructive, like improve health outcomes. And some of it is very technical and nitty-gritty around standards and so on. So I'm still looking for an upper middle ground, which is pretty high minded, but sort of gives me and maybe all of us a picture of five or ten years from now, how will healthcare look in America. Who is going to be connected to who? Who is going to pay the bill? What's the nature of the exchanges and so on? And I think it's very tough. I'm very sympathetic to the committee's challenge. But I hope there's sort of a visioning layer that can get articulated in here that will help the general public understand what we spend all of our time churning on.

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

You're just looking for a straw case, aren't you, David?

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

Adam?

Adam Clark – Lance Armstrong Foundation – Director for Health Policy

Yes. Thank you very much. Going to the theme four, I really appreciate the principles and objectives you've put together. This is something that Live Strong and the cancer communities are very interested in, giving the needs of cancer patients out there and what we're learning about the disease. Clearly, comparative effectiveness research is a big area, and we are talking a lot about molecularly informed comparative effectiveness research as well, given some of the interventions out there.

We're also going to see just molecular medicine moving in very quickly. The use of genetic and genomic technologies is making its way to the clinic very rapidly. What always lags behind is the regulatory processes and the policies, and so I would just ask, as you look at the principles, clearly patients and providers are called out. But how this is going to inform regulatory bodies like the FDA, subsequently CMS for reimbursement based on maybe new technologies. Just more keeping it in the principles is something that all of this information should segue to in real time.

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

Charles?

Charles Kennedy – WellPoint – VP for Health IT

Yes. I also want to applaud the notion of a learning healthcare system and comparative effectiveness and the like. One of the things I didn't see was a mention of administrative or claim data, not so much from the perspective of having to focus on it, but if you use real world data and don't have an appreciation of things like benefit design changes, you'll likely come up with erroneous conclusions. So I just want to highlight the importance of appreciating the dramatic changes that benefit design and administrative changes can make in the underlying data sets.

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

Connie?

Connie Delaney – University of Minnesota School of Nursing – Dean

Yes. I want to say thank you to the group for the capture of this innovation and thought. I have two areas of comments. The recommendations or the themes are infused with patient engagement and such, and I'm wondering if there might be value in pushing that envelop further toward people empowerment. One, we don't assume just the patient dynamic. Two, it's not just about engagement, but true empowerment. And then the second, this might be irrelevant or outside the scope of what we're about, but it seems to me that for sure we need, and it may or may not be relevant here, an emphasis on the synergy between this whole agenda that we've been talking about and the synergy with education and development of the science of best practice, as well as the regulation and policy. What the second comment is about is I would encourage the group to consider infusing this with the necessary synergy between all of what we're talking about, the IT, and people's health, and how we educate not only the public, but the generations of healthcare providers or the discovery of new knowledge, etc.

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

Neil?

Neil Calman - Institute for Family Health - President & Cofounder

I too want to compliment you on theme four. I think it's the new part. And I think it's incredibly important. And I just want to make sure that we don't see these things in some sort of temporal sequence, like one, two, and three is what we're doing now, and four is what we're going to do at some time in the future. So

I would like to put something out there. So there are a couple different ways you could look at number four.

One way you could say is that's sort of the wraparound right now. That's sort of the wrapper for the whole piece. I mean, in fact, the whole reason we're engaged in this is because we believe that we're creating, we're implementing tools that have the capability of transforming the healthcare system, even though we don't know exactly what dimension that's going to take at the moment. So in a sense, it's not really like – the other way to look at it would be that there are people at high levels of adoption already in organizations, and entities and systems at high levels of adoption and use.

And that while we're getting the rest of the country to adopt and to achieve meaningful use, we should have another component of what we're doing that supports the frontrunners and the front-running organizations, and I plead self-interest in this, to be able to say that some of the larger integrated healthcare systems that are completely adopted and already are beginning to figure out how to use the technology they have to completely transform the work that they're doing and reporting on outcomes and improving quality, that we ought to have a component of our work that really supports that at all levels now because that creates the map that others are going to follow. Just like a lot of the components of what we're doing now have been created by others who have sort of come before. So I just want to make sure that as we sort of approach the ends of the earth, people are drawing the map of what comes next, because I think it will help us define our work and keep us moving in the right direction.

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

I hope you applied for beacon.

Neil Calman - Institute for Family Health - President & Cofounder

What?

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

I hope you applied for beacon.

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

Unfortunately, he can't. He can't apply as an individual organization. So you want Magellan to be able to find his way home, Neil? Is that the--?

Neil Calman - Institute for Family Health - President & Cofounder

Right. Actually, I want Magellan to be able to find his way away from home towards the future to keep going.

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

We still don't know whether the world is flat.

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

Yes. Gayle?

Gayle Harrell – Florida – Former State Legislator

Yes. I would also like to add from a public perspective, I think it is important that we incorporate some aspects of public education and making sure that the public understands what this is all about. There is a great deal of fear among a lot of segments of our population that health information exchange is going to lead to the ability of the government to control their healthcare. So I think that needs to be discussed as part of that committee.

I think we need to make sure that comparative effectiveness research doesn't become the buzzword for rationing care, and that we need to really look at how it is presented to the public, and that they understand that we are really trying to create a healthcare system that's going to improve outcomes and make healthcare better for everyone and not go about rationing or limiting care, but making sure that the very best providers are providing the very best care, and that they have the information and the tools that they need to do that. So I think that needs to also be a component of this.

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

I think the whole translation is a challenge for every aspect of what we do, and trying to create language that people can understand is always a challenge as well, particularly in a highly technical area such as the one we're working in. Any other comments on the strategic plan? You're not being asked to process anything here. This is just an update, informational. Wanted your midterm reaction.

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

Are we going in the right direction?

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

Right. Okay. I think, Judy, we're probably ready to take public comment.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you. Those in the room, if you would like to make a public comment, there will be a microphone in the aisle. Please queue up. And those of you on the telephone already, if you'd just press star, one, you'll be connected to the operator. And those of you on the Web, if you want to dial in via phone, please dial 1-877-705-6006, and we'll take the first comment, if you would please state your name and organization, and remember you have a three-minute time limit, Robin.

Robin Raiford – Eclipsys – Director of Government Initiatives

My name is Robin Raiford. I'm director of government initiatives at Eclipsys, and I'm also cochair of communication and outreach for HITSP. I would tell you that when we got this great body of work, I madly tore into it, and personally was so thrilled it was less than one thousand pages. I was beside myself, and then I had four words: oh, no, no bookmarks. So I went to fix that. I have taken the whole very robust table of contents in both documents. I did the CMS document that I want to give credit to Keith Boone from GE, the interoperability architect. He bookmarked the interim final rule. Then I also took it upon myself to take the 59 tables and put it in Excel, so I sent it to Judy.

Myself and Keith are very active HITSP members, so of course we sent it to our HITSP nation leader, John Halamka. He has put it on his blog at geekdoctor.blogspot.com. But I wonder if there might be a place to put on the health IT buzz, on ONC, so others can find it if they're not hooked into John's blog. And so that if you do put it on the blog, and you don't get a thousand comments, if you take a PDF and save it to Word, and then copy it into Excel, it doesn't give you six rows of Excel for one cell of PDF. Just to let you know that's how I did it.

Then to Deven's comment and to Dr. Blumenthal, you said you're learning more about certification than you ever wanted to know. If you want a vendor to be able to turn it on and turn it off, you've got to tell us the system shall or the system shall have the ability to, and we will know exactly what to do. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you, Robin. Next in line?

Bob Bryant – Pediatrix Medical Group – CIO

Good afternoon. I'm Bob Bryant with Pediatrix Medical Group, a national group practice of more than 1,200 physicians that includes over 900 neonatologists, 100 pediatric cardiologists, 70 pediatric intensivists and pediatric hospitalists, and 140 maternal fetal medicine specialists and obstetric hospitalists who provide patient services for patients with high risk pregnancies and premature births.

We appreciate the hard work of the committee to date, especially with respect to the EHR incentive program proposed rule. We are grateful for this opportunity to provide public comment. Pediatrix Medical Group has successfully used health information technology, including electronic health records, advanced electronic health record databases, and systems processes to improve patient outcomes, identify meaningful differences, and reduce disparities in outcomes. Our EHR is an internally developed system that today enables the consistent documentation of care provided by physicians practicing across the country. The physician's digital documentation of care through daily progress notes populates a de-identified clinical data warehouse that now comprises more than 600,000 patient encounters and 11 million neonatal patient days.

From this clinical data warehouse, we are able to extract data to assess outcomes, develop strategies to improve care, and make meaningful changes that continuously enhance the delivery of care. Today, data warehouse queries yield evidence-based answers that drive clinical research, continuous quality improvement, and continuing medical education. In addition to improving patient outcomes, this approach helps reduce costs through appropriate utilization of tests and pharmaceuticals, and ultimately reduce average length of stay for our patients. Pediatrix's initiatives in the health information technology area can serve as a useful model for federal efforts to promote improvements in healthcare and health quality through the use of health information technology. Thank you for the time.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you. Next in line?

Lindsay Hoggle – American Dietetic Association – Independent Consultant

My name is Lindsay Hoggle. I'm here today on behalf of the American Dietetic Association, and I just wanted to comment on several things in the discussion today. First of all, thank you very much for making such remarkable progress in this area, and also for the opportunity to comment.

There are several foundational themes that continue to recur throughout, which I think are great in helping other people understand, those being insuring safety and privacy, making sure that there's good health outcomes, and engaging the consumer. Hopefully we're at a point now after this progress to start engaging the consumers and non-providers, non-physician providers in the goals and the strategies that you have. While most of those do not receive direct incentive payments from the HITECH Act, we do get a great deal from that by being able to improve quality of care and also allowing consumers to finally become engaged on healthcare.

There are several areas, one in terms of patient education. I think the ... Internet American Life Project has done a great deal of information, and most physicians will attest. Patients are going to find information whether we direct them to it or not, so it would be nice if we direct them in the right way. And the other point there is that we can still include patient education as part of the meaningful use by handing it off to non-physician providers. An example of that is the BMI that we discussed earlier. BMI is merely a screening tool, an inexpensive screening tool, but it should trigger a reaction in terms of a referral, education, information, or some other discussion with the patient. So that could be another way of engaging both the patients and non-physician providers.

The other area is in the area of quality measures. I agree wholeheartedly that we need kind of an incentive for all of us to be involved in that, and that we continually update those, as we have more quality information and quality data from the EHRs. A good example of success of that is just hemoglobin A1c where patients now know their values. Other non-physician providers know values that that patient should have, as well as the provider. And it just allows that teamwork to ripple through all parts of.... Thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you. We do have one caller on the phone. Could we take that caller, please?

Operator

We have a comment from Don May with American Hospital Association. Please proceed with your comment.

Don May – American Hospital Association – Vice President

Hello. Thank you very much. My name is Don May, and I'm with the American Hospital Association. On behalf of our nation's hospitals, we really do appreciate the work of the policy committee and really recognize the timeframes that you've had to deal with, and the really good product that you have put forward over the last, I guess, nine months, several months. And so I first want to start there, and we appreciate the Herculean effort that CMS and ONC had to do to get these rules out in the timeframes after the stimulus bill was passed.

In saying that, we also have the same concerns and goals that all of you do that we bring electronic health records into all hospitals across the country and insure that we can improve patient care and safety, as we implement these new systems. And I think we've seen over time, and we'll see a continued willingness of hospitals to put these efforts at high priorities in their hospitals, and that means putting the resources behind them. And I think, to some extent, with or without incentives. At the same time, being able to access some of those incentives and really meet the intent that Congress put into the stimulus bill is, I think, going to be very important. And I think we do have some concerns that we hope that ONC and the policy committee will weigh in on as part of this comments process to help provide some more flexibility around the requirements and some of the burden that we think the proposed rule, meaningful use, and the incentives really create.

I know that Dr. Tang highlighted some issues where there is going to be some concern, whether that's around eligible providers, some burden of reporting and denominator issues. A lot of this being outside of the control of providers and hospitals, and we agree with many of these comments. I think two things we really want to stress though is first the all or nothing approach that has been put in the proposed rule is something we're very concerned about. It's very inflexible. And that type of approach really fails to recognize that something less than all 23 objectives really can be meaningful.

I think, for the systems, the hospitals that have implemented systems, maybe not all 23 components, there are many hospitals out there that have done a whole lot that would think that they're doing meaningful work with their IT system, but it would not count in the system. And I'm not really sure that is what Congress intended when they said, let's reward the providers who have done something. And we really believe that this all or nothing approach is something that has to change if we really want to see this program really be an incentive and not further exacerbate the digital divide.

The last thing I wanted to say briefly is we are very concerned about the timing. I think whether it's vendor queues or the lack of a certification process, and likely a certification queue process where there's going to be a queue in getting certification, and just the fact that it takes 18 to 24 months to add systems

is a real concern that we have, and we really would encourage you as experts in this field to recommend to CMS to expand some timeframe differences that would expand what is required and allow something less to be included as meaningful in 2011 so that we can eventually get to what I think the policy committee and what we would like to see as an EHR, a fully functional EHR in all hospitals across the country. I just am concerned about the timeframe.

One last point on some information that we have is we have a survey that we've done on 3,300 hospitals on IT, and this is the same survey that Dr. Blumenthal and the Harvard Research Team used. What we found in that survey is that we only have ten of these objectives in that survey.

Judy Sparrow – Office of the National Coordinator – Executive Director

Mr. May, could you please sum up? Your three-minute limit is well over.

Don May – American Hospital Association – Vice President

I apologize. I guess the bottom line in my point is that as we look at actual data of what hospitals have, they have a lot of things in place, but there are very few, I would say less than 50 hospitals today that have in place the meaningful use objectives, and we would encourage a better approach at allowing these incentives to be fulfilled. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you. We'll have the last comment from Mr. McNamar.

Tim McNamar – e-Certis

Tim McNamar from e-Certis. We do second generation XML software. I really congratulate you on the strategic plan and thinking ahead, and item four, I might suggest something you could add to it, which is the use of social networks to change behavior. When Peter Elkin was at Mayo, he and I developed a process to – we didn't finish it – basically to take measurements of children's health behavior and habits, and take a picture of them, and then, through visualization, project them as they would get older. And at the time, we didn't have Facebook as developed as it is. I'd rather suspect having a Facebook page for every classroom in America and being able to do that, based on good habits and bad habits, could affect some change. And I'm sure there's a better way to do it than I just suggested. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you. I'll turn the mic back to Dr. Tang.

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

Thank you, everyone, and thanks to the committee members and all the participants in the workgroup for generating such wonderful products that we get to review each meeting, and have a safe travel back. Bye-bye.