

HIT Policy Committee Meeting
Final Transcript
May 19, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director

Good morning, everybody, and welcome to the 12th meeting of the HIT Policy Committee. Happy anniversary. This is a federal advisory committee, and it is being conducted in public. We have members of the audience in the room, as well as on the phone and the Internet. There will be opportunity at the end of the meeting for the public to make comments, and the transcript of the meeting will be posted on the ONC Web site at a later date. Just a reminder to members of the committee to please remember to identify yourselves when speaking for people listening in. With that, we'll go around the table and introduce ourselves, beginning on my right.

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

Good morning. Scott White, 1199 SEIU.

Marc Probst – Intermountain Healthcare – CIO

Marc Probst with Intermountain Healthcare.

Charles Kennedy – WellPoint – VP for Health IT

Charles Kennedy, WellPoint.

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

Jim Borland, Social Security Administration.

Gayle Harrell – Florida – Former State Legislator

Gayle Harrell, former state representative from Florida.

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

David Lansky, Pacific Business Group on Health.

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

David Blumenthal, Office of the National Coordinator.

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

Paul Tang, Palo Alto Medical Foundation.

Paul Egerman – eScription – CEO

Paul Egerman, software entrepreneur.

Christine Bechtel - National Partnership for Women & Families – VP

Christine Bechtel, National Partnership for Women and Families.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Larry Wolf, Kindred Healthcare.

Adam Clark – Lance Armstrong Foundation – Director for Health Policy

Adam Clark, Livestrong.

Deven McGraw - Center for Democracy & Technology – Director

Deven McGraw, the Center for Democracy and Technology.

Tony Trenkle – CMS – Director of OESS

Tony Trenkle, CMS.

Judy Sparrow – Office of the National Coordinator – Executive Director

And I believe we have a number of members on the phone. Connie Delaney, are you there?

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Connie Delaney will be joining momentarily.

Judy Sparrow – Office of the National Coordinator – Executive Director

Art Davidson.

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

Yes, I'm here. Thank you, Judy.

Judy Sparrow – Office of the National Coordinator – Executive Director

I know they dialed in. Anybody else on the phone? Okay. I'll turn it over to Dr. Blumenthal.

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

Thank you all for being here. The 12th meeting is a sobering number given how briefly we've been together, though it's getting to seem pretty familiar and comfortable to be in this room or in this hotel for this purpose. We have a very packed agenda in which I guess one of the highlights will be the consideration of the health IT strategic framework, the report from the workgroup on that issue. We're also going to be, and I'll let Paul go over things in detail, but we continue at ONC, now having done a lot of the program development.

I guess I should note that since we met last, we've released the Beacon Award grant initiative. It was very well received, and we had, as I've said before, 130-some applications. We were only able to give 15 awards, but we are going to be, in short order, considering another smaller round of grants totalling about \$30 million because of the enthusiasm that we've found in the community for these grants and the numbers of qualified, unfunded applications. That was the major thing that happened in the interim between our meetings, and our working groups continue to plow away at many important things, and we will hear about them later today. With that, I will turn over to Paul Tang, the job of going through the agenda.

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

Great. Thank you, David. This is primarily a meeting with updates from many of the workgroups. It starts off, as David mentioned, with the final, the presentation of the final strategic work plan draft document that this committee will then review and provide comments before we submit it to ONC. Then next, turn to the information exchange workgroup update where they will bring us up to speed on what they're working on, how they've sort of divvied up some of their work, and split off some of their work, and Deven will lead that.

We'll have the lunch break, then come back and update you on the patient engagement hearing, as well as laying out the work plan for the rest of the year. Come back to Deven, number two, who has got the privacy and security policy workgroup update, which includes some of the things that pertain to the information exchange activity. And the second part of the information exchange is the NHIN workgroup update that'll come from David Lansky.

Finally, Jodi will present an update from the Office, and then we'll conclude with public comment. Any questions on the agenda or additions? Great. Thank you. I guess we'll go ahead and begin with the update from the strategic plan workgroup.

Paul Egerman – eScription – CEO

...the minutes...?

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

That's right. Sorry. Thank you, Paul. You all have a copy. Were the minutes distributed?

Paul Egerman – eScription – CEO

Yes.

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

Okay. Are there any updates or corrections to the minutes? If not, I'll entertain a motion.

Paul Egerman – eScription – CEO

Yes. Motion.

Deven McGraw - Center for Democracy & Technology – Director

Second.

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

All in favor?

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Aye.

M

Aye.

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

Any opposed? Any abstentions? Thank you for that. From the other side of the table, wearing my other hat—

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

Pauls, you know, how many – welcome, Paul.

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

Thank you. Jodi and I are happy to present to you, the committee, the results of our many months of working on the strategic plan recommendations to the Office, as is required by statute. I want to first acknowledge and thank all of the members who participate on this, a lot of calls. One of the things that was really important was having both the number and diversity of people participating. Every call, there would be new things that we might have missed or a new twist, and we just constantly improved the

product as it went through this process, so thank you very much for all the people who participated, as well as the public.

The charge that we had was to develop a set of recommendations. In the HITECH statute, the Office had to update its strategic plan, and this group was asked to make recommendations to the Office. We've gone through, since, in the past five months, we've had nine meetings, which were mainly over calls. We've had a public listening session, and we've had numerous comments, including from this group, and we've worked all that back into the final document that we're going to be presenting to you and that you received earlier. And it's basically motivated by this vision, and it's a vision that Dr. Blumenthal articulated in one of his New England Journal articles that talks about a learning health system that can use the evidence available to provide the best care to the right people, the right time, including the right places, which are not always in the bricks and mortar institutions that we have.

In addition to that, that being our primary goal then, there are a set of other activities we would like to use this data and the knowledge that exists around the network to constantly improve the system of care and of health to insure the innovation, the quality, safety, and value in healthcare, as well as reduce disparities. Graphically, or in this graphic depiction, we have a set of activities on the left that happen within a system of care and of health that serve the needs of the beneficiary on the right. And so, in the middle is always the individual, the individual patient, the individual consumers, and the population that we want to address as well. If we do this right, then we produce a set of results that lead to a safe, timely, effective, efficient, and equitable person centered healthcare.

The government plays a huge role in this. It's the largest provider of care. It's the largest payer of care. But ONC neither pays for nor delivers care yet. But it has a role in producing the infrastructure. You never know what's going to happen—

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

Thank you for that qualifier.

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

But ONC's role is to help us put together an information infrastructure so that we can support this learning health system. The plank begins at the bottom with a policy and a technical – it's important that we add the policy infrastructure to this so that we can layer on top of it policies of privacy and security, and eventually end up with systems that we can deploy in the field to which meaningful use can generate the good things in health and healthcare that we would like to achieve. At the pinnacle of those infrastructure planks is the learning health system. That's the pinnacle of the value chain we've created, and we'd like to build that up for you in a series of recommendations for your goals, objectives, and strategies. And we're going to begin with the policy and technical infrastructure, which Jodi will present.

Jodi Daniel – ONC – Director Office of Policy & Research

Thank you, Paul. I just want to thank Paul for his leadership on this workgroup. This was a lot of work in a short period of time to try to put this together, and he really was a master at facilitating a broad array of perspectives, and the workgroup members themselves were very engaged in all the discussions, both from a high level, looking at this from a big picture, as well as at a detailed level, really thinking through all of the words, what they meant, and whether or not it was something that was a role of the government or not, and how we could help meet the objectives, the vision of a learning healthcare system.

There is more detail in the framework that you have all been given. We're just focusing today on the goals, objectives, and strategies. Then when ONC looks at recommendations that come out of this

committee, we will be looking in developing our full strategic plan at developing tactics and measures as well to support the goals, objectives, and strategies that we laid forth in the strategic plan.

I will start from the bottom of the pyramid with the policy and technical infrastructure. This is the goal for policy and technical infrastructure to enable management and secure exchange of electronic health information to meet goals for meaningful use of health information technology and a learning health system through the development and support of appropriate policies and technical specifications. There was a lot of discussion about how those need to be developed in tandem to support both meaningful use and the broader vision of a learning healthcare system.

The first objective was to look at policy standards, implementation specifications, and certification that incrementally enhance interoperability, functionality, utility, reliability, and security of health IT. The incrementally enhanced was sort of the whole escalator approach. Let's work on this in an incremental fashion and get folks to build interoperability functionality and utility over time, but focusing on all of these important points.

There is a set of strategies here to meet this objective. The first is to identify and prioritize types of data for transmission that facilitate improvement in national health priorities, and there was a lot of discussion of the workgroup about making sure that everything we're talking about is grounded in national health priorities and the outcomes that we're trying to achieve and not just the technology itself, so some of those priorities are listed here, and there's a fuller discussion in the document.

The second was focused on standards implementation specifications and certification criteria focusing on EHRs, but there was discussion that, to the extent appropriate, we should be looking beyond EHRs to PHRs, mobile health, and home monitoring devices as well, so looking at other health IT beyond EHRs in the future.

The third was to focus on a core set of policy standards and services to enable secure exchange of health information over the Internet to support the meaningful use and the national health priorities. And the fourth was to encourage and facilitate the provision of resources to support secure exchange, so making sure that we're providing resources or encouraging the provision of resources necessary to support providers and others in conducting secure exchange of information for these important priorities.

Do you want to just go through all of this, and then we'll do comments? Okay.

The second objective under policy and technical infrastructure is focusing on market sustainable mechanisms to insure reliable, secure, and protected exchange of health information, again to focus on improving health and healthcare. There are three strategies under this objective. Encouraging the development of innovative technologies to support care, community indication, and coordination among consumers and their healthcare providers, not just between healthcare providers. Engaging public/private sectors jointly to develop mechanisms to increase business demand and public support for exchange. Then there was also a discussion about coordinating and leveraging federal and state policies and efforts towards this goal. And the third strategy was to collaborate with federal partners, specifically focused on broadband access. This was specifically called out as an issue that ONC or HHS should focus on with our federal partners.

The third objective under policy and technical infrastructure was to increase market competence and safety of EHRs. A lot of this goes, or some of this goes to some of the recommendations that we heard from the certification and adoption workgroup last month. Three strategies here: The first was to establish and maintain the certification program for testing certification of EHR technology. The second

was to assess and address unintended consequences that may arise from health IT, and there was a discussion about looking at unintended consequences beyond just patient safety, that there may be other issues that we should be looking at as well. And the third was focusing on monitoring patient safety, safety concerns related to health IT. And this was consistent with the recommendations that were discussed last month.

That's it for policy and technical infrastructure. Those were the goals and strategies that were discussed.

The second plank in our pyramid is focused on privacy and security, and the goal here was to build public trust and participation in health information technology and electronic health information exchange by incorporating affective privacy and security solutions into every phase of its development, adoption, and use. I will start with the first objective, which was to develop, promote, and enforce privacy and security laws and appropriate policies related to health IT and health information exchange. There were two strategies here with a lot of sort of sub-bullets if you look at the framework document, so there are a lot more to these than comes up in the rolled up strategies.

The first strategy was to assess and implement federal laws and policies related to privacy and security for broad use of health information, communications technologies, amongst all the parties that are involved in access or exchange of health data. The second was focused on actively engaging states, both to learn from their experiences and to encourage development of consistent and strong privacy protections and interoperability policies at a state level, which ONC has a few activities that are focused on.

The second objective was looking at increasing understanding, implementation, and compliance with laws and policies and practices to protect privacy and security, so making sure that there is not just the appropriate laws and policies in place, but that people understand what they are implementing and complying with them appropriately. Three strategies here: The first was to explore and promote emerging technologies that may enhance privacy and security protection. The second was to implement federal privacy and security policies through guidance and through leveraging our health IT programs at the federal level. And the third was to try to increase understanding of and compliance with laws. Specifically, there was a recommendation ... through the meaningful use criteria and through other HHS programs. Again, I think there were a number of more detail underneath these strategies as well under this objective.

Third was focused on consumer engagement, so increasing consumer engagement through widespread consumer access. Three strategies here: The first was developing and maintaining a national education initiative to increase consumer awareness and acceptance of the knowledge and benefits of health information exchange, and then also to have a national dialog and enhanced public transparency regarding the uses of protected health information and individual rights with respect to such information. The second was promoting an environment of consumer empowerment and informed participation. And the third was to support availability of accurate, electronic health information to consumers through safe and reliable consumer access. That was all focused on the objective of trying to increase consumer engagement in healthcare.

With that, I'm going to turn it over to Paul for the next two planks in the pyramid.

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

Thanks, Jodi. I mean, it's really been a pleasure to be working with Jodi as our copartner in crime. It just shows the caliber and the strength of the folks that are in the Office supporting the National Coordinator. It's been lovely.

It's also good that we finish this before she goes off and clones herself. Deven and I have to do it the old fashioned way. But Jodi has it down pat. I think she has a much better approach.

Jodi Daniel – ONC – Director Office of Policy & Research

...than the government hiring process at times.

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

Now that we have the technical and the policy infrastructure in place, we've layered on top of it a privacy and security infrastructure, and now we're going to deploy the system and try to help insure that they are used meaningfully. The first goal is the goal of the ..., which is to get all of our health information, the country's health information into electronic health records and HIT systems by 2014. That's enshrined in the HITECH provision of the Recovery Act through the timelines that are in that program, and the goal then is to improve the health and the healthcare of individuals and populations, and to reduce health disparities.

To do that, a year ago, the meaningful use workgroup proposed to you, and you accepted that we focus in on the national health priorities, particularly the ones that we have evidence that can be addressed through proper use of HIT. Secondly, we laid out that sort of bend the curve graphic where we said get the information in, in a standardized way, make use of it to improve our processes and support clinical decisions, and then finally to continuously improve the health outcomes. We'd like to keep that roadmap front and center, and revise it as needed.

Then this committee took an approach of instead of boiling the ocean with so-called 500 measures, to try to find measures that could demonstrate that if you could do these kinds of activities, you would show that, one, we have an infrastructure that would support it. Two, we have systems that are capable of doing that. Three, we have a way of implementing it. Four, we have a way of demonstrating that we can use this to improve outcomes and hopefully lead to the outcomes that we are so targeting. That was the approach, and we tried to use that, and particularly use so-called clinical quality measures in order to drive that system.

Fourth, and it's maybe sort of the Achilles' heel, regardless of policy, money, permissions, we still need, and we have a lack of a sufficient number of trained workforce throughout the entire spectrum, throughout this whole supply chain that leads to activities that improve health. There are programs already onboard that are addressing that.

Then we have to worry about these smaller entities, and not small in impact, but small in terms of their access to capital and their access to the knowledge to do this function very well. There's a deliberate objective and strategy to support the primary care providers, the smaller providers, the rural health systems, and the safety net providers. They need special attention, and many of the programs are directed towards them. Last in this objective is our important goal of bringing the patients, the individuals and consumers and their surrounding caregivers into action. They're part of the health team. We need to do everything possible to support that.

The second objective starts out as a government program through HITECH legislation, but it really is just a lever to activate the entire stakeholders throughout the country, so this truly is a public and a private cooperation and collaboration in order to accomplish all the tasks we have before us. One is to provide the resources whether it's time, energy, or funds to help all of the organizations participating in individual health to achieve meaningful use.

Second is not everyone is a direct participant in, for example, the Medicare and Medicaid incentive program, but everyone is a direct participant in the infrastructure that we talk about. Everyone will benefit from privacy and security from the standards that evolve, etc. So everyone does have some benefit from here, but we certainly want not to exclude or not include the folks who are not direct participants in the Medicare incentive, for example.

Then the care coordination and the communication amongst consumers and their professional health teams, so consumers are part of the health team. We want to make sure that there's communication between and amongst all of the people on that team. Then, finally, in this objective to support the workflow and the behavioral changes that are needed, so everyone keeps saying that it's not just the technology. It's the changes that they technology help to enable.

The third objective in the meaningful use category is really one of our favorites, which is to make sure that we directly engage the patients and all the folks that support the patients in their health and healthcare. So part of that is to actually communicate because that's not something that's already been happening. To communicate how would you use HIT? What good is it? And how would you engage directly in your own health and healthcare using HIT? To improve the usability of both these systems, for both the provider side and the consumer side, and then talk about information sharing not as only information push from the provider to the patients, but a bidirectional kind of information sharing where patients are submitting information to be incorporated in what the professional team uses.

The final objective is to work on the efficiency and the administrative burden. That's a huge cost, both in time and in money in the current system, and we certainly hope to address that through meaningful use of HIT.

The pinnacle is creating the health learning system, and what do we mean by that? We mean that the National Coordinator should transform the current delivery system we have into a high performance learning system by leveraging this new technology. Not to worry. We have the five-year plan, so it won't happen overnight, but we have five years.

A lot of this focuses on using this network data and the network experience that we're trying to create to create new knowledge. How would we create it, discover it, recognize it, and put it to good use? Again, we're recommending that there's an involvement of the public and the private sectors to do a number of things. We have to advance the care delivery. We have to eliminate waste. We have to change the payment systems. None of those things can be done alone by the government, and it can be done very successfully with the combination.

The second point is the global health dimension. There's an organization called One Health, which you might think of as one global health. But actually the organization is about one health meaning the animal kingdom is also part of the human health issue. You need only think about swine flu and avian flu to recognize it's really a global dimension in multiple dimensions, and that needs to be taken into account, as we build these health systems.

Secondly, there's the education and communication. This learning, thinking of the care delivery system as a learning system is sort of a new thing, I think, both to the professional side and to the patient side. We need to communicate what that means for everyone's benefit and the role of HIT. One of the ways we learn is by continually assessing how this program is doing, how all the provisions in HITECH are doing? How are the ONC programs doing? Constantly evaluate the success, find a way to disseminate that.

Having true informed and shared decision making also is a concept that's been out there. It's not widely practiced. How do we support individuals in making their informed decisions? How do we use that data for societal benefit while protecting the privacy? And what kinds of educational materials can help consumers, one, understand even what their data means, but, two, more importantly, understand how they can use the data and the accompanying knowledge we hope to disseminate to improve their own health and health behaviors.

Professional societies are going through multiple, so there's a program called maintenance and certification, for example. There are multiple ways that professional societies constantly update their knowledge. How can this participate in that effort? Now that they're having access to the information, now that they have access to network knowledge, how can this play a role in continuously updating our whole knowledge base of the people who practice on the professional side? Finally, again, emphasizing the consumer and individuals, it doesn't start when you become an adult. It should go K-12 and on a lifelong basis, so we understand what it means to practice good health behaviors, to maintain your health, to constantly improve your health.

Finally, how can we use the data? We have the gold standard of randomized control trials. It's designed to discover and to control for variables so that we know scientifically what new things, whether they're better or not. But there's a lot of data that we leave on the table, and that happens through the everyday practice of medicine. How can we tap into that at the population level to motivate new thinking, to discover new knowledge, and to serve as input to new RCTs, randomized control trials?

We need to stimulate and support innovations in this kind of learning, in the delivery system, in the acquisition of knowledge, in the management of knowledge. We hope to leverage this health learning system to do that. We don't know everything, even how to deliver these systems, so there needs to be continuing research on how do we overcome the obstacles that impede the creation not only of the systems themselves like HIT, EHRs, PHRs, but the system that contributes to knowledge.

One of the ways we can do that is to reward and showcase and leverage what we already know. It may be known in sectors of the country or the system, and we need to find a way to leverage that through this system. Finally, once we do create new knowledge, how do we disseminate it? We all know about the 17-year transition between discovery of new things, proving new things in medical science, and its eventual use in practice.

That concludes basically the four infrastructure planks, and we're at the point now where we've gone through this deliberative phase. We've heard from a lot of people. We've tried to incorporate that into this document, and we think that over the next five years, the National Coordinator and his office will certainly deliver on these promises. No pressure. At this point, we'd like to open it up and take in your feedback and discussion of this document that we're preparing to submit to the Office of the National Coordinator for members of the committee. Thank you for your attention.

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

Any comments, suggestions? Yes, Charles?

Charles Kennedy – WellPoint – VP for Health IT

I think the document is great. If you're going to do studies that support comparative effectiveness and safety studies and quality assessments, you're going to have to aggregate data. I think there are some fundamental policy questions in there about who gets to aggregate this data under what circumstances for what purpose, and I didn't really see that called out. Maybe I missed it, but I didn't see that really

called out in the policy and technical infrastructure discussion. I was wondering if you might comment on do you think that fits, and if so, where.

Jodi Daniel – ONC – Director Office of Policy & Research

There was some discussion about that. I think it falls, and other folks on the workgroup, feel free to jump in as well. I think it falls within, when you're talking about access the information, aggregation, and protections of the data, I think it falls in the privacy and security section. There's the strategy about federal laws and policies related to key privacy and security issues, as they relate to both exchange of data for individual and population health. And I think there was discussion in that section about making sure that we're looking at policies, as they relate to some of these broader learning healthcare system kind of issues, not just about exchanging data between providers for healthcare delivery.

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

Under objective one....

Jodi Daniel – ONC – Director Office of Policy & Research

Christine, did you want to jump in?

Christine Bechtel - National Partnership for Women & Families – VP

Yes, building on that, I think part of that discussion, we talked at length about creating a policy and a technology framework that would encompass a broad set of policies, data aggregation policies included. My comment actually was going to be in that area, which is, that's something that you find under – it's on my page nine under policy and technical infrastructure. There are a number of references to a policy framework, but I think what's happening is that it's getting a little bit lost, and so I'd like to suggest two things.

One is that it be separated as its own strategy, so creating a policy and a technology framework be its own thing. Right now it's coupled under 1.1.3 with standards and services. It often gets married with sort of standards and specs. I think, what we know from our experience, but also from the American health information community, is that it's a lot easier to focus on technology and standards than it is on the policy side, so I'd like to suggest that we list it out. And I'd like to also suggest that that lift out be actually the first strategy instead of the types of data element. I think the policy framework, policy and technology framework has to come first. And then, Charles, I think that's where we had also envisioned that being, but also being very closely tied with the privacy and security policy.

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

Can I just make sure I understand your suggestion? That's 1.1.3, which I think says what you said. You want to bring it out as an objective instead of a strategy?

Christine Bechtel - National Partnership for Women & Families – VP

No. What I'm saying is creating a 1.1.1 that is solely focused on the creation of a policy and a technology framework. Under 1.1.3, you have adopt a core set of policy standards and services. But I think, when we leave those things all together, our tendency is to focus on the standards and the services and the technical functions because it's easier in many respects. And so I'd like to suggest that we actually call that out as the first thing and alone a policy and technology framework. Does that make sense Paul? Okay.

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

Yes. Gayle?

Gayle Harrell – Florida – Former State Legislator

Thank you very much. I can say this is quite comprehensive, and a whole lot of work has gone into this, and the one thing I'd like to address specifically – I have several different things, but I'll start with this first is in dealing, again, with the policy and technical infrastructure, the 1.1.2, I believe it is, when you're talking about the incremental approach. I think we want to make sure. Perhaps it's 1.1.1. I'm not sure.

Anyway, when you talk about the incremental approach, I think, at the very beginning of our hearings, we always talked about privacy and security being foundational, and I don't believe you can be incremental in defining privacy and security. I think you have to start out with basic privacy and security. Yes, there may be changes in the technological enhancements that come along with privacy and security, as we learn more, and we do more, and we have innovation going on in privacy and security, but I don't know that you want to be incremental with your privacy and security. You want it to be foundational. Perhaps some wordsmithing there in pulling out and identifying privacy and security, not lumping it in with everything else as incremental in approach might be really significant.

Jodi Daniel – ONC – Director Office of Policy & Research

Let me make sure I understand. You're saying where it talked about incrementally enhancing these things, you're suggesting that the security piece should not be incremental.

Gayle Harrell – Florida – Former State Legislator

Correct. It should not be included there, and perhaps called out separately as being foundational, and then also as enhancements come and innovation comes, that would be included, but you want to not be incrementally building, as we are within the EHR, you know, with the first data collection, then use of data and things of that sort. It's a different level for privacy and security.

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

Although we have a separate layer, the privacy and security, we didn't explicitly, and that's your comment, I think.

Gayle Harrell – Florida – Former State Legislator

Correct.

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

One, to say that's foundational, and there is a threshold you have to cross.

Gayle Harrell – Florida – Former State Legislator

Correct. There is a threshold you have to cross, and then you move forward. Whereas the others, it's a step-by-step building, as we have seen with our meaningful use of building upon things, and that's the difference.

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

Got it. Thanks.

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

Neil?

Neil Calman - Institute for Family Health - President & Cofounder

I guess I have the advantage of not having been on the workgroup and trying to digest this for the first time when I got it in the e-mail. It's thick. I guess it reads to me to be very academic, and I don't know. Given all of the work that we've done trying to make things sort of publicly accessible, this doesn't feel

very accessible to me. I mean, it doesn't feel like people, other than those of us inside the computer system, could really digest this and understand what it means to them. So I guess I have two recommendations.

One is to try to tie this into the words that we've been using all along, which are really sort of the meaningful use goals that that stuff on the left all the way through. It starts that way, but in a very brief sort of introduction, and I think it really, people who need to read it need to be able to connect it to what we've been saying for the last year, which is what are we saying about this stuff and how it relates to improving people's healthcare and whatever. It's not just sort of the introduction. It's really sort of the underpinning of it, and I think it has a lot of the process stuff in it, but I think it would be hard for people outside of us to kind of digest this.

Second, I guess, is sort of about the graphic. Maybe what we need resting on top of the pyramid are those goals so that it's really clear that all of this stuff really supports the outcomes that we're trying to achieve because I think, all along, we've been trying to stress that it's about the outcomes. It's not about the process stuff. And yet, sort of this whole document, because it's a strategic framework for how it's done, you kind of can get into it without really appreciating that it's still about the outcomes. I guess I'm just talking about how we could configure this, so it's a little bit more digestible, and maybe even have a publicly translated version that makes it easy for people like me who haven't been involved in the nine meetings to just be able to pick it up and understand what it is we're trying to do in more simple terms.

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Or put it through the Google translator. Excellent.

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

David and then....

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

Do you want us to respond a little bit to that? Do you want us to respond to that?

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

Go ahead.

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

Neil, even though you weren't on the workgroup, your spirit was there. This was a comment we clearly discussed, and that's why we raised the question, well, who is the audience for this. One, the audience is ONC. Second, we did try to address it through the preamble, essentially the background, which tried to lay it out. And maybe we can even do a better job on that. But in strategies under meaningful use, as you point out, it's 3.3.1, which is where we talk about a compressive communication strategy. That is the translator that we asked for to say to consumers, what are we talking about? How would this benefit you? And what would you have to know to take advantage of it? Those we saw as critical, and so that, we placed your thoughts there in that strategy. But it is a message to the office. As far as the graphic, now you can tell us that we didn't do a good enough job, or that's not an appropriate target, but that's how we dealt with your spirit.

And the second piece was the outcome. Now we did, also on the top of the graphic, the results speak to the outcomes and speak to the IOM6 aims. Again, it is – your spirit is there. It may not be rendered very well.

Jodi Daniel – ONC – Director Office of Policy & Research

If I can respond, I'm wondering. Maybe we can, from a graphical perspective, we might be able to pull this and that pyramid together to make it one simple visual that people might understand to get the outcomes with those planks. The second thing I would say, Neil, I really appreciate your comment. It's something that actually came up, I think, in our listening session as well, if I recall. I think that's where it came up. I think it's sort of, as Paul was saying, this is advice to ONC, this framework. But I think your point is also good advice to us about how we communicate this in making sure that when we do put this in a more comprehensive strategic plan, which will probably be even more information than what's in here when we add tactics and measures that having a digestible version of it that explains sort of some of the key points, I think is a very good suggestion that we'll take on as well.

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

I'm going to go to my right side for a moment here because I've been left oriented to this point. Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

Again, I'll concur with everybody, there's a tremendous amount of work here, and it's really terrific. Let me add a few more strategies for us, so we have even more to do. Under your efficiency section, you pulled out the HIPAA transactions and code sets, which clearly is a place where we could build on an opportunity that's been out there now for many years. But we've got some additional opportunities, I think, and one is to think about coordinating and harmonizing the federal regulations that require providers to supply data to various government agencies today so that as we're automating the clinical information, that we're actually building on a consistent infrastructure and a consistent set of deliverables.

And that we also encourage the development and use of outcome measures that can be derived directly from the documentation of care in EHRs. So to work towards a simpler abstracting process that, in the end, can become no abstracting. Many of the meaningful use criteria do try to do that or head in that direction, but there are a lot of existing reporting requirements in place that didn't assume an EHR, so now that we're beginning to assume EHRs to build on that. So placed, you know, the big phrase a few years ago was to harmonize all the standards because we had so many, and now we should harmonize all the data reporting and achieve a similar goal. Thanks.

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

David?

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

Certainly add my endorsement to all the work that went into it. It is a huge amount of helpful material to my thinking in here. There are a couple places. I think either, again, map the things I'd like to suggest either get mapped down to the next phase of more operational planning, but some of them feel, to Neil's point, that we have an opportunity to create some umbrella concepts in the story that we tell that might communicate to various audiences more clearly.

I'll just lay these three things out and see where they fit. One of them is, I think the accountability of the various key entities, including ONC, HHS, CMS, what is their job? We have very ambitious goals described in these goal statements that are not measurable or tractable for the coordinator, and I think it would be helpful to be able to say, here's what we're going to accomplish by what date as a strategic template.

The second is, I'm concerned. I mentioned this earlier, that we haven't got enough in here about ... money. As the stimulus payments play out, what is the role of the larger payment system, including federal initiatives, but also private sector initiatives and payment reform more broadly in sustaining or

accelerating or disrupting and innovating within the HIT space. I think, strategically, a huge amount is going to depend on how we understand the dynamics of the marketplace and take advantage of that.

The third is what I'd call governance and jurisdiction, which I think should be spelled out as a strategic question. Not only the question of, we obviously have surfaced it in the NHIN discussions, but more broadly, what's the role of the state? What's the role of the federal agencies? What's the role of regulatory versus legislative action on the policy side? These are fundamentals to our strategy.

I think, providing some direction there, as well as what Christine said about creating visibility for the policy framework, part of that needs to be the implementation, governance dimensions of the framework, so I hope we can find a way to, either in the implementation phase next or in re-crafting the storyline here, give those big dimensions some visibility because I think that'll help the public understand what is the government's role in this is the governance question. How does payment reform sustain or perhaps confound our progress? Those things, I think, have to be given some visibility.

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

I think Paul Egerman is next.

Paul Egerman – eScription – CEO

Yes. Thank you. First, like everybody else, this is a terrific work, and I want to thank you both for your leadership and having sat through the calls, I thank you for your leadership and your patience. This was a very challenging process.

I had two comments. First, I wanted to actually disagree with what Gayle said about objective 1.1 incrementally. If you read 1.1, we did not read incrementally improve privacy and security. We said security, and a lot of people get mixed up between the difference, between privacy and security. Security is much more for like the technical thing in terms of access.

The issue in my mind is I think what's written here is correct. If you're going to change the functionality over time, you're going to increase interoperability. Probably change technology. You probably also have to incrementally enhance security. In also in my experience, that's just how it works. You've got a lot of security gurus, and based on new technology and things are learned every year. There are new ideas as to how to enhance security, so I actually think what's written there is correct.

I had also a suggestion about one of the strategies. I think it's on slide ten, 1.3.3, which Christine helped point out to me. It says monitor patient safety concerns related to HIT. I think we want to do something more than just monitor the concerns. I think we want to do something like monitor and address patient safety concerns, or monitor and respond to. I don't know what the right word is, but I think monitoring is good, but I think we want to go a step further.

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

Judy?

Judy Faulkner – Epic Systems – Founder

I, like Neil, wasn't on the original – wasn't involved with the original discussion, so this is, again, new to me, but I'm worried about it. To me, there's a morphing from the original purpose of the group, which was the three workgroups for HIE, meaningful use, and adoption and certification. What I think there appears to be a slant, as I read this, and I am nervous about it and worried about it is that it's morphing a little bit into potential committee, government control of the development of EHRs. I think we have to decide. Is that accurate or not accurate? Is that what you want to do or not, and make it clear which direction.

In looking at some of these, I think, such as in the first objective, 1.1, it says enhance the – and included in there is the functionality and utility. Functionality, if in fact this is interpreted to mean that the functionality of where electronic health records go is going to be defined through this process here, I get really worried that it won't be as good as leaving it to the open markets to define functionality because any small group, rather than thousands and thousands of pieces of feedback back that's going to influence each vendor's decision of what do I have to do next is not going to be, in my opinion, as good.

As I read through it, there are various sentences in here that could easily be interpreted that way. I just feel that it leads us to a dangerous thing because sometimes I see people who want their job to be, I want to define what the EHR is going to be, just an individual. I think it's interesting because I say, okay. And what will you do for the other 360 days of the year because, within just a few days, you can keep the vendors busy for years. And so my worry is that if in fact this becomes heavily the functionality definition of what's going to happen to EHRs, there may not be time left to do anything that's coming from the users themselves in addition to what is here, and I think that has to be addressed and handled.

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

It's a useful comment, and I guess I'll say the opposite of what I said to Neil because I don't think that interpretation was present at all in the discussion. Let me read the words, and then you just comment on that. That same one, which is objective 1.1 where it talks about establish the policies, standards, implementation specifications, certification criteria that incrementally enhance the interoperability functionality and utility. For example, it's really hard to have care coordination in an EHR product sitting in one organization. How would you enhance that functionality of med reconciliation, of care coordination without somebody worrying about the standards and the policies of exchanging data?

Judy Faulkner – Epic Systems – Founder

Which one did you read, Paul?

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

1.1, it's objectives, so I thought that's what you were pointing to.

Judy Faulkner – Epic Systems – Founder

Right, and underneath it, 1.1.2 where it talks about functionality and utility.

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

It still uses the word enhance, and that's what we meant. If that truly, if what we were intending does not come across, we can certainly address that, but no one thought it was government controlled. That's point one. And that we all thought that these kinds of things and, in particular, the sharing of data for care coordination, which a single vendor, a single organization can't do by itself was really important, and that's what we meant.

Judy Faulkner – Epic Systems – Founder

I agree with that. I agree with that, but I think it's too easy to read other things into this. And I also think that as we define meaningful use here, I think vendors across the country are seeing their development move towards meeting those criteria. But if it continues on, and on and on, and that is what vendors have to do year after year after year, then the defining of that criteria becomes the definition of what EHRs are. People have to be very careful not to go that way.

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

Yes, Christine.

Christine Bechtel - National Partnership for Women & Families – VP

On the meaningful use section, and I'll just start by adding my thanks for all the hard work that both of you have done and all the staff at ONC. I know Seth, Suniti, and others have done a lot too. Under the meaningful use, I have a question and then two small comments. I'm looking at strategy 3.2.4, which says support providers and consumers in addressing the key workflow and behavioral changes necessary for meaningful HIT use. I wasn't sure what consumer behavior change is required to achieve meaningful use.

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

As an example, it can also relate to the bidirectional information sharing comment. Right now, certainly in paper, consumers walk into an office and get information pushed and shoved towards them, and there's not a whole lot of absorbing and tailoring the recommendations to a consumer or patient on how that person can absorb this and modify some of their behaviors to improve their health.

In the future world that's envisioned in this learning health system is that it's a bidirectional exchange of information, and that some of the workflow and behavioral changes are sharing what you're doing and tracking some of your behaviors so that you can, let's say, plot it against some of the other goals for your health situation. There is a difference. In a sense, it's a different relationship in that we thought there's a different workflow and there are different behavioral changes that are part of that.

Probably embedded a little bit in that because it did come up in the discussion, some of the accountability that David Lansky referred to is somewhat, some absorbing of some accountability for your personal health, and that's a behavioral change as well. But what we're intending is it's not just, well, you have some new accountabilities and new responsibilities. I think you have some new tools to change, to make meaningful change to your health.

Christine Bechtel - National Partnership for Women & Families – VP

I'd like to suggest then that behavioral change comes something else in every place in this document, but starting here, and maybe here it might be more like cultural changes that are necessary. I think there are certainly a lot of culture changes that need to happen in the provider community, as you said, Paul, that support a different kind of relationship. But I don't know that – anyway, I just want to flag in the next section as well the idea of behavior change, the language of behavioral change of adherence, of compliance, just really rubs consumer communities the wrong way, and I don't think it's actually necessary, but we communicate the same thing by sort of broadening to improving their health, as opposed to focusing on the behavior. I'm happy to ... talk all day about that, but the bottom line is that some of the best and most advanced health initiatives really have a different focus where providers are actually taking on responsibility for supporting consumers in a different role, but not calling it behavior change, compliance adherence, etc., so I'll flag that.

Then the last thing is that under the shared decision making kinds of strategies here, and I'll give you some line notes that will help, but one in particular that I want to point out under 3.3.3, which is assure that meaningful use policies support shared decision making through bidirectional information sharing between patients and providers. Information sharing health information the way that we're conceiving it under meaningful use is not shared decision-making. It's laying that by connecting it to tools and resources. To get really to shared decision making, which I think is the core of this, I think we need to just add on the back end of that sentence, "and appropriate linkages to education resources." So I'll give you some hard copy on that.

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

Thanks. Jim?

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

Thank you. First of all, I'd like to congratulate the workgroup on developing a robust and comprehensive framework for furthering the goals of the HITECH Act. I'd like to make a comment, kind of on a broad swath of the framework itself. The framework obviously relies very heavily on consumer education to promote consumer engagement and adoption.

One of the things that I think maybe the framework ought to acknowledge is that health IT consumer engagement doesn't happen in a vacuum. It's a part of a much, much broader effort to promote consumer engagement in health. I'd like to see some language around leveraging existing federal, state, nonprofit, and private efforts that are aimed at promoting healthy behaviors, healthy lifestyles, and leveraging them to include messages around health IT rather than, and again, going back to the fact that the framework is very ambitious, to use existing mechanisms to promote health IT adoption wherever possible.

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

Marc?

Marc Probst – Intermountain Healthcare – CIO

Great job. You guys have taken herding cats to a whole new level, and it looks like it's still going on. Early on, when I read this, some of the early drafts, I came back with some comments because I didn't really understand how it impacted me, not as a member of the HIT policy committee, but as a CIO, someone actually trying to implement some of these products. We had good discussion that this really was for ONC, and focused on that direction.

But I think the question I have then is what's next with this because I do think it's probably from the Office, Dr. Blumenthal, that people are looking for some guidance, and if we don't create those bounds, I think we do get into what Judy is talking about. You could read into this all kinds of new development activity or security activity or things that we need to work on if we don't understand the bounds of what this plan is supposed to do because there are certain things I'm looking for from someone. I don't know if it's from the Office of the National Coordinator or not, but they're very specific items that aren't addressed in this, nor do I see the plan to where they will be addressed, so things like consent on a national level for HIE. Is that anywhere going to come out of the specific items that will be dealt with, and that we'll get the information?

I guess I'm just looking for the handoff between this vision, this framework, which is excellent. It really does lay out a great vision for the country, and then the next step where the specific items are going to happen because that's the question. What's going to come out of this?

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

I'm not a strategic planner by trade. We have to develop a strategic plan. The legislation requires that. This is going to be absolutely terrific input into that process. Plans are not implementation maps, as I understand them, so I'm not sure we're going to be able to answer all your specific questions in the form of a strategic plan.

What a strategic plan will do, I think, we hope will do is give us some guardrails and directions for our policy development and our implementation choices. And so I think, from the standpoint of the ONC, this is a very valuable set of advisory documents that we can build on in our own internal work that will speed

along our internal process of meeting the legislative requirement to have a plan and developing a plan that actually is useful.

I should point out that nothing is simple in the federal government, and the ONC will produce a plan that will likely reflect a lot of this thinking. But then we will pass it along to our brethren in HHS and then the Office of the Management and Budget, who will then pass it on to Jim Borland at SSA and Steve Andra, who is not here, at the VA, and our colleagues at the DoD and Commerce and on and on, and eventually will come up with a plan that hopefully will reflect, still reflect the excellent thinking that's gone on in this group.

In terms of the specific questions that are not addressed, it sounds to me like some of them are more at the level of implementation guidance than the kinds that would be addressed in a plan of this type. If you have a list of them, we would love to have them to have that kind of feedback. In terms of the specific issue of consent, I would just wait a couple hours because we're going to be talking about that a little bit later.

Marc Probst – Intermountain Healthcare – CIO

That's great. I do think, ultimately, the plan may not be able to answer specific items, and I understand that. No, I don't have a complete list. I would hope there's a country full of questions out there that need to be answered, but I think we need to address the fact that some process has to be in place to answer some of the questions that are out there that many of us in the country have that would help move this forward.

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

Gayle, I'll get to you in a moment, but maybe what we need to do is, as part of the communications, talk about what a strategic plan is and what it isn't. Gayle?

Gayle Harrell – Florida – Former State Legislator

Yes. I'd like to go to the issue of PHRs. I know they're called out specifically, and I don't believe legislation really empowers the ONC to address them. And I didn't know if you put that within a strategic plan that you are overstepping the bounds of what the legislation does. I think it's really geared specifically in the HITECH Act, and perhaps I'm misreading it, in that it is for electronic health records specifically addressing providers, eligible professionals, and hospitals. And it's very delineated who it is to address. Perhaps you might want to comment as to why that might be within the strategic plan.

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

Others might note it in more detail. I thought of it more as HIT health information technology, and I'll make another comment that personal health records are actually called out, and I don't know whether it's in the context you're saying, but for example, dealing with personal health records and business associates, and whether they are or are not, etc. There's certainly reference to that, and so I believe that it wasn't very restrictive.

Jodi Daniel – ONC – Director Office of Policy & Research

If I could chip in, I think, from the standpoint of the incentives program, the CMS incentive program, there is definitely a focus on EHRs as opposed to PHRs. But in the section of HITECH where it talks about ONC's authority, it is a lot broader. It talks about health IT more generally to improve a lot of the outcomes we've talked about. There is, in the privacy section, reference to consumer access, so there is reference to privacy protections and breach notification with respect to PHR, so I think there is a lot embedded in there. I think you're right with respect to the incentive program that it is mainly EHR focused. But I think there are a lot of places where the legislation talks more broadly about health

information technology and some specific references to PHRs that would allow us to do some of the things that folks have talked about in the context of the strategic framework.

Gayle Harrell – Florida – Former State Legislator

Perhaps I need to ask a further question then. What is the vision then of the role of the ONC in guidance, in regulation, in determining where PHRs go? Here again, with basically what Judy has brought up, are we looking to become more prescriptive in defining and then perhaps limiting of where PHRs go? What is your vision as to what that – what door does that open?

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

I think ... vision ... in this strategic plan, recommendation document, and that is part of the meaningful use criteria is that patients, consumers, caregivers are an active participant in their data and the communication about their data and health. So that's not prescriptive, so hopefully it's addressing your question of our vision definitely encompasses the participation by individuals. I don't think anybody had intended it to go in the way that Judy talked about, so it's a good perspective because we want to have a new sensitivity to that, but there wasn't any intent by any members that participated in our meetings to that affect.

Jodi Daniel – ONC – Director Office of Policy & Research

...for two seconds and say that if you – and I know that it's tense, but if you read it, I think there are a lot of very intentional references to market innovation and how do we play an appropriate and minimal role as, how does ONC do that as the government entity, but, at the same time, foster that innovation? If I think about the PHR, market, which, as a consumer organization, we're obviously very interested in, I think the market itself has been hampered by the fact that, up until now, consumers have to manually enter their own health information, and who wants to do that? And so there is a role for government to the extent, for example, meaningful use and NHIN efforts can begin to free up data. Then the market can innovate around that. I think that was something that we were pretty careful with at the workgroup level to really talk about a minimal role for government. I hope that's helpful.

Then just as a sort of historic note to your first question, it's interesting to me that the very first strategic plan that ONC issued under David Brailer actually was very far reaching and encompass multiple federal agencies because that is now statutory, but then executive order authority for ONC. And so, VA And Social Security and Indian Health Service, they all had appendices in it, so it was far, far reaching, which I think is appropriate for an office that is charged with coordinating health IT policy generally, so just my own view.

W

If I can just elaborate on that, just as far as ONC activities, we have started. Well, we had initially, but have started more actively reengaging with our federal partners to talk through what this workgroup has come forward with, and to talk with them about how their activities may fit in with this, where there might be areas where their activities are not adequately addressed, and trying to make this a much more integrated plan that considers the other issues that are raised by our federal partners. I think that is within the scope of what we're hoping to do internally with this document, and as we develop our full strategic plan, so that's very helpful feedback.

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

Adam?

Adam Clark – Lance Armstrong Foundation – Director for Health Policy

I want to reemphasize again thanking the hard work that went in. I was particularly happy to see the informed and empowered patient because that is going to be a critical role of what we're doing here, but it raises some challenges that I'm seeing just internally, and I think that are going to come about. The consumer engagement is going to be very, very hard. The general public doesn't understand what we're discussing. They aren't going to go into their doctor and say, are you using a meaningful use EMR. I think, even just asking if their doctor is using EMRs, for many patients is going to be very intimidating.

I think that there's a role for patient advocacy groups. That in and of itself is going to require education. I think the ONC active engagement with many of these groups is going to be very valuable. But I wanted to bring up two points that, as I was looking through this, that I thought were great, but they left me asking how, and that's the one under 2.3.2, which is promote an environment of consumer empowerment and informed participation. How are we going to go about doing this? Could we expand that to some sub-bullet points, maybe things that are going to identify groups who can help with that because I think it's easy to say that we're promoting an environment, and I think we all have the best intentions that we are, but we need to hear back from patients whether or not we're actually doing what we think we are.

Then a point that was brought up by Christine, 3.3.3, to assure that there's a shared decision making through bidirectional information sharing. We know and we've done some surveys. Patients do want to share information. In particular, they want to share information that's also important to them. Simple things like I'm in pain. It's not being addressed, and we know pain is one of the symptoms that particularly in cancer is very poorly addressed on many things. I think that's a way you will actually find patients will be engaged.

They want to tell their doctors things that may not be identified and what we may be considered meaningful use, but are very meaningful to patients. I would just try to give that some thought. I know Christine said linking with resources and educational materials, I think that's great. There may be some other things that we can help to build out more activities for how patients could get engaged.

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

Great comment. I will help you with your first problem. EMIA has a button called Got EHR.

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

Also, we have just contracted through a consumer survey to assess consumer attitudes toward electronic health systems. That was on the way. If knowledge is a beginning, we're starting. David?

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

Under 3.3.4, which references efficiency, which is one of the core goals we've identified from the beginning, I think this section really could benefit from being beefed up and given more visibility, actually is the very front matter of the whole report. I think the elephant in the room is the cost of the healthcare system, and we don't, in this strategy framework, really call out how does the IT investment help bend the curve and the economic curve, the cost curve.

I think, in this section, 3.4, it's fine to acknowledge the administrative simplification under 3.4.1, but I think there should be two or three or four more bullet points under strategies that remind everyone how we believe the HIT investment will improve the overall cost profile of healthcare. And I think we can talk about coordination of care, reducing readmissions, reducing redundant tests, clinical decision support to improve practice at the point of care, the opportunities for disruptive innovation, and the larger delivery system and so on. I think it's not only within this bullet point, but we should have a reference early in the document that we realize that's why Congress has made this commitment, in part, and there's a very

strong emphasis, which I, of course, endorse on improving health outcomes throughout, but we want to also give visibility to the public investment we're making.

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

Gayle, you're – I'm sorry. Latanya?

Latanya Sweeney – Laboratory for International Data Privacy – Director

I just have a question about the big vision for ONC moving forward. I guess it kind of resonates with some of the questions and comments that came up earlier, but I guess I don't really understand. A lot of the reason we're able to – ONC is able to motivate action and activity is because of the stimulus funding. It's 2016, and let's suppose most of this plan is as it is, I mean, is this going to be, we recommend. Is this going to be you must?

Independent of the question of innovation, and the issues and problems that will come up in EMR adoption itself that aren't address in the strategic plan, sort of what Marc is saying, and innovation ideas, whether they're PHRs, or whether they're from vendors, ONC will be voicing things along the learning health system model, but how do you think these pieces are going to connect? One of the things I heard from David was maybe they would connect if the argument was we're doing these things because this will bring, you know, reduce expenses by 10%, or we're doing this thing – you know, if there was some concrete way that you're relating it. Otherwise it's not clear to me how the rubber meets the road.

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

That's a great question. It's a fundamental question of governance. When you have a strategic plan, how do you translate it into action? You all are, as you process this, you are processing your plan. I happen to be the chair of this group, but I'm not going to vote on this plan because it's going to come to me. I'm chairing the discussion because Paul is really, for the moment, only in one person's body right now. He can't be in both places.

But one of the things that having a plan does is it gives you a vision against which you, and a set of goals against which you strategize and then form tactics. That involves policy development at every level, decision-making in countless ways throughout the way every day of the year. It also informs budget development on an annual basis. Once we have a strategic plan, the Office of Management & Budget will ask us when we propose a budget at ONC to show how that budget furthers the strategic plan. So there will be many ways in which the plan will, if it's a strong and effective plan, and a realistic plan in which it will inform how decisions on a day-by-day basis and on a year-by-year basis. It's hard to be more specific than that because, in fact, we don't have the plan in front of us, but I assure you that one of the things that the budget documents that we produce have done in the past is continuously reference old strategic plans and justify themselves in terms of those strategic plans.

Latanya Sweeney – Laboratory for International Data Privacy – Director

Just to follow up on that, so one way of interpreting your response is that you are looking for federal funds to force this plan into action.

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

We're looking. Once we have a plan, we will look at all our authorities, and the authorities of our sister agencies, and try to mobilize funding authorities and policy making and regulatory authorities and try to marshal them in pursuit of the plan's goals. Gayle?

Gayle Harrell – Florida – Former State Legislator

Yes. I want to go back to what David was discussing with the sustainable healthcare system. When reading the original document that came through, I had a big asterisk by this particular paragraph. I want to make sure that as we do that, and as you look at this, and if you're going to enhance that bullet point that looks at leveraging HIT for reducing costs, I think we need to be very careful in how that is done and how that is phrased so it does not become a mechanism for limiting appropriate care and rationing care. That's the elephant in the room when you talk about comprehensive effectiveness research, when you talk about limiting payments. Here it talks about dealing with HIT offers tools that expand current capabilities to collect and manage data that can help creation of a sustainable system that facilitates getting the right care.

Right care can be in the eyes of the beholder and the payer. So I think this opens a door that needs to be carefully addressed and that patients need to be the center in improving care and improving quality outcomes needs to be the center of that. If we're going down that road, let's talk about the elephant in the room and really address it appropriately. I'd like your comments on that.

Jodi Daniel – ONC – Director Office of Policy & Research

I'll defer to Paul.

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

I'm feeling a little bit like Don Berwick must be feeling, which is, the more you say, the more can be said about what you say. Perhaps after the National Coordinator starts providing care and paying care, then he can then reform the payment system. I think it's along the lines of what Judy was saying.

There's a lot – a lot of people will be – well, it is a target as a recommendation to the National Coordinator, so I'm not sure how broad it was intended to be, and I think he understands our intent, both by written document in our discussion. I think we want to go back with these new sensitivities in mind to make sure we clarify the language in a way that they were intended, and none of the possible interpretations that were somewhat raised were what the committee even talked about, let alone intended. So we'll be careful with those words and definitely recognize the sensitivity.

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

In the interest of time, what I'm going to suggest is that the staff and committee go back and respond to the suggestions that were made here, produce another draft, and I'm not sure whether we want at this point to present it again for discussion at a formal meeting, or whether we want to do a phone meeting to react to it over time, but one way or the other, the committee will get a chance to see it again before its approved for transmittal to the Office of the National Coordinator. Does that sound okay, Paul?

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

Yes. I want to thank the committee for a very rich discussion. It's been very, very helpful. To Marc's comment about cats, I think it's a privilege and a pleasure to work with a bunch of smart cats.

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

Any comments on that closing comment? All right. Deven, would you step up? You don't have to step up to the mic. Lean forward to the mic.

Deven McGraw - Center for Democracy & Technology – Director

Lean forward, pull it closer.

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

Bring us up to date on the information exchange workgroup.

Deven McGraw - Center for Democracy & Technology – Director

Information exchange, okay. Micky, are you on?

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Yes, I'm on.

Deven McGraw - Center for Democracy & Technology – Director

Since I'm listed in many places in this agenda, I thought I would defer to my cochair, and I'll refrain from any cloning jokes in that regard on the slide. Why don't we tee up the first slide, and I'm going to let Micky take the lead on this, and then I'll chime in as necessary and, of course, be here to answer questions. Go ahead, Micky.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Great. A lot of people do think that Deven and I were separated at birth because we look alike. Good afternoon, everyone, or good morning, everyone. I apologize I can't be there in person today, but we have just a relatively few slides to give you an update on the information exchange workgroup and our current thinking about the agenda going forward.

On the first slide, I just wanted to run through some background and summary, and then we'll go into just a couple slides that provide a little bit more detail as to what we're thinking about. First, just to give sort of the broadest background, the information exchange workgroup was initially launched I guess just about a year ago with a fairly broad charter, which, as you can see here, was related to all the various aspects essentially of health exchange.

In the sort of ensuing work that took place over the last summer, I think there was a broad recognition that the original charter was too large for a single workgroup, which led to the launching of the NHIN workgroups and the privacy and security workgroups, which now has sort of the beneficial outcome of allowing the information exchange workgroup to focus on what we think of as breakthrough areas, which are very specific types of transactions related directly to meaningful use. Those are areas that we would define as where policy barriers prevent providers and/or states from becoming effective enablers of broader and deeper health exchange. Indeed, the first two areas that we tackled last fall were in that spirit, the first being labs, and the second being e-prescribing.

The two areas that we think about, as we think about these breakthrough areas are, one, are broadening that set of transactions under consideration to the set of clinical transactions that are already identified as important to meaningful use, and we'll talk about that in a couple of slides. Then there is a second category, I think, which is about critical issues that will inevitably get unearthed by the various programs that are now underway. Most of them now just beginning, but when we think about the enormous resources and the activity that has now been generated in state level HIE, regional extension centers, beacons, and NHIN Direct, we think that there is probably going to be a lot of other policy issues that start to emerge from those activities because one experience that I think any of us have had as we've tried to implement health information technology and health exchange is that a lot of the policy issues start to arise as you're in the implementation. That it's hard to anticipate in advance all of the policy issues that you're going to be confronting. But we would think that the primary focus is really on the first bullet about the specific transactions that are already identified as important to meaningful use, as we think about these breakthrough areas.

The other important role that we believe that we can play to be helpful to the HIT Policy Committee and ultimately the National Coordinator's office is to be a conduit for state level policy issues that may need

policy committee attention. There are two categories of those. One would be for issues that are in the information exchange workgroup charter, being able to identify and recommend solutions to such issues for the policy committee, which is kind of the role we perform today. There is a second category that's equally important, which is issues that are outside of our charter, helping to navigate those to the most appropriate workgroups and facilitate and coordinate that as necessary because the last thing in the world that we want to do is have redundancy and recognizing that there already are gray areas between some of the workgroups and helping to stay focused on our charter and be helpful in terms of navigating issues that seem to be important issues to the appropriate workgroups so that they can focus on them within their own charters. That seems to be a very important role for us.

In terms of our recommended next steps, what we'd like to do is finalize our agenda for the remaining calendar year and, importantly, aligning that with the other interoperability working groups, and to the extent possible with the standards committee agenda, to the extent that it has information exchange elements in it and interoperability elements in it. We also, as we're looking forward at the agenda and this sort of focused charter, we do think that it may be beneficial to adjust the workgroup membership a little bit, and we can talk about that. Then, finally, one of the things that we've thought about that we think could also be helpful would be to establish some type of communication channel for state level HIT coordinators to have some kind of communication channel about these emerging issues that are coming up, as they go through their implementations, and there could be a variety of forms that that could take. We've thought about an advisory panel, for lack of a better term, and would welcome any comment or discussion on that, but that's one of the things that we see as being an important element here that could help the policy committee be able to stay on top of issues that arise before they sort of get to a point that they come up in other ways that are less helpful.

The way we've thought about this is that there are some focus areas, and what we'd like to do is as I've described, think about those in two categories, but the ones that we think are where we can be most helpful, certainly in the near term, is around the meaningful use transactions. Labs and e-prescribing, as I described, were the ones that we first started with. But as we think about some of the other ones that are important to meaningful use and stage one meaningful use, at least as articulated in the NPRM, we'll see how that looks in the final rule. But public health, administrative transactions, summary exchange transactions, quality measurements, and particularly reporting, and then patient facing applications, all of those are important elements, I think, as all of you know with stage one and stage two.

Trying to think some type of evaluative framework, as we look at those, to say, sort of ask four key questions that in our minds can help us help inform what type of recommendations, if any, we think might be needed in each of these areas. The first would be in terms of the evaluative framework. Is the transaction universally and affordably available in the markets today, because certainly if we would like participants and providers to be able to move forward with respect to meaningful use and take advantage of the incentive dollars that are available there, we would like these things to be as universally and affordably available, and being able to get some measure of that with respect to each of these transactions.

The second would be, if not, if they're not universally reportably available, where are the gaps, and what market or policy barriers have created and/or perpetuated these gaps? Then moving to the third item there would be, third and the fourth, what are the kinds of actions that we might be able to recommend that could help rectify that? Some might be, first and foremost, I think the bias would always be toward what type of policy recommendations could be market correcting or reinforcing? But there could be some areas where it may require perhaps a recommendation around a more assertive role for government and around the orchestration of state and federal policies to complement those market solutions and catalyze removal of those service gaps.

Then looking at the third column there is really about what types of policy levers might there be as we think about recommendations. What I've done is just take that snapshot, which is the depiction that I think many of you have seen from the NHIN presentations from Doug Fridsma and Farzad Mostashari and others, as well as from the NHIN Direct. We could structure those any way we wanted. It's just a familiar way of showing them, so I thought it would just be useful to show it in that familiar sort of context. This doesn't suggest that policies are third in the hierarchy. This is about policy levers that could relate to policies about existing policies, whether they need to be refined or changed, policies about services, about standards. I think the trust fabric is really an outcome of all of those. It's not as if that's something specific on its own.

Let me just, the one thing I would just come back to before I pause here for a second is in terms of emerging issues, some of the things that seem to be bubbling up, and again, these are all just sort of thoughts right now, as we're thinking about what appears to be there on the horizon is HIST, first and foremost. How do they intersect with state law and with state organizations, and is there something in that intersection that could prevent broader and deeper exchange from happening on its own. There are some policy issues that we need to consider. Related to that is the intersection of NHIN Direct and meaningful use transactions. Then, finally, coordination with Medicaid programs is one area that's come up repeatedly, as we've tried to reach out and talk to various HIT coordinators and gotten feedback.

Let me pause here and see if Deven, first and foremost, if you have anything to add, and see if there are any questions or comments.

Deven McGraw - Center for Democracy & Technology – Director

I don't have anything to add. I think the bottom line here is that while we think it's important to revive this group because there are a number of issues that do need to be addressed. And given the bandwidth of the other workgroups, it's important that they have a home. And even if they don't necessarily get resolved in IE, they can be funneled from IE to other workgroups and/or staff, as necessary. So we just don't want them to fall through the cracks. Go ahead, Mick.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

On the next slide, which I won't go through in detail, but I just wanted to just show, you know, the feedback, some of the raw feedback, I would say, from a very unscientific reach out to various state level HIT coordinators to get their perspective on what the information exchange workgroup should address, as they think about this. I will say that I don't think that they were all sensitive to the delineations between the NHIN workgroup and the privacy and security workgroup and the information exchange workgroup. So some of these, as I noted on the bottom, are things that wouldn't necessarily reside within the information exchange workgroup.

I would also point out that a number of these, I think, really fall into the category of being bigger kind of framework sort of questions that, at least from our perspective, are things that probably need a little bit more maturation in terms of some of the programs for the IE workgroup to say that these are things that we ought to take on, but two things I wanted to do with this slide. One is just give you a sense of what are the issues that we're hearing about, but two, really articulate that we believe that, at least right now, the IE workgroup can be most helpful to the policy committee and to ONC at large by focusing on those breakthrough areas related to the meaningful use transaction without losing sight of these, but focusing first and foremost on those for the time being.

Deven McGraw - Center for Democracy & Technology – Director

This is our last slide, which actually has the recommendations.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Right. Our recommended next steps here are to adjust our plan according to any suggestions, comments that we might get today. We do have thoughts about adjustments of the workgroup structure and composition to better fit the future agenda. Some of them, in the way of membership changes, would be that looking at those meaningful use transactions and the issue that appear to be arising would be greater representation from public health and perhaps from some Medicaid directors as well, as two areas that seem to have the most immediate needs in terms of having some policy issues that the workgroup could be helpful on.

Then also, you know, again, pending the conversation here and the suggestions from the committee, moving forward with respect to some type of communication channel, perhaps more formalized communication channel from state HIT coordinators, so we're able to maintain that link and act as a conduit. Working with the NHIN and the privacy and security workgroups on coordinating interoperability agenda for the next three months so that we're all in line and not cross wires, stepping on each other's toes, and making the most effective use of time and the most effective use of sort of the policy recommendations that we want to have moving forward.

But very high level proposed priority areas would be around public health, labs to the extent that there are still outstanding issues that we're hearing about, Medicaid coordination, and summary exchange transactions. But I will just say those are very preliminary. I think that we would need to have the workgroup engage in that conversation and get the input from other workgroups and from the committee, as we think about that. And then what we'd like to do is present a new work plan and IE workgroup structure and membership changes at the June 25th HIT Policy Committee meeting.

Deven McGraw - Center for Democracy & Technology – Director

That's it.

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

That's it. Okay. Great. Any comments? Let me just say by context that as I listen to this presentation, it strikes me as a very nice example of how working groups can change and coordinate over time, and hopefully in a fairly organic way, so regardless of what is said about this particular proposal, the idea that a workgroup would look at itself and say, you know, things have changed a little bit. The issues are a little different. We want to rephrase what we do in light of other developments and come forward with a proposal, I think is just a great example. Anyway. Paul?

Paul Egerman – eScription – CEO

Thank you. Thank you for those last comments. This is an excellent example, exactly what you said, Dr. Blumenthal, of sort of restructuring the workgroup and making sure that it has an important focus. My comments are on, I think it's slide number two where you talk about proposed focus areas and policy levers. The focus areas that meaningful use transactions and emerging issues, and I would like to suggest that there might be a third category of focus areas, which I don't know if I word it right. I call interoperability and adoption that fundamentally there may be interoperability issues for, like, small medical groups or for other issues that are problems with adoption that may involve transactions that are not included in meaningful use.

To give an example out of the air would be maybe you could see that people are having difficulty ordering radiology exams, which isn't discussed anywhere in meaningful use, but maybe there's some issue there. Then if you establish some standards around that that would improve that situation. So I'm suggesting

that interoperability, especially related to option, is sort of a separate focus area. It is called out separately in the strategic plan that was just discussed.

And also, as a policy lever, it seems to me certification is a policy lever that's a very powerful lever, especially powerful for interoperability and exchange because, if you establish something required for certification, then all these systems will operate according to that. So even if it's not required to use it in meaningful use, it could be an example of the government having a big impact to straighten out a situation that might need straightening out if there's no single standard being used.

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

Gayle?

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Thank you. I think those are great suggestions, Paul.

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

Gayle?

Gayle Harrell – Florida – Former State Legislator

Thank you very much. I think I really want to point out the importance of addressing governance within state HIEs. We are seeing states. I know Florida is already stepping up to the plate, and there's been major discussion within the state of Florida. However, they are moving forward in governance and what the systems that they are setting up, certainly the assistance coming out of the National Coordinator's office in the way of financial assistance has been significant. And I think that should be a priority because they're already – the train has left the station, and we need to make sure that we have appropriate governance, again, addressing interoperability, privacy and security specifically so that when everybody is linked up through the NHIN that there is a level of confidence of the public that there the system is going to work, and it's private and secure.

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

Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

...quick comments, again, some really good thinking here. I want to build on your notions about learning from the experience of the states. We're funding a lot of state planning right now and setting up HIEs. We're going to see some more examples of those, as they start to take off, that we really start to look for where are they really working well, and how can we use those 50 experiments that we're running to actually inform how to move forward.

One of the things that occasionally gets above the radar and makes it onto the list is the area of coordination of care. It seems to me that this a really key area where health IT can both facilitate the care process and improve outcomes and also address some of the costs and cost control in a very positive way rather than a restriction of resources way. And so to specifically look at what does it take to do good coordination of care and start to look at those use cases, I think, would be very helpful.

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

Paul? I'm sorry. Neil? Everyone's named Paul.

Deven McGraw - Center for Democracy & Technology – Director

Everyone's name is Paul.

Neil Calman - Institute for Family Health - President & Cofounder

My middle name is even Paul. I guess I would just suggest two things. One is that we change the name of the committee to reflect the fact that this is going to be the landing spot for state HIT issues, which I think has been needed for a while. I think that the Medicaid piece of this is huge, and it needs a home in one of the workgroups. And if this is going to be the home, we should make it clear that it's not just about information exchange, but this is the place where the state HIT issues are going to come to rest and be considered.

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

There was another hand. David Lansky?

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

I just wanted to ... thank you for taking the leadership to think through some of this and drive some proposals to us. And, I think, for the NHIN workgroup, this would be a very helpful complement to the things we see on our agenda, so I see this as very complementary and, as you said, David, part of the evolution of the workgroups that we need to keep advocating.

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

Judy?

Judy Faulkner – Epic Systems – Founder

I kind of feel like I'm coming from a whole different spot on this. David, you'll probably tell me that this is not under the realm of this group, but I really worry about the 50 different states, one coming up with a rule that says A, the other one coming up with a rule that says not A, and how do they all coordinate? And so has there been thought given? Is it possible?

One more thing too: There are so many healthcare organizations who serve people from multiple states. They may be near a state line. I believe there are some who are physically over state lines, and serve multiple states. Has there been thought given to pulling it into regions, so there maybe can be a small number of regions, maybe four or six, throughout the U.S. where these states coordinate so that it's not going to be as chaotic?

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

I guess that question is addressed to the Office of the National Coordinator, and the fact is that we've given a lot of thought to this. Congress said that we were required to spend a minimum amount of money. We've actually augmented it somewhat on state based, either through state government or designated entities, work on information exchange. And I think that represented a judgment that the states were critical players. Their involvement was not sufficient, but it was necessary to insure information exchange.

We have actually had all the state health information technology coordinators here earlier in the week or maybe it was the end of last week. And we are working to develop with them a real partnership. The states have powers that are accorded them under the constitution, and the federal government has separate powers. And we share powers, and we try to coordinate as best we can. There are some things over which we can have influence, and other things of which the states have primary influence, and in which we are in the role more of persuasion and guidance than we are of control.

The states run Medicaid programs in collaboration with the federal government, and they are going to continue to run those Medicaid programs. We can't tell them precisely how. We can only try to enlist

them in an exchange and information coordination activity that we hope will be in our mutual interest. So they also run public health programs.

They have constitutional authority, and all the data that is associated with those. We believe they should be part of a comprehensive exchange framework. We need their cooperation on that. They set privacy and security regulations that can exceed the HIPAA regulations, and a number of states do that. A number of states have really pioneering frameworks for privacy and security and have gone well ahead of what the federal government has done in terms of setting up, trying to create a trust fabric that the states, that their populations will embrace and buy into, and so we have a lot to learn from that.

Having said all that, so I guess, Judy, there are some things that we just can't control, and we have to live with that. There are many people around the country who are very happy that we can't control those things, and we recognize that. So we are trying to develop a partnership, and the funding that has been provided is a way of empowering the states to work with us, and to hopefully develop partnerships that lead to a common outcome, and we're working through how to minimize the obstacles that may exist to exchange information, as a result of state based autonomy.

One of the things we are addressing or thinking about is how to deal with cross-state exchange of information and what our preference would be for the management of privacy and security in that situation. We don't have a policy yet, but it's one of the things that we'd like to tee up very quickly for a working group of this committee to look at, and then present recommendations to us.

Deven McGraw - Center for Democracy & Technology – Director

Can I...?

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

Yes, Deven.

Deven McGraw - Center for Democracy & Technology – Director

This is actually tangentially related, but I want to clarify what Micky and I are proposing, which is, we do think it's important that there be a home for the state level issues, and we suggest that the IE workgroup could be that home. But we are not – while I don't mind expanding the name to put state in there somewhere so people recognize that, I want to make it clear that we're not suggesting that this become the state HIE workgroup, that in fact we do think that there are other sort of targeted issues that are not necessarily ones that are exclusive to states and have national implications that we also need to resolve, so I just want to be clear. We are suggesting that we could be a home for the state issues, but we're not morphing ourselves into the state IE workgroup, and that's not what we're suggesting.

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

Paul?

Paul Egerman – eScription – CEO

Yes. It's Paul Egerman. I just want to say, I agree with that. Just going back to the example I gave. When you look at the laboratory area, part of what we do is simply to define priorities for the standards committee. And so that's still, in my mind, an important function for this group is to look to see what's going on. Even within areas we've already done work, like e-prescribing, there may be some reason why you're going to establish a priority that some aspect of that needs something to happen, and so that's not state HIE. That's an important function.

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

We're a little over. Any other comments or thoughts? If not, I'll assume that in the absence of objection that this direction is supported by the policy committee and that we appreciate and thank the workgroup for thinking so carefully about how it can be more useful to us going forward. Micky, thanks very much for being with us. And, Deven, thanks for your first of your several contributions. We have an 11:45 to 12:45 lunch break, and be back here then at 12:45.

Micky Tripathi - Massachusetts eHealth Collaborative - President & CEO

Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director

Can you please take your seats? We're ready to begin. All right, I'll turn it over to Dr. Blumenthal.

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

All right. We are starting now with a report from the meaningful use workgroup, and surprise, surprise, Paul Tang and George Hripcsak will lead this. Maybe George will take the leading role on this one.

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

Very good. Thank you, David. Thank you, committee, for the opportunity to present. To remind us that we have our three stages of meaningful use, and we've submitted our recommendations for one. We're waiting to hear back on the final rule, and we're in the process of producing stage two and eventually stage three.

Recently, we held a patient family engagement hearing. It was held on April 20th. One interesting innovation as part of, during, and then following the hearing was our federal advisory committee blog, which had, as of Monday, 49 comments, and input is still welcomed on that. Actually, the results, the summary of the hearing that I'll be giving includes not only the testimony of the hearing and the comments afterwards, but further comments on the blog that have followed, and that's kind of our new way of doing these hearings. This approach is part of our planning trajectory for the evolution of the meaningful use definition.

We held our hearing, and I'm going to report on that now. We had three panels. One was the meaningful use of health information technology in the real lives of patients and families. The second was incorporating patient generated data into the meaningful use of HIT. And the third was policy challenges and infrastructure requirements to facilitate consumers on meaningful use of HIT.

And so I've summarized that here, and I'll just go through that quickly. First, we heard from the panel that from the people testifying that the time for incremental change is over, and we need to move beyond the status quo. And that was heard loud and clear. Now you can argue that any time you have a hearing on patient engagement, you're going to invite people who are certainly at the forefront of patient engagement. But it felt like it goes beyond that, and it represents a movement in the country, and that there's the swelling that we really are going somewhere, and people are expecting more of the HIT, more access to their data, and more engagement in care. I think that the people at the hearing, a broad range of people from patients to academics, reflected that.

One of the things we heard loudest and clearest was the demand, patient's demand for universal and immediate access to their data. And we heard some compelling stories. Some of them were from patients who, by accessing the data, were able to change the course of care of their loved one. In that case, it was largely access to the paper record because that was available at the time, or a mixture of paper or printout from the electronic health record.

I think a couple people on the panel, I mean, members of the workgroup had kind of felt like a big switch there that, okay, this could produce a profound change. If we go ten years from now, and look back what we accomplished in meaningful use, one of them is going to be, well, just promising will the money get people focused on electronic health records, and we've already succeeded in getting the focus there. But what other innovation really changes things, having a free, low barrier access of patients to their data could cause changes later on that could create new markets for how we offer services, new markets for decision support, different ways of doing health information technology that we don't know what it is now, but if we can get those data shared to patients, we may see new ways of practicing healthcare. The converse of that is bidirectional data, that is, incorporate patient generated data into electronic health records, and we talked of some examples during the hearing of the promise of that.

The next point was that we need to engage the public into meaningful use. The legislation itself is not really going to change healthcare in America, and the incentives are not enough to change healthcare in America. It's the public that's going to push forward healthcare in America to the degree that we can engage the public in meaningful use. And, as I say in the sub-bullet there, reorienting meaningful use criteria to what's meaningful to patients and to the public. That's what will push forward this effort in years to come.

We want to encourage innovation, which is the positive version of the thing we're trying to avoid, which is, we don't want to discourage innovation by deciding exactly how patients should interact with the chart and interact with their doctors. We want to create the incentives for that engagement, but not determine it ahead of time. And there were some discussed, some bold initiatives. For example, 50% of care rendered at home for patient engagement.

Next, electronic health records, when you build an electronic system, often the first thing you're doing is creating a database so you can record what you have. And the next thing you do is you focus on communication, so communication being the key element. We want to create a sense of community among patients and with the healthcare team as being a key ingredient for meaningful use. Furthermore, we were, as a framework, we were looking at the four E's to engage, to educate, to empower, and to enable patients. And what came out of there also was meeting the needs of a diverse population. How do you achieve those four E's for everybody, not just a select few? And in fact, that'll be the topic of the next panel I'll talk about in a moment.

Last, we want to focus more, and then we heard this in the morning, focus more on patient oriented outcomes measures. That is that these measures are both for and by the public, and not limited to the policymakers and to the healthcare providers. Then let me start with the moderators and the chair of the panel to see if there's anything you want to add to that on the summary, Paul, Christine, Deven and, I guess, David.

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

Very good. We'll have questions in a moment.

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

Upcoming hearings, we'll have health disparities, which we're just finalizing now, actually over lunch, will be coming this June 4th. Care coordination coming tentatively in the summer, and population and public health, I'm looking forward to very much, tentatively also in the summer.

Here's our timeline. Here is an ultimate version of our schedule. Just so the public can get to see sausage being made. I will read off the actual schedule we ended up with, and you can refer to that, as I said.

We will have our four panels over the spring and summer. In September, we'll discuss the preliminary stage two and stage three criteria. In October, the meaningful use workgroup will present those proposed stage two and three criteria to the policy committee. In November, here's where I'm swaying from the slide, the policy committee will issue a request for information on preliminary stage two and stage three criteria, giving us ample time to hear back from the public. And we believe that in the second quarter of 2011 is when the policy committee will finalize its recommendations to ONC. Will this be correct on the Web?

Judy Sparrow – Office of the National Coordinator – Executive Director

Yes.

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

So the schedule will be correct on the Web. There's this balance here where we want to get the stuff out as early as possible, so the vendor community can do something about it, but we want to wait long enough so we can hear how stage one went. How can we finalize anything before we even know how we did in the first stage?

The way we're finagling that a little bit is that we can issue our preliminary criteria in November, which gives us, like, an extra six months to see where we're headed. Yet the final recommendation is coming out sometime after that. It gives us a chance to see how stage one went. I welcome recommendations on modifications of that.

The final slide just to emphasize the same point that stage two meaningful use criteria will be drawn not just from our recommendations, but we'll base it largely on the real world experience with stage one. That's my final slide.

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

Thank you, George. Focusing the mind, stage two, right upon us. Some of us who are still up to our ears in stage one are maybe a little dizzy at that prospect. Any comments, thoughts, additions? Yes, Charles?

Charles Kennedy – WellPoint – VP for Health IT

I was just wondering if any of the people on the panel had any interactions with health plan provided PHRs, and if there were any comments in that regard.

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

Given the use rates, probably not, but....

M

Where would we have found that person?

Deven McGraw - Center for Democracy & Technology – Director

I'm trying to remember if anyone testified as to Kaiser.

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

Kaiser being its own....

Charles Kennedy – WellPoint – VP for Health IT

...little different. Okay. Sorry.

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

Yes, Paul?

Paul Egerman – eScription – CEO

I wanted to comment, George and Paul. This is Paul Egerman. I'm really pleased with the tentative timeline, I mean, for a lot of reasons. I did notice that it says winter for – it says RFI for public comment. I didn't know what that meant.

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

No, that's the ... ultimate version of the schedule, so this is the schedule, and it doesn't have the word winter in it. So it says the RFI comes out in November from the policy committee to gather public input. And then the next bullet is second quarter of 2011 is when the policy committee finalizes its recommendations to ONC.

Paul Egerman – eScription – CEO

That's different than what's in the slides?

Deven McGraw - Center for Democracy & Technology – Director

Yes.

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

Correct.

Paul Egerman – eScription – CEO

I'm sorry. Could you just do it one more time?

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

Sure.

Paul Egerman – eScription – CEO

I know you've done it twice already, but maybe....

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

The first bullet is correct. The second bullet is correct, although I have stage two and three criteria, we're looking at it preliminarily. October is when the workgroup presents stage two and three to the policy committee. November is when the policy committee issues a request for information on those criteria in November. Then it doesn't have to finalize its recommendations until the second quarter of 2011.

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

Maybe I can add a little comment.

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

The release is earlier than winter.

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

Let me add a little commentary on the rationale behind it, and then we'd love feedback, particularly from Dr. Blumenthal. You know that the industry and the community needs as much time as possible to prepare, plan, and implement systems and processes in order to accomplish any future criteria ... any

future criteria. And yet, at the same time, we don't want to be stuck in a vacuum of information of what is going on, what is feasible, and how's the community reacting.

One way to try to get some of that information sort of ahead of time would be through this RFI process. People now trying to meet the stage one criteria, what's their experience? Can that be fed into the development of the future criteria? That's the RFI process?

Then the question is, should we proceed based on that and offer our recommendations to ONC as early as possible, and that could be quarter one, or should we wait for some more input from the people who are just meeting their first stage one payment criteria because that can happen within 90 days, and that would push it to quarter two. So it's to try to get as much information out there as possible while trying to take advantage of as much information that's preceding it.

Paul Egerman – eScription – CEO

Thank you, Paul. That was very helpful because I didn't quite understand how this concept of RFI fits with the whole NPRM process, and just a couple of observations. In the last meeting, we approved a recommendation of the adoption and certification group that the certification criteria for stage two would be available by April 1, 2011. Now we had this discussion whether it would be finalized or available, and we decided on available. And so it looks to me like this schedule is consistent, as long as we have a clear definition of the word winter because some people think winter goes ten months during the year. But as long as we have an idea that we would have, by April 1st, a fairly clear picture, that would give the vendors a chance. In other words, a clear picture would be ideal, but the schedule would be such that the first, whatever, we need IRF or whatever would be actually on the certification side published by then.

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

So you'll recall that we had sort of an RFI process with the very first matrix, we'll call it, so we put out something for comment. Now we are having this face-to-face sit down meeting in September to try to come up with the workgroup's draft, taking everything that we have of the directions for two and three. It could be that it's not very disruptive. Whatever it is, that's why we want to get feedback early on.

Then in some sense, we're sort of waiting for that to see how can we synch it up with your certification criteria. I think everybody is sort of interlocked, and you're pointing out interdependency, and that's why we commented last time on the word final versus available. We'll all try to get as much information as possible. And I think, once we sit down, having digested all of these hearings that have produced, you know, contributed to the new thought about the two and three, the later stages, we'll have a better handle on how different that is and then try to get the public's reaction to that.

Paul Egerman – eScription – CEO

That's great. That's very good. Thank you.

M

George, this is great. Thank you very much. The time for incremental change is over. Just a little more on what was being said there because I'm not feeling real incremental right now.

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

I think it's a feeling that was the feeling on the part of the public that there needs to be a chance of course. Now that doesn't mean it gets accomplished in day one. But not slowly feeding out data. Okay, we'll try this experiment in this little area, but a feeling that we need to start heading right now towards giving patients their data. That'll take some time to accomplish that, but we need to just head in that

direction of getting patients their data, and engaging patients in meaningful use also. The whole thing is we've got to just head in that direction now. Is that accurate?

M

Clearly, overall, the sense that I'm getting is that more people want definitive stage two and three. I mean, stage one too, Tony, just to let you know, but stage two and three as well so that, I mean, these plans don't happen in two-year increments. These plans happen in ten-year increments, and so to get to the end is obviously what we're all trying to do, but okay. Thanks.

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

Adam?

Adam Clark – Lance Armstrong Foundation – Director for Health Policy

George, on the incorporating patient generated data into an EHR, is this patient reported outcomes, so maybe like the e-pro initiative that's going on at NIH, or is this other information patients are providing, or both?

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

Both, so it includes home monitoring devices, as well as patient outcomes.

Adam Clark – Lance Armstrong Foundation – Director for Health Policy

Okay.

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

David?

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

I wonder if there's a step we could somehow insert around September that is, and maybe it's a wiki or something, some mechanism for input. I know a lot of groups around the country are right now drafting what they think we should do for stage two and stage three, and they're taking our framework and starting to populate it with their own approach, and I think that's great. It stimulates. There are a lot of creative ideas going on. Rather than us sitting in a room and coming up with our first draft, I there's a way to capture some of the energy that's been released by all kinds of stakeholders and groups early enough in the process that we could digest it and then bring it into our process for consideration. That might be helpful.

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

If we could use our pack of blog mechanism maybe for them to post their, you know....

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

Yes, it's an excellent idea. Judy?

Judy Faulkner – Epic Systems – Founder

A little bit ... comment I made before. When I think of the patient information, the patients could put in changes to the record that they think is something wrong, outcomes, and many other things that I think are very valuable. If you really look at the amount of time that may take a vendor to do, it's non-trivial. It's a lot of people.

Now I think, for the larger vendors, that's probably fine. I do think we have to think about what this may do to the smaller vendors. As you go through these choices, I don't know if you want. It's almost like

what David was saying about cost earlier. This is a different kind of cost. This is the vendor's entire R&D team perhaps to do this, and how do you evaluate that as you make these decisions.

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

Yes, Neil? Sorry. Do you want to respond?

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

I hear your comment, definitely.

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

Neil?

Neil Calman - Institute for Family Health - President & Cofounder

I just wanted to address again the question about the incremental change issue in relationship to how I recollect that it came up. And it really came up around sort of the fundamental principle that people should have – pretty much the second bullet that people now should have immediate, unbridled access to all of their health information, and that instead of talking about how we're going to develop systems that release some labs now and some a week after they're seen by their provider and all this other stuff that basically there's a sense after the hearing that there's a fundamental change in the philosophy about what the medical record is about. That it's really owned by the patient.

It really is the record of their healthcare and the fundamental change is that that has to be brought to bear right now so that we're not going through all kinds of contortions to get to that point, but that you state that as a sort of principle of where we should be almost immediately. I think that what George said before about how people felt that that would begin to roll out a process of people being much more engaged in their own healthcare and in health improvement activities and in other things, and that we don't really know where that's going to go. But I think there was almost, you know, you sort of walked away from the day thinking like how come we just haven't been there before? And that, in fact, the technology gives you an opportunity to give people that ready access to their information and that that should be fundamental, and we should state that going in.

M

Did they talk about that in the context of privacy and security? They're not necessarily conflicting issues, but they seem to – I just wasn't there. Was that discussed?

Neil Calman - Institute for Family Health - President & Cofounder

To my recollection, I don't think people felt like they were in conflict, so I don't think that really came up.

M

Okay.

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

Christine?

Christine Bechtel - National Partnership for Women & Families – VP

I wanted to suggest in terms of our timeline and how we think about preparing for September that we might start now coming up with what the key question set is that we need to answer in terms of the information that we should have going into a more in-depth discussion. And I think David Lansky's point is exactly right that we should kind of collect. What are people saying externally? What are we hearing in the four or five panels that we've done? And I think also how we start to map, once we see the final rule,

the functions and the features that were in the rule and the kind of care that that enables so that we can begin to focus a lot more on outcomes rather than features and functions.

I think it requires kind of that mapping one to another. So I sort of have a list, but I think Judy's idea too, as part of any evaluation framework, we ought to think about what's the impact on small health IT vendors, etc. I'd like to suggest that we kind of start now figuring out what the information is that we would like to have and then begin, month over month, as we're meeting in our regular workgroup sessions to start to consider some of that in advance.

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

Gayle?

Gayle Harrell – Florida – Former State Legislator

Thank you very much. I have two comments. First of all, on the issue of patient access and moving forward, no holds barred, I think you really need to remember we have a U.S. constitution that does give states rights, and this is something that you really have to look at the individual states that have already in existence specific laws. Unless there's a preemption by the federal government of those laws, I don't believe. I think you have to keep that in mind as you move forward that you really need to look at what each state situation is.

Secondly, I think when we talk about privacy and security, I think that's a key element on patient access to information. You have to make sure that that patient is indeed that patient, and that those privacy and security things, requirements need to be built into that. So patients may not think about. They know I'm who I am, and I want my information, and I totally understand that. I want my information too. I just don't want somebody else getting my information who isn't me and pretends to be me. Those are extremely important things that need to be addressed.

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

Larry?

Larry Wolf – Kindred Healthcare – Senior Consulting Architect

A quick comment more about another opportunity where we might learn from the early adopters here. We recently funded beacon communities, and also there were some SHARP grants, so perhaps we can have some presentations from the folks who have been out there doing this for a while and are seen as the national leaders to actually tell us what's been successful in terms of our overall objectives and to learn from these initiatives.

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

In ONC time, a six-month-old program is an old program. I'm reminded of, I think it was the fear of relatively that positive that the faster you go, the more time slows down. So if we keep moving the way we are, maybe we'll have lots of time at the end in order to finalize our regulations and everything else. Any other comments on the meaningful use workgroup plan? If not, thank you George and Paul. This is a suitably ambitious plan. Our timeframes are very demand and continue to be, and we'll do our very best to meet them. Now Deven and Rachel.

Deven McGraw - Center for Democracy & Technology – Director

I'm actually going to move my chair because the slide clicker is here, and it's a little harder to do that when I'm over there. I just want to check and see if I have – I could be another Paul. Is Rachel on the phone?

Rachel Block – New York eHealth Collaborative – Executive Director

Yes, I'm here. Thanks, Deven.

Deven McGraw - Center for Democracy & Technology – Director

Great. Terrific. Thanks. I got two. See. I just cloned my nametag. All right. Let's go to the first slide. In fact, let's go to the first slide. This is just a repetition of our charge here, and it sort of goes back to the point we made in the IE workgroup presentation a little bit ago that it was a very broad charge. This one is longer and equally as broad, in part because we sort of have all things privacy and security arguably in our bucket to resolve, which is a very large bucket of issues, and they're particularly contentious.

We have a terrifically dedicated workgroup resolving these, and we are still probably not moving as fast through these things as I think we would like to. But we do have a set of recommendations to put on the table today, as well as a number of issues to tee up and to resolve in very short order, which may actually require us to maybe meet more often. It's not something I've discussed with my workgroup, but to the extent that time might feel like it's slowing down, it still feels to us like it's moving very fast. And we're not tackling these in as efficient and effective way as I think we'd like to. Having said that, I do think we have some very good foundational recommendations for you to consider today, and a lot more work to do in the very near future.

I want to start out with a couple of framing comments, as we always do. To quote Gayle Harrell, "Privacy and security are foundational to achieving meaningful use." I don't think we have any disagreement on that. A comprehensive set of privacy and security protections that really build on current law and specifically implement those lofty principles that are in the nationwide data sharing framework, it's really critical to building the foundation of trust that's going to support and enable meaningful use by providers, hospitals, consumers, and patients. And we eluded to this in the strategic plan certainly that there is a need for very specific policies in this regard and that they should be consistent with this set of principles that ONC put forth two years ago, but that are largely based on fair information practices and provide sort of a guidepost. But, sitting on their own, they don't tell us very much about the specifics about data access, use, and disclosure, who can do it, and for what purposes, what are the security protections, etc.

Consent is absolutely a part of the framework, and we started out this discussion in the workgroup focusing on consent. But what you find very quickly is that consent is just one piece of a bigger puzzle. And if you were to take consent as your one and only or most important protection, you might end up with individuals essentially bearing the burden of protecting their own privacy through the decisions that they make about whether to participate or not to, and just what kind of a decision is that if there's a fair degree of uncertainty about how exchange is going to operate and who can access data, and for what purposes.

And we recognize, of course, that we have a scenario here where exchange to meet meaningful use is likely to take place in a number of ways. And what might be needed to build and maintain public trust is probably going to vary based on how the exchange occurs. Whether it's through a large state health information exchange that allows a query and response type of infrastructure to gather data versus what some of us call, before we get corrected by the technical people, push models where the data is essentially the data holder vets whether the data gets released either by pushing it out or by affirmatively agreeing to respond to a request for data.

I want to go over what some of our general themes are before I get down to our specific recommendations. One-to-one exchange where you're talking about a provider directly sending information to another provider in order to facilitate treatment where there isn't sort of an entity in the middle, whether you call it an intermediary, a facilitator, a trust enabler, whatever sort of nomenclature we've been throwing around in different settings here. Where there's no entity in the middle that actually

can access identifiable patient information, and you'll see later I qualify that to being either expressly or impliedly identifiable through an easy, put two-and-two together type of scenario. That's probably the closest to the present set of circumstances that we have. And one that, in terms of our workgroup discussions, was one where the workgroup in general felt that, for the most part, although not completely, the current legal infrastructure assumed that type of exchange, one-to-one, particularly where it's limited to treatment of that patient where there's patient relationships by both providers in the exchange.

But when you have an entity in the middle facilitating the exchange that has some ability to access the information, whether that's in the message header or in the actual content, and the information that they can access either expressly identifies the patient or impliedly can through, you know, it's got something, for example, in the header that says it's lab data and it comes from the Whitman Locker Clinic here in D.C. While you might not know who that patient is, and one could even spin out a scenario where there might be patient level data in the header depending on what our policies are in this regard, there's a lot that you can tell from what's in that message potentially based on the header, again depending on the scenario and the architecture of what you're constructing.

And so we, again, we started out trying to think about the consent issue in isolation, and it pretty quickly broke down, and it broke down in particular around this issue of what are these facilitators, intermediaries? What access to data are they going to have in the middle, and that's going to vary depending on the model of exchange. In some cases, it might be none. It's a simple exchange over the Internet from one provider to another. But in some intermediary scenarios, especially when you've got an entity in the middle that actually has been contracted to perform a set of services like transforming data from not structured content into structured content, or providing data analytics as an add on service.

We have such a plethora of potential models out there that grappling with this from a policy standpoint is incredibly challenging. And we don't think, in fact, that what we have in current law today adequately addresses the activities of these exchange facilitators. Again, given that they might play a broad range of roles, and that led to some great difficulty coming to some resolution on the issue of consent when we haven't resolved this set of issues about, for example, intermediary or facilitator or entity in the middle access to data.

Throughout all of our discussions, one touchstone theme continued to surface, and we give Paul Tang credit for this, and one of our members actually calls it the Paul Tang Principle. What would a reasonable patient expect? Now this is not what would every patient expect because I think we know that one of the places where we fall down is in transparency, and patients quite often don't know what's done with their data who has access to it, and for what purposes.

But to the extent that when we look at models that are provider-to-provider for treatment where there isn't any entity in the middle with access to data that they might then use for a range of purposes that are unknown to the patient. There is a sense that when you have that sort of direct one-to-one exchange, it's much more consistent with what the patient expects versus when you construct a scenario where there's an availability of data through a more robust query response system, the creation of a separate database that the patient's data has been accessible through, or a lack of really strong protections on what entities facilitating exchange in the middle are able to do with the data that they either have access to in the payload content or in the message header. You can see where easily the patient expectations test starts to say to you, we're straying into territory that is well beyond what many reasonable patients would expect, and we have a responsibility to meet that with a strong set of policies in order to build trust and create a set of circumstances where what patients expect is in fact what we're doing.

All levels of exchange, so consequently, I think we all agreed that all levels of exchange needs to be subject to very specific policies and technology requirements that are adequately enforced. All of this is actually stated pretty clearly in the strategic plan regardless of whether you have patient consent required or not required. In other words, you don't want to take consent and use it as the lynchpin of privacy because then you've asked the patient to bear that burden. At the same time, there is a role for consent to play. In particular, where we do leave exchange governed by – not governed by clear rules or with inadequate enforcement, at the end of the day, you want to give patients a choice as to whether their information is exchanged by that model, and it's a very unhappy scenario where, if you can't come to agreement on a set of really strong policies that are adequately enforced to build that trust framework, and you're giving patients a way out as a gap measure, you know, I would think we haven't done our job, and I think we can do – I personally think we can do better. I think the workgroup wants to move in the direction of the specific policies and technology requirements that will create a scenario where, when you give patients the right to either opt in or to opt in of having their data exchanged through a particular model, it's really an add on.

Then I think one of the other themes, but one that we really need to talk about more as a workgroup is that there may be some models of exchange that are in fact so new, so beyond what patients expect that even with good protections, we still might want to give them some choice. And as examples, I put the database model of all records being contained in one database and/or query response type of health information exchange models, but we have not really mined that to a great degree in the workgroup. We need far more discussion on that. And we will do that.

Now to the recommendations, and these won't surprise you, given the themes. This is all orchestrated to lead up to all of this. We need specific policies, as well as technology requirements, to govern all forms of electronic health information exchange. We should specifically implement those principles. Ideally the work should take place before, but at least should be in conjunction with, given our very short timeframes here, what's being done on the technology side. The technology needs to implement policy and not inadvertently make it.

Filling the gaps in current law, we have them. HIPAA, love it, hate it, however you feel about it, it still didn't envision the infrastructure that we're creating today, and we need to think about how to build on what we have. And, importantly, we have to address facilitator access to identifiable information when they have it, and that can include constraints on collection, access, and use, constraints on data retention and reuse and, in particular, security requirements.

The second recommendation to get a little bit more specific, and I'll say it back to the first one, so we get that we need these policies and that we're in a position to give you those recommendations, and we want to do that work. I think we're going to need to work a lot harder over the next several months and faster in order to do what's also proposed on this slide, which is to be doing this work in conjunction with, at a minimum, the technical standards work. But I think it's absolutely necessary, and I know my workgroup feels the same way.

One-to-one exchange from one provider to another for treatment purposes, even when you have no facilitator, so here's the place where it's most consistent with reasonable patient expectations. It should at least include encryption so that the facilitator can't, at a minimum, access the content, and this encryption ideally should be required any time that there's a potential for the transmitted data to be exposed, and we had a little bit of an e-mail back and forth among some members of the workgroup about what does that mean when the exchange is internal to an integrated delivery system or even internal to a specific facility, and what if there's a sort of virtual private firewall of network established for intra-facility communications, and certainly, as always, the devil is in the details with this. But in all of our

discussions, I think what we had in mind was when that information is potentially exposed in transmission that it ought to be encrypted.

Right now, the law has a strong bias towards encryption, but it doesn't expressly say that you need to do that. And I think we need to be specific when we're giving guidance to people here where we can. There ought to be limits on either identifiable or potentially identifiable information that's in the message header, and I think there's more work that needs to be done here, but there were definitely surfaced in workgroup discussions, some discomfort about who can access the payload, but also what's actually in that message header, and is there either expressly patient identifiable information in it, or is there enough in there that inferences can be drawn by somebody who might access it who shouldn't be.

Then, finally, of course, identification and authentication, and this is a topic that we're not bringing up for the first time. Certainly the NHIN workgroup has been talking about this, and I know actually that in fact in the NHIN Direct technical discussions, they're focusing very strongly on this set of issues, and obviously they need to in the same way that when patient data exchange occurs with Gayle Harrell, she wants to make sure that it is in fact the right Gayle Harrell. Certainly when her doctors exchange information, we need to be certain that it's the intended sender to the intended recipient, and that the data has not been altered in the transit. Again, in some ways, we're just reiterating some of the issues that the NHIN workgroup has already teed up for us over the last couple of months.

When you have strong policies such as the above are actually in place, and I say such as the above because I'm not sure that we have completely set out the list of requirements largely from a security standpoint, not exclusively from a security standpoint, but in terms of setting up the requirements on one-to-one exchange, strong policies that are enforced. I think we've come up with a good head start, and that may in fact be the list, but I leave us some room to add others in conjunction with what NHIN workgroup is talking about with respect to the trust framework.

But if you have those strong policies in place and enforced, then in that particular scenario, that one-to-one exchange where there's definitely a vetting role being provided by the patient's care provider, we don't think that that scenario would need any additional consent beyond what is already required by law. Of course, consistent with an earlier theme that I discussed, if we're not able to put those strong policies in place, and we're leaving a path of great uncertainty for patients, then in fact we might want to say, you know, we should give patients some choice not to have this happen with their data because we haven't actually reached the point at which we have felt like we've done what we can to protect this data.

In particular, I think we have a bit more of a comfort level as a workgroup with these models where the data holder has some vetting role in whether the data gets released or not released. But again, in the sort of other models like a database model or a query response type model for which I think Latanya has argued, there's much more utility in those models because the ability to sort of access data from multiple sources is much greater. The risks are greater.

Those are the three specific recommendations that we have on the table, but I also want to say that we've left a lot of things still left to do. So when we say that we need more specific policy in this regard, we need more specific policy in this regard, and I think that we, as a policy committee, much less the workgroup that I cochair is very interested in being part of that process to get that done. It's not always an easy thing when you're dealing with people who have other jobs, and are essentially volunteering their time, and are meeting on a monthly or even twice a month basis. It's still hard to make significant progress without a substantial amount of work being done in the interim. But I'm actually still hopeful that we can use the workgroup and also the policy committee to get some specific recommendations done in a short period of time.

This is more me personally talking based on discussions that I've had with some workgroup members. But I think it might require some more dedicated work in the in-between aspects of the meeting and maybe meeting with our workgroup more frequently. But that's definitely one that's open for discussion. But I'm hard pressed to see how we get to the level of specifics that I think we'll need to get to without that sort of process in place.

In terms of some of the other questions that need to be resolved, one of the things that has come up fairly often is the question of whether we have this all covered already because aren't all these intermediaries in the middle, aren't they required to be business associates anyway given that there are provisions in the stimulus legislation that in fact say that HIEs and RHIOs and e-prescribing gateways are required to be business associates, which is a very helpful provision. But, unfortunately, it doesn't fully answer the question. And we've only just begun in the workgroup to discuss the ways that while the business associate agreement lever is an attractive one to look at from an enforcement perspective, it's not exactly square peg, round hole, but it doesn't create a vehicle that's as perfect as we would like it to be in order to govern. For example, creating some constraints on what facilitators or intermediaries or entities in the middle can do with data that they might have access to in the process of routing a transaction or in the process of providing some higher level of data services.

One thing is that business associates are only one level removed from a covered entity. To the extent that you might have chains of entities performing these services, the BA rules and an ability to hold an entity accountable as a business associate stops after you reach one level past a covered entity. And so, after that, they're subcontractors, and the ability to hold them accountable is then limited to contractual obligations, which usually only the contracting parties can enforce.

There could be a balance of power issue, so think about an entity in the middle that's providing some routing services. It might be a national business with a fair degree of resources, and the covered entity is the country doctor in Montana. And how do you expect that doctor to hold that business associate accountable when they're servicing multiple covered entities with much greater bargaining power.

Today, the business associate rules we have today, although we are waiting for some additional guidance through the privacy rule that's pending from the Office of Civil Rights, interpreting the provisions and the changes in ARRA that have to do with the HIPAA privacy and security rule. Nevertheless, based on what we have today in business associates, there is very little that specifically has to be incorporated in a business associate agreement. It's actually really up to the contracting parties, and there are a number of reasons why that's the case. And it's not entirely clear to me from a legal standpoint that we could, through requirements on those agreements, dictate the types of constraints on data use, retention, disclosure that we might want to see across a broad range of facilitators.

There might be some other policy levers other than business associates. Meaningful use and certification, we understand, I think, the powerful role that they can play in shaping the playing field in this regard, but it's only going to be limited to meaningful users, so to the extent that there's always going to be a subsection of the provider population that doesn't participate in the program, and we hope it's small, but they'll still be out there. Anything that we try to enforce through constraints on those programs is going to have some limit. What role can and should the states play? And some of this is straying towards the governance issue, which continues to pop up, NHIN governance.

And then what is the role of the DURSA? For those of you who don't know what the DURSA is, it's the data use and reciprocal support agreement that was generated as part of sort of the original NHIN with the federal health agencies and the original NHIN grantees. It's not necessary a business associate

agreement, but it does provide some rules of the road for exchange in that regard. And where does that sit? And what might its role be in different exchange models that are being considered?

As I have said throughout this presentation, we need more work here, and I think we want to do more work here. I know I want to do more work here, and certainly most members of my workgroup have said to me, we need to be doing more and quicker. That is the specific policies and technology requirements really for all models of exchange, and this needs to be done in conjunction with our existing workgroups, as well as working more closely with the NHIN Direct technical group, which is moving very fast on specifications and standards.

Thinking about what is the role that consent should play in non-direct models, we've raised that before. Consent at a more granular level than all in or all out, and that's a difficult one that we've had some discussion, but not very many, and that we're hopeful to have a technical hearing in the near future to sort of get a grasp about what's possible from a technology perspective. Greater transparency for patients, and then de-identified data has come up numerous times. In part, if we were to construct a scenario where we had very strong controls on facilitator access to data that's identifiable, but sort of took the approach that we have today with absolutely no constraints on de-identified data and not monitoring of how that de-identification takes place and whether there's re-identification.

It's a huge issue. It keeps coming up in our workgroup conversations, and in an effort to try to keep us focused, so we can start incrementally ticking off some of these and getting recommendations to the policy committee in an efficient way, we keep tabling that. But I'm putting it on the slide, one, because I agree that it's an issue that we need to talk about, and we need to do it sooner rather than later.

So it's a big list, but we want to start tackling it. But to do that, I think it's going to require. I think we're working hard now. I guess I'm saying, we need to be working. We need to be doing more on this, and we're willing to do more. Rachel, let me see if you want to jump in.

Rachel Block – New York eHealth Collaborative – Executive Director

No, I think that, Deven, you certainly summarized all of the key policy issues that we've discussed and some of the issues that we need to move forward with. I guess the only observation I would make, now that I've had a chance to look at this in sort of a coherent whole presentation is that, and I'm not sure if it's our role or not, but someone needs to be paying attention to the administrative and workflow requirements associated with any and all of these decisions as well.

We could call for encryption and security and granular forms of consent and all sorts of things that would make sense from a policy perspective, but may prove to be difficult or unworkable in the "real world", so just to throw out that we didn't try to tackle that yet. And maybe it isn't the role of the policy committee to try to do that, but I think that certainly from our experience, those real life, you know, you talk about reasonable patient expectations. Patients are pretty accustomed to having consent forms done in doctors' offices, but we may be adding on significant new requirements if we go in some of the directions that Deven just summarized. And we just need to take into account how we want to sort through the impact of some of those decisions.

Deven McGraw - Center for Democracy & Technology – Director

That's fair.

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

Rachel, one of these further work requirements – this is David, by the way, David Blumenthal.

Rachel Block – New York eHealth Collaborative – Executive Director

Hello, David.

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

One of the further work requirements talks about working with state grantees.

Rachel Block – New York eHealth Collaborative – Executive Director

Right.

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

Do you want to talk about your – as a representative of states, I know you mostly represent New York, but thinking about your sister and brother states, do you have a sense of what you need and when from the policy committee and from ONC?

Rachel Block – New York eHealth Collaborative – Executive Director

I think the kinds of things that we need are quite consistent with the kinds of issues that we've outlined in this presentation. Whether you look at this through the lens of NHIN, or you look at it through the lens of a state HIE program, there are some decisions to be made in terms of what kinds of policies should apply under different HIE scenarios. And, as you've indicated, I think, quite clearly, and I think that many others support the idea that there will be different HIE scenarios in the future. I think that creating some mechanism to help states to determine what sorts of policies, at a minimum, may be appropriate for those different scenarios would be something that would be needed.

I think, however, that there are some consequences to that variation, which would potentially add onto the existing variation in state laws. So if you had different HIE models within a state and different HIE models across states, but were expecting to be able to facilitate a broad availability of information sort of irrespective of the HIE model, which is being used, you could see how you could quickly get into some real complexity in terms of anything like a DURSA that could possibly capture all those different scenarios.

I think what I'm describing is a combination of some further policy work, which would potentially be included in what Deven just described and our work with the other two workgroups. But I think obviously some of it will also be technical assistance. Then, ultimately, as we've discussed in a separate discussion, at some point we need to get clearer, I think, about whether the federal government has a sort of regulatory role or responsibility over states with respect to these kinds of arrangements that would be either the same as or different from any regulatory relationship it might have with other entities. That might imply the need for some kind of approval of these state models and what would be some of the policy and practical considerations associated with that.

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

Timeframe, Rachel?

Rachel Block – New York eHealth Collaborative – Executive Director

The timeframes also will vary, so we have a statewide policy in place. We'll need to reevaluate it, as we adapt to some of the new HIE models that both we are likely to come up with, and which might arise as a result of these new federal activities. I think most states are still a ways off from having operational capabilities, but what we found is that it took us quite some time.

As you know, the states are not only dealing with this, but they're setting up their own governance structures, and this is usually the first topic that a governing body, and I think it was Gayle earlier

mentioned an interest in examining a little bit more closely how states are setting up their governance structures and how consent policies might be developed in that context. Unfortunately, I think you probably have to deal with a situation where you're going to have kind of a rolling set of requirements at the same time that the policy framework itself will be evolving over time. And that, I'm sure, will cause some angst, not only for states, but for their stakeholders and for consumers as well.

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

Paul?

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

I'll pick up on this thread of the conversation to ask you, Rachel. Do you think there's a threshold in the scope of regulations or policies that, if set by the federal government, would make it easier to balance the exchange of information, the protection of privacy, and while allowing for differences in the states and protecting innovation? It's probably too long a sentence, but do you think there is such a thing as a threshold where we could find a bright line that helped actually elegantly helped all causes at once, and yet didn't tie your hands?

Rachel Block – New York eHealth Collaborative – Executive Director

I think we were maybe hoping that was the case, Paul, but as Deven said, in the context of this presentation, we were hoping, for example, that the one-to-one exchange scenario was so simple and so consistent with current practice that maybe we wouldn't need to say anything about it at all, and it turned out that the workgroup didn't feel that way, and so we captured here some of the things that we felt needed to be addressed, which may or may not be addressed adequately in terms of current policies and standards. I think that, at a very simplistic level, whether you're dealing with the one-to-one versus a more federated network model, and the – I'm sorry. I just lost my train of thought there for a second.

One-to-one versus the federated, and the point that we made here about the use of facilitators or intermediaries, which again will not be required under federal policy, but will not be precluded under federal policy either, and so I think, you know, the general approach that we took was trying to sort out roles and responsibilities of different levels of HIE scenarios, and so it's very hard to say that there is one threshold unless we go to what Deven covered in the slides in terms of the one-to-one, and that very basic level of the encryption capabilities that we want to suggest in that arena, even that got a fair amount of back and forth within the group. But I think there was consensus on that point. But I don't know if you could go much further than that, again, just given that the context for HIE will differ depending on the different models.

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

David?

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

I think it's a really good presentation and work by this group, Deven and Rachel, and definitely in terms of the questions that just came up. From the California point of view, our timeframe is essentially October, I would say, we need to have many of these questions answered, and I think the folks in California will do that themselves if they don't get some guidance from ONC and this larger process that you're leading. So I'm hopeful that some of these things that are now draft and proposed can get framed and more robustly over the summer because I think that's when we'll need it, as we're starting to stand up some services in California, and all these questions, of course, are in play, which raises the second point, I think, which is a resource question that you alluded to, and I think we feel on the NHIN workgroup as well.

I think we need something more like a 3-part process than the current sort of 1.5 part process. I think what we need on some of these aggressive policy development tasks is some kind of staff or consulting resource that can promulgate or integrate proposals that reflect a lot of the state-of-the-art that we know and bring them to the workgroup for deliberation. Then the third piece is a feedback loop with the community of practitioners, for lack of a better word, whether people like Rachel and others around the states who are facing these issues very operationally who can really inform the policy development work that we're doing through the committee process.

I don't know what the blending would be of some kind of aggressive drafting process with consultants or others that the workgroups could review and then send out, as we've just discussed on the meaningful use side, for validation and criticism by the practice community to try to get us through this. I know the timelines are really incredible, and the issue is very complex. And there's a combination of dealing with the policy development, plus bounding it by the technical strategies like NHIN Direct is meant to do. But there is an inevitable, it appears to be, creep that even the simplest approaches engender a lot of these same issues that we don't have yet a consensus view of how to resolve.

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

Latanya?

Latanya Sweeney – Laboratory for International Data Privacy – Director

First of all, I wanted to just talk on David Lansky's point. I actually think that, and I've sort of pushed this over quite a few times. I do think we need a group to really sort of analyze the possible design patterns out there and do a risk assessment and bring that information back. But I wanted to make just four quick comments, the next one being to Paul Tang's search for the magic bullet and asking Rachel if there's a magic bullet in policy. I wanted to just put on my computer science hat and tell you no. There's no magic bullet in policy. It's only possible through the design of the architecture, something that we really haven't hammered through.

Then the other two observations, I want to first thank Deven and Rachel. I thought that was a really good presentation, putting the pieces together. But I do want to underscore something that I said before. Recommendation number two, for example, is really about the identifiability of the information in the message headers. That's a good example of over-fitting to NHIN Direct as if it is the only model of the NHIN. And so then we could ask ourselves, if we look at other models of the NHIN, does that play a role at all? The answer would be no. Or if it did, it would be odd as to how I figure it out.

The last point I wanted to make is that Deven made a comment. She said that other models that Latanya has brought forward or design patterns that are not NHIN Direct have more utility and, therefore, more risk. I just want to correct you that that's not true. There are many other models out there that seem to have both less risk and more utility than NHIN Direct or NHIN exchange, but we've not been able to actually bring them forward in any meaningful way.

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

All right. Adam?

Adam Clark – Lance Armstrong Foundation – Director for Health Policy

Hello. Thank you both for putting all this together. I know how tough of a subject this is. I wanted to talk a little bit about the general theme on what a reasonable patient would expect, in just thinking that there are different reasonable patients, and particularly a patient who just heard the words "you have cancer" is at a very different level of reason. In fact, many times they really, at that point, don't care who's seeing

what and how it's being shared, particularly amongst provider to providers. It's also a survival community where they, as long as it's de-identified, want researchers to be able to use the information.

But it's also going to be a community that demands a lot. And I think, from their end, reasonable would be they want access to whatever is in there, and they want the ability to share it with whomever they want, particularly as they look at getting their own second opinions. They want to find out are what they're being told is correct information. As we look going down the line where patients may be having more and more access and the ability to control that, they already feel that they should. How would this model change when it's a patient, not a provider-to-provider, but a patient to other providers actually getting their own records and transferring it?

Deven McGraw - Center for Democracy & Technology – Director

Right.

Adam Clark – Lance Armstrong Foundation – Director for Health Policy

Is there a thought to that, or is this something that needs to be thought about?

Deven McGraw - Center for Democracy & Technology – Director

It needs to be thought of. In essence, those of you who will remember the brief discussion that we had at the last committee meeting where we started with one-to-one, and whether there needed to be sort of additional consent, in addition to other protections layered on top of a sort of direct one-to-one transaction, we started it thinking of it in terms of stage one of meaningful use, which includes sharing data with patients. It doesn't necessarily include the bidirectional flow that I think we're envisioning for stage two, at least per discussions in the meaningful use workgroup, but definitely sharing data with patients, at least in one direction.

But what we were able to, in the time that we had on workgroup calls, again, because we have right now we're twice a month. One could argue we could probably meet every week in tackling this stuff. I'm not suggesting that necessarily. But we ratcheted it down to just provider-to-provider for treatment, the sort of simplest case because it wasn't entirely clear to the members of the workgroup. And we didn't meant to leave out the patient piece because there was some level of concern about that that made us not comfortable with putting it on the list. But just to the extent that today, under the law, providers are permitted to share data for a pretty broad range of purposes, we drew that line of treatment as a starting point, and that's where we got. But those are really good points that you raise.

Adam Clark – Lance Armstrong Foundation – Director for Health Policy

Just as a followup, I know everyone is talking about how quickly this is moving. What I'm seeing, the more patients are learning, getting a general understanding, they already think they should be able to go in, get it, and give it to whoever they want. So as we look at engaging the consumer community, just being prepared to discuss this topic, I think, is going to be important.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

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

Tony?

Tony Trenkle – CMS – Director of OESS

Deven, I just wanted to drill down a little bit more on the data kept by the facilitator.

Deven McGraw - Center for Democracy & Technology – Director

Right.

Tony Trenkle – CMS – Director of OESS

Obviously there's some data that has to be kept for addressing purposes to make sure that it's routed correctly. There's other data that needs to be kept for audit purposes, for payment purposes, for liability purposes. There's a whole multitude of issues why the facilitator would need to keep at least some data for a certain period of time. And I guess some of this gets back to Paul's issue about how do you balance all these requirements. Did you take a further look at some of the facilitators' data needs to think about how some of this could be balanced without creating so much disincentive that you wouldn't have facilitators jumping in at all, or they'd be jumping out quickly?

Deven McGraw - Center for Democracy & Technology – Director

Right. We did not get to that level of discussion, and I think we need to. We did, at one point, start looking at a range of different direct models in terms of what level of access that an entity in the middle might have the data, and it ranged from just simply what's needed to route it appropriately from one point to another, and certainly there is some information that needs to be gathered and retained in that transaction. But without a sort of clear set of rules about what further could be done with that information, and not a clear sense of how much information was necessary in order to appropriately route that transaction, and that was the simplest model. You went from there to ones that provided both routing and identification and authentication, and then you get to another level where it's all of that plus data content transformation because we want to encourage more structured data, and we know that that doesn't exist out there today, so they're providing that. And then you go up. You sort of climb the level where then there's data analytics.

Tony Trenkle – CMS – Director of OESS

Right.

Deven McGraw - Center for Democracy & Technology – Director

Then suddenly you have, you know, I think we all recognize how valuable this information is and lots of business models based on monetizing it.

Tony Trenkle – CMS – Director of OESS

Right. Exactly.

Deven McGraw - Center for Democracy & Technology – Director

And so it really does need a deeper dive into what's under minimum necessary, standard minimum necessary principles with fair information practice. What's the minimum data that you need to perform what policy has decided as a legitimate function for you to perform.

Tony Trenkle – CMS – Director of OESS

Yes.

Deven McGraw - Center for Democracy & Technology – Director

Right now we just don't have that level of detail.

Tony Trenkle – CMS – Director of OESS

Right. It's a balance between what role these facilitators can play and what's the minimum data necessary.

Deven McGraw - Center for Democracy & Technology – Director

Right.

Tony Trenkle – CMS – Director of OESS

Because even from our perspective, we may need some of these facilitators to provide us data to insure that the requirements for meaningful use are being met.

Deven McGraw - Center for Democracy & Technology – Director

Yes. What if they're handling reporting requirements?

Tony Trenkle – CMS – Director of OESS

Right. Exactly.

Deven McGraw - Center for Democracy & Technology – Director

And so you can see how the complexity of this does make it difficult. But if you – what I like about what we've got on the slides is it sets out the concept that we do need to think about the roles that the entities in the middle might play, what access to data they might have, what access to data they might need, and some rules that are better, quite frankly, than the ones that we might have in place for the business associates that we have today about what they can do with that data, and definitely not fully thought through.

Tony Trenkle – CMS – Director of OESS

Right.

Rachel Block – New York eHealth Collaborative – Executive Director

If I could just add in again of a practical consideration, but I think it has policy implications is that even if we came up with some reasonable array of policies that could capture these different scenarios, we're making – we're not really delving at this point into important questions about whether and to what extent we would assume that there's some regulatory infrastructure associated with overseeing that above and beyond any certification requirements that might emerge to address some of these issues. To go back to David's question. If there's an assumption that the federal government is going to take on that regulatory responsibility, that has one set of resource and other considerations, and if we're assuming the states are going to do it, that's another bit of dialog that needs to happen sooner rather than later.

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

Judy?

Judy Faulkner – Epic Systems – Founder

Thank you. One thing that's on recommendation one, the sub-bullet that says technology should implement policy and not make it. I kind of like – I wish that we could do the same with medical technology because we say that death by cancer should not be tolerated. I'd love to say that.

Deven McGraw - Center for Democracy & Technology – Director

I think you've got Adam's vote on that one.

Judy Faulkner – Epic Systems – Founder

Yes, right. Anyway, I think I would recommend that we put in something that I've heard us talk about a little bit, but that is the technology capabilities must be taken into account so that we create policies that are technologically practical to implement. I'm not saying possible because a lot is possible, but practical what can be done. I just recommend that.

The next thing is that the second bullet under the general themes, all levels of exchange should be subject to specific – well, I might even go to the first. What do reasonable patients expect? I would like to add another foundational thing that we don't talk about very much. We talk about privacy as foundational, but I would like to add that foundational to me as a patient is take good care of me, and that to me seems very foundational.

Then going to the next one of all levels of exchange should be subject to specific policies and technology requirements. In the city where I live, Madison, Wisconsin, all healthcare organizations pretty much now have just started being interoperable, so wherever a patient shows up for the ED, information comes from wherever that patient was previously at. I heard a physician CEO of one of the organizations say that day one he believes that they saved lives because of that, which I thought was very impressive. What I did want to mention though was the overwhelming concern that I knew that the healthcare organizations had about the imposition of written consent and retainment of it and stuff like that. So I think another thing we have to think about very carefully is not just what the patients need and want, but also what is practical and feasible for the healthcare organizations to implement.

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

Charles?

Charles Kennedy – WellPoint – VP for Health IT

I just had a quick point of clarification on recommendation one where you talk about all forms of electronic health information exchange. Would that include clearinghouses that are involved in the transmission of claims to health plans for purposes of billing?

Deven McGraw - Center for Democracy & Technology – Director

We'd like them to be subject to some rules, but I think we are trying to focus our recommendations on exchange to meet meaningful use.

Charles Kennedy – WellPoint – VP for Health IT

Meaningful use, right. Yes. Okay. Thank you.

Deven McGraw - Center for Democracy & Technology – Director

And clearinghouses could have a role to play in that.

Charles Kennedy – WellPoint – VP for Health IT

Sure.

Deven McGraw - Center for Democracy & Technology – Director

But not necessarily with respect to submission of claims function.

Charles Kennedy – WellPoint – VP for Health IT

Thank you.

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

Paul?

Paul Egerman – eScription – CEO

Thank you. It's Paul Egerman. First, I just wanted to pick up on a comment that you made, Judy, about that section about technology should not lead policy. I think that was really a reference to a concern that

the standards committee is out ahead of the privacy committee in putting forward standards about issues like consumer preferences before we've defined the policy. That's the way I understood that, and so my view is that's actually an excellent statement in that context.

I have a question, actually a couple questions. One is when we look at recommendation number two concerning encryption. What is the target of that recommendation? Are we recommending that ONC alter the HIPAA privacy rule? How do you implement that recommendation other than changing the HIPAA privacy rule?

Deven McGraw - Center for Democracy & Technology – Director

I mean, I think, in many ways, so one way to implement it affective across a broader range of participants than meaningful users would be to push for a modification to, in this case, it would be the security rule in HIPAA. But it's not, I mean, it almost goes to the second to the last set of slides about the sort of various policy levers for getting something accomplished, so it came through to me very clearly that the workgroup thought that at least with respect to the transmission pipeline, to put it in non-technology speak, that that ought to, at a minimum, be encrypted.

And there were lots of folks who felt like the content of a message that was flowing from one provider to another ought to be encrypted. So in many respects, what we're putting out here is this ought to be the policy, but it is absolutely what's the most effective way to get that enforced, I think, goes right to issues of governance. And if you have a set of rules that are, you know, what are the sort of multiple ways that you could get that done? Meaningful use certification criteria, we have encryption capability in the certification criteria IFR, for example. But we didn't necessarily have, and Tony wants to answer ... requirement, for example, of meaningful use that you actually use the encryption. And I think we actually said in a previous policy – I know we actually said in a previous policy committee meeting that one way to fix that would be to require it as meaningful use.

But a probably more effective way, quite frankly, would be to get the security rule modified so that it was – you know, right now it's addressable, so if you don't use it, you have to come up with a darn good reason why and document it. But it isn't expressed as a requirement. And, in many respects when we're dealing with a set of users here for which these are very new concepts, calling something addressable versus a requirement creates a huge amount of uncertainty that was of discomfort to at least some members of the workgroup.

Tony Trenkle – CMS – Director of OESS

Yes. The only thing I was going to say is when you're using encryption, you need to be careful about defining the rules around it because you don't want to encrypt something that has information that's critical to a patient and then the party at the other end can't un-encrypt it.

Deven McGraw - Center for Democracy & Technology – Director

Right.

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

Jodi?

Jodi Daniel – ONC – Director Office of Policy & Research

Thanks. I obviously have been involved in the privacy and security workgroup discussions, but somehow seeing things on paper and hearing discussion brings--

Deven McGraw - Center for Democracy & Technology – Director

Funny how that happens.

Jodi Daniel – ONC – Director Office of Policy & Research

--yes, brings some new, fresh ideas. In looking at recommendation one, you talk about implementing the nationwide privacy and security framework principles, which I obviously think very highly of and have a lot invested in, and filling gaps in current law and talking about facilitator access. My question is, obviously there has been sort of a desire from the workgroup from what I've heard about not taking things piecemeal, but kind of thinking of things a little bit more comprehensively. But obviously you can't do everything all at once. You have to start somewhere.

The question I have, and you may not have an answer for this or may need to think about this, but both of you and Rachel, it seems to me that the area where there might be a lack of clarity on consumer expectations where there might be lack of clarity on the legal structure, where there might be lack of clarity on what the rules of the road should be is on that facilitator piece, the intermediary. I'm trying to think through what implement the framework principles means in the context of all of this. But just wondering what your thoughts are on whether or not focusing on that intermediary, facilitator, whatever we call it, and some of the kinds of services we know are going to go on, based on meaningful use, or based on experience, if there are certain principles, so transparency seems to be one that has come up. Patient choice seems to be one that's come up. Security and safeguards seems to be one that's come up, and the use and disclosures, just to pick four out of the eight that are there. I'm wondering if there's sort of – what your thoughts are on whether there's sort of focusing on that intermediary as a piece where it might be something new, different from consumer expectations, and there might be a lot of questions as a place to focus the workgroup's attention, at least as a starting point. It doesn't completely narrow the field, but at least helps to scope it a little bit in thinking about the work going forward.

Deven McGraw - Center for Democracy & Technology – Director

Yes. I would definitely put that high on the list. It came up over and over and over again in our conversations. I don't know of any ... I mean, the list is long.

Jodi Daniel – ONC – Director Office of Policy & Research

Right.

Deven McGraw - Center for Democracy & Technology – Director

But since this one is so tied to making sure that exchange, that we want to have happen can actually happen in a way that has the trust of the public seems pretty key.

Jodi Daniel – ONC – Director Office of Policy & Research

Yes. It seems like the issue kept coming up and then in the context of the NHIN discussions and the context of the state HIE discussions, it's sort of the them that keeps repeating and the area where there isn't direct HIPAA coverage of these intermediaries, so it seemed like at least it sort of met the gap in current law kind of concept.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

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

Thank you, Jodi. Thanks, Deven and Rachel. A comment: We really appreciate your and the working group's willingness to think about meeting more often and maybe in a slightly – we'll take your opinion as that of the workgroup.

Deven McGraw - Center for Democracy & Technology – Director

Yes.

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

And we are, I think, willing to try to support you, as David suggested, with more sort of affirmative crafting of your recommendations for reactions. The question is, there are issues of timing and prioritizing issues. So we heard from David Lansky that if we don't get something to California by October, they'll do it themselves, which they've been doing for a long time, so what's new. But at the same time—

Deven McGraw - Center for Democracy & Technology – Director

It's not clear if we got them something....

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

That's right. Not clear whether they – that they'd pay attention.

Deven McGraw - Center for Democracy & Technology – Director

No. Yes....

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

But if we, the Office of the National Coordinator, speaking for the federal government, were to want to get them something by October, that doesn't mean that your recommendations can arrive on October 1st.

Deven McGraw - Center for Democracy & Technology – Director

No. That's right.

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

So I think we're dealing with something that has to get done in weeks, not months, and if we're to have a chance of affectively using your excellent advice and otherwise we can just let the states and regional extension centers and all our grantees and the system kind of go on its own on these issues. Or we'll try to put together something ourselves that is good enough, but doesn't have the benefit of your view, the legitimizing process of doing it in the open, etc.

I guess I would reinforce whatever message you may have received about time, and the way in which the workgroup model can be reconfigured to try to be helpful to us. I know that that's a big burden, and I know that the ... may not work. But having a few critical questions answered that give us a chance to get our grantees started on the way to meaningful use with some confidence that at least the ones who are willing to accept our advice are getting it, and that it's good advice, and that it will withstand scrutiny, that would be enormously helpful to us. Sorry to unload on you that way, but I thought – so I really think that the timing issues are very, very critical.

Deven McGraw - Center for Democracy & Technology – Director

We specifically teed it up because I think we universally agreed that it was necessary, and so, of course, if we say it, and we're the privacy and security workgroup, then I think we'll have to find a way to get it done. And it ma be that we can take it on. I mean, one of the suggestions of one of the workgroup members was, and it's very hard to do this when you have discussions about privacy and security, but try to stay out of the real nitty-gritty details, but go one to two levels farther than what we've already got in principles. So that we may not answer all the questions, but if we can succeed in providing better guidance, then we're already ahead of where we were ideally. There will still be what if, what if, what if this, what if that. It's inevitably the core of our conversations revolve around the ways that the facts can

change and completely change the way you look at something. But if we continue to strive to go a couple of levels deep, but try to stay out of the rabbit holes, I think we have a better chance of getting it done.

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

Very good. Thank you.

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

Do we know what those critical questions are, or is it easy to find out?

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

I think some of them are actually – I don't know them all, but some of them are captured on this, and I don't think they're all different from one another, but I think that giving the states some guidance on consent for the various common models of exchange would be extremely valuable. Giving them some guidance on specifically, that includes, I think, both NHIN Direct and NHIN exchange. I think that those would be, I think, a good start. I think the question of how states can move data back and forth from one state to another is another one that keeps coming up as states talk with us about problems they can't solve on their own, not that our guidance will be definitive.

And I think the question of what needs to happen in order to create the trust environment that we are trying to create for the first stage of meaningful use is probably a third related, but somewhat different question. It's sort of what's the minimum that we need to do? What's the threshold we need to get to in order to get us to 2013 when we can revisit this set of responsibilities?

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

Privacy summer camp.

Deven McGraw - Center for Democracy & Technology – Director

Privacy summer camp.

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

Okay. Thanks very much. I guess we'll move on now to the NHIN working group.

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

It's a very short report. I think actually Deven teed up pretty much all the issues that we're talking about in the NHIN workgroup as well, and we don't have much new recommendations or conclusions to report this month, so I'll just remind you where we're at, and then summarize how we are also addressing some of the issues that Deven and Rachel just brought to us.

You'll all recall, we've been meeting since November. We've developed several iterations of a very high level framework for thinking about creating a trust fabric across the Nationwide Health Information Network. That fabric, as we brought it to you last month, had five components that we think have to be addressed for health information exchange, and they included an agreed upon set of business policy and legal requirements, oversight mechanisms, accountability and enforcement mechanisms, identify assurance, processes, and guidelines, and then the technical requirements that would be generally adopted across users.

That's where we got to as of March and April, and we are now preparing a draft letter that once it comes to this committee and is approved, would go to the National Coordinator, which would capture what I just briefly summarized in a few pages with a little more elaboration on it. So you'll see that in the next few

weeks or probably at the next meeting, we'll have a chance to take that up for consideration. That's sort of the phase one was laying out a framework, and I think we have a good start on that.

The next question we had was how do we apply it to the real world problems that are beginning to emerge from the application community. There we, I think, collide directly with what Deven just presented to us from the privacy and security group, and I think we are looking to the privacy and security workgroup to propose answers to a lot of the questions that our framework raises. When we say we need a business, legal, and policy framework, we're going to turn to that workgroup to provide that.

But that, in turn, if we had such a thing, I mean, if the answers to the questions that Deven just posed and began to sketch some answers to, for example, on the question of encryption and what the role of a facilitating entity is, if we know what the policy recommendation is, we still have the question of oversight and enforcement and technical requirements that support that policy goal. I think we're going to have to turn our attention very quickly to the question of governance, for example.

In the last few weeks, our workgroup, also meeting about twice a month, has begun to look at NHIN Direct and the point-to-point or push exchange of data as a first test case for our framework. I think we were interested to find out that as we began to take our framework and apply it to the NHIN Direct work that's coming out of that, the NHIN Direct team, some of the questions we didn't realize would be triggered by NHIN Direct were triggered. For example, the role of a facilitator and does it or doesn't it have the permission or ability to look at the payload that it is helping address and route, or are we going to say there is a constraint on NHIN Direct in which thou shall not have the capability to do that? Those issues began to emerge.

I think it then raises the question of whether our workgroup or the privacy and security workgroup will bring forward recommendations to this body addressing that and how we work together to do so. So we're right exactly on the cutting edge of that question right now, so I think this next few weeks, and as we just talked about, this will be the time for us to sort out, going all the way back to Micky's presentation, should our workgroup and the privacy and security workgroup re-craft its work plan a little bit in order to be able to provide some guidance on these questions very quickly.

I think we've been taking a very deliberative approach, and we're now asking ourselves whether we need to move more expeditiously to produce some guidance that will be of value to the people in the field. I think that's the sum of my report at this point unless there are questions or comments from others who have been involved in that committee.

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

I would like to encourage you all to find some common ground to meet and talk.

Deven McGraw - Center for Democracy & Technology – Director

...and we're going to plan to do that. We're trying to think through how we're going to....

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

All right. Moving right along. All right. ONC update.

Jodi Daniel – ONC – Director Office of Policy & Research

I was just going to talk a little bit about the enrollment workgroup that David had mentioned at the Health IT Policy Committee call, which most folks were on, but not everybody, just to give an update on what that is for those who weren't on the call and what we're hoping to do with that.

By way of background, no good deed goes unpunished, so the fact that this group and the Health IT Standards Committee have been so helpful and productive in providing advice to ONC, the Congress thought it wise to provide more work for these two committees under health reform. There was a section that specifically asked the Health IT Policy Committee and Standards Committee to identify a set of standards to facilitate enrollment in federal and state health and human services programs, including such things as electronic matching across state and federal data, retrieval and submission of electronic documentation for verification, ways of eligibility information, capability for individuals to maintain eligibility information online and notification of eligibility.

What we have mentioned in both the policy committee and the standards committee is having a workgroup that would consist of members of both of the committees, as well as other experts from outside since this is a little bit different than some of the work that's been done in these two committees. And we've got a very tight timeframe. The legislation gave us 180 days, and I'm not exactly sure what the count is now, but we're in the 130-day range, so again, summer camp for the eligibility workgroup.

What we're hoping to do is we've been having some internal conversations in HHS and do some initial scoping along the lines of what David was recommending, trying to get some work teed up so that the committees can work more quickly, and kick off a workgroup beginning in June that would meet biweekly to start scoping this out. What our hope is that the workgroup would look at whatever we can put forward in advance, and sort of identify some of the scoping of what should be focused on, some of the policy decisions, and types of information for which standards should be developed, make recommendations to this committee first, the policy committee sort of leading the effort, and then the standards committee reacting with standards recommendations. Then we would take those recommendations and try to work internally to figure out and identify some standards that could be brought back to the workgroup. The workgroup would then deliberate on those and make recommendations to the standards committee, hopefully all by September, which would be our 180-day deadline.

That's sort of a kind of nutshell of what we're trying to do and the timeline. We have invited and both have accepted, Aneesh Chopra and Sam Carp to cochair the workgroup, and this is breaking news. They have accepted, and we're still working on membership, both, like I said, from this committee, from the standards committee, and other experts who may have some more expertise on enrollment, on some of the human services programs, etc. That's still in progress. We're also looking at how we can get more public input from either request for information or otherwise so that we can broaden the discussion and get a lot of information really quickly to help inform the deliberations.

That's sort of the nutshell of what we're trying to do with the enrollment workgroup. I don't know, David, if you have anything to add to that.

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

Yes. I'm sure most of you get this right away, but why is this important? What in the world was the Congress thinking when they said the policy committee and the standards committee should worry about health and social service enrollment? Think about people who don't have insurance who you would want to get to be insured and where did they have contact now with the federal government or the state government or other public authorities that could channel them into an insurance arrangement. Well, it's places like WIC programs or Head Start, schools, the Motor Vehicle Department. It's the whole range of social service organizations that could potentially, where they go for their essential services. Obviously they're not in touch with the healthcare system because they're not insured, or at least they're not as much in touch as they need to be.

The question is how to – now the ideal thing is that they would be enrolled after these contacts, or at least the opportunity for them to enroll would be channeled toward the right program for which they're eligible. It could be a Medicaid program. It could be a CHIP program. It could be a state health insurance exchange where they would become eligible for a federal subsidy for purchasing insurance in the private market. Any of those are possible, but the question is how to make that easy to happen, that triage process and the follow-on enrollment process.

This is actually, in the electronic age, this is actually a pretty fundamental part of the process of getting our population insured, and 180 days may sound short to people around this committee and around this table, but the pace at which the Department is having to regulate on fundamental issues is just extraordinary in terms of the issues related to, for example, coverage of uninsured children and the rules surrounding the state chronic disease programs and the whole series of things that have even 30- and 60-day timeframes that are extraordinarily complicated.

This is a big, big issue. It's something of a Holy Grail in social service, and that only makes it more formidable. It is set up for us in the legislation as though it's an issue standards, as though standards are going to solve the problem, but that's not in fact sufficient. There is a set of grant authorities that are associated with this provision, which are available, but not funded. They're authorized, but not funded, for the purpose of doing pilot programs and grant programs to actually test whatever systems are recommended. And we are trying to get some sense of the chances that those programs will be funded because, in an ideal world, what you would do is propose a solution, test it, re-craft it, test it again, and so on. In fact, the exchanges don't go into existence until 2014, so there is a fair amount of time to do some rapid cycle improvement. That's just by way of context. Latanya?

Latanya Sweeney – Laboratory for International Data Privacy – Director

...actually, it's not just that they came here. Obviously that can be the outcome of that work can be a game changer on identification and authentication and, therefore, the discussion of the full space of NHIN designs, identification authentication is always an issue with any one of them. But if this is a backdrop, it changes totally a lot of the design issues, and also the design questions. I mean, it's a big deal, and it definitely just underscores more the need for the integration across privacy and the NHIN. I mean, because identification and authentication is a part of it. What you're basically saying is that we're going to come up with a mechanism that's going to have a kind of super master index of a kind, described in some kind. Then the question is then you could just leverage off of that. And, of course, how it's designed could dictate good or better or make existing NHIN designs better or worse.

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

These are the kinds of issues that we're going to have to get into very quickly. But I'm not smart enough to understand all of what you're suggesting, but maybe you can educate me. Neil?

Neil Calman - Institute for Family Health - President & Cofounder

I guess, number one, there are a number of people working on this issue of sort of across eligibility things. We're engaged in a process now where we were given a grant to hire four such people working with a computer program, and the cost was about \$250,000. In the first 12 months, they found \$7.5 million worth of benefits that people were eligible for, including everything from childcare to educational benefits to everything else. So I don't know whether it requires, I didn't get what you were saying either. I'm sorry. But from a very simple point of view as a healthcare provider, the ability to be able to do eligibility stuff, which we do for healthcare anyway, and see it cross over into other areas brought people a lot of additional benefits that we didn't know about. And, number one, I could put you in touch with some of the people that we're working with in that area that would be interested in working with you.

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

Yes, Gayle.

Gayle Harrell – Florida – Former State Legislator

I have some basic questions, and perhaps this shows my ignorance of where we're going with this, and I can see why we're tagged with it, but I wonder what doors this is opening and what amounts of money will have to be expended, and what the responsibility of the states will be. Are we saying that we're going to integrate the databases of all eligible entities within states? Our Medicaid system, our child welfare system, our food stamp, the federal food stamp program, our state welfare recipients into a centralized database that's going to tag into? I'm not seeing where we're going with this. Can we be a little bit more specific in it?

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

Well, I wish I could explain to you exactly where we're going, but we're going to count on some people to help us do that. What I think we want to do is create the ability for people who come into contact with one of those programs to find their way into a health insurance exchange, so it's not like we're taking over their database. We're simply giving them a pathway from the mother who shows up for WIC or food stamps to be able to enroll her child in the child health insurance program.

Gayle Harrell – Florida – Former State Legislator

How far down are we going? Are we going down to now test this and things of that sort? Is the program the states...?

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

That's not specified. It's not specified, so we have to....

Gayle Harrell – Florida – Former State Legislator

The states, every kind of welfare program the state runs would then have to link into something.

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

Well, this is an opportunity. It's not a mandate, so it's not a regulated authority. It's a service that could be provided to people who could benefit from a new entitlement under the federal health reform law.

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

This is David. Just to be clear, when you talk about health information exchange, are you using that terminology as it exists in the healthcare reform legislation, which is a little bit different than we've been saying about HIEs?

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

You're talking about health information exchange. I'm talking about insurance exchange.

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

This is a health insurance exchange. This is a marketplace of insurance policies. It's not the HIEs that we've been talking about.

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

It's HIE-2 or HIE-X. Now, that doesn't work – HIE-NX. Okay. Judy, we're ready to, I think, move to public comment.

Judy Sparrow – Office of the National Coordinator – Executive Director

Great. Yes. This is the public comment portion of the meeting. Anybody in the audience who wishes to make a public comment, please step to the microphone. We'll need your name, your organization, and the reminder that you have three minutes. Anybody on the telephone, if you're already on the phone, just press star, one, or if you're on the computer, please dial 1-877-705-6006. I'll wait a few minutes to see if anybody on the phone dials in. Please go ahead.

Chantel Worzala – AMA – Senior Associate Director of Policy

Good afternoon. Chantel Worzala at the American Hospital Association. Thank you so much for your very thoughtful conversation today, and you obviously have a lot on your plates. I just wanted to talk about two areas. First, the strategic plan document, and then also what was put forward by the meaningful use workgroup.

On the strategic plan, I'd like, as ONC takes that to the next level, really emphasize the coordination piece of that strategic plan. There are so many parts of the government that affect and actually control enforcement and regulation of areas that this workgroup thinks about. We have OCR enforcing privacy and security in the HIPAA rule.

We have CMS with a \$10 billion innovation center to look at care coordination and innovative approaches to delivering care. We've also got OCR looking at enforcement of civil rights and disparities in healthcare. And I look forward to a strategic plan that really delineates who is responsible for what, and how those various regulations actually come all the way down to that single point of the provider who is actually responsible to all of those regulatory agencies and not just ONC.

Second on the meaningful use workgroup, I thought you had a very nice presentation there. I'd really encourage you, as you deliberate on the next level of meaningful use requirements, to really conduct an assessment of market readiness for those areas that you're looking to embellish on and increase requirements for. This really needs to be market readiness across the whole spectrum of providers. We're not talking about what an academic medical center can do after a 15-year investment in health IT. We're talking about all providers. We're talking about 1,300 critical access hospitals across this nation, which have 25 or fewer beds, as well as many community hospitals in both rural and urban areas.

Please do not wait for a response to the RFI. I hope you can include that thinking and that market assessment, readiness assessment as you move along. And, finally, that really does need to be done in the context of very real capital workforce and vendor capacity constraints.

Also, I'd like to encourage the meaningful use workgroup to consider all of its recommendations in the context of the recently passed health reform bill, which has many, many, many provisions. Over 1,000 times the words "the Secretary shall" appear in the health reform bill, and it does have provisions on disparities. It has provisions on quality reporting. It has provisions on value based purchasing. It has provisions on reducing unnecessary rehospitalizations. And it has provisions on creating and providing opportunities of innovative models of care delivery and new ways of coordinating care. I think this workgroup is doing a lot of great work, and really want to make sure that it's done in the context of all of the other healthcare reform provisions. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you very much. We do have one caller on the line, if you could please identify yourself.

Fassel Karashim – Independent Healthcare Consultant

Fassel Karashim, an independent consultant in healthcare. The question I have....

Judy Sparrow – Office of the National Coordinator – Executive Director

I'm sorry. We didn't hear your name and organization.

Fassel Karashim – Independent Healthcare Consultant

Yes, Fassel Karashim. I'm an independent healthcare consultant.

Judy Sparrow – Office of the National Coordinator – Executive Director

Yes, sir. Please go ahead.

Fassel Karashim – Independent Healthcare Consultant

Yes. The comments earlier by Dr. Blumenthal regarding the differences in roles between state HIT and the meaningful use regulations with regard to the business associates, that's something that I know that you guys kind of discussed that a little earlier, and it'd be helpful if there was a lot more clarity because it seems that that might be an issue going from state-to-state where one state might have weaker regulations on what a business entity is as far as an intermediary. That's probably the weakest link that's going to happen in between the health and information exchange. Maybe a future meeting that something like that could be discussed in more specific terms.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you, Mr. Karashim. I'll turn it over to Dr. Blumenthal.

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

Do we have anyone else waiting to make comments? No. Okay. Well, I'm not sure I fully understood the last question, but we'll try to address it in a future discussion. Unless there are other comments or suggestions, we can adjourn until we see you again in a month, but we hope that some of you will be busy in the interim and appreciate it very much.