

# HIT Policy Committee Meeting Transcript July 16, 2009

## Participants

Judy Sparrow, Executive Director, Office of the National Coordinator for Health IT (ONC)  
Latanya Sweeney, Director, Laboratory for International Data Privacy  
Deven McGraw, Director, Center for Democracy & Technology  
Jim Borland, Special Advisor for Health IT, Office of the Commissioner, Social Security Administration (SSA)  
Neil Calman, President & Cofounder, Institute for Family Health  
Adam Clark, Director for Health Policy, Lance Armstrong Foundation  
Christine Bechtel, VP, National Partnership for Women & Families  
Paul Tang, Internist, VP, & CMIO, Palo Alto Medical Foundation  
David Blumenthal, National Coordinator for Health IT, Department of Health and Human Services (HHS)  
Judy Faulkner, Founder, Epic Systems  
David Lansky, President & CEO, Pacific Business Group on Health  
Gayle Harrell, Former State Legislator, Florida  
Mike Klag, Dean, Johns Hopkins Bloomberg School of Public Health  
Charles Kennedy, VP for Health IT, WellPoint  
Paul Egerman, CEO, eScription  
Tony Trenkle, Director, Office of E-Health Standards and Services (OESS), Centers for Medicare & Medicaid Services (CMS)  
Larry Wolf, Senior Consulting Architect, Kindred Health care  
Michael Weiner, CMO, Defense Health Information Management System  
Connie Delaney, Dean, University of Minnesota School of Nursing  
Roger Baker, CIO, Department of Veterans Affairs (VA)  
Jodi Daniel, Director, Office of Policy & Research  
Scott White, Assistant Director & Technology Project Director, Local 1199  
Art Davidson, Director, Public Health Informatics at Denver Public Health  
George Hripcsak, Chair, Department of Biomedical Informatics Columbia University  
Marc Probst, CIO, Intermountain Healthcare  
Micky Tripathi, President & CEO, Massachusetts eHealth Collaborative

## Presentation

### **Judy Sparrow – ONC – Executive Director**

Good morning, everybody, and welcome to the third meeting of the Health Information Technology Policy Committee. This is a Federal Advisory Committee, which means it's being operated in public. We have an audience in the room. Telephone lines are open if you care to listen to the meeting, and it is being Webcast.

Minutes of the meeting will be put on our Web site in about a week following the meeting. Members of the committee, please remember to identify yourselves when you're speaking so we have proper attributions in the transcript. And in the room—let me go around the room, and you can introduce yourselves, beginning with Latanya.

### **Latanya Sweeney – Laboratory for International Data Privacy – Director**

Hello. I'm Latanya Sweeney, a professor of computer science technology and policy, and I'm also the Director of the Data Privacy Lab.

**Deven McGraw – Center for Democracy & Technology – Director**

I'm Deven McGraw with the Center for Democracy & Technology.

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

I'm Jim Borland, Special Advisor to the Commissioner of Social Security for Health IT.

**Neil Calman – Institute for Family Health – President & Cofounder**

Neil Calman with the Institute for Family Health.

**Adam Clark – Lance Armstrong Foundation – Director of Health Policy**

Adam Clark with the Lance Armstrong Foundation.

**Christine Bechtel – National Partnership for Women & Families – VP**

Christine Bechtel with the National Partnership for Women & Families.

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

Paul Tang, Palo Alto Medical Foundation.,

**David Blumenthal – HHS – National Coordinator for Health IT**

David Blumenthal, National Coordinator for Health Information Technology.

**Judy Faulkner – Epic – Founder**

Judy Faulkner with Epic.

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

David Lansky, Pacific Business Group on Health.

**Gayle Harrell – Florida – Former State Legislator**

Gayle Harrell, Former State Legislator from Florida.

**Mike Klag – Johns Hopkins Bloomberg School of Public Health – Dean**

Mike Klag, Johns Hopkins Bloomberg School of Public Health.

**Charles Kennedy – WellPoint – Vice President for Health IT**

Charles Kennedy, WellPoint.

**Paul Egerman – eScription – CEO**

Paul Egerman, software entrepreneur.

**Tony Trenkle – CMS – Director of OESS**

Tony Trenkle, CMS.

**Larry Wolf – Kindred Health care – Senior Consulting Architect**

Larry Wolf, Kindred Health care.

**Michael Weiner – Defense Health Information Management System – CMO**

Michael Weiner, Military Health Service.

**Connie Delaney – University of Minnesota School of Nursing – Dean**

Connie Delaney, University of Minnesota School of Nursing.

**Roger Baker – VA – CIO**

Roger Baker, Veterans Affairs.

**Jodi Daniel – Office of Policy & Research – Director**

Jodi Daniel, Office of the National Coordinator for Health IT.

**Judy Sparrow – ONC – Executive Director**

Do we have any members on the telephone, please?

**Scott White – Local 1199 – Assistant Director & Technology Project Director**

Yes.

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

Yes.

**Judy Sparrow – ONC – Executive Director**

I'm sorry?

**Scott White – Local 1199 – Assistant Director & Technology Project Director**

Scott White from 1199.

**Judy Sparrow – ONC – Executive Director**

Okay.

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

And this is Art Davidson from Denver Public Health.

**Judy Sparrow – ONC – Executive Director**

Great. Well, Scott and Art, thank you, and I'll turn the meeting over to Dr. Blumenthal.

**David Blumenthal – HHS – National Coordinator for Health IT**

Thank you, Judy. Welcome, everyone. Good morning. Thank you for being here. Thank you to those of you who are on the phone, those of you who are looking in over the Web. We appreciate your interest. We appreciate your work. I especially want to thank the members of the committee, who have worked tirelessly to get us prepared for this meeting and past meetings and, I hope, future meetings. We hope not to burn you out. This has been a—we're on a very fast schedule, and there have been countless hours of volunteer time devoted to the work that you're going to be hearing about today. There have been also countless hours of staff time from the National Coordinator's Office and from the Center for Medicare & Medicaid Services and from other Federal agencies that have made it possible for us to make a great deal of progress on a wide variety of very, very complicated issues. And I hope that, as we process this work today—and I'm confident that as we process this work today—that we'll make substantial progress towards getting the committee to provide the recommendations that will be so helpful to myself and to the Department and ultimately to the American health care system.

Our agenda today is a busy one. There are two new formally seated members today. One is Tony Trenkle from the Center for Medicare & Medicaid Services. Tony was here as an observer in the past, but now he is a member of the committee. And the other is Jim Borland, who is representing the Social Security Administration and who coordinates the agency's internal health IT efforts. And the Social Security Administration is a major utilizer of health information technology and has a great deal of interest in this committee's work. So we welcome Tony and Jim.

We are going to cover quite a number of tough and complicated issues today. We were going to start in a moment by approving the minutes. But we are then going to go on to get an overview of the public comments that were received in response to the meaningful use discussions that we had during our last meeting. We're then going to have a presentation on the response of the Meaningful Use Workgroup to the deliberations of the committee last time and to those public comments. It's my hope that by the end of that discussion, the committee will feel ready to adopt or not the recommendations of the commit—of the workgroup. And in a moment, I'll discuss what I'd like to do in the way of process of approval or not approving those recommendations.

We'll then hear from the Information Exchange Working Group, which has worked very hard on that particular attribute of meaningful use and of the health information technology infrastructure. We'll then have a break, and then we'll talk—hear recommendations from the Certification Adoption Working Group. And then finally, we'll get a briefing from the Health Information Technology Standards Committee, which will be meeting next week and is waiting breathlessly to see what we do so that they can develop standards that embody our decisions and which can then be embodied, in turn, in regulations that the Office of the National Coordinator has to issue in an interim final form by the end of this calendar year.

Let me start now the—more formally by asking the committee to adopt the minutes from our last meeting. Yes, Gayle.

**Gayle Harrell – Florida – Former State Legislator**

I had one change that I've already talked with Judy about that I'd like to see put in the minutes, please.

**David Blumenthal – HHS – National Coordinator for Health IT**

Okay. Are we all set on that, Judy? Do you think we need to share that with the rest of the group, or is it—?

**Judy Sparrow – ONC – Executive Director**

Oh, no, she's just including more information on her remarks on CPOE, which is fine.

**David Blumenthal – HHS – National Coordinator for Health IT**

Okay. So any other comments on the minutes? [Pause] If not, do I hear a motion to adopt? [Pause] And a second? All in favor?

**Unidentified Man**

Aye.

**David Blumenthal – HHS – National Coordinator for Health IT**

All opposed? [Pause] Terrific. Thank you.

So let's just—let me say a little bit about how I've thought about the process of accepting recommendations. In a parent organization to this—and we don't need to be bound by this precedent, but in a parent organization, the organization that existed under the previous Administration, the American Health Information Community, recommendations were frequently adopted by consensus. And that strikes me as, in some way, the optimal way for us to go. Hopefully, we will be able to achieve consensus on recommendations. That may not always happen, and if a vote is desired, I will entertain a motion for a vote if people would like to see a vote.

But I don't want to officially call for votes unless there is a sense from one or more members of the committee that there's sufficient controversy so that a vote is required. That's not to say we won't have votes. We certainly will have them if we need them. But rather than do that as a standard process, I'd like to continue the tradition that has existed previously and adopt by consensus unless there is a requirement to do otherwise. Anyone have any objections to that or any problems with it? [Pause] Okay. Terrific.

In that case, what I'd like to do is begin the portion of our meeting which pertains to the “meaningful use” definition. The matrix that Paul—and I want to also recognize George Hripcsak, who has become a Co-chair of the Meaningful Use Workgroup, replacing Farzad Mostashari. Farzad was disqualified as a member of the working group because, much to our pleasure and to our benefit, he has joined the Office of the National Coordinator as a Senior Advisor, so he's transitioned from one form of assistance to another form of assistance. So thank you, George, for your willingness to work with us.

At this point, I'd like to turn it to Jodi Daniel, who will talk about the, it turns out, 720-some comments that we received. We—those, of course, were received for 10—over a 10-day period after we last met. We last met on June 16; the comment period closed on June 26. Judy will correct me if I'm wrong. We received the comments, and with the help of two terrific first-year medical students, who I think may never want to

hear the term “meaningful use” again, we were able to process those and qualitatively, we think, get the benefit of the comments and the kind of content of the comments. We don’t have a quantitative rendering of those comments. We are looking at ways to slice and dice the data. But I do think this was an enormous amount of work to process these in a very expeditious and, I think, fair way. All kinds of matrices and spreadsheets were blooming up around the ONC office in response to the comments. But we are grateful to the public and to the many professionals and groups that submitted their very thoughtful comments, and Jodi is going to give us an overview of what we saw in response to our last group meeting.

**Jodi Daniel – Office of Policy & Research – Director**

Okay, great. So thank you, David. We—as David had mentioned, we really appreciated the input of the Meaningful Use Workgroup and the great discussion of this committee last month. And there was a decision to table the conversation, but that was meant far from dropping the conversation. In fact, it meant kind of heating up the conversation on this topic.

Since our last meeting, there was a lot of activity and input. We did have our public comment period, which I’ll discuss in a little bit more detail. And then we had a couple of meetings of the Meaningful Use Workgroup to discuss the comments and all the input that we received on that; discuss the input from this committee; and to revise the recommendations, which we will hear a presentation on today.

I want to just, before I get into the comments, talk about a couple of process issues for today’s meeting and sort of what’s going to happen next, just to sort of set a context for the deliberations today. So as David mentioned, we’re working under incredibly tight deadlines, and we really appreciate all the hard work of everyone in trying to get us to this point. We’re very hopeful that there will be some consensus from the group today to help inform our deliberations.

I just want to clarify that these are recommendations of an advisory committee. They are not HHS’s opinion. Whatever there is an agreed-to consensus on, David Blumenthal sits here as the Chair, but he’s wearing two hats, one as the Chair of the committee and one as the National Coordinator, and he will receive the recommendations from the committee as the National Coordinator.

What—we see the advice of this committee as extremely important input into our process, but we will then take those recommendations and incorporate them into our regulatory process. So we will work very carefully from all of the work that we’ve heard from from you all, and I expect that they will be an important contribution into our work. What we will do, because David wears two hats, is that any recommendations that come out of the committee will be transmitted from Paul Tang, our Co-chair, to David Blumenthal as the National Coordinator, and then they will be considered by David Blumenthal and others at HHS as—in our regular agency process.

Our next steps, once we get recommendations from you all—ONC and CMS, as I’ve mentioned in prior meetings, will be developing regulations on standards and certification, on the certification process, and on incentives as—and the definition of meaningful use. CMS will be coming up with the proposed rule on the incentives, including the definition of meaningful use, and get comments and then go to a final rule. ONC will be developing an interim final rule, as set forth in our statute on the standards and certification criteria, which we will also get comments on and come up with a final rule after comment. The time frame for both the interim final rule under statute is December and, as CMS has stated, their proposed rule will also be targeted to come out in December.

So there’s going to be some limitations on what we may be able to say or do after today’s meeting with respect to feedback and input. We’re going to hopefully—we may be able to come back to the committee in August with some additional questions or some thinking from the National Coordinator’s Office. We’ll see. We’re going to talk to our general council about that, but there’s going to be some period of time where we’re going to be heads down writing our regulations and working on our process internally. And like I said, there will be comment opportunities again on these topics in December.

So with that, I will go into the comments that we received on meaningful use. David already covered most of this. We had a 10-day comment period. I guess we have some numbers issued. The number that I had was 792 comments received. We're—it was quite a substantial number for a 10-day comment period. There was a lot of interest in this, a lot of great feedback that we received and incorporated, and provided both comments and summaries to workgroup members of the Meaningful Use Workgroup to take into consideration.

There are some general themes I wanted to bring up. The majority of folks believe that meaningful use really should be focused on measurable improvement in health outcomes and not adoption of technology for its own sake, and commenters really applauded the emphasis on quality and outcomes measurement overall. We had a lot of support for the work of the Meaningful Use Workgroup. More than a third of the commenters expressed general support for the initial guidance that came out of the Meaningful Use Workgroup, which is a testament to all of the hard work that they did.

And—but many people suggested specific changes to objectives or measures, either changes to the measures themselves or the timeline. A lot of folks said, "It's too aggressive; you need to delay some of these measures to later years." And then we got many folks who also said the opposite: "This is something we can do in 2011; please move this up," or "This is something that's critical; you need to move it up earlier." So we got comments sort of on both ends of the spectrum: "Move things sooner." "Delay things; it's too hard to do now." "No, this is too important; you need to do it now." So we got a lot of pushback in both directions on the timeline.

We also got some requests for items to be clarified or terms to be clarified. There was a lot of question about what some terminology met. "What is coded format?" "What are patient preference?" So there were a lot of questions about some of the details in the terminology we used, which—obviously the workgroup thought about some of those, and that's something that we would flush out through our rulemaking as well.

We received a lot of feedback in three particular areas that I wanted to highlight. One was on CPOE. The second is on information exchange. And the third is on patient access to their own personal health information.

There was a general recognition that CPOE was a critical function for early implementation, but there was also a lot of concerns raised about the workflow and how this could be done in 2011. There were some questions about having other providers other than physicians being able to do CPOE. So those were kind of the flavor of what we heard on that topic.

For information exchange, there was general support for information exchange. And of course, it is something that is required by the statute for meaningful use. But there were some questions about the time frame for requiring exchange, the amount of information that would be exchanged in early years, and whether or not HIEs or RHIOs or similar type of organizations needed to be used for those—for the exchange of those kinds of data.

With respect to patient access to their own health information, there were differences in what folks thought were the scope of the challenges in doing this. There were a lot of folks who said—a lot of commenters who said it was really important to give patients access early on. "This is a critical component to meaningful use." Others who—were talking about some of the challenges of doing that in early years or the ways that we would do that in early years. And then there were some who recommended that we have some more measures in certain areas, particularly efficiency measures. And that was something that the workgroup considered, and you'll see some evidence of that.

On the measures front, like I said, there were a lot of folks who asked for additional measures, particularly as they relate to specialty providers. There were—we got a lot of comments from specialty groups—specialty providers who were concerned about how the measures applied to particular specialties.

We also had a lot of commenters who said—who encouraged us not to create measures de novo, but to use existing measures. And here is a sample of some of the sources for those existing measures that folks recommended. I'm not going to read all of these off, but this was the full array of the sources that folks suggested for—that the workgroup and that HHS look at for making measures decisions.

On privacy and security, we heard a lot of concerns about the measure for this. And there was concern that the way it was written might make it very difficult for large provider organizations to achieve meaningful use, because they may be subject to complaints for HIPAA violations, even if they've done nothing wrong, just based on the volume of patients and transactions and activity that they have, even if those organizations are then cleared of the complaint and, in fact, there's no violation found. So that's something that the workgroup addressed.

There was some concern about unintended consequences—that if it was tied to an investigation—that entities would be reluctant to report breaches or to try to improve on their processes and make information public, because it might affect their ability and their provider's ability to get meaningful use payments. And then there were others who were questioning whether—what was necessary, because they thought it was redundant with the HIPAA laws, which already providers would be required to comply with. And so, there was some question about the redundancy and whether or not meaningful use needed to include reference to HIPAA as part of the calculus.

And then finally, although we didn't ask for comment on certification, we received a lot of comments regarding certification. So this will be a topic today on the certification process from our Certification Adoption Workgroup. I just want to highlight a couple of things that we heard. There were many that suggested that the certification standards should be designed to support meaningful use and not be as broad as they have been in the past. There were some additional suggestions about the ability to have modular systems certified—that having criteria that promote interoperability to a greater degree—that there be certification of specific functions for EHRs and certification for specialty provider EHRs—something that is being considered now, but there isn't widespread certification for particular specialty EHRs. That's just some of the flavor of what we heard on certification.

So we've fed all of our thinking; our understanding of the comments; and any summaries that we had, as preliminary as they were, with the Meaningful Use Workgroup. And you will see, when they present, how they address many of these issues in their recommendations. I also want to add to David Blumenthal's thanking of our medical students to say that there were a few analysts that worked tirelessly to go through all of the comments, to try to summarize them, to figure out how we can get information to the workgroup in a way that would be helpful to their process. And we really appreciate all of their hard work.

#### **David Blumenthal – HHS – National Coordinator for Health IT**

Thank you, Jodi. Any questions for Jodi? [Pause] The—I think you will see that Paul and George will revisit some of these comments in their comments, which are just about to come. I also want to mention that it is a priority of the Obama Administration to be open and transparent and to collect information from the public in whatever way we can. We did hold—in addition to receiving public comments, we did hold a series of listening sessions in collaboration with the Center for Medicare & Medicaid Services, in which I think there were a total of 20 or so listening sessions. [Inaudible], is that right?

And we heard from a wide variety of informants: rural providers, urban providers, large and small, big groups, small practices, associations of providers, the public. Those comments were extremely useful. We have not tabulated them, but some of them were shared with the working group in a less systematic form than in the formal comments that we received from—based on our deliberations here a month ago. And of course, many groups and individuals have taken advantage of the opportunity to contact me directly and other members of our group to share their thoughts about the meaningful use work of the committee.

So with that, let me ask George Hripcsak and Paul Tang to talk about how the Meaningful Use Workgroup has taken into account the discussion we had last time and the comments to reformulate recommendations for this group. And let me place one thing in context also—or a couple things in

context. We are—we have a 2011 statutory, you know, sort of milestone in which providers will become eligible for the first round of incentives. And I think it's only natural that, given the fact that 2011 is, by my reading of the calendar, a lot closer than 2013 or 2015—that we've tended—there was a tendency in the working group, I think, to focus on 2011, and the most detail is associated with the 2011 meaningful use criteria.

As Paul will say, we are not—nevertheless, certainly I'm not unmindful of the aspirations that we have for future years, for 2013 and 2015. And the fact that we will devote a good deal of time to the 2011 discussion, I expect, because of its specificity, shouldn't divert us from the fact that our recommendations, directional—and even if they're only directional—are very important for my office to hear—wearing my hat as the National Coordinator, not your Chair today—and very important for the public to hear. So keep in mind that this is a matrix of recommendations that is—includes 2011, 2013, and 2015 components, even though the 2013 and 2015 components are likely to be somewhat less specific than the 2011 components. So with that, Paul.

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

Thank you very much, David. Let's see here. So I am also appreciative of having George as a Co-chair. He's a Chair at the Department of Biomedical Informatics at Columbia University and has a lot of experience in running the shop there at New York Presbyterian.

So I want to also acknowledge the terrific workgroup we have on meaningful use, the subset of this committee, and others, and how flexible and diligent and passionate they've been at taxing this responsibility. At the last call, we said, "Well, you know what? It's going to take us more time, so we're going to call—we're going to talk tomorrow morning." And people dropped their schedules and just did that. So I—people are very, very dedicated to this effort.

The other thing—I've been searching for a long time for how to extend the 24-hour day [laugh]. And I've found that having bicoastal Co-chairs adds 3 days to every 24 hours, so there's not a waking—there's not a time when one of us isn't working. So this is great; I've found the answer [laugh].

Quickly, I want to—so this is what I want to cover in today's presentation. And George gets a buy just for this one meeting, because he's just joined us, and we're going to be sharing it in the future. So I want to quickly remind ourselves what's the framework that we set out. You've heard a summary of the public comments. You heard last time's comments from this committee. We're going to talk about how we digested that and came up with a revised recommendation and then talk a little bit about our future work.

So first, the framework: As you recall, as David mentioned, it is clearly directed—pointed towards measuring and continuously improving outcomes. We've really, totally made sure that the focus is not on software but really is on the health outcomes. But we also recognize that we can't get from our low adoption rate now to the dream—the vision of having everybody adopt EHRs by 2014 in one fell swoop.

So we mapped out three sort of phases. One is, get it in the system in standardized format and get it to the people who need that information to make decisions. The second is to use that information in different care processes that are going to focus on the patients. And finally, we'll be in a position, if we've accomplished those stages, to be able to measure and continuously improve our outcomes.

Now, as you know, even in statute, it's both the President's goal as well as in the statute that by 2014, we have adoption of—widespread adoption of EHRs. And so, that sets the time frame. By 2015, you're no longer eligible, at least for an eligible provider, to get incentive payments. So the 2015 goal is there. The 2011 is the first time when incentive payments would be made, and so that then sets our time frame. Then, as we mentioned last time, working backwards, we then carved out criteria for meaningful use in those three general areas: 2011 focusing more on the capture and share data; 2013, use it—use clinical decision support in advance or care processes; and finally, improve outcomes in 2015.

These are some of the considerations, and we use these in almost every decision—discussion about the revisions. That is, our purpose here is to improve the health care system, reform it, focus on health

outcomes, but balancing that sense of urgency—the 2014 sense of urgency with what it takes to both install and implement and effectively use these systems. We know that we're starting from a low adoption rate. We're sensitive to the underresourced practices, like small practices where a lot of health care's delivered, the community health centers, rural settings, a lot of those issues.

But we still have to get a job done. If we're going to reform this health system, I don't know that anybody believes you can do it without these tools. These are tools, not an end, so we still have to work towards that goal of getting it out there as quickly and as safely as possible. And the Recovery Act provisions do set the timelines. The 2015 is there. That's the end of the incentive program, at least for the provider side, and the beginning of 2011 and '12, so that's when we have to make our first contribution. And the funding rule's being frontloaded. The most money is upfront. Those are set in the statute as well. So those are the constraints. We talk about that every time when we talk about changes to these criteria.

This is not for reading, but just to remind you that we came out with an initial proposed matrix last time. The group saw this; we reviewed it, got comments back, and you heard we also have public comments. So let me review for you how we approached the comments and what we suggest or recommend as our draft recommendations to this committee for further discussion.

There are sort of buckets; let me talk about them in the framework timing, patient engagement, efficiency, specialist care coordination, and privacy security—a lot of the topics that Jodi just mentioned. So in the framework point of view, we're really gratified that I think it's almost universal adoption and endorsement of the approach, meaning focus on the health outcomes and the quality measures. So the other major approach that we took, beginning with our last set of draft recommendations, was to be parsimonious in the objectives. We could choose among—we could choose to say we're going to set 500 criteria, and just sort of pick and choose which ones should apply to you; or go for the few sets that if you were to be able to report on and improve on these over time, by golly, you'd probably have a comprehensive, robust EHR and are making good use of it. So underlying—the underlying assumption for our approach to the criteria is, if an organization can demonstrate that they have the capability of reporting on these MU meas—these meaningful use measures and continuously improving them, then we're really assuming that you are making—you have a good EHR system and are making meaningful use of it.

So the first piece you heard from Jodi is—the comment is, you want it when? And the recognition is that there's only 18 months between now and at least the beginning of 2011. And this is a good time to mention that—to remind people that the incentive starts 2011 or 2012. With either of those years, you'll get the full 5-year payments that equal \$44,000, at least for the majority of providers in the Medicare system. And CMS will decide, and so that gives you up to—now that's admittedly towards the end of 2012, but you get the point; it's probably another 3 years. Now, CMS will determine what's the measurement period to quality for the incentives, etc., and that's to come. But just to remind people that it's probably more than 18 months then they have—that they have to do this job.

The second point is, if an org—we've found that there's sort of a double jeopardy. If you can't make the 2011 and the 2012 criteria and you're coming in at 2013, gosh, in 2013, bar has been raised higher. It's a bit of a double jeopardy. It's almost as if you can't get into the game at all. So although you might think of "A rising tide floats all boats," if you're not in the water, it just doesn't help. So we're trying to get—find a way to get people to be able to participate, even if it's a little bit delayed.

So the approach that we'd like to recommend has to do with the concept of an adoption year. So write now, it's written as 2011, 2013, 2015, but what if we considered 2011 as your first adoption year no matter when you come in? And I'll explain a little bit in this next slide. And then 2013 would apply to your third adoption year. Let me go into that. And actually, what—so this is a table from the statute of how you qualify for these incentives. And as you see, if you come in and qualify in 2011 or '12, you get the full \$44,000. And again, that's just the Medicare side.

Our initial matrix, and the matrix we're presenting today, spells out the 2011 objectives and measures, the 2013, and the 2015. What we'd like to propose in this new method of adoption year is to substitute. Instead of 2011 criteria, call it Adoption Year 1 criteria and measures. So these are the first year and how

that would map out into the incentive program. What we're suggesting is, we would apply Adoption Year 1 criteria to the first year no matter when you start. There's no change in the money. You still, if you start in 2014, are only going to get \$12,000 compared to the \$18,000 in 2012, but you have a consistent set of criteria. And I think—we think that this sort of relaxes that and gives people a fair shake and doesn't have the double jeopardy built into it. Now, CMS—this is a recommendation from the workgroup and for the committee to consider: CMS has its consideration in terms of the system's ability to administer such things, and so, they will determine the final rule.

Now, the other feedback you heard—the second most popular feedback or the most common feedback was, CPOE is being asked for too fast. And we heard that primarily from the hospitals. The unintended consequence of—it's not just a software system. You have to build the order sets, for example, in a hospital environment. You've got a lot of training to do, so it takes calendar time to get this work done.

Now, when we initially set up the objectives and the measures in the first round last month, we actually didn't necessarily say you had to have 100 percent adoption of CPOE in the first round. So there's a difference between the objective, which is sort of the signal or the timeline—the roadmap that the goal is to achieve full CPOE use, but the measure was actually a reporting measure. So what's the percent of your physicians, let's say, in the hospital that are using CPOE directly? It didn't set a threshold purposefully.

Now, I understand that the—it may have been interpreted to be 100 percent CPOE, but that wasn't necessarily the initial intent. So we've come back and said, "Let's put a number"—it's nowhere close to 100 percent; it's 10 percent—is our suggestion—"that allows people to get started, to have a pilot up and running—maybe certain subset of physicians or certain units in the hospital—some way of making sure that you are on that road to CPOE but not insist 100 percent by 2011."

Turns out there's—in the interim, there was a survey by CHIME with health care CIOs. And admittedly, that's a selected group. But 70 percent—over 70 percent of them said they could accomplish 100 percent—they were going on the 100 percent measure—within 3 years.

You wanted to say something?

**Unidentified Man**

I was going to ask if you could clarify who the respondent population is for that.

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

For that—CHIME is a group of health care CIOs. So that is one group—one input where they actually did a survey of their members.

**Unidentified Man**

Small and large hospitals—tend to be larger hospitals...?

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

It is a mix, but probably there's only—probably the folks that are further along are members of this organization. It's not a data point that we use, but it's just a confirmatory data point that says it's actually humanly possible.

The next point—and it came from [laugh] this group as well is, "Gosh, why don't we move clinical decision support up from" —we originally had it in 2013. Why? Because that's the payoff. If you're—that's how you influence the orders that are written; that's how you're going to influence care, or one of the main ways you're going to influence care, at least using these systems.

On the other side, it's sort of a sequential act: When you implement these systems, you've got to get it in, you've got to get it collecting data, and you've got to get people to use it before you start firing off these alerts and putting things in front of them. That's the normal pattern. So that would be the argument for delaying it: keeping that sequence in place as we had it last time.

So our compromise is, “Okay, let’s start with one rule but make it really important.” So we put in that we recommend that you implement one clinical decision rule that’s relevant to your local priorities. Each hospital or health organization or region has priorities that are local to them, and that’s the way we’ve constructed that.

Now, the other piece in the patient and family engagement—as you heard from Jodi, there was a lot of requests for earlier access. We had a copy of your information electronic—provided to you electronically, and the request was to have access by 2011. So we responded to that and moved and included not only the copy of but also the access to, in electronic format, your health information. So these are from organizations that provide—that do have an EHR in place.

And we moved up the real-time access; that is, as information becomes available—let’s say lab test results—those would automatically be available to the patient. And that originally was in 2015, and we moved that to 2013. So we’re trying to be very responsive on saying that the consumer patients are really part of this deal, and we want to recognize that they have not only the right, but it’s in our—all of our best interest that they have access to the information.

Efficiency measures: It was pointed out that we have a dearth of efficiency measures in our last matrix. Well, the reason is because there are a dearth of efficiency measures that are out there to use. NQF has been asking for those for a long time, but they just haven’t been that quick in coming forward. So that clearly is one of the priorities for the country; it’s a priority enumerated in the National Priorities Partnership goals, and so we’re proposing an initial starter set. And those are the following.

One is, we do know that there is—that choices are made between generic medications and brand name ones and that there’s a huge cost difference. So our measure is, what’s the percent of medications that are entered as generic when those options exist? Not in every drug class is there a generic option, but when they exist, let’s have a measure that says what percent are prescribed as generics.

The second piece is, there are high-cost imaging services, and we would like to inform the provider who’s ordering those on the most appropriate imaging test, if any, at that particular—for that particular indication. Although we don’t have the evidence at hand that says, “Well, how do we write that decision rule?”, we wanted to start putting ourselves on the roadmap to going there. And so, our first proposal for 2011 is to have—at least record the indication for ordering a particular test in a structured way so that we can analyze it and provide feedback to providers.

The third and fourth examples are really having to do with efficiencies surrounding the payment system, the claims—that the claims be submitted electronically to both public and private payers, and that we have eligibility checks performed electronically.

Specialists: the “What about me?” question. It’s a fair question. It turns out that the majority of EHRs in current use or—and in current products address primarily primary care. So we have to do a better job of both getting those products developed as well as being able to certify them. Once again, we’re faced with a couple options. One is the 500-criteria model, which is “Well, let’s make sure that we have a measure for everyone.” But yet, there’s very few to choose from, at least that are NQF endorsed.

The other model is to take—let’s—what are the critical few that we could build upon? And if you were to satisfy those criteria, again, you would prove that you probably do have a robust EHR and are using it effectively. So that was the approach that the workgroup took: that is, the exemplar measures that if you fulfilled these, we have a good indication that you’re a meaningful user of this tool.

And in 2013, again, since there are not very many measures that are in current use—by 2013—that we would start with specialists participating in electronic registries. There are certain organizations that already have these up and running and have a lot of data in those. And that’s a good way for the country to both start measuring and getting the advantage of this data collection and using it.

Care coordination: We clearly need—we—well, one of the top goals is improving care coordination. But yet, we do have a paucity of measures that can measure whether that's happening. NQF has a call for measures in this area, because it is an NPP priority. So we're proposing that, in 2013, we measure something—measure the 10—we know the 30-day readmission rate—maybe a third of patients are readmitted within 30 days of being discharged from a hospital. That has to improve. So we're putting out there, for your comment, a 10 percent reduction in the 30-day readmission rate compared to the year prior as a 2013 measure, and to continuously improve on whatever NQF-endorsed measures are there by 2013.

Now we have the problem of the health information exchange. Clearly, in 2015, it is the goal—and I fully expect, in 2015, we're going to require for the incentive payments that people do participate in health information exchange in interoperable ways with data standards. That world doesn't exist today, at least, and we need to do something between now and, let's say, 2011. So our thought—and this is for further discussion—that we talk about requiring the capability in your EHR to exchange following the standards that evolve over time. They aren't mature at this point. CCHIT does have some interoperability standards in their certification criteria. We're deferring to the HIE workgroup for the specific requirements and the roadmap, but what we'd like to put on the table is that they use EHRs that are capable of doing that following the standards that are available. And as I say, CCHIT has some of that built in.

Now, pro—I mentioned that CPOE was the #2. The #1 thing that everybody commented on, I think, is this thing about investigations and HIPAA. And clearly, the issues were as presented by Jodi. We do have a principle in this country of innocent until proven guilty. That still exists in this world. And the intent of the subgroup—of the workgroup that put the original language together was not necessarily to say, "Oh, gosh, if you have any complaint, that eliminates you from the program." So we've sort of clarified that. The intent was, it seems funny that if you have a proven violation—that you should be continuing to get money from the Federal Government. The revised wording talked about withholding payment until those—the—any confirmed violations are resolved to HHS's satisfaction.

And then the other comment was, we did have—you have to comply with State regulations. Well, one question is, "How does the Federal Government enforce State laws?" Well, that's a good question. So we took that out of the Medicare program, but State—but Medicaid, as you know, is administered by the States, so we left it up to the States to make sure that people are following their local laws as they qualify for these incentives.

So the future work—there were some achievable vision bullets that were put out in the last presentation. Those were set out as examples. The workgroup is going to refine those and get consensus on a set that we can put forward—put before you. We need to—after we're done with the 2011, need to march on with 2013, 2015—they still are going to come—and find a process for how do we, in an ongoing way, update this, as required by statute that we have more stringent measures as time measures on. And we were also asked to review the barriers to broad adoption of meaningful use and make recommendations back to this committee on how to address those.

So with that, I wanted to open the floor for comments/questions from the group. And George is willing and able to participate in that. The closing statement is, we really appreciate the strong industry endorsement of the outcomes-focused framework. It's a clear stretch—we recognize that—to accomplish this in this short a time. We also know that it's more than money that prevents people from getting there. It's the workforce; it's the education. There's other aspects of the Recovery Act that are meant to address that, like regional extension centers and even other research on how to make these implementations go better. So while this is extremely ambitious, if we can get the incentives in a good direction, I think we—it's a vision that's achievable and maybe this community's contribution to health reform agenda. Thank you.

**David Blumenthal – HHS – National Coordinator for Health IT**

George, would you like to add anything? I realize that you're a new arrival, and...

**George Hripcsak – Department of Bioinformatics Columbia University – Chair**

Well, let me just—you know, I think it is, in some ways, a high bar, but it's a clinically relevant bar, and that's what we're here for. I think that the measures—you know, coming in as a newcomer, the measures in one sense are parsimonious. Some might say they're comprehensive. I think they're comprehensive enough to avoid gaming the system. If you have too few measures, you just focus on those things; you don't really—if you can achieve everything in this list, then you really must have a pretty good use of your EHR. And it's a stretch—actually, the—coincides with the 40<sup>th</sup> anniversary of the moon walk, so this is our next boon shot at health care—is to achieve this vision, so I'm excited about it.

**David Blumenthal – HHS – National Coordinator for Health IT**

Thank you, George. I think you can see, regardless of whether you agree with everything on this matrix—and I think you can see, #1, that an extraordinary amount of thought and detailed work has gone into this. And I want to, again, applaud everyone who was involved. I think this is a really—breaks new ground in policy development, and not just in the health information technology, but really in setting criteria for improved practice that may be implementable. We are struggling to develop incentives and performance criteria in many elements of our health care system.

This is, I think, the first time that any group of this type has tried to be this specific related to particular dates and particular programmatic elements and particular statutes in laying out an aspiration for what's not only desirable but achievable. So my hat's off again. And I hope the comments will—as we go on, will understand—will take into account the complexity of this work; the demands of the statutes; and the intention here, which is overwhelmingly to use a very promising technology to make the care of patients better and more efficient. So with that, I have one hand raised: Tony Trenkle.

**Tony Trenkle – CMS – Director of OESS**

Thank you, David. Paul, just a couple clarifying points and a question for you. You say 2011, but actually, on the hospital side, it's October 2010. And then your chart on the #13 is actually Medicare, not—it doesn't include Medicaid.

But I did have a question on your slide where you talked about the bar—raising the bar over time. And I guess I just had a couple—maybe a thought and a question. You talk about—people were joining up in 2013—be held to the 2011 bar for first year and, I assume, the 2012 bar for the second year. But won't the bar in 2013, what's in the landscape, be changed enough in 2013 that, for example, information exchanges in 2013 will be much more ubiquitous and developed than they were in 2011, same as quality measures? So should the bar for the first year in 2013 not only reflect 2011 but also reflect the changing landscape? I think that's just one point I wanted to make.

The second point is, you have 2013; 2015 is when the incentives—disincentives, actually, cut in. So are you saying that someone who joins in 2014 would be held to the lower bar but then, in 2015, would have to jump up to the higher bar? So I guess what you're saying by this meaningful use year—you're delaying the pain, but you're not getting rid of the pain. Is that, I guess—?

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

That's correct. Outstanding points, Tony, of course. So let me answer your second question first, which is absolutely true. In other words, everyone has the motivation to adopt this as—and effectively use this as early as possible. And I think your scenario was absolutely right saying, "Okay, you got in, but you know what? The pain side is still there, and we're not making any recommendations to change that."

And your first point was the changing landscape, and that's a really good point. So if CMS were to adopt the adoption year approach, then I think you could very reasonably ask us to come back and say, "How do we accommodate those—that approach when measures change just with the change in time? So like you said—so there's now a different measure in this area. Can you change that?" And I think that would be something we'd be very willing to work on, if that approach is adopted—that is, the adoption year approach. Thank you very much for the questions.

**David Blumenthal – HHS – National Coordinator for Health IT**

Neil and then Marc.

**Neil Calman – Institute for Family Health – President & Cofounder**

I just wanted to – this is Neil Calman. I just wanted to respond maybe with a little bit of a different take on why the delay is important, because if you think about the actual implementation that goes on, the day you start implementing your electronic health record—for most people, that means they're seeing patients for the first time with their electronic health records. And there's really no way to import all of the history and everything that goes on. So until you have a year's worth of data or a year and a half or 2 years' worth of data, the reporting out of quality things becomes almost impossible. You're reporting out on the people who you saw in the first month of your implementation.

Second of all, the whole process is one in which the first year of implementation is really focused on extensive training and teaching people how to optimize the use of the systems. And expecting them to also be thinking about how patients are going to have access through a portal to information that's just being put in for the first time—it's just impractical. And I think, you know, when I first brought this up—I think it was two meetings ago—I think it just reflects the practicality of the implementation process and how you can begin to use systems. So although the landscape is going to change, I don't think it's going to change much what my original concern was, which is that there's a process of implementation that actually takes a year or 2 until people can truly use all of the functionalities in the system that we're expecting them to do. and that's what—

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

I'm not disagreeing with your point; I'm just pointing out that, the way the incentive system is structured with the disincentives kicking in, there's—it's still going to create a problem beginning 2015, given the law, unless we just—unless we get the law changed.

**Neil Calman – Institute for Family Health – President & Cofounder**

It will, and that was, I think, the committee's understanding—was, there's still plenty of incentive for people to get in there early. And it's just that we don't want to create such a high bar after 2011 that people can't get in at all in—you know, in a practical fashion.

**David Blumenthal – HHS – National Coordinator for Health IT**

Marc?

**Marc Probst – Intermountain Healthcare – CIO**

I just had one clarification question and then just kind of a broader question. The first one was 10 percent of all orders, any type. So does that say that if we did 10 percent of all of our drug orders, that would be meeting that, or is it—does it mean something different than that?

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

Okay, so the clarification is, imagine you—it's 10 percent of all orders that are submitted. So in your example, it would not be just 10 percent of your meds order. We tried to say it's—we're dealing with all orders; that was what the friend meant. And it's 10 percent of the—all orders. The way you might measure this is, bills are one way those orders get executed. That's your denominator—what percent got into the cut—entered by the provider.

**Marc Probst – Intermountain Healthcare – CIO**

Okay, so 10 percent of the total [inaudible] orders; doesn't matter which type.

**George Hripcsak – Department of Bioinformatics Columbia University – Chair**

Or you could choose if you—either way, you could do all med orders, which may represent 10 percent of all your orders; or you could do a certain number of services, which represent 10 percent of the total.

**Marc Probst – Intermountain Healthcare – CIO**

Okay, thanks. And then—

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

That's the denominator [laugh].

**Marc Probst – Intermountain Healthcare – CIO**

Then the broader question—and I'm not sure if it's significantly similar to Neil's, but in the broad spectrum—you know, we talked about CHIME, and I mentioned that, you know, that is 70 percent of CHIME members, but I'm a CHIME member and have a lot of technology in place. Likely, if you don't have technology in place, you're not a member of CHIME. And if you look at other statistics—and I think, Dr. Blumenthal, you went through a study earlier this year about how much adoption is really in place in electronic medical records.

And then playing a little off of what you said, George, you know, this does show significant meaningful use of an electronic medical record. But if you don't have a data center or a network or a PC or the people that install those or put the security in place or any of those things, the bar is way, way high, I think, for a lot of individuals. And I know we have a fixed period of time. We didn't get to set the law, right, from 2011 to 2015, so I know it's difficult. And I don't think I'm even looking for answer other than just putting it on the table—that this is going to be a very significant bar for a lot of people that may not have the same voice. Even the comments that came into us—you know, they may be members of AHA and have gotten their feelings in from that, but likely they aren't a member of some coalition that was put together of people that are meaningful users of EMRs.

So I think it's terrific work, by the way. I really think your group did a great job. But I am concerned about those people that aren't yet into technology.

**David Blumenthal – HHS – National Coordinator for Health IT**

Connie?

**Connie Delaney – University of Minnesota School of Nursing – Dean**

Thank you, David. Paul and George, I want to commend the working group on listening, compromise, and still maintaining the significant bar. My comment relates to Slide 16: Efficiency Measures—and primarily a verbal comment. It builds on the discussion that Marc just facilitated.

Given that the majority of States have in place prescriptive authority for advanced nurse practitioners, and given the significant role of advanced nurse practitioners and particularly addressing the primary care health needs of U.S. citizens, I would like to request that the discussion of CPOE particularly reference provider such that the advanced nurse practitioner can be encompassed in these measures related to efficiency and percent of orders.

**David Blumenthal – HHS – National Coordinator for Health IT**

Okay. Gayle?

**Gayle Harrell – Florida – Former State Legislator**

Yes. I had several questions and also a comment. And you may have received 720 comments through ONC. I can tell you, I have received not quite that many but a significant number of comments locally from constituents around the State of Florida. So I can tell you that 720 is minor compared to what probably all of us have received.

But in the way of clarification, I do have some questions. We are talking about the measures. In order to receive payment, are you going to have to meet all the measures? For instance, would an ophthalmologist have to verify whether or not I had a mammogram? Would they have to take—know what my body mass index is? So are we—or where there are—and I'm glad that you're going to go down the road of specific measures for specialists; I think that's important. But would—is there a percentage of these measures that you have to meet to prove meaningful use, or can you simply meet one of them that's appropriate to your specialty?

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

Our thought was that we would have a set that, in fact, all providers would have to meet. That's admittedly not in this matrix as it stands now, but many of the ones would apply to all specialties—would be a thought, even, for example, vital signs. The other poss—the other way to look at it is, let's say, the BMI; I think that's what you mentioned. If you practice in a group where there are other physicians that do cover—that record the BMI, that's in the record. And so, it—we want to make sure that that BMI is in the record. That's just one example. So I think the first answer to your question is, not all these may apply to all specialties, and we need to be clear, as it goes through the rulemaking process, how do we determine which ones must be satisfied by all providers.

**Gayle Harrell – Florida – Former State Legislator**

And a way to follow up on that. If you—for instance, a percentage of smokers offered smoking cessation, does that create a liability for a physician to offer that, and if—are you going to be penalized if you don't offer that? I.e., is it going to be a checkup process that—if you do not check up on the mammogram, are you setting up a liability?

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

No, I don't think there's any intent for these cri—these proposed criteria to incur any medical liability, for example. So these are things specifically designed for this HIT incentive program—this HIT accelerating adoption program, and doesn't have any reflection on care and liability.

**Gayle Harrell – Florida – Former State Legislator**

So if I'm receiving a record in—if someone has sent me—if I'm an ophthalmologist and someone has—for instance, I've imported a record from an OB/GYN and there's not been the follow-up care on the mammogram, I have no liability to do that.

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

I think it's totally out of the scope of these criteria.

**Gayle Harrell – Florida – Former State Legislator**

I have many questions from physicians on liability and whether this opens the door for them to—when they receive that information, if they don't act on it, are they then liable?

**George Hripcsak – Department of Bioinformatics Columbia University – Chair**

You know, I—the question of what causes liability or doesn't is an enormously complex one that I don't think we have the confidence here to comment on. And I think we have to stay focused on what we think appropriate and good care should be. And we can't, unfortunately, sort out our medical liability system here.

**Gayle Harrell – Florida – Former State Legislator**

I totally understand that. I'm just bringing this up as an issue that I have been—many physicians have expressed to me that they are concerned that if they—when you have measures in this, how many of these measures will they have to meet to qualify? And then, does—in order—because they then have that information, are they liable? Do they have an increased liability? So this presents a real fear out there for many people who may not adopt because of that. I want to bring that out.

**Judy Sparrow – ONC – Executive Director**

[Inaudible] question. Is the fear of liability about measures that are unrelated to a particular specialty, like an ophthalmologist—

**Gayle Harrell – Florida – Former State Legislator**

Correct.

**Judy Sparrow – ONC – Executive Director**

—who's getting information about mammograms? Okay. So it's really—it's about the—it's coming from the specialists who wouldn't normally be following up—

**Gayle Harrell – Florida – Former State Legislator**

It's coming from the specialists about what standard they will be held to if they have information within a medical record, and then they don't act on it. Also, the concern that they are going to have to measure things and report things that will—that is not within their purview, that they normally do not do, that perhaps their family doctor should be doing, will that prevent them from receiving incentives if they don't have that information in their record? Are they then liable? Then do they have to do it if they've not been able to import? So that degree of payment, but also whether or not it opens up a can of worms on liability.

**David Blumenthal – HHS – National Coordinator for Health IT**

So just to clarify, I heard from Paul a recommendation, not necessarily specified here, but that the measures be specialty related or specialty appropriate. And that's a recommend—that could be the subject of a recommendation by the committee to me, taking off my hat as Chair of the committee, and—

**Gayle Harrell – Florida – Former State Legislator**

I personally would very much—and those I've been speaking with would very much like to have that very well-specified within the recommendations—that the measures on which you're going to be evaluated be appropriate to the area of specialty.

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

And second, there'll be two sets of measures. There'll be those process measures that everyone is measured by.

**Gayle Harrell – Florida – Former State Legislator**

Process is certainly [inaudible], you know—

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

Like, if you're doing prescriptions, you need to do it electronically, no matter who you are. And there'll be quality measures for reporting, say, in 2011, where we would need to work on the mechanism to do what's relevant.

**Gayle Harrell – Florida – Former State Legislator**

Exactly, and I think that clarification between quality measures and process measures needs to be carefully articulated.

**David Blumenthal – HHS – National Coordinator for Health IT**

The other question about liability is one that I don't think we can address here. There are so many things that are nominally right to do or appropriate to do that create complications in our liab—in our medical liability system that if we were to have to think through the liability consequences of everything we did, I think we could get tied in knots.

**Gayle Harrell – Florida – Former State Legislator**

Exactly.

**David Blumenthal – HHS – National Coordinator for Health IT**

It's a fair question.

**Gayle Harrell – Florida – Former State Legislator**

I want that discussion on the table, realizing that there is a great deal of concern out there among providers on that issue, and that the—a public discussion that needs to happen in a much broader arena than this committee, but it needs to happen.

I still—I'm very pleased that we—the—for the hospitals, the 10 percent of all orders—that clarification is significant. However, I still have a significant concern, and I want to reiterate what I said last time on the process of moving small hospitals—community hospitals who have no expertise, no background, or even if they do have some—that because these measures—because everything is—the bar is raised so high,

they will be changing systems, the whole decision process to do that—the certification discussion we had yesterday is going to complicate that even more—that these time frames are very, very short. And I'm afraid that we are perhaps setting ourselves up for failure, in that we're not going to get the adoption rates because of that. I want—my goal is to encourage adoption. I want to see every hospital, every provider do this. But I think, again, we are creating some very significant timing issues.

**David Blumenthal – HHS – National Coordinator for Health IT**

I have Charles, then Paul, then Judy.

**Charles Kennedy – WellPoint – VP for Health IT**

Thank you. Thanks for the presentation, Paul. My comments are around the efficiency measures. I agree with you: there are a dearth of efficiency measures. However, we might wish to look at the efficiency components of quality. For instance, we've looked at several States where we've seen ambulatory adverse drug events represent up to 5 percent of hospital charges. That might be a good component of a quality measure to look at the economic impact.

Then the other comment I would make is, we'll have to be very careful with some of these measures. For instance, the percent of all medications entered into an EHR as generic may not be representative of the value of health IT, because that would imply to me the physician had already made a decision to prescribe a generic drug. We may need to look at things like therapeutic substitution, where health IT provides a unique capability, because you need the clinician's judgment to see if that substitution is appropriate. So I might make some suggestions around some tweaks of the measure.

**David Blumenthal – HHS – National Coordinator for Health IT**

Okay, Paul.

**Paul Egerman – eScription – CEO**

First, I want to congratulate you, Paul and George, and your team. It's really a very exciting, very impressive amount of work. On this issue of the specialist, I just had a comment, which is, there's a lot of discussion about measurements, but there's also these things called the meaningful use objectives. And a lot of the solutions to some of these issues with the specialists could possibly come by looking at the objectives and asking for specific specialists or certain specialties. What's the best way to measure against those objectives? So that might be another way of accomplishing that whole issue and addressing some of the issues that Gayle is making.

And also, I just wanted to agree with what Charles said—that I was very pleased to see the slide on efficiency measures. When you say that there's a dearth of measures focused on efficiency, I think you're being generous in terms of describing how efficiency currently is measured in most health care organizations. And so, this is very exciting. I did actually have a question, though. As I happened to notice in your initial starter set when it comes to medications and orders, you measure a percentage, but then it says "claims." There's no percentage of claims submitted electronically. I'm just curious: Why—is that sort of, like, a different metric? Is that just an oversight in the slides, or is there some reason for that?

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

I think it's probably an oversight, in the sense of—I'm not sure people would—once they turn on the spigot, would say, "Well, I'm going to only let half of it go through." I think the idea is that they would implement their systems so that they would be submitting claims electronically to the payers.

**Paul Egerman – eScription – CEO**

Okay, thanks.

**George Hripcsak – Department of Bioinformatics Columbia University – Chair**

One—may I have one follow-up on something that Paul mentioned. It is very key, and I appreciate the comment about the specialist and looking at the objectives. So there are two columns; one are objectives, and one are measures. And the measures are, in a sense, part of the recommendations to CMS about what to consider as ways to evaluate whether they are a meaningful user. But the objective really is a

strong signal about the roadmap—the direction. And just like Paul mentioned—and that would invite people to suggest measures that might be specific to their domain, in this case specialists. And it's a very important request, and the workgroup committee would benefit from that. And as you noticed, the specialists aren't really addressed significantly until 2013. It's to accommodate that need for more public input.

**David Blumenthal – HHS – National Coordinator for Health IT**

Judy?

**Judy Faulkner – Epic Systems – Founder**

A couple things came to my mind when I looked at this and heard your talks. First was wisdom of the crowd and all that input that you got, and second, all the work it must have done—it must have taken to do this—throw it all together. And I think this is a real improvement, and I really like it. Thank you.

A couple specific things: In 2013, you have measure of percent of orders entered by physicians for CPOE. In 2011, you have 10 percent. Is it acceptable if the 10 percent includes no physicians, and is it acceptable if the 10 percent of the orders are orders such as supplies? So I'm wondering if you want to specify a little bit more in there or not as you do that, #1.

Number 2, ICD-9: This may get a little bit to what Tony was asking about earlier, but just what is the process for moving that to ICD-10 as that becomes the next thing? CMS diabetes—one of the things I know that is a constant struggle is, what is the definition of diabetics? Is it in the lab test results? Is it the diagnosis, the problem list? Should there—is it okay if everyone uses their own judgment as to that definition, or should there be set up how to define diabetics? Not—I'm not saying medically, but I'm saying in the computerized medical record, because there's an awful lot of variation on that.

And then the last thing I had on this was... well, actually two things. On the generics that folks were talking about, SureScripts and RxHub do have generic substitutions and can—and that can be suggested to the physician, and the physician does the order, so that does get people through that.

And then the liability—I agree with both David and Gayle. I agree with David: it's not for this. And I agree with Gayle: I was speaking to a judge after a trial where the physician was ruled liable for not seeing something within the medical record, and I know I've spoken to physicians who are very worried about HIE bringing not only their own medical record there but medical records from other sites and their liability as they have to go through all of it. So that is an issue that somewhere has to be addressed.

**David Blumenthal – HHS – National Coordinator for Health IT**

Okay. Roger?

**Roger Baker – VA – CIO**

Let me add my voice to the chorus of people that are congratulating you on great work. It's a complex area. I have four or five comments, and I think I'll start from the longest one first.

On health information exchange, to me, the key aspects there are how many and how much, you know, how broad and how deep. And so, what I would encourage we think about is, at what point do we want to say that meaningful use means having all of the patients that are seen in the facility available for information exchange with other folks? And the other one is implementation of the standard and making a volume of information available. VA and DoD are wrestling with both of those things or have wrestled in the past in our interoperability piece with that. And so I think, as we drive the standards forward for information exchange, it's going to be important to make certain that we have incentives for organizations to participate with those standards.

And another aspect of this—and I think we probably all recognize it, but whatever we set here will start to drive the way that EHR vendors market to their customers, the people that they want to sell to. So one of the things I would—the reason that I would like to see us have some fairly stringent things in there about information exchange is that that needs to be part of the selection criteria. If we see hospitals and

providers selecting EHR vendors that don't have a good plan for information exchange, that will impact us in our ability to achieve that. So I'm trying to go in order of length so that if I get cut off, I get to my shortest ones last [laugh].

I would say, on privacy, one of the things that we've found at Veterans Affairs—and I think we can we speak with some authority on this topic at this point [laugh]—is that disclosure is highly driven by the management approach of the organization. We have taken the approach that we want to see the privacy—the unintended disclosures—the things that cause privacy disclosures so that we can deal with them and stop them in the rest of the system rather than persecuting the individual who made the mistake. I'm not exactly sure how to factor that into the discussion of, you know, whether there is currently an issue going on with a provider, because at the same time that you want to make certain that you're motivating them to deal with privacy issues and disclose them, you also, if you put too much money behind it, are going to cause them to not disclose them. And I think maybe where I come down on that is that it's much more important that we get them disclosed and dealt with than that we get them hidden from view.

The—I would just suggest that we define real time. "Real time," to me, has definitions everywhere from within 50 microseconds, which is a particular thing in simulation, to within 24 hours, which is what banking seems to think it is [laugh]. So I would just encourage us to—you know, to do a little bit more on the definition of real time. It probably has to do with episodes of care. How fre—how fast does it need to be up in order for the patient to walk out of Hospital A and walk into Hospital B?

And on page 14, we talk about folks starting with one rule and making it important. I wouldn't want to think that we would let people define their own rule and tell us what's important in their facility. Potentially, we would have, if you will, a pull-down list of rules you could select from that we think are meaningful ones. And maybe there are 10; maybe there are 100 different things that you could select from and say, "This is one that matters to me." But I can tell you that if I were allowed to select my own meaningful rule, it would be one that I already accomplish. So those are just the quick comments.

#### **David Blumenthal – HHS – National Coordinator for Health IT**

Thank you, Roger. Christine?

#### **Christine Bechtel – National Partnership for Women & Families – VP**

I just want to come back to the measurement issue for a second and say that I think we are all on the same page: that specialists and a broader type of clinician need to be able to see themselves in the definition of meaningful use, no doubt. But how we get there, I think, is a different story, and I want to reinforce what Paul has said. As CMS goes through and looks at how to translate the objectives into measures, I want to sort of weigh in on the side of those who don't think that there should be a list of, you know, 15,000 measures that everybody can pick and choose from or just 15,000 measures, period. I think it points me to the importance of what I think we've called the health outcomes policy priorities that are in the matrix: care coordination, patient and family engagement. Those are things that—everyone can do patient and family engagement and do it well. So I think we can arrive, as Paul said, at a core set of measures that everyone can contribute to, whether that's avoiding medication errors or other, but also have the ability for particular specialties. You know, right now, we've expressed that in, you know, reporting to our registry. And I think we will be able to evolve that over time, but I just want to be sure we're careful on that.

And then, before I give up the mic, I just want to say a huge thanks to Paul in particular and to Farzad and to John Glaser, who have provided fabulous leadership to this. We had very spirited discussions. And you guys are absolute pros at negotiating and navigating those dynamics. And I am really excited about this definition. I look forward to moving it forward today and hope we can do that.

#### **David Blumenthal – HHS – National Coordinator for Health IT**

Any other—yes, Latanya.

**Latanya Sweeney – Laboratory for International Data Privacy – Director**

How are you guys? Is—being on the committee but absent for some of the committee—the spirited committee meetings, you guys have done a great job, and I wanted to reiterate that.

One of the things that I want to make sure got on the record is that even though there are categories called privacy and patient empowerment issues explicitly stated, there's sort of this caveat around these fair data share and practices that I think are crosscut—a little more crosscutting. And that really gets to sort of what Roger was bringing up, because in that way it's sort of a conflict or a little bit of a tension. So sort of like, as Gayle pointed out, despite how much e-mail I got from this committee, I got about three times more in response during the comment period from organizations and even individuals, too, and almost all of them are on this issue of wanting some kind of control—either the provider to have control or them have control in the space of opting out. And that has a direct [inaudible] tension—has a tension with having all or a percent of the records available as an outcome measure. And I think that's something that we have to kind of [inaudible] out and work some of those issues through. But I did want to say that there are some reasons that some of these things may not be directly put out as measures.

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

Well, and I think opt-out is a pretty important piece of this.

**David Blumenthal – HHS – National Coordinator for Health IT**

Adam?

**Adam Clark – Lance Armstrong Foundation – Director of Health Policy**

Again, along with everyone, thank you and the workgroup for all the hard work you've put into this. This is more just a question of clarification, particularly on the matrix, as I look at “improve population and public health.” It calls out specifically immunization registries as one of the objectives. There's then another bullet point that talked about surveillance data and public health agencies. Does that include other disease registries? Clearly, from the Lance Armstrong Foundation, we're interested in the cancer registries, but there are other disease registries out there, and I just wanted—as a point of clarification, because I know some of the groups were concerned about that, if that was going to be included.

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

Well, I think registries per se is probably most included in the 2013 state. Again, you need to get the data and then be able to share it. So in the 2011—or the first adoption year, we're thinking mostly of getting the data in the structured format. Then we really acknowledge the important role of registries. It applies a lot to specialists, even the ones in the example that you brought up, and that is clearly in there for 2013. And we'll have to get more specificity as we get closer to that date. We'll probably actually start working on it right away once we finish up with 2011.

**Adam Clark – Lance Armstrong Foundation – Director of Health Policy**

If at all possible, because I don't specifically see disease registries in there—if that can be a point of consideration in the verbiage, that would be very helpful.

**David Blumenthal – HHS – National Coordinator for Health IT**

Okay, we're—are there any other comments? We're just about at our time limits. Yes, Neil.

**Neil Calman – Institute for Family Health – President & Cofounder**

Just something that I think got dropped that might be important, and that's in the area of improved care coordination. In the prior draft, we said that there was a capability to exchange key information, but we sort of lost the phrase that said, “and actual exchange when possible.” And I wanted to just sort of put that on—I think that's actually required in the legislation, the way I read it—that the actual exchange of information is one of the things that's required in the meaningful use definition. And I think we had put that in, in a way, so it's—sort of watered that down a little bit, but I didn't want to drop it completely. If there's—if the possibility of exchange exists, that should be in the criteria for 2011, I would think.

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

Neil, may I clarify? Do you mean electronic where possible, #1?

**Neil Calman – Institute for Family Health – President & Cofounder**

Yes.

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

And do you mean electronic wherever possible?

**Neil Calman – Institute for Family Health – President & Cofounder**

Well, it says elect—it says—yes. But no, not whenever possible, because I think—

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

So what do you mean by “where possible”?

**Neil Calman – Institute for Family Health – President & Cofounder**

What we had suggested was at least one electronic exchange of information when possible in the 2011 criteria. And I think that was—that would be a useful thing to put in here, and it would help us meet the legislative intent.

And the second thing: I just wanted to—I do think it’s going to be absolutely critical that—and at least from the feedback that I’ve gotten as a physician, I think it’s going to be critical for us to specify which of the things are—we are requiring for which specialties. And I know we don’t want a big, exhaustive list, but it’s got to make sense to people. And I think the comments that Gayle got are absolutely right on target. Everybody—are psychiatrists supposed to take blood pressures with every visit? I mean, we just need to be really clear. And I don’t see any way of doing that if—with the set of measures, except to go specialty by specialty and be fairly specific.

And the last thing I wanted to make just picks up on the liability issue in a very different way. When I’ve start—when people have asked about liability, what I say to them is, “What’s happening in the country right now is, we’re creating a new standard, which very shortly will mean, since the standard of care in the community is sort of the test for a lot of whether somebody is giving good care or not, that we are creating a new standard in the community that at some point, probably very soon, probably within a few years, people who don’t have electronic health records and commit some sort of an error that could have been prevented by electronic health records—somebody will turn to them and say, ‘Why don’t you have an electronic health record? It is the standard of care in this community to have one.’ And in fact, the kind of liability will be increased by not doing that.”

And I would say the same thing about exchange: that somebody will turn around and say, “That information was available to you.” So I think the answer to the physicians is that we are actually changing, through this—we are changing the standards of care, and we’re changing them in a way that’s getting physicians to be more responsible more broadly for the health of their patients. And that’s a good thing; that’s exactly what I think we should be doing in terms of getting health technology to support health care reform.

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

Well, I don’t think we want to engage in a debate about that right now [laugh].

**Neil Calman – Institute for Family Health – President & Cofounder**

Proved unanimously.

**David Blumenthal – HHS – National Coordinator for Health IT**

Yeah [laugh]. So we’ve had a number of suggestions for changes. And I think what I would like to suggest is that we consider these—this matrix with the understanding that we will be responding to the suggestions and that you will get a chance to look again, of course, at the matrix, but that you—that we

can consider this without all those specific changes. So let me summarize what I heard, and I don't think I have a full recording of them, but I think I captured some of the bigger ones.

One is that it is the sentiment of the committee that measures should be appropriate to specialties and that, going forward, the Center for Medicare & Medicaid Services should adjust the measurement of meaningful use to the specialty—to be appropriate to the specialty involved, and that there could be a number of ways of doing that. And there will be an opportunity for the public to comment on the notice of proposed rulemaking and to take—to make its views known and for the special—for specialists to make their views known.

The second is that we need to work, still, a little bit more on efficiency measures. And Charles Kennedy offered to help us a little more with that. We discussed a generic—the percent generics. There needs to be a little bit more thinking about that. But there was, I think, general support of the direction that we were taking.

The adoption year framework seemed to meet with general approval. It—obviously, CMS will need to think through its implications. But again, we are in the business, as a committee here, making recommendations, not rulemaking. So we can make a recommendation knowing that it will have to be considered for its implications for the actual development of regulations.

I think there was a concern expressed about liability. I would prefer that the committee not recommend to me that we change the liability system in the United States. But I think that the record should note that that was a concern that was raised here.

There are a number of issues where clarity is needed for when the rulemaking process goes forward, for example, around the definition of diabetes. I'm sure that will be true around the definition of elements in many areas that we are going to be—that CMS will be rulemaking upon.

The opt-out question we just barely got to, but it does seem to me an important contextual consideration, namely that the implementation of records by providers needs to be—take into account the preferences of consumers and patients for whether their information should be recorded in electronic format and exchanged. And I think, rather than discuss that at length right now, we might want to come back to that at a future time.

And then there was an embrace—an endorsement of the use of disease registries. That could be used for many purposes. The one that was specifically floated in Paul's recommendation had to do, I think, with a solution to the specialty nature—or the specialty-specific nature of reporting, namely that there might be a way of using reporting to disease registries by specialists as a way of recognizing or engaging in meaningful use. That would have the dual advantage of giving specialties a specialty-specific set of measures to report as well as creating incentives for specialty organizations to work at developing specialty-specific measures, which many have done, but not all.

Are there any other points of that nature that people would like to get on the record? Yes, Gayle?

**Gayle Harrell – Florida – Former State Legislator**

Yes, I want—if you could clarify, please, if you must meet all measures for payment or if there's a percentage of measures you must meet for payment.

**David Blumenthal – HHS – National Coordinator for Health IT**

Any comments on that from the working group?

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

Well, I think ultimately, CMS will, through their rulemaking process, decide some of this. I think the workgroup recommendations is that they would meet all of them—the **module of**—the comment of “There's some that don't apply to some specialties.” So all the ones that are relevant—I mean, that's a conceptual framework—would have to be met as part of the recommendations.

**David Blumenthal – HHS – National Coordinator for Health IT**

Okay. Any other questions? If not, I would like to ask whether there's any objection to adopting this matrix with those caveats and recommendations for future work, adopting this matrix as a recommendation. And maybe, Jodi, I should—I don't know if I should step aside in making that motion—or making that suggestion and Paul should do it, or whether I should—doesn't matter? Okay. So [laugh]—so anyway, are there any objections to adopting this by consensus?

**Gayle Harrell – Florida – Former State Legislator**

The comment I would like to make once again is that I have a great fear of these time frames being very aggressive. I think as we move forward—and I will be part of the consensus, but I still want to note that the CPOE time f—implementation and the time frame for this and the time frame for both providers and hospitals to meet the definitions of meaningful use sets up a very high bar, and I have a great fear that we may have people not adopt.

**David Blumenthal – HHS – National Coordinator for Health IT**

Just for clarification, I think that's a fear that was widely shared in comments and certainly one that is very pertinent and appropriate. There—by using the adoption year criteria—or criterion, how late could someone adopt—or an organization adopt and still be eligible for incentive payments under the meaningful use standards?

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

According to the chart, it would be 2014—could be on the Medicare side.

**David Blumenthal – HHS – National Coordinator for Health IT**

So that would provide 5 years.

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

By the statute, if you started in 2014, you would only have 3 years left, because there's a final year. In 2016, that's the final payment year for—again, for Medicare.

**David Blumenthal – HHS – National Coordinator for Health IT**

You'd have 3 years left to get compensated, but you would [inaudible].

**Unidentified Woman**

When it's the final year, you can adopt to receive full payment.

**Unidentified Man**

So 42 months maybe potentially for—

**David Blumenthal – HHS – National Coordinator for Health IT**

2012.

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

Can you ask the question again, please?

**David Blumenthal – HHS – National Coordinator for Health IT**

The final year you could adopt and get full payment.

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

Oh. That's 2012. That remains unchanged.

**Unidentified Man**

It remains to be seen whether you can just make it at the end of the year or not. That will be up to CMS—which would give you 42 months instead of 18 months, which is a big difference.

**Unidentified Man**

Right, that's one of the reporting period issues we're working on.

**Gayle Harrell – Florida – Former State Legislator**

[Inaudible] my suggestion—excuse me—my suggestion on that would be that we lengthen that in CMS—use that—the longest time frame possible under the law.

**Tony Trenkle – CMS – Director of OESS**

And once again, people will have an opportunity to comment on whatever we come out with in the NPRM, and I'm sure we'll get a lot more than 700 comments [laugh].

**Gayle Harrell – Florida – Former State Legislator**

I'm sure you will.

**David Blumenthal – HHS – National Coordinator for Health IT**

Yes, Judy.

**Judy Faulkner – Epic Systems – Founder**

And the other thing I think that I'm hearing health care organizations say—the academics of clarifying if they are certain structures of academics with employed physicians—do they qualify or not? That's a big question for some of them.

**David Blumenthal – HHS – National Coordinator for Health IT**

That's fortunately an issue that doesn't come before this committee.

**Unidentified Woman**

What does that [inaudible]?

**David Blumenthal – HHS – National Coordinator for Health IT**

It's a CMS rule.

**Tony Trenkle – CMS – Director of OESS**

It comes out in the rulemaking.

**Gayle Harrell – Florida – Former State Legislator**

Will there be a time—when will that be done?

**Tony Trenkle – CMS – Director of OESS**

Rulema—the NPRM, the Notice of Proposed Rulemaking, will come out in December of this year.

**Gayle Harrell – Florida – Former State Legislator**

Okay.

**Unidentified Woman**

I have a question, too.

**David Blumenthal – HHS – National Coordinator for Health IT**

Can I exercise the Chair's prerogative—

**Unidentified Woman**

Yes.

**David Blumenthal – HHS – National Coordinator for Health IT**

—to rule that—I don't know what the—how the Congress would term this, but—to raise a point of order, you know. So I think we have so much to do that I'd like to keep us focused on what we need to do today. I didn't hear any objection to adopting this by consensus, though I did hear Gayle's request to include in

the record her reservations about the time frame and her suggestion to Tony and his colleagues that a longer—that the interpretation of the time frame be as generous as possible. Hearing no objection, I consider these rules adopted by consensus—or these—this matrix adopted by consensus, and I appreciate the committee’s attention and their diligence and especially, again, both the ONC staff and the working group members and Paul and George and Farzad—John Glaser, who may be listening in or may not be. Thank you all very much again.

Okay. Let’s move [applause]... If we’re running 15 minutes late—but our next topic is no less complicated, though it is—goes by a different name, and that’s the question of health information exchange. The Health Information Exchange Working Group has been working just as hard as the Meaningful Use Working Group. Deven McGraw and Micky Tripathi have chaired that group. It looks like Micky may—is Micky here? Yes, he’s here. Great. We wouldn’t want to leave Deven just carrying all this by herself.

**Deven McGraw – Center for Democracy & Technology – Director**

Yeah, I’ll kill him if he doesn’t show up [laugh].

**David Blumenthal – HHS – National Coordinator for Health IT**

So welcome, and we know you have a presentation, and we look forward to hearing it.

**Deven McGraw – Center for Democracy & Technology – Director**

We do. Thank you very much. We—our lack of a slide calling out our other workgroup members should not be indicated as a—to be a lack of appreciation for their significant contributions to what we’re going to say today. At the risk of leaving somebody out, I’m going to go ahead and do this: several from the policy committee, including Judy Faulkner, Gayle Harrell, Charles Kennedy, Connie Delaney, Latanya Sweeney, myself, Micky; we also have Dave Goetz from Tennessee, Marty LaVenture from Minnesota, Jonah Frohlich for California... did I get us all?—and the quite able assistance of Kelly Cronin from the Office of the National Coordinator. I think I got it. Okay. Thank you. That—hopefully that bodes well for this presentation.

All right. So on our agenda today, we’re going to talk a bit about health information exchange—and really, what we’re talking about is “information exchange” as a verb—and meaningful use. Really, the first set of things that we’ve done as a workgroup is try to contribute to this discussion of what constitutes meaningful use and what pieces of health information exchange are going to be necessary in order for providers to demonstrate meaningful use.

After the brief presentation that we gave at our last committee meeting, there was a lot of questions from policy committee members about the general landscape of HIE—what’s going on out there today, which is, of course, quite relevant to what our expectations can be and what our recommendations would be for 2011, much less in subsequent years. And we do have some recommendations to go through today for health information exchange with respect to meaningful use.

So with that, we’ll get to sort of what—so what’s the scope of decisions that have to be addressed? So here you have—again, we have a set of policy objectives that we need to meet and, of course, what the Meaningful Use Group has teed up for us. And what we just approved is a set of meaningful use objectives and measures. And one of the first things that we did as a workgroup is to provide some informal feedback on that approach, particularly with respect to the implications for health information exchange.

Essentially, the—again, we—as we’ll talk about in a little bit in this presentation, we’ve identified essentially that there are some key information exchange functions that are necessarily going to be needed for effective meaningful use. And of course, in order—consequently, there also need to be policies and requirements that facilitate that exchange in order to make it happen. At the same time, you also need to have the EHR functionalities as well as EHR policies and requirements that go along together. At the end of the day, what you hope to achieve with all of this is, in fact, meaningful use by these providers so they can get their payments. And even more importantly is meaningful use measure—

being able to measure and report this through these systems, ideally, rather than through mere self-attestation.

So what we've been able to accomplish is essentially—as a workgroup, is really, again, providing the feedback and starting to identify some of the HIE—both functions and policies that will need to be put in place. You know, ideally, there are a lot—many more questions that need to be answered in subsequent months. Whether we as a workgroup will have an opportunity to do that, I think, in part, depends on the aggressive timeline, over which I know we don't have really any control, so... [laugh].

So moving along—so again, we have—again, we've just been through a very good presentation and session on meaningful use. There are objectives and measures that involve HIE and some that do not. So since we're the Information Exchange Workgroup, we didn't really focus much on the ones that didn't. Essentially, there are some that really require health information exchange to be done, and there are some that would really be enhanced by HIE in order to make them really, truly effective or meaningful. (I hate to use that word.) But again, that's really been the primary focus of our workgroup.

And maybe even most importantly, you know—that the ability to both conduct and really measure meaningful health information exchange is going to strengthen the effectiveness of these objectives and measures. Paul, in his—in your earlier—in the presentation, you talked about how the clinical decision support was sort of a key lynchpin of meaningful use. Well, I would put information exchange either equally up there or maybe the close second cousin.

You know, looking at the previous matrix we had identified, again, there—you know, of the 94 objectives that were in the initial definition, which hasn't changed really appreciably that much, 42 of them seem to involve health information exchange, without a lot—a huge difference between the inpatient setting and the outpatient setting. And more particularly, in this slide, we kind of broke up the categories of meaningful use into those that really would specifically invoke HIE (health information exchange) and those that would be better enabled with health information exchange. And again, since we're on a little bit of a tight time frame, we'll let the slide speak for itself.

But really, for the most—the more important point being, for each of these and, again, maybe even be for others—I don't know that we even got this list exactly right. You know, how much do we really want to specify the way in which this happens via health information exchange; the way we measure that it's happening via health information exchange; and whether it happens through participation in some sort of formal exchange organization, which we're going to call an HIO in order to distinguish it—the noun form of “health information exchange—organization” versus exchange, which really—when we say that, we mean the verb form—or whether, in fact, it happens just through point-to-point transactions?

And so, we really started with a threshold question of “Is it really necessary at all to set any particular exchange requirements in order to make the meaningful use that we want to see happen and that we all just endorsed—to see that actually come to fruition?” And you know, the reality is that the market just hasn't responded as quickly and effectively as needed in order to have exchange today, even among those providers that actually have adopted electronic health records. And our sense as a workgroup was that meaningful use could be significantly strengthened and focused with some level of policy and technical requirements related to exchange. We think it could lower the cost of interoperability, lower the difficulty of actually achieving interoperability—those are obviously closely related—and then really raise the bar on achieving the public policy goals that are identified so persuasively and clearly in the meaningful use matrix.

And so, in trying to decide what these sort of HIE requirements might look like, you know, we sort of start from first principles. Obviously, there are many models of exchange in place today, but there are some sort of consistencies across them. You know, what we have today is a very large installed base of disparate, heterogeneous systems; a fragmented market with significant State and local variation; rapid and unceasing technological innovation, which is, of course, good and also challenging; rapid and unceasing market structure change; looming health care reform—I mean, all of these are things that we don't have any control over but have to take into the account in our recommendations. And, essentially,

we want to create a framework of policies that allow us to meet the goals and the vision of meaningful use through exchange; enables information to follow and benefit the consumer really across continuums of care; incorporates privacy and security protections; creates conditions that the Federal Government must take into account; still recognizes and allows for local market variation, because that's not going away, and in fact there are a number of us who believe that's a good thing; does not inhibit valuable technological innovation but instead actually channels it in a way that makes it easier to meet the goals of meaningful use; and, to the extent possible, builds on what's already been done in the past in order to minimize market confusion and not, you know, try to reinvent the wheel.

So with that, I'm going to turn this over to my partner in crime, Micky, so he can take us through what does HIE look like today.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO**

Great. Thank you, Deven. So, you know, one way of characterizing what we're—you know, what we're doing here before launching into this description of the current landscape is that the—you know, the what, the when, the why, and the who are essentially given to us in many ways. And what we're really focused on is the how.

Now, you know, it is certainly true, however, that the how can actually affect the what, the when, the why, and the who, right? Yeah [laugh]. What? But you know—that the degree—to the degree that you can make the how easier, that can, you know, raise the bar on some of those other things. And Who's on first, and What's on second, and—I forget—What's-His-Name's on third.

So first, just, you know, a short description of the current state of health information exchange: You know, there is a lot of health information exchange that happens today. We're certainly not saying that nothing happens. Yet the vast majority of it occurs in a relatively small number of transaction silos, such as labs and e-prescribing, you know. And even though those constitute millions of transactions, you know, the penetration of e-prescribing today is—even that, as a well developed silo, is really quite low when you look at the denominator, in terms of percent of overall prescriptions. So we have a long way to go.

The barriers to adoption are, you know, very, very complicated, but they're high because of technical and transaction costs. The technical costs are, you know, certainly there, and they're real. Standards harmonization is indeed happening—progressing quite rapidly. You know, a lot of the work with HITSP, other organizations—that is progressing rapidly. However, I would say—and we would say, I think, the market and/or regulatory enforcement mechanisms are still lacking. So you can have quite robust harmonization of standards, but at the end of the day, the question is, how do we monitor and enforce those standards being used?

And that's very different than billing codes, for example, because those transactions are monitored every single day. Every single day, millions and millions and millions of ICD-9 and CPT-based claims are filed with commercial health insurers and with Medicare and Medicaid. And there is—as a part of the work stream of getting the work done, there is that built-in enforcement mechanism around that—a built-in monitoring and enforcement mechanism that keeps the system together. That is not true for lab results delivery. It's not true for most clinical transactions. There is no monitoring—robust monitoring that's a part of the workflow, which makes this fundamentally different in certain ways.

The transaction costs are also high, because our health care delivery system is so highly fragmented, and that makes it different than any other part of the economy. So while there are a significant number of organized—there are also a significant number of organized health information organizations, as we would call them. I think, as we all recognize, those are in various states of maturity, and each of them very significantly as well, right? So, you know—so we've got a lot of variation out there in the market today, and penetration is low and non-uniform.

So, you know, I think that, you know, what we're going to do now is talk a little bit about the models, really just to educate all of us on, you know, what—if we were going to characterize in very simple terms what are some of the key, you know, parameters or factors affecting the market—and they really affect our—

the policy decisions that we think are in front of the policy committee today—we really want to present the models. Now, this is responding to the Chair's request from the last meeting to have a picture—some pictures. And though we were tempted to fly out to Indianapolis and stand with Mark Overhage in front of the Regenstrief building [laugh], smiling with him, we thought that that probably wasn't the spirit in which that request was made.

So what we've done here is try to make some illustrative models. I will point out before walking through those that these are not normative models. The committee—you know, the workgroup is not saying, "This is how the world should be." What we're saying is, "Here are different representations of how the world is today and how the world might, you know, seem—if it follows current trends, might head." So it's really, you know, in that spirit that we might just sort of offer some of these models just to explain, you know, what it is we're talking about.

The first thing I'd like to do, though, is drill down to the transaction level just to—you know, just to talk a little bit about some of the complexity here, which is about the technical and the legal and business, you know, obstacles that face us today. And the main obstacles are really—in data liquidity are not only technical, but they are, you know, significantly about business and legal issues, which are harder to, you know, grapple with from a, you know, government policy perspective. We can—you know, we can focus a lot on technical standards, but at the end of the day, there are these other threshold issues that—you know, they must be overcome in order to have better data liquidity.

So if we were to just sort of look at a representative, single interface transaction from a sending system A to a receiving system B, you know, you've got to walk through a certain set of considerations. And every single one of these, you know, you've got to go through in some way, shape, or form. For example, message content and content standard: What is it that you're trying to communicate, and are you going to send it in a way that the receiver is going to understand? There are different levels of understanding. Human understanding is a lot more forgiving than machine understanding, so that's one of the things that you have to walk through.

The next, you know—and these aren't necessarily in order—are consent for the transaction you're talking about. Do you have permission to do that type of transaction? And that varies by State, I think, as all of us know, and that varies somewhat by the clinical transaction that you're trying to conduct. Some of these things are kind of packaged in the transactions that happen today. So, for example, lab results delivery: We don't think of there being formalized consent around that, but in—you know, for all lab results delivery, there is consent somewhere along that chain of events. However, for [inaudible]—on all of that, because it's within a referral relationship; it's within a particular episode of care that that happens in a way that's a little bit behind the scenes, for the most part. However, when you start talking about clinical summary exchange, about persistent data sitting there readily available outside a particular episode of care, that's where you start getting into these more complicated permission environments. And so, that's why there are some qualitative differences, as we start thinking about where meaningful use is headed and how permission might play a bigger and bigger role there.

So communication standards: Again, you know, I can communicate a message in a certain way. Is the receiving system going to be able to get it?

Authentication: How do I know whoever is knocking at my door is someone who I want to be—or who they say they are? And that happens at the entity level. I may know that that is a computer that is within Beth Israel Deaconess Medical Center, and I'm sitting as Partners HealthCare, and that is okay. The next-level question would be there on the right: Am I okay with the policies and technologies within that system that allows users to access the system? Again, these are—you know, some of this is more art than science, but these are very real business questions that every single organization faces today in thinking about this. It isn't just a matter of sending a message to that other organization and assuming that because they receive it, everything's okay; they open the door and "Let's do it." There are a lot of overhead there.

So, not to go through every one of these, but there are some overarching concerns as well, some of them about record location. As you start to think about this happening more and more and more across more and more points of exchange, how do I even know where those records are? A patient shows up at my door who's scheduled to come to me. I really don't know where all of his or her records are. How does that happen today? You know, with labs, it's relatively easy. You start thinking about these other things, it starts becoming harder and harder.

Entity clinician patient matching: Again, how do I know that that record at that other place is from the same physician when we have a lot of, you know, variety in the way those are represented?

And then finally, data use agreements: Again, we tend not to think of these that much when we think about lab results, e-prescribing... There is a data use agreement in there; it's just one that is relatively industrial standard and that we all agree to relatively implicitly. However, as you start getting into more and more areas of clinical transactions that are outside of those, you know, kind of well-defined areas, data use agreements become more and more complicated. And in a point-to-point world, you start thinking about having to do that every single time; it starts imposing a cost on the individuals driving that transaction.

So I'm going to walk through four models here, and I'll do it very quickly, because I know we're pressed for time. But they're really, again, just illustrative. I'm happy to go down to any details.

So what we've done is, for those four models, sort of articulated three levels, where you have a national level, State and local level, and then a care setting level; and then sort of, you know, laid out, you know, the possibility of two regions. Now, those could be care markets, you know—"care coordination zones," they call them in New York—I mean, however they want to be represented—but the idea is it's a relatively self-contained health care market where the majority of patient encounters for an underlying patient population might occur. And then we've, you know, sort of represented their EHR systems, which would be, you know, either in a hospital or in an ambulatory setting; local radiology and lab results—and the reason we've pointed those out is because, if you look at the market structure today of lab results delivery, for example, a lot of it happens locally, even though we do have large national vendors like Quest and LabCorp. In most States—or in many, many States, the vast majority of lab results are actually delivered locally, and so that's got to be a consideration.

And then finally, we have e-prescribing: Right now, Surescripts are [inaudible] the source of national e-prescribing. There could be other models going forward, but, you know—but that is a national-level service now.

So as we think about, you know, point-to-point, the—you know, the reality of that is—and this is really illustrative, and—is that, you know, those are just as you would describe—just as you would think of them: point-to-point considerations. Now, it's not as if every single one of those points has to happen. Trading partners would identify who are the trading partners that they find important, and they will then, you know, engage in, as we were showing before, all the details of that transaction and, you know, with all of the complexity of doing that.

Where health information exchange happens today, this is how it happens. Now, the cost that we bear, I think, you know, is one thing to—for us to think about here—is that the costs that we bear are either, you know, the costs involved in every one of those individual point-to-point transactions—so, as we noted before, some of those are technical issues. Some of those are the business and legal costs that are associated with every one of those. You know, I think we would argue that the real cost, though, that society bears is that we don't do most of these, because they're so hard to figure out. And that's a larger cost I think that all of us bear.

The main advantage, I think, is that, in principle, this kind of approach is an option that's open to everyone. In principle, this is open to everyone; you don't need any other outside network; you certainly need access to broadband. But then—and then you would, you know, to the degree of your own

capability, have to figure out all those issues around standards and then data use agreements and all of that. But in principle, this is an option open to everyone.

The disadvantage, obviously, is that with the current technology and business constraints, there are limits to how much value can be obtained from this. When we start thinking about, you know, public health reporting or quality measurement with normalization of data, for example, it's hard to start—you know, start understanding how that could happen in this kind of environment.

The next model would be what we would call hub-to-hub. This is—you know, so we'll start with the same picture, but then we'll, you know, move to thinking about what is actually happening today in the market, which is EHR vendor hubs that are starting to deal with this question. So you have different EHR vendors and other types of vendors, but in this case, we're just representing EHR vendors that are actually standing up local hubs. As were represented here—I don't know if this is going to work here—you've got—some hubs are actually almost—can be national, so you can have a national EHR vendor hub that's really connecting up all of the individual installations. Other vendors have gone for more of a community or local approach, where they'll stand up a local hub that will connect up the underlying, you know, EHRs underneath.

The main advantage of this is certainly that it's aligned with where the main market players are headed today. And you know, to the extent possible, obviously, we want to be able to align ourselves with what the market is doing on its own. You know, the main disadvantage, I would argue—and there are many, man, you know, advantages and disadvantages here, so I don't want to say that these are the only ones—I would argue that the main disadvantage of this is that it starts to hardwire parts of the system behind proprietary walls. It, you know, certainly provides some advantage in terms of that aggregation happening in the market, but again, you don't have visibility and connection down at the point level, which may, you know—which may be a factor as we think about other things we want to do.

So, you know, obviously, the clinical exchanges start to happen more and more through these hubs and start getting mediated through the hubs. You could have a lot of variety around how a national lab provider, like a Quest, either provides to the hub or provides individually to the EHRs down at the database level. The mar—right now, in the market, you see every variation out there, in terms of the way that's delivered.

Same thing with community labs—you see the same thing out there. Some of them are delivered in some markets into that community hub that's created by the EHR vendor. Sometimes they—even though they have that hub, certain labs will just deliver point-to-point. It's, you know, still very complicated and still very market specific—I think, is probably the point at the end of the day.

E-prescribing, again, is the same way. Some vendors do that through a centralized hub that—and then some vendors do it, you know, down to the database level. Again, you know, I think the point is that there's a lot of variation across the market, but this is just to point out that there—this is one way in which the market is moving to aggregate some of this stuff in the ways that we've been thinking about.

Third and fourth would be about some type of mediation by either a State or local-based health information organization or a national one. And let's just move first to the State or the local HIO mediated. So we start again with the same picture—trying to make sure that we don't lose anyone along the way here. And the idea here is, you know, what we think about as RHIOs, to use the old term, right?—so the standard kind of view of a health information organization that's State or local based.

Let me move through this quickly. I think that, you know, this picture is probably one that's familiar to most people—that the transactions start to go through that hub. There's a lot of variation in that. It isn't as if those are simple solutions. And you know, there is a lot of variation there, but the idea is that that starts to aggregate more of that.

And the final point that's different than the others is that those HIO hubs can actually then or, you know, indeed ought to be required to connect all of the underlying points via HITSP-compliant, NHIN-mediated exchange, right? So that would be the idea of how you would scale that up to a national level.

Let me move quickly to the next model, where—you know, there's a little bit of variation on the last, but the reason we want to raise it is because it does inform some of our recommendations as we think about this later. One of the, you know, problems with the HIO-mediated approach is that it is—one of the advantages is that it's a more open approach to network development rather than have it be, in a lot of cases—be behind proprietary wealth. One disadvantage is that HIOs are not mature. And they also are highly varied, and they're not widely available. So if we were to start to think about health information exchange as it relates to meaningful use, you would put—be putting out a model that the vast majority of physicians are not able to access immediately. And that would present, obviously, a very practical problem.

It's also fair to say—and this is probably an understatement—that sustainability is still unrealized for most health information organizations. So that's, you know, obviously another concern as well. You're not really aligned with where the market by itself is—you know, is headed in many cases.

As we think about, you know, another variation on this kind of approach, one of the reasons that we think about a national—the opportunity for a national health information organization is that if we were to say that health information exchange, as it relates to meaningful use, ought to happen through organized health information exchanges or that it could be facilitated, you could see the market itself start to develop different types of options. And one would be sort of a national health information organization option. So, for exam—we already see that a little bit, to the extent that you have affinity groups, like the AMA, with their deal with Covisint.

And you also have single silo companies right now, like Emdeon, Quest, SureScripts, RxHub, that provide this kind of exchange at a national level via a silo. If we were to start to say that health information exchange related to meaningful use has to happen according to a set of requirements through an organized network, any of those could expand to accommodate those other types of transactions and offer that as a service, right? There's no reason that Quest or LabCorp needs to be restricted to lab results delivery; that just happens to be what they do today as a part of their business. If a requirement was imposed that said that they—that clinical summary exchange is a requirement for—according to a certain set of standards, is a requirement for providers to demonstrate meaningful use, there's no reason that they couldn't expand and say, "We can offer that service on—you know, on a pay model and all that," and expand their network to do that. So it allows, you know, the opportunity for them to innovate in that way.

Some of the main advantages of this kind of model would be that it offers some of the benefits of HIO-mediated exchange to literally anyone in the country. Even though you may be in a State or a region that doesn't have one of what we traditionally think of as RHIOs, you could have Emdeon offer that service to you. And as long as you had access to broadband, presumably you would have access to that service nationally. And indeed, maybe that's how you would see those developed—that those national organizations start to target areas that don't have those kinds of, you know, traditional RHIO sort of organizations.

So the main disadvantages are that—obviously, that it's not mature yet, and it could create considerable market confusion in distracting competition—let's call it—in the near-term as people start to think, "Oh, is Quest already—you know, I thought they only did labs. Now are they doing this other thing?" All right.

So some key policy questions that arise from these models that really inform our recommendations, you know: What do these models suggest? You know, first off, you know, some of the key policy questions that came to us, I think, are, what are the policy and technical requirements that are needed to make meaningful use real? And how would these requirements be monitored and enforced? And we started to think about these questions as we thought about these models. What's the role of formal health information exchanges in facilitating this type of exchange? Should it be required—should the exchange

be required to meet certain meaningful use criteria? And if so, what are those criteria, and how do we ensure that? How much jurisdiction should the States have vis-à-vis the Federal Government here? And we'll get a little bit into that when we discuss the recommendations. And then finally, how can this approach be pursued without overly hampering market innovation?

Let me move quickly here to—now to turn it over to Deven for a beginning discussion of the recommendations.

**Deven McGraw – Center for Democracy & Technology – Director**

Okay. Now's the really interesting part. That was all [inaudible]—you had to hear that, I think, for any of this to make sense. And I had to give that to Micky, because it's really highly complicated [laugh]. But really, you know, the bottom-line is that sort of those different models that Micky presented—they're not going away, and in fact, we need them to be there in order to facilitate exchange. But at the same time, we need some core exchange criteria that are going to apply in order to make sure that we get in 2011 what we don't have today, which is the ability for data to be exchanged among providers that are in sys—different systems and using different models, whether it's an HIO or point-to-point, hub-to-hub, or through some sort of national vendor.

And what would these core requirements look like? Well, communication standards or transport standards—content standards. The—you could probably loop both of those under the broader umbrella of interoperability. And I know we're going to hear from the Certification Workgroup a bit about that. But we, you know, would underscore that that's obviously critical. If the—if proprietary interfaces continue to choke off our ability to exchange data, then we're really going to be in trouble.

Privacy and security: We raised a little bit the opt-in discussion—or opt-out, and it's a complicated one. But clearly, there are some policies that need to go along with this. It's not just about the technical aspects of it. Resolving this is critical. How are we going to monitor or enforce any policies that we put in place? And these legal business and even governance issues that—you know, if you talk with folks that are try—that have tried to stand up, some of these networks are even more complicated often than the technology.

So that really leads us to a set of recommendations that are kind of in four broad criteria—four broad categories, and we'll go into these in a bit more detail. But in general, we think that the meaningful use objectives and measures that involve health information exchange really need to be bolstered with exchange requirements that are technology and architecturally neutral so that, again, they apply to exchange regardless of what model it takes place in—and that really apply to all of the participants.

And the second bucket, again, is that Federal policy really needs to facilitate any network approaches that will make it easier for participants to meet meaningful use requirements. And that would include the ability to actually report in a verifiable way that they're actually meeting these requirements in a way that is stronger than mere check-the-box adherence.

Third category is that the Federal Government should certify both networks and products that meet the meaningful use exchange requirement to ease the burden on physicians for meeting and demonstrating adherence with those requirements, again.

And then the final category is the—sort of the federalism point: Federal and State government approaches to this really need to be complimentary. I think all of us are aware that while we spend a lot of time talking about the incentives that are going to be driven down to individual providers, there are other pieces of the economic stimulus legislation that involve building of the infrastructure; and that in some respects, much of what we're talking about today is marrying those two aspects.

So without any delay—get to more details on what those requirements would look like.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO**

So thanks, Deven. I mean—so, you know—so as Deven described, I mean, at the end of the day, it is our feeling that HIE is necessary, but the requirements are necessary to make it easier and to make sure that it's done in adherence with State and Federal laws. It's also true that HIEs can make meeting those requirements easier for individual participants, but—because they can provide a bundled approach to health exchange, and they can ease the monitoring and reporting for individual participation and for CMS, which I think is an important consideration here as well.

The problem, obviously, with HIO-mediated exchange is that they're not widely available. And they may add a degree of overhead that some individual participants just don't want to have to deal with, whether either paying for it or just being a part of it. So our recommendation is that health exchange be subject to a set of requirements that are neutral, as Deven said, but allow both the government and individual participants to take advantage of organized network solutions where they exist.

So, you know, the first set of recommendations we talked here—talked about here are just that: that—you know, that it's a little bit of a process point on the second and third bullet. The first, I think, has already been expressed by Deven. The second two are really about the interconnection between the work of these various workgroups. So we have, you know, our workgroup, Meaningful Use, and the EHR Certification Group. And because of all the—you know, the burden of the timelines and the incredible amount of work that was required up until now, those have operated relatively separately. So, you know, one recommendation would be that as the policy committee moves forward in thinking about an integrated recommendation—that we have a little bit more coordination—

**Unidentified Man**

We need some information exchange between the groups. Is that—

**Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO**

Yes, exactly [laugh].

**Unidentified Woman**

It'll have to be certified first, but...

**Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO**

We can make it standards based. We'll create the standards very quickly [laugh].

So, you know, the second point is that—is really that such requirements should be part of certification and be a set of—be part of a national level and enforced through provider-specific reporting and clinical exchange activity. As we have said, that can be architecture neutral and technology neutral so that if you're a part of a health information organization, that certification would be that that health information organization is able to perform those transactions according to the requirements that have been laid out. If you decide not to participate in that, you could have a certified EHR system that is capable of performing those on a point-to-point basis.

Now that—as we've pointed out, there are a whole bunch of legal and transaction issues—to cause issues that would then be the burden of the provider, who chose that route. However, from a technical perspective, the EHR could be certified to do that. And also, the EHR could be required to add functionality for reporting to actually—so we would—so that we're not in the world of having to have a single provider level at a station that they are doing this—that goes beyond merely providing them or having them certify that they have the capability to do it, but they should actually be able to have to demonstrate—it would be our view that they have to demonstrate they're actually performing these exchanges and provide some robust reporting to CMS for that, in return for the \$45 billion that they're going to be getting as a group.

The certification requirements should, at a minimum, address the following categories. I think Deven's gone through those. We'd be happy, in the Q&A, to dive down into details of that. The devil is obviously in the details here, so we don't want to pretend these are easy, but we're just at the—right now at the point of just being able to name the categories.

We would, you know, recommend that this certification be at the product level, as I said, for exchange that occurs absent a formal exchange infrastructure, or at the HIO level. That would allow providers to choose the mechanism that they would like to demonstrate that. So we're not saying that it's dictating a health information exchange organization-mediated exchange; we're saying that the—that a provider ought to be able to be able to choose how they do it. And you don't change the requirements just because they choose to either participate in the health information organization or not. But the requirements are the requirements, and then they can choose the vehicle that they want to use to meet those requirements and to demonstrate to CMS that they have met those requirements.

The other issue here that's a complexity is that States may impose their own State-level requirements on information exchange to satisfy State-level meaningful use definitions. And our recommendation would be that to qualify for meaningful use information exchange, the State must meet Federal requirements to qualify for Medicare meaningful use, and they may also be required by a State to meet State-level requirements. So the idea would be here that within a given State—that certification for exchange that's mediated over a health information organization would be fine from a Federal perspective, as long as the State is essentially choosing HIOs that are already on the Federal list.

So if the Federal Government certifies a certain set of health information organizations—let's say it's the SHNY in New York and NHIN in Massachusetts and Emdeon and SureScripts at a national level—that in Massachusetts, they would be able to choose any—from any one of those as long as they're already on the Federal list, because we don't want to have a disconnect between States certifying health information organizations at a State level that would not allow a provider in a State to use that health information organization to also qualify for Medicare meaningful use. You want to be able to make sure that that's lined up—but also recognizing that States have varying needs around what they want with respect to health information exchange at the State level. So we try to strike that balance there.

So... sorry, I keep moving on my computer and not on the screen. So finally, we would recommend that "proof," quote-unquote, of meaningful use be also incorporated within that certification generated by a certified network or by a certified EHR system, which again gets us to a point of having more robust reporting down at the provider level of the exchange that actually happens, rather than either having, you know, blank self-attestation—or blanket self attestation or having a representation just that they have a system that is capable of doing exchange but may never do exchange, even though it may very well be capable.

So, you know, finally, I think this has benefits both for the provider, because it allows them the opportunity to choose the way they want to do it, but allows them to use—health information organizations were developed to make it easier for them to do that. It also has a lot of benefits for CMS, because it allows them to have more robust reporting than they might otherwise have, but have it in a much more efficient way as well than they would otherwise have.

So, in terms of the—you know, the next steps and the future work, I think they're relatively straightforward. One is, obviously, approval of recommendations of the HIT Policy Committee and anything that we can do to help you with information to get to that; and then further development of certification criteria, which I think, as Deven raised at the beginning, is sort of an open question right now about what the next steps are for the process as a whole.

**David Blumenthal – HHS – National Coordinator for Health IT**

Wow! [Laugh, applause]

**Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO**

Did we talk fast enough? [Laugh]

**David Blumenthal – HHS – National Coordinator for Health IT**

The ratio of content to speed was very, very high [laugh]. So these are very, very thought provoking. I think that you did very well with the pictures. As much as I like Mark Overhage, I think these were more informative [laugh] than a picture of him would have been.

The—if you could talk for a moment about two issues, one is, there seems to be a big choice here about how assertive the Federal Government—government in general, but we're talking here about the Federal Government—should be in setting the rules of the road for information exchange. Can you characterize this in term—are there camps or viewpoints on this? And could you take us back to an overview of the sort of pros and cons of the two views? So one view might be “Let the market do this,” and the other view might be at the other extreme. The Federal Government should create an exchange capability; organize it; govern it; and, you know, encourage everyone to participate in it. And then there are probably many variations in between. But what do you see as the tradeoffs between those? I use those as caricatures that you—that are more for heuristic purposes than actually necessarily real choices.

#### **Deven McGraw – Center for Democracy & Technology – Director**

I think—I'll say a few things. I think on the market side, the big question for me is, if we left it completely up to the market, would we ever have a set of circumstances where people could actually exchange data across the country versus competitive behavior on the part of kind of proprietary vendors to try to grab as much of the market as possible with their particular set of communication standards and not be able to exchange with the group, you know, in another part of the country that is actually more vendor driven by another? Certainly the market, I don't think, has gotten us as far as we'd like to be today. And you know, certainly, one of the common themes is, “Yeah, I've got an EHR, but I can't get data into it from the lab that's down the street,” or, “I can't accept data from, you know, the hospital down the road, where I want to send my tertiary care payment—patients.” And that—it really should be unacceptable at this particular stage. We sort of tried that approach, in my view, and it didn't work very well.

The other extreme would be a completely federally controlled system that said, “Here are the ways you have to do it, and there aren't really any—there's no wiggle room in that.” And not all—and that—the danger there—the obvious one is that it stifles innovation and maybe cuts off the forms and mechanisms that people who are already doing this—the pockets of success that we have in the country—but suddenly, you know, we've left them out, because they're not doing it in exactly the way that we prescribe.

So I think what we're proposing is actually a bit of a middle ground, which is to set some standards that give the market a direction to flow in but still allow for the innovation at the bottom with respect to how exchange occurs, but making sure that at least with respect to some core criteria—and again, we haven't really had enough chance yet to flesh those out—not sure whether there will be; I think we'd be willing to if there was time—that's essentially the way I respond.

#### **Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO**

And I think that's characterized very nicely. And I think at the extremes, I think, are the—you know, the view. And some of that's represented, I think, on the policy committee and also on our workgroups. So certainly we welcome that as a—you know, those participants to amplify these points. But one extreme would be to say that all that's—all that are needed are requirements or standards for exchange—that all we would need is a CCHIT-like organization to just have very specific standards, tell the vendors to do that, and then they can connect up. And there's no other overhead that's needed for that—or very little or minimal overhead that's needed for that.

The other—and I don't know if this is the other end of the—you know, of the spectrum from—but as you move more and more and more toward more organized, you know, kinds of forms of that exchange or having more sort of “governance”—I'll put that in quotes—over that is the view that—you know, it's probably a couple of views that drive it. But one is certainly that there is a system perspective that is not taken into account if we just allow that point-to-point type of exchange. And I think that that's made more meaningful in the health care sector than in others, because it is so fragmented, because the supply side and the demand side are so fragmented and—which is unlike any other part of the economy—that it is sort of stating that there is no systemness otherwise, unless you have these other kinds of organizations

that try to take account of some of those market failures to provide more like a utility service, as it were. As one member of our committee, David Goetz from Tennessee, noted in one of our meetings, you know, that would represent a part of that view. I don't want to pigeon-hole anyone, but I thought it was a very good example where he said, you know, "In Tennessee, we allow people to drive on the roads, and they can drive wherever they want, but we don't allow anyone to just create any road wherever they want. We do, you know, want to have some regulation over where people put roads so that it's done in a way that benefits everyone."

**David Blumenthal – HHS – National Coordinator for Health IT**

Roger?

**Roger Baker – U.S. Department of Veterans Affairs – CIO**

At the risk of going down too many analogies here, one of the things I thought was interesting as I looked at your second slide on the hub-to-hub is how much that looks like the way the credit card market evolved, recognizing that there are central places that are not governmental but eventually figure out how to talk together to further the market. And so, I think, kind of going down that path, the conversations that I've heard you talking about, which is—there have to be standards relative to allowing something to occur but not then dictating the market architecture, because we don't know what the right architecture for that will be. And as a—I just find that [inaudible] with that one on a government standpoint. As a government person, I strongly encourage that the government not be the organization to build any of the systems involved in here. Just had—I've just seen that too many times.

**David Blumenthal – HHS – National Coordinator for Health IT**

Yes, Latanya.

**Latanya Sweeney – Laboratory for International Data Privacy – Director**

Counter to the analogy of the credit card market, several of the Internet companies have been very vocal, at least to me, anyway [laugh], about, you know, the fact that they do hundreds of millions of billions of transactions that are ena—that are for enabling. In other words, they're not engaged in the content that's going past; they just provide an infrastructure that enables that content to pass. And their question to me was, you know, "Why don't we do something similar in the space that's health care?" And you know, as a committee, we certainly haven't talked—haven't had a chance to get down to those levels of questions. But you brought up the question, and so—that I wanted to say that would be a role—the issue there is, how do you make the system work as robust as the Internet? And that would enable any of the models that provide it there. What is the piece that you need?

And that answer is that you need some type of master name service. I have to be able to know I have this; that needs to go to a lab. Where is that lab? And I want to know information about this patient. Where is that information? So there has to be some model of a master name server. It has huge privacy implications; it has a lot of issues there. But if there existed such a thing, if we were able to do that and set that up, then, in fact, the rest just follows. The market can decide whether hubs are more efficient than point-to-point, if they can make a decision.

**David Blumenthal – HHS – National Coordinator for Health IT**

Let's see; I have Adam, then Neil... [inaudible]... then Larry... Paul.

**Adam Clark – Lance Armstrong Foundation – Director of Health Policy**

Okay [laugh], I think we've got seven names now after me. So first, thank you, and I hope I'm not speaking out of turn. I was trying to capture everything you were saying in the models. I just have two things that I'd like to bring up. So one is, you mentioned consent in there a couple times. And this is just something that we face, particularly in the cancer world: considerations for consent when somebody's a minor, versus after they turn 18 years of age. I don't know if it's being discussed; I don't know if this time is the appropriate time to discuss it, but—wanted to bring it up. It's a point that's going to be very challenging when electronic records are floating around hubs if someone doesn't want them there.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO**

Deven says she's got that one [laugh].

**Adam Clark – Lance Armstrong Foundation – Director of Health Policy**

She's got that covered? Fantastic [laugh].

Secondly, this is more of a comment that what—and I'd like to get, actually, your comments on. When I look at each of the models—and I understand the different points of information flow and where you were going—what seemed absent to me was where the patient was in that, particularly as we look at 2013, where personal health records start to come into play. I saw things funneling into an EHR. I didn't see the back-and-forth between the patient—either the patient and doctor or the patient and other patients. So I was wondering if you could just comment on that and what some of the perspectives would be as far as impacting those models.

**Deven McGraw – Center for Democracy & Technology – Director**

You know, I breezed through some of those earlier slides pretty quickly, but in terms of where we identified the need for exchange and exchange requirements among meaningful use, the exchange with patients was included in that list. It just, I don't think, shows up as well in the—with your model creation. But that was always in our mind: that essentially what we're talking about is getting data out of where it sits and into the hands of the person who needs it, whether that's a provider who's taking care of the patient subsequently or the patient. So...

**David Blumenthal – HHS – National Coordinator for Health IT**

Neil.

**Neil Calman – Institute for Family Health – President & Co-Founder**

I guess my statement is—and question is similar to that. I think the diagrams, Micky, are incredibly helpful. Thank you. I finally believe I'm beginning to understand some of this stuff.

I think there's two things that are confusing to me about them. One is the place that the patient plugs in. So I don't understand in the various models. And then, we're not—whether you're a patient or a provider, what we're not plugging into is a discrete packet of information about a prescription or a lab test. The thing I think we've been talking about is, how do you create a meaningful view of what's in all of the data, and how does that get passed around? So it's not—I can understand from the diagrams how a prescription gets passed around—or information about a lab test, but who's consolidating the information into a meaningful view that I, as a provider, would look at in any of these diagrams?

And then, also, who's creating the—what would—I think would probably be a different meaningful view of that that a patient would want to access? In other words—and because I think that there's some thought and processing that goes on there and some decisionmaking—and those views might be different, so I guess the corollary of that is, do we want to say something about what those views should contain for—so that patients have sort of a common expectation about that and that somebody doesn't just sort of plug in somewhere and the only thing that's available to them is a lab test or a summary? I think we need some minimum standards about what should be accessible to people. And I know in the provider community, there's a lot of push back about, you know, what things they want people to be able to see of their own. But we've come out before saying people should have access to everything. So the question is, how does the everything view get sort of passed around here?

And I really think the diagram should include those two things: that—the sort of comprehensive view, whether you call it a CCR or however you want to call—a comprehensive care record; and then also a patient view. And figure out—part of the diagrams are figuring out how those things get moved in these various models and in other models that might exist.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO**

Right. So, I mean, I think that's—I think those points are fair, Neil and Adam also. So just a couple thoughts: one is, you know, it's certainly true that we could—you know, we could add the patient—you know, patient portal—patient-facing technologies in there as a part of that. Not much of that happens

today, although those—you know, they are available, so, you know, I think we can do that. I—you know, I think it's also true that those don't become truly robust and truly meaningful until you have the provider systems actually exchanging information; otherwise there's nothing in them, right? So—but I think it's a very good point that we should add that.

The second—I think Neil, too—and this is my view, and Deven, you know, can express whether she agrees with it or not—is that I think a part of that consideration is back to this issue of what are we doing versus the other groups—that as I said, you know, we're really focused on the how. And we're not, you know—and I think we didn't get a chance yet to go into the details of the requirements. So I think in that consideration would be where we are then answering the question of what is it you want accomplish at the end of the day, and then we could think about, you know, what might be the various ways of doing that and how requirements would feed into that. But we didn't really see that as a part of our, you know, sort of mandate right now.

**Deven McGraw – Center for Democracy & Technology – Director**

In other words, we laid out the—we wanted to lay out, as a first matter, that having some requirements associated with exchange should be part of what gets considered with respect to meaningful use, fully recognizing that what would those requirements look like is another, very complicated question that would require some time to unravel, but we certainly couldn't do it by today. But that's why I'm taking notes: in case we have to do that next [laugh].

**David Blumenthal – HHS – National Coordinator for Health IT**

We agree it's very important. Absolutely agree with that. Okay, Larry?

**Larry Wolf – Kindred Health care – Senior Consulting Architect**

So that's a great segue to my question and comment—is what we need to do to actually make this engage. There certainly are examples of the early credit card systems that were closed—proprietary. There were a lot of things—companies trying to provide e-mail services or online information services to people. And suddenly in the mid-'90s, we had the Internet happen, and we started creating network effects. And it was huge explosion in the presence and availability and value that people could get out of this.

So I guess my question is, what do you think is missing? So we have meaningful use that hopefully includes leveraging the network capabilities. But do you feel like there are missing things from the current matrix that would, in fact, move forward the value in exchanging information? Because the technology solutions are there. I mean they've been there for a while. There are some maybe key things missing around standards and main services and things. I don't want to minimize those, but I sort of feel like if we had a strong value proposition, we would solve those problems. And meaningful use is our value proposition; that's the place we're going to provide leverage.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO**

Personally, I would agree with that, absolutely. I think that when you ask what's missing, up until now, I think it's not about the technology. It's, you know, frankly, that not enough users want to exchange information. I mean, I think that's what—you know, we talked about the credit card industry—the, you know—and in almost every other industry, the standards were formed, you know, in a way. It wasn't that the standards got defined and then everyone exchanged. The standards got defined because people had an overwhelming interest in wanting to exchange and were—and in some cases, I think we talk about that in the opposite way in health care, as if we need to lay down the standards and then everyone will want to exchange.

I think that, you know, there's a combination of incentives and compulsion. And it related a little bit to Neil's point earlier that—and I know we don't want to go down this road of all the deep cultural and, you know, socioeconomic aspects of why we don't have more exchange in raising standard of care, but I think that the combination of incentive and compulsion behind the \$45 billion that we're talking about giving you incentives could be the thing that gets more and more users to actually genuinely want exchange, which I think will move all of this forward. I think that's the piece that's missing the most.

**Larry Wolf – Kindred Health care – Senior Consulting Architect**

So I guess I also think there may be something missing in the model, and that's what we need to consider. So, for example, the people who are using the Internet today to send e-mail—we all had needs to communicate 10 years ago, but we didn't communicate in the ways we do today. Some things have happened in between that shifted the value proposition so that we send text messages in a way that we never imagined possible 5 years ago, maybe, even. Southwest Airlines demonstrated that people actually want to fly from Louisville, KY, to Chicago, but not for \$300. So when they dropped the rate to \$59—or \$29, I guess—at the beginning, they suddenly created a huge market where none existed before.

So I think there may be some things missing in our formula, if you will, that we'll suddenly discover: "Wow, there really is a huge, pent-up demand for people to share information." But we're not—we haven't found the button yet that's going to enable that—and that we have homework to do. Otherwise, we'll say we've got all these great standards, and we make everyone use the standards, but we're still not going to get exchange.

**Unidentified Man**

Right, I think [inaudible].

**David Blumenthal – HHS – National Coordinator for Health IT**

I have a—we have to do a time check here. It's a quarter of. We're 15 minutes over and 15 minutes into our break. What I'm going to propose is that we have a couple of other quick questions, but what I think we really need to think about is what the committee should do next. My sense—and I would welcome other thoughts about it—my sense is that this is an incredibly valuable first step toward consideration of the exchange issue, but that what we need at this point is a kind of a—to adopt a direction rather than a set of recommendations. So while we finish up the questions, I would encourage us to be thinking about what that direction might be.

The next person on my list is Paul.

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

I'll try to go as fast as you did, Micky, but I don't think I can do it. You clearly set the bar high.

I have a couple of quick observations and a question. The observations are, when you went through the point-to-point structure, I do believe, in a point-to-point system, you still can get aggregate public health data. There's mechanisms to do that. I think all the architectures are functionally the same. They're all able to accomplish that.

The other observation is that—these national exchanges, where at least one was really a company that grew through acquisitions and acquired a lot of local organizations that simply didn't abide by standards, so they set up an exchange nationally to deal with all of that. And that's a vendor exchange, but I don't necessarily think that's a good model for anything. I mean, it's—in fact, there's aspects of that model, in my opinion, that are actually troubling.

And as I think about that model, the question I have for you, which you don't have to answer now—just what I'd ask you to think about—is whether or not there is a hidden assumption in what you're doing. And the hidden assumption is that the current state of sort of lack of compliance with standards that exists throughout the health care industry—that the assumption is that that will continue. And that's just something I'd like to ask you to think about.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO**

So—well, on the last point—I guess I don't really understand that point.

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

Well, at some level, the existence of exchanges that have a lot of content in them sometimes represented failure to abide by simple interoperability standards.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO**

Right. No. Well, I think, as we pointed out earlier—that the problem, in our view, isn't that the standards don't exist; it's that the market is structured in a way that there is no coherent ability to enforce and monitor that in a sector of the economy that we would argue is fundamentally different than almost every other sector of the economy, because it's so fragmented on the supply and demand side. So if you could take labs, for example, how would we monitor lab standards right now? Wouldn't the vast majority of them be delivered by community hospitals? No one is in that transaction every single day to monitor those standards, which is very different than credit cards.

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

Okay, thank you.

**David Blumenthal – HHS – National Coordinator for Health IT**

I have Charles next.

**Charles Kennedy – WellPoint – Vice President for Health IT**

Okay. [Inaudible] I'll make this quick. When I look at HIEs, I try to keep the perspective of what is the clinical utility of the health information exchange. How does it influence what a doctor does or what a patient does? And when you bring that perspective to those diagrams, I think you very quickly realize that that data is transactional in nature to—largely to automate a function: a lab, a radiology, whatever it is. But what we want to do, I think, is to convert that transactional data into something that supports better decisionmaking for the doctor and the patient. So what's missing for me is, if we just connect System A to System B and give the doctors a pile of transactional data, the data's going to be duplicated. So they're going to see, you know, a claim, a lab, a this or that. It's not going to, I don't think, create a particularly compelling foundation for improved decisionmaking. So what's missing for me is some kind of data architecture that takes the transactional data and converts it into a foundation for decision support and physician use.

**David Blumenthal – HHS – National Coordinator for Health IT**

And David?

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

Most of my thoughts have been expressed by others. I think the key thing, for me, [inaudible] David's opening comment is, as a policy committee, what is the compelling reason for Federal action on behalf of certification and so on? And I think to get to that decision at some point, I would like us to think about a way to present, if it's what we believe, a compelling case that advocate—that justifies Federal action in this particular market space. And I'm not myself convinced of it yet, but I think it may be worth drafting or commissioning a white paper that addresses some of the things that have been surfaced here, particularly how other industries have or have not required certification of exchange capabilities and what reasons would be distinctive, in our case, that would justify a Federal action around this set of standards.

And the second thing that we might do very specifically—and I agree strongly with Larry's point that our premise has been that the meaningful use criteria would create the market pull for driving exchange of information, but that means that we have to look at our criteria and test them against this question. And one place we could do that, having now moved a little bit off of 2011, is to ask whether the 2013 criteria that we're going to continue to talk about are sufficiently stringent in pulling data across the network. And if every end user—300,000 or whatever number of end users face significant financial incentives by successfully pulling information across the network as you described, I think there's a chance that would create the market response that we're talking about. But that's a test I think we have to ask ourselves as we go forward—and maybe do some more homework on 2013 and 2015 to really amplify that incentive.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO**

Right. I mean, I guess I would say on the last point that, you know, now that the meaningful use matrix has been approved, we, you know, as a workgroup are happy to engage in that level of detail. As we said, we were unable to do that up until now.

**David Blumenthal – HHS – National Coordinator for Health IT**

Judy?

**Judy Faulkner – Epic – Founder**

Two things: One, on the standards, I think that HTTP for the network effect, and SMTP for e-mail have helped a lot in standards. And I think one of the reasons that the various EHR vendors are doing it separately is that more standards are needed so that they can go and exchange among them. Secondly, my experience has been that the barrier isn't really the incentives of meaningful use. The CEOs and the physicians really seem to want interoperability. Where the problem has been, almost universally that I have seen, is with the compliance officers and the attorneys having too many worries to allow their organizations to move forward. And so, that is the big barrier that I see that it needs to get through.

**David Blumenthal – HHS – National Coordinator for Health IT**

Christine?

**Christine Bechtel – National Partnership for Women & Families – VP**

On the market questions, I think what strikes me is—and a lot's been written about the market in health care not being particularly functional, and I'd say I agree. But what strikes me is that clinicians today can provide care without any data exchange whatsoever, with no real economic consequences, right? I don't know that, you know, my care is good or bad. It's hard for me to pick up and go somewhere else based on any kind of objective data about their performance.

So I think that the market here hasn't done a good job of creating sustainable business case for information exchange. I am inclined toward this approach that I think you're recommending, which I want to make sure I understand. So what I'm hearing you say is that HIE-slash-, you know, information organization should be part of validating meaningful use specifically. That's going to require some kind of certification that they're doing that based on the right criteria in an objective way and that those requirements should be set at the national level but be technology neutral and architectural neutral.

So just—I think, first, I want to make sure I'm understanding what your set of recommendations is; and then second, if I've got it right, I think that's very interesting, and I like the fact that it could be potentially less burdensome on providers and yet still fairly robust for meeting meaningful use criteria. I'm not sure whether this sort of bleeds into the larger issues that I think David Lansky's raising around certifying networks broadly, and is that a good case—good thing or not? And maybe it's a distinction without a difference, but I guess I'm thinking of what your recommendations are in the specific context of meaningful use. So if you can tell me if I've got it, that would be helpful.

**Deven McGraw – Center for Democracy & Technology – Director**

I think you basically have, although we went off of what the Meaningful Use—our Meaningful Use Workgroup was doing, which requires exchange and thinking through how, again, Micky's emphasis—what—how is that going to happen? Because it's largely not happening today, and essentially what we're saying is, in order—we're proposing that in order for that to happen, we have to set out some minimum sort of sets of requirements to facilitate that “how” while also allowing for innovation underneath, so not being so rigid in how that gets done that there isn't room to do it through the various models that Micky presented and even more that will likely occur.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO**

Right, so—and I guess, just to—I'm not sure exactly that I agree with how you characterize this. Let me just try it another way to make sure that we're saying the same thing—that, you know, first off—that, you know, with meaningful use—and we were focused on health information exchange as it relates to meaningful use. So I think that's, you know, part of what we need to remember with respect to what we were focused on. It wasn't about health information exchange now and generally; what's a, you know, HIO sustainability model; what are all the great things that HIOs can do. It was really about health information exchange as it relates to meaningful use being defined by the Meaningful Use Working Group from the last meeting, okay?

So that was, you know, what we were focused on— that if we have a situation in which the government is putting a lot of compulsion and incentive—more incentive than compulsion, perhaps—behind exchange— that our first view was that there’s a certain set of requirements that set the guardrails of how that exchange ought to happen, because we’re basically, as a society and as a government, telling physicians, “You are required to exchange data. And you know, in effect, we don’t want that to happen”— I’ll put this in quotes—“we don’t want that to happen irresponsibly,” right? And I’ll put that in quotes. No one’s trying to be irresponsible, but it’s a very, very complicated area. So that was, you know, the first thing—is that we’re requiring exchange, so aren’t there some guardrails we want to put around it?

So then we moved to saying we want to have a set of requirements that are completely neutral about how you do it—that it’s not saying that you have to do it through an organized health information organization; you just have to meet the requirements. And that leaves it open to the individual choice and to the technology vendors to do—you know, to provide various means for doing that. And so, that’s the second point—is that the requirements apply across the board to health information exchange—or health exchange, not to organizations but to any organization that wants to do this.

The third was to allow the possibility of taking advantage of health information organizations, either as they exist today or as they could exist, which would be a benefit both to the government and to providers. And what we mean by that is that, to the extent that we’ve laid out requirements, if you have health information organizations that are able to certify that exchange, as it relates to meaningful use, can be accomplished through the rules that we set up in our own network here and it corresponds to those requirements—that we ought to—you know, that the government ought to be willing to say any physician who conducts their exchange through that health information organization will, you know, sort of get credit—will—in effect, the burden of proof won’t be on them any more to prove that they have met the requirements that we’ve laid out for appropriate, you know, guardrails around health information exchange.

They still have to conduct the exchange, obviously, you know; it’s not just that “I’m a member of this, and—but now I don’t, you know, send a single clinical summary through it.” You obviously still have to do that. But that would facilitate, you know, sort of more efficient, more effective, you know, participation, because it lowers the barrier for individual physicians. It also provides a benefit to CMS by allowing more of that to be aggregated. And obviously, in order for that to happen, there is some level of certification you would need for those health information organizations. Again, it’s not requiring that someone do it through a certified health information organization; it’s just saying that if you want to get credit for doing it, and if you want to have robust reporting through that and, in effect, have that organization report on your behalf, that would need to be a certified one.

**Christine Bechtel – National Partnership for Women & Families – VP**

But are you talking about meaningful use criteria writ large or just the criteria that apply to exchange only?

**Deven McGraw – Center for Democracy & Technology – Director**

No, exchange.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO**

Right. Just exchange.

**Christine Bechtel – National Partnership for Women & Families – VP**

See, because I actually was very intrigued by criteria writ large, because I think you, Micky, in your organization—you get quality data. You know how they use, you know, what’s happening when a drug alert fires. Do they turn it—I mean, you know that stuff. That was interesting, but I think a larger issue.

**Micky Tripathi – Massachusetts eHealth Collaborative – President & CEO**

Right. You could have variation, right? Some HIOs could offer—I mean, you could imagine someone saying, “Well, I do my e-prescribing through SureScripts, they’re certified at my lab’s request, and then I

do clinical summary exchange through the Indiana Health Information Exchange. Now I'm doing it through three."

**David Blumenthal – HHS – National Coordinator for Health IT**

So I think we have to draw this to a close. I suspect that all of us are learning a lot from this discussion and that we're not ready yet to make recommendations or consider them.

In terms of what might get us further along, I had a couple of questions that I thought you might address for us, and I think they mostly had to do with reconfiguring your recommendations and packaging them with some argumentation or at least assessment. One is, I think it's pretty clear that if—there's a school of thought that believes that if there's a market, the market—that, you know, the exchange will come. And that—regardless of whether you believe that's a sufficient condition for creating exchange, it is clear that the stronger the market, the more likely exchange will be to happen effectively.

So one question would be, in 2013—in 2013, have we—this committee—and in 2015, has this committee done everything it could to make sure that there will be an effective market using the meaningful use criteria? I think, for 2011, we don't have a lot of flexibility, but for 2013, we have more. And we should consider our recommendations in light of that sort of demand pull criterion.

The second: It seems to me that the committee—at least I might benefit from three packages of recommendations. One might be a minimal; a second, a moderate; and then third, a more robust set of Federal interventions specified and—with some commentary on their pros and cons.

What you've done is given us a wonderful compromise between opposing points of view, but it doesn't give us a chance to consider the views that were not—that were rejected or that you didn't accept, and what the dangers might be of those views, and a chance for us to consider how comfortable we are with accepting those risks and benefits. So one risk of a completely unregulated or unstructured market might be that it just doesn't happen; nothing happens, you know. We keep waiting and waiting and waiting, and it doesn't happen. And we have to decide whether we would accept that risk and how much it would be mitigated by the first level of Federal standards.

So I think we could—we might then be able to get to a recommendation about the Federal Government's posture, what it should seek, what level of intervention we're looking for. We might end up right where you left us, you know, but we'd get there in a more considered form with a set of arguments about why we got there.

**Deven McGraw – Center for Democracy & Technology – Director**

With more time to think about it [laugh].

**David Blumenthal – HHS – National Coordinator for Health IT**

Does anybody else have any suggestions for the working group? I took the Chairman's prerogative in order that people who want lunch could get it eventually.

**Unidentified Woman**

I would like—I liked very much the con—there was a thing that was happening that was good. It sort of said, "Look, you know, if you view it—if you view this operation from the point of the exchange of information, what, then, is the comprehensive view back to the clinical care of the patient for the clinician and for the patient?" And I think that's sort of a really important point, because all the diagram and the emphasis has been just on facilitating the transaction, not on what's required to coordinate and then pull back. And that's—that just has to go well beyond what the market is currently considering, for example.

**David Blumenthal – HHS – National Coordinator for Health IT**

Mm-hmm. So one of the criteria for evaluating the options—they're all "how" options—might be its effect on the availability of the kind of record that Neil conceptualized: a longitudinal, intact, personally associated record that either a physician or a hospital or patient might want.

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

David, this is Art.

**David Blumenthal – HHS – National Coordinator for Health IT**

Yes, Art.

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

Yes, just to kind of maybe bring together your comments about creating a market in 2015 or 2013, maybe the group that worked on the matrix—the Meaningful Use—can just revisit and make sure that we've explicitly stated the value of that view in some of the metrics that we have stated so far.

**David Blumenthal – HHS – National Coordinator for Health IT**

Okay.

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

That's part of the Meaningful Use Group—maybe a task that we could take on as well.

**David Blumenthal – HHS – National Coordinator for Health IT**

Mm-hmm. Okay, I think hunger has got the better of us. So I want to—I think that's a product. First of all, this has, I think, moved us a long way—the work you've done. I think we now know what ballpark we're playing in, and now we just have to do a little bit more work on the rules of the game. Thank you very much. [Inaudible]

Oh, yes, actually, when do we return? Not tomorrow. Why don't we take 20 minutes?

[Break]

**David Blumenthal – HHS – National Coordinator for Health IT**

We are understandably losing time, in terms of trying to stay on schedule, and we'll have to try somehow to make it up. But I want to give the—I want to give Paul and Marc and the Working Group on Certification and Adoption a chance to discuss their report and recommendations. So if Marc and Paul could go to the front of the room and share with us their work... it gets repetitious to talk about how hard people are working and how much we're indebted to them, but ditto, you know [laugh]. So I hate to keep repeating myself, but thank you both for your dedication and your work on this.

**Marc Probst – Intermountain Healthcare – CIO & VP**

Okay, then we'll get started. We were asked to look at certification and adoption and more specifically certification, and we'll get into that. (And I just pushed the wrong button. There we go; let's try the one that works.) Okay, again, this is our committee, and they have worked extremely hard. We have had lots and lots of phone calls in between the meetings that we've had. We also just spent a couple of days all together, which was very useful. So this is the workgroup that we have going.

This is the agenda for today. And I won't go through it in detail, in light that we're trying to move things through quickly. But we do want to go through the progress that we've made and the initial recommendations that we've come up with.

This is the broad charge that we were given to—that was given to us—is to make recommendations around adoption, certification, HIE, and the workforce. And again, specifically, we were asked to look at certification right now. And we were given 4 months to do this—and I told John Glaser I'd bring this up: We were given 4 months to do this, and then about 3 days later, we were given 6 weeks to do this. So I know all the workgroups are familiar with that.

And I know we're a little late on time, but it reminds me of a story of [laugh]... I come from Utah, and I was just over at the capital yesterday, and they have a statue. I didn't know every State had two statues, but in there, they have a statue of Brigham Young. And Brigham Young—a Catholic priest came to Salt Lake City, and they went up on the bench looking over the whole city, and they said—this Catholic priest—and

Brigham Young had been there about 3 years—said, “Man, what you guys and the Lord have done to this area is just fantastic.” And Brigham Young looked at him and said, “You should have seen it when just the Lord had it.” [Laugh] And that’s the way we feel about certification and the direction we were given: You should have seen it before our group got it [laugh].

The process we’ve been through was really to understand what certification was. Some of us were more familiar than others and have been involved in the process. Actually, some on the committee are very experienced in certification and help set up organizations such as CCHIT. And it was great to have their knowledge.

We defined a series of questions we wanted to go through to understand, and I will share those questions with you. And again, to be brief, I’m not going to read through all of them, and you have them in your packets. But we did set up a series of questions that we wanted to answer relative to certification. A lot of good input: Each of you have mentioned about the e-mails that you’re getting, and I can assure you each of us got a lot of e-mails around certification. And there are varying interests and varying direction and, you know, a lot of organizations with opinions.

We set up a 2-day series of testimonies. That happened—well, it was a day and a half—that happened on Tuesday and Wednesday of this week. And I really thank the workgroup members for being there, but also the people that came to speak to us. They were excellent, and the presentations really did help us to get our ideas focused. And now we’re going to share some recommendations here in just a minute. So that’s the process.

Here are just some of the questions. So we broke them into two areas; one is the criteria for certification and what should that criteria look like. Right now, the criteria for certification is primarily defined by CCHIT, and it’s a fairly broad set of criteria and was created for a purpose. And that—we think they’ve done a pretty good job with that, you know. But how does this really focus relative to ARRA and the HITPC Act and the things that we’re dealing with? So we really considered these questions around criteria.

We also looked at the process itself for certification and how it was being done today and how was that—how did that apply, really, to the process, as we look forward, that we should be doing in support of the act—and a lot of focus on CCHIT, again, because it’s the organization that’s been doing it, and how they play in the overall scheme. So we took a look at criteria, and then we looked at the certification process.

And these are some of the initial learnings that we came up with. Relative to CCHIT, there’s a broad spectrum of thinking and a lot of opinion out there around the organization itself. It’s important to note that CCHIT was organized or set up prior to the passage of ARRA—well in advance of that, and for a significantly different purpose than what certification around ARRA is. And you know, they’ve done a good job within the spectrum of certification for what they’ve been asked to do at this point.

There’s a lot of confusion around CCHIT—what is their role, how do they set up their criteria, how do they apply that criteria—even amongst some of the members that are involved in being certified. Significant discussion around how detailed CCHIT is and what they focus on—a lot of question around how CCHIT was formed; “By vendors” would be the remark that we got probably more than any, as its roots go back to HIMSS and to several vendor organizations. And is CCHIT still too closely aligned with these individuals?

They’ve been criticized for setting up the criteria and testing it, so it’s been one organization that’s done those things. And there has been a lot of comment from organizations regarding a modular approach. So right now, CCHIT certifies a system—an EHR. And a lot of systems are composed of multiple pieces—and that those modules should be able to be certified and then brought together to create a certified electronic medical record.

We talked a lot about nonvendor systems—those that have self developed systems or those that might use open source or even those that might bring a lot of components together to create their EHR. And

there was significant interest in this. The—those that are self-developed kind of wonder, “What does the certification do for me?” You know, if certification is to help someone in the acquisition of an electronic medical record, well, you’ve already acquired it. You’ve built it, and you’re using it. What is the purpose of certification? On the flip side, some of the other organizations were believing that “Hey, certification is a bar one should pass to be eligible to receive these funds, and everyone should have to pass that bar in an equal manner.” And so, we’ve discussed that quite a bit.

The open-source community was really interesting, I think, in some of their comments. They really believe they have a great product. Primarily, we talked to Vista, and they brought a lot and wondered how it could be impacting them—this whole process, because in open source, you’ve got a very liquid system—or “fluid system” is probably a better term—that changes quite often, because you have so many people modifying that code.

There was concern about curtailing research. People that are pushing the envelope a lot of time are these research institutions that are developing their own systems. And how do you get certification in place and not just stop any kind of innovation that’s out there? And then clearly, the costs associated with certification were very—were discussed and could be a barrier for some organizations, moving forward.

We discussed whether or not certification is a seal of approval or if it’s something different. And there were a lot of varying response relative to whether it should be a seal of approval or not. Should it be broad based or specific? Should it focus simply on what meaningful use defines, or should it focus on a broader range of requirements? Should we look at things like vendors’ viability in moving forward? Is that the purpose of the certification?

Certification and privacy: Privacy came up, as did security, in all the conversations that we had. There was a lot of suggestion that maybe there wasn’t enough focus right now on things like privacy and security in the current certification processes. And there was a discussion about “feeder systems”—that we called them—systems that feed into the HER. And what kind of interoperability requirements should they have, and security and privacy, and should those all be lumped together? And then, should certification include vendor fitness or provide vendor readiness? And as I mentioned a minute ago, we talked about that. Is that an appropriate thing for the certification process?

As we looked at certification, we really wanted to get clear as to what we were trying to define. And we broke—I’m just going to build this slide out, because we broke it into three categories: that of validation, certification, and assurance. Now, whether those are the right terms, those are the terms we used.

And validation being, “Is your system really doing on site what it’s supposed to do so that you should be able to receive these funds?” And that could be done through a whole variety of ways. That’s to be determined by other people that are actually going to disperse those funds. But that was the idea of validation.

Assurance was more the seal of approval. “Is this something that is good? Is it a good product? Does it have good usability? Is it something—as you compare it to other products, is it better than that product?” And so, we looked at assurance as something outside of what ARRA was suggesting and not really in the scope of what certification is.

That—certification really is, “Will the product do what ARRA and Meaningful Use are suggesting it should do?” And if you purchased that product or you built that product or whatever—you cobbled together that product, when it was there—it needs to be certified that it will do what the meaningful use criteria suggests that it should do. And we suggest that this should be done by a third party or through the government, and we’ll talk about our recommendations in a minute. But again, that was the focus of certification. We weren’t dealing with validation, although that does need to be dealt with at some point to give clarity to the purchasers of these systems or the users of these systems, and we weren’t dealing with assurance.

So that led us to the following definition of HHS certification. And we are using the term “HHS certification” very specifically. HHS certification means that a system is able to achieve government requirements for security, privacy, and interoperability and that the system would enable the meaningful use results that the government expects. HHS certification is not intended to be viewed as a seal of approval or an indication of the benefits of one system over another. So as we go—as Paul goes through the recommendations, it’s important to keep in mind that this has been our working definition to come up with those recommendations. Paul.

### **Paul Egerman – eScription – CEO**

Thank you very much. I’m Paul Egerman, and I’m going to take you through a series of recommendations that the Certification Adoption Workgroup has. And this is as a result of all of the work that we’ve done.

Earlier this morning, Paul Tang made a comment about meaningful use. He said this is an opportunity to talk about patient outcomes and not technology. Well, certification’s actually an opportunity to talk about the technology, so that’s a lot of what this is all about, although we allowed the meaningful use definitions to drive what we have done. So we’ve actually driven by meaningful use, which is also one of the comments that were in the public comments about meaningful use, for that is what we have tried to do.

We have these five recommendations. And what I’m going to do is tell you just quickly—so, like, an executive summary of these five recommendations. And then in each of the five, I’m going to take you through a slide and tell you a little bit more about it.

So the first recommendation is to focus certification on meaningful use. And that may not sound all that impressive to you at first, but basically, this is a focus specifically on meaningful use and on meaningful use at a higher level. This is a change from the certification process that I would describe as comprehensive and oriented around feature and functions. So that is the first recommendation.

The second recommendation is to leverage the certification process to improve progress on security, privacy, and interoperability. Privacy is, of course, besides a basic goal of the legislation—is clearly stated in the legislation as an issue that is very clearly on the minds of consumers. We see it a lot in the public comments. And interoperability is an issue where we received basically a lot of information and a lot of criticisms about the low level of existing interoperability.

The third recommendation involves the certification process itself. We had a terrific presentation from Dr. Cita Furlani from NIST (the National Institute of Standards and Testing). And she told us a lot about international certification standards, and we have recommendations that ONC should work with NIST to improve the objectivity and transparency of the certification process.

The fourth recommendation is to expand certification to include a range of software sources and includes the open-source community; self-developed systems; and also systems that, in the public comments, are called “modular”—I think they call them “components.” So we have recommendations on that.

And then finally, we have a transition plan, because we realize the first four items will not be done overnight, and something has to be done so we can tell what is the transition.

So those are the five recommendations. To give you a little bit more information about them—basically, to look at the focus on meaningful use, if you read the very first bullet, one of the things you will notice is, we were saying we want this to be sort of like a minimal set of criteria. It’s not necessarily a comprehensive description of a complete medical record system. And it also says, under B, to achieve the meaningful use objectives. So again, consistent with the discussion we had this morning, we view the meaningful use objectives as basically the roadmap. And so, our view of HHS certification is, if somebody buys an HHS-certified system, then they will have the necessary tools to meet those objectives. They still have to do the work, but they’ll have the tools to meet the objectives.

To call your attention to the third bullet, it says, “Criteria on functions and features should be at a high level.” So the first part of that, “at a high level”—I want to give you an example of what that means. What

that means would be, if you were certifying a system, you might say, for example, that, gee, you want an alert given to the physician if there's an abnormal laboratory test or an abnormal result. So you'd say you want an alert, but you would not say explicitly how that alert would work, what it would like—and the idea being by—sort of like having “less is more”: by having less specificity in the requirements, there will actually be opportunities for more innovation. It's also a concept that by doing that—doing it that way, the “less is more,” we'll have a certification process that is less expensive—you know, less time consuming and less expensive to achieve.

And while saying that less is more for meaningful use, if you look at the second part of that sentence, “Criteria and interoperability should be more explicit,” we're taking the opposite approach when it comes to interoperability and also privacy. You'll see that on the next slide. In that case, we're saying more is more; what we're looking for is more explicit criteria and more criteria in general. So—but on meaningful use and on functionality, we're saying less is more.

Now, as we say that, I know there might be some vendors who are—might be a little upset, because they've done a lot of work to get comprehensive certification from CCHIT. They might be very proud of the work that they've done, and rightfully so. And if you look at the next to the last bullet on the page, you'll see that what we're saying is that, to the extent that, you know, vendors have done this—have gotten comprehensive certification, and to the extent that that's valuable to purchasers—that CIOs in the marketplace find that kind of comprehensive certification important, well, it should continue to exist. It should be—exist in the marketplace as basically advisory services. We think that that's a good thing. It's just not required to get incentive payment under the system. But that's a positive thing that should continue to exist if the marketplace thinks it's positive and wants it to exist.

And if you look through the recommendations on meaningful use, we also touched on this issue that was discussed this morning and raised at the last meeting by Gayle, and it's the whole issue of specialists. And what we said about that is fundamentally that the focus on meaningful use should reduce the barriers currently faced by vendors that focus on specialists. The very concept there is, the meaningful use objective should be used to figure out how to provide incentives for the specialists, but that we are not going to provide certification for each individual specialty. We're certifying at the sort of base level of the meaningful use objectives.

So that's Recommendation #1. Recommendation #2, on security, privacy, and interoperability: We said we want to leverage the power of certification. Marc Probst did a very good job of talking about some of the things we learned, but one of the things we learned is, certification's really very powerful. I mean, it has a powerful, powerful influence on vendors. Whatever you say that you have to do for certification, people do it. And since people do it, well, we need to use this to address these issues—privacy, security, and interoperability—which, as I say, are indeed stated goals of the legislation. And so, what we are asking for or saying is that the criteria has to be more explicit, more detailed—that there has to be basically more of it.

We also came across various issues relating to our standardization process. And on the standardization process, basically what you'll see here is that there needs to be tighter integration between standards and certification. We saw all kinds of issues where certification and standards seemed to be not synchronized, so there needs to be tighter integration. And we also said, if necessary, ONC should commission and not just harmonize the development of standards. So if—you know, if we run out of patience—if we feel that, gee, we can't get the standards that we need from the various standards organizations, we're recommending that ONC should go ahead and commission the development of the standards.

Another thing that's very interesting on this recommendation is the next to last bullet—is the concept of creation of test harnesses—is actually a great idea that came out of recommendations made by Cerner Corporation. The idea here is that there should be a process for the user—for the physicians and providers and hospitals to be able to test their own systems easily to determine if they meet the interoperability specifications.

And then the last bullet that you see here under this recommendation is to say—it says, “Prioritize focusing on criteria for interoperability and data exchange.” And the reason why we’re saying that is, one of our roles as a policy committee is to establish priorities for the HIT Standards Committee. And so, we’re saying very clearly this should be a priority [inaudible] interoperability. And we’re saying that to the standards committee, but we’re also saying that to any vendors who might be listening. We would encourage you, instead of creating functions and features, to be looking at interoperability, privacy, and security.

So that’s our second recommendation. Our third recommendation deals with the actual certification process. And there’s, like, a number of headlines here. The very first headline is that we are recommending that the process of defining the certification criteria should be separated from the process of testing. In other words, the organization that tests or certifies vendors or certifies products should not be the same as the organization who defines the criteria. So that’s sort of like the very first headline here.

And if you read through it, the other headline is, later on—we were saying that ONC should work with NIST on the whole concept of conformance assessment. It includes testing certification, accreditation, and surveillance. Surveillance by itself is an interesting issue. On the issue of accreditation, we are recommending that ONC identify and establish at least one accreditation organization that will accredit the certifying—the certifica—certifying organization—the testing organizations and will monitor them.

And then the other sort of headline here is towards the bottom. We are recommending that multiple organizations be allowed to perform HHS certification testing and provide that certification.

Now, that recommendation is probably a recommendation that we’re going to get a lot of comment about. A number of vendors, including the EHR association, actually recommended the opposite: that there be only one certification organization. But after giving the issue a lot of thought, we felt that, basically, competition is good and that, fundamentally, this would be a good thing for the industry. We are sympathetic to the concerns the vendors have, and we did say that vendors will only be—only need to get HHS certification from one certifying organization. It’s set up so you only have to go to one place, but there could be more than one to go to. We think it’s also important because we are concerned that there may be a bottleneck—that there may be a lot of organizations that need to be certified, and so this could create a competition—I think, could be one way to respond to that.

So that is our third recommendation. Our fourth recommendation is called flexible software sources. It corresponds to some of the recommendations or comments from the public comments. First is a general statement that we want to provide certification support to a wide range of EHR sources. And then it steps through a few, but one of them is this concept of what we call certification of components, the idea being—and I think it’s in the comments; people call this “modules” or “modular.” But the basic idea of component certification is that it should be possible for a physician, a provider, a health care organization to get a certified system by buying different components from different sources. They don’t necessarily have to buy a single electronic medical record from a single vendor—that they can get this from the multiple components.

We did spend, as Marc said, a lot of time considering various issues relating to the open-source community, which are really wonderful people to talk to, because they’re unbelievably enthusiastic for what they do, because it’s—they’re just great people. And basically, to try to assist and encourage open-source—the entire open-source community, we have a recommendation relating to something called the lockdown requirements to give them a little bit more flexibility to be able to make changes. We feel that plus the idea of the test harnesses—we—you can provide for a little bit more of a dynamic software development environment.

And then we also have a recommendation for self-developed software, so people who have software they developed themselves—the recommendation is to provide an optional alternative certification process in which there would be some sort of site inspection. And the site inspection actually could be a virtual site inspection; this could be done using, like, remote access to computer terminals. But a site inspection is a basic meaningful use objective. It’s another vehicle for the self-developed software organizations.

So that's our fourth recommendation on flexible software services. And then we have the fifth one, which is the short-term transition. Now, the idea with the transition is to realize that everything we just said is all very interesting, but it's going to take several months to get it all together. And I actually—I don't know the number of months. People wanted clarity about what's going to happen right away, especially since, you know, this whole thing is part of the economic stimulus bill. And we've heard a lot of concerns that actually, decisions to purchase are being delayed because of the absence of clarity, and so—on certification. So we wanted to provide that certification in a short-term transition.

So the first two bullets are basically that ONC would evaluate the existing CCHIT certification process and look for sort of what we call gaps. And there's, like, two gaps. The first gap would be issues that are just missing from the current criteria, like public health. And the second is to talk about—perhaps gaps might exist, for example, in e—an example is e-prescribing, where existing criteria is good, but we need to somehow change it or expand it and, based on that, to create what we called an MU—which stands for “meaningful use,” but since this is technology, we felt we could use our own acronyms [laugh]—MU gap certification. And so, the idea is that there would be this gap analysis—a gap certification process, which hopefully is not, especially since it would happen at a fairly high level—will not be hard to do or expensive to do, and then say that anybody who is currently certified—CCHIT certified—that in effect, we will grandfather them into HHS certification—it would be certified—HHS certified, according to the statutes, through 2011, as soon as they also complete the special MU gap certification. So that's the way to sort of grandfather in the existing certifications.

And then there's still the issue of what happens if new vendors want to get certified and we still don't yet have our act together, in terms of the new process. And the idea there is that CCHIT would be encouraged to continue to do their current process plus the gap certification so that it could continue to certify new products and new vendors until we are able to completely roll out the process that we have determined.

So these are our five recommendations. They represent a very significant change—a significant change in certification and a significant change in health care IT software. For next steps, first we have, obviously, comments here. And we've got the idea that this was opened for public comment. And based on that public comment, we'll be delivering certification recommendations to this committee next meeting.

#### **David Blumenthal – HHS – National Coordinator for Health IT**

Well, thank you, Paul and Marc. I'm continually impressed with the wisdom of the Congress in creating this committee and empowering it to give the Office of the National Coordinator recommend—its advice, because that advice has been of such high quality.

Let's—what I'm going to suggest, given the shortness of the time, is that we not focus on all the very interesting and useful subrecommendations in 1 through 5, but that we focus on the overall recommendations to whether the—how the committee feels about the headlines. By that, I mean the slides aren't numbered on my copy, but—the first slide, dealing with recommendations, which is “Focus certification on meaningful use; leverage certification process to improve progress on security, privacy, and interoperability; improve objectivity and transparency; expand certification; and develop a short-term transition plan.” So it would be helpful to know if those were directions in which the committee felt comfortable going. And if possible—and I haven't thought this through completely, but if possible, also to focus on the short-term transition questions. So if—given the shortness of time, those two segments of this very, very full and provocative and interesting set of recommendations seems to be where we ought to start, knowing that we can come back to deal with the more specific recommendations later on.

So with that, yes, Tony?

#### **Tony Trenkle – CMS – Director of OESS**

Just a quick comment: I think you lay out some pretty intriguing ideas in your proposal, but I guess the question I had is, I see a real—if this—we get to this desired state—to get there, there's a tremendous need for education and outreach, because I can see, as we move from today's state to this more evolved

state, both for the vendor community and for the provider community in selecting the EHRs, there's going to be a tremendous amount of potential confusion and potential—almost a disincentive in some ways. I can see the advantages, but I just wondered if you could address that.

**David Blumenthal – HHS – National Coordinator for Health IT**

Excellent question, Tony. Basically, I mean, the title of our workgroup is “Certification and Adoption.” And so, those are—the issues that you raise are adoption issues and training issues—are issues that we are—as a workgroup, are supposed to be addressing. We're just not addressing them today. We felt that we had to address the certification issue with a sense of urgency as it relates to the statute and as it relates to what needs to happen. And you've got to remember that to get the incentive payments, the provider has to do two things: They have to have a certified system and have to have meaningful use. In some sense, these are equally important, and we felt it important to do our best to establish clarity on that right away. But you're absolutely right: there is—we have much more work ahead of us on training and adoption issues.

**Tony Trenkle – CMS – Director of OESS**

I just don't think they could be treated separately. I think you have to kind of look at it as overall while you're—when you're going down this route. That's all I wanted....

**David Blumenthal – HHS – National Coordinator for Health IT**

That's helpful. Gayle?

**Gayle Harrell – Florida – Former State Legislator**

Thank you very much, and I want to commend—the group I had was part of that discussion to some degree yesterday—and appreciate the hard work you all have done. I do have some concerns, however. And again, I go back to this whole time frame. We're talking about gap certification for existing products that people have bought that were certified. They have spent huge resources in—whether it's hospitals or providers spending huge resources—and are in the process, either in the recent past or in the very near future. Is there going to be time to implement gap certification; to set the rules for gap certification, which is a process itself; to establish what those elements are; set the rules to do it; have the entities certified to do it; and have a product on the market that is going to be available for purchasers in 2011?

I just have, again, this huge fear that we are setting up a system that simply will not work and that we're not going to be able to have the products—have the education component out there for all of our providers who want to buy these products to make that decision. Decisionmaking on a major, \$5 million investment doesn't happen in a week. That's a long-term process in an institution to do that. Again, another roadblock—another problem in moving this whole process along and creating that need to really address time frames.

**David Blumenthal – HHS – National Coordinator for Health IT**

And actually—that's a good question, Gayle, but this roadblock is not as difficult as the others, because again, through the transition period, the concept of gap certification—and fortunately, there's already a fair amount of information known. We didn't know for sure everything about meaningful use, but we knew a fair amount about it. We certainly knew what the existing specifications are. And there have already started to be some discussions with CCHIT about this. It's my understanding that there's a belief that we could have this certification—the gap certification process completed and announced by Labor Day. So if you have that announced by Labor Day, there would be an opportunity to start certifying people, you know, later this calendar year.

And I do think that the vendors will be ready. I mean I've talked to a couple of the vendors. They're very comfortable, actually, with the meaningful use criteria, at least to get started, you know. It's just an issue of trying to figure out what are the mechanics to do this. So I think this is doable.

**Gayle Harrell – Florida – Former State Legislator**

Follow-up.

**David Blumenthal – HHS – National Coordinator for Health IT**

Yes.

**Gayle Harrell – Florida – Former State Legislator**

Follow-up—yes, to follow up on that, we also have the HIE component that is part of meaningful use as the statute provides, which the recommendations today were tabled to move forward. And you're going to have to include that in that gap certification as well, because there are—in order to meet meaningful use criteria, you have to be able to exchange records.

**David Blumenthal – HHS – National Coordinator for Health IT**

Yeah, it's actually not a problem as it relates to the gap criteria. You know, this is really certification for products that will be purchased by, you know, hospitals or physicians. And to the extent that there's, as part of their criteria, already standards published, the vendors already know those standards. We're not certifying the HIE organizations; we're only certifying—those are [inaudible] —we're certifying the EHRs [inaudible], you know.

**Gayle Harrell – Florida – Former State Legislator**

Correct, but one of the components of meaningful use, statutorily, is, you must have exchange of data.

**David Blumenthal – HHS – National Coordinator for Health IT**

Yeah, but we can certify simply that the providers can exchange according to whatever the specifications are for that.

**Unidentified Man**

I don't see the issue being as much the certification process the way it's defined. I mean, there are steps that need to be gone through with NIST to follow that process. It is more the meaningful use criteria that's being certified against. And I think you mentioned it a little earlier, Gayle, about the challenges with that. But I think the process—if we leave it, you know, at that, this isn't putting that big of a hurdle out there for organizations to come over.

**David Blumenthal – HHS – National Coordinator for Health IT**

Yes, Neil?

**Neil Calman – Institute for Family Health – President & Co-Founder**

I have a question about the recommendation that the certification standard-setting pro—organization has to be different than the certifying organization and the testing organization, and also the fact that there be multiple testing organizations. I mean, you can look at NCQA; you can look at Joint Commission; you can look at—I mean, the purpose of this seems to me—of doing this seems to be twofold. One is to give some guidance to people who are purchasing systems, but the other is, those standards in those organizations seem to sort of drive the industry forward. In other words, they set new benchmarks each year for what people should be able to expect. And I don't—I'm just wondering what the rationale was for both of those decisions: (1) to separate the organizations and (2) to have multiple organizations. I think if there are multiple organizations, what they're going to compete on is the word on the street of which is the easiest organization to get certified through, rather than competing on some other—you know, some other mechanism or cost. What are they going to compete on?

**David Blumenthal – HHS – National Coordinator for Health IT**

Sure. This is really a number of questions. And also, to be clear, what we're doing is—we're saying is, we want to separate the definition of certification criteria from the process of testing against the criteria. Now, some of that concept came from advice that we got from NIST, who is very good at basically setting up these certification processes. But it also came from a sense that we needed to make sure that the entire certification process and the certification organization was objective, and we had a transparent process for determining this. And there was a lot of concern that in the current environment, we have one organization that sets the criteria, does the testing, seems to have very little monitoring of what's going on—that that's a formula for a problem. And we didn't see that there have been any problems, but there

was a concern that that's not correct from a control standpoint. And so, since we're setting up an environment where we want to do things right, this is the advice as to what it takes to do it right.

Relative to the idea of having multiple certification organizations, I don't even know whether or not that will occur. But again, part of the benefit that we perceive for that is a fear for—actually, some of the very issues that Gayle is talking about is, well, you know, there's, like, several hundred vendors and products already been certified, but what's going to happen going forward? And will one organization be able to handle it, or will it be a bottleneck? And there's also concerns about the pricing of that organization. We felt if you have competition, that's a way to address both of those issues. There were specific reasons why we did this in terms of problems.

I agree; your comment is a good one, and there's two comments. I suspect the competition will be one where we'll get a lot of comments. A lot of vendors will be not happy with that decision.

**Unidentified Man**

Christine and then David.

**Christine Bechtel – National Partnership for Women & Families – VP**

First of all, you guys have done an inordinate amount of work. I mean, 2 days of public hearings in the Meaningful Use Workgroup didn't approach that, so kudos to you. We wouldn't have slept, or maybe not Paul [laugh]. Yeah, exactly.

So my question is this: Coming back to what I remember as the original—part of the original impetus for certification was the concept that we needed to moderate the risk on behalf of the clinician buyer that they would buy a product that wasn't going to really work for them or, you know, all of the things that we sort of know: it wasn't going to work well; the vendor was going to go away—whatever the case may be.

What I'm hearing is a really interesting approach that would inject a lot more flexibility into this. So have you guys thought about how you would continue to make sure that what now is a taxpayer investment is protected and the tools that we're going to use to help physicians and clinicians make sure that what they're buying is workable and good?

**Unidentified Man**

Well, I think that drives more toward the seal of approval process that we discussed, in that we really didn't see it in the context of what we were looking at to do that seal of approval or to raise that bar to say, "There's so many—so much variability between what you buy and how you install it." I mean, some people can take Vista and make it successful, which is the open-source product; some can't. So I didn't—we weren't trying to drive to that level of "Yeah, this assures that you have an excellent system in place." What we were driving more to is "This assures that the pieces or the system that you buy will achieve meaningful use per the definition that we're given"—and that how you implement it—I mean, that is another discussion, and that is something we need to go through. But I don't think we gave it much more conversation than that.

**Christine Bechtel – National Partnership for Women & Families – VP**

So did you envision in your group, then, that there would be something else that would be sort of a seal of approval?

**Unidentified Man**

Yes, we did.

**Christine Bechtel – National Partnership for Women & Families – VP**

Because for better or for worse that's what CCHIT, I think, in many respects, functioned as. And so, if we're taking that out of market for a host of reasons, then I just—it would—

**Unidentified Man**

We didn't envision that that would go out of the market. In fact, we thought that would continue to be a—if you think about it today, where—it's a very useful tool for people that are purchasing systems to find that it's CCHIT certified. We believed, in the future, there's still going to be a purpose for that seal of approval. But for the specific requirements of HHS certification, we didn't think it had to be that broad.

**Christine Bechtel – National Partnership for Women & Families – VP**

Okay.

**Unidentified Man**

I'd also add that there are other organizations that already are doing some level of seal of approval—there's this organization Class or Class Reports; there's Gartner reports—that do reports on vendors. And some people tell us that that's more useful in terms of this sort of seal of approval concept. We'll let the marketplace do that function.

**Unidentified Man**

David?

**David Blumenthal – HHS – National Coordinator for Health IT**

Well, I primarily want to thank you—commend you for doing this. I think it's—you've really been fairly brave in setting out some directions for how this process needs to evolve. And I think it's a service to all of us that you've done that and taken on some pretty tough issues. And I—on broad strokes, I really support—endorse the path you're laying out for us.

The only mechanical question I have is really this timing questing that Gayle teed up. And the transitional period you've imagined for the—pending the HHS certification process being enabled—and maybe it's a question for Tony or David—how long and how difficult will it be for HHS to establish a process by which it certifies the bodies that would ultimately do the product evaluation? And is that 3 months or 2 years, or what do we—how long will CCHIT, in effect, be the de facto certifier?

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

That's a great question. I'll defer that to my colleague, John Glaser [laugh]. You know, basically—and first of all, I shouldn't say that. John's been excellent in terms of—let me make sure I say that. He's really great—usually, very, very helpful. And we have that same question with John. We just could not quite—I don't have an answer, actually; I didn't understand the entire HHS regulatory process, in terms of how long it takes. I mean, hopefully, it's something that's measured in months, but I just don't know.

**Unidentified Man**

We are asking ourselves precisely this question as we meet. And we're going to—we're asking the Office of the General Counsel to give us some advice about it. So I would not—I can't answer it, but it is very much on our mind. And I think David has put his finger on a critical question, and you have been thinking about it, I know. So we'll just have to see what—how our lawyers interpret the statute, in terms of the flexibility that we have for some transitional plan. Ultimately, we have to go through a rulemaking process, I believe—Jodi, don't you agree with that?—to specify the certification process. Whether there's any flexibility around that in the short term, I don't know.

**Unidentified Man**

Yes, Judy?

**Judy Sparrow – ONC – Executive Director**

From a patient's point of view, if we're trying to improve health care for the patient; if a software system is self-developed; and if the criteria is sufficient to establish that, indeed, it meets the certification goals, then shouldn't that criteria be equally good on the non-self-developed? So in other words, are we lowering our standards for the self-developed, and is that the right thing for the patient, #1?

Number 2, I think some of the self-developed systems—let's look at Marshfield, which sells **cattails**; let's look at Vanderbilt, which sells software. It is self-developed, but it's sold.

**Unidentified Man**

Yeah, and so, I'll answer #2 first, which is, if it's sold, then it should—it's got to fall in the same rules. I mean, it's a commercial product.

And on the first question about the site, that is being put forward as sort of like an optional alternate path. It should not lower the bar in any way. And when you get all done with the process, I'm not necessarily convinced that we even need that. But the reason for doing it was, again, when we did our information gathering, we found a lot of the self-developed systems, and they had good systems in place, but they're not vendors. They weren't prepared to do the kinds of things that were necessary in the entire judging and evaluation process. They're saying, you know, "We're not offering our products for sale; why do we have to do all of this stuff?"

**Judy Sparrow – ONC – Executive Director**

Maybe to some extent, it depends on the number of patients this year, the number of providers. So I absolutely agree on the three-doctor clinic who has its own software, but if it's a 1,000-doctor facility, perhaps the standards should be different.

**Unidentified Man**

Yeah, well, I don't think we made it explicitly clear, but we think the criteria is the same for anyone, whether it's self-developed, whether it's vended product, whether it's open source. That suggestion was simply what might be the most effective way to apply the testing. And as Paul says, we're not convinced that we know enough to suggest that's the right approach. But there might need to be some consideration for people that aren't in a vended position. That's all.

**Unidentified Man**

But let's give a specific example, Judy—example, you know, where we alert for an abnormal result, you know. For a self-developed system, we might just see a—have an inspector come in and see that alerts occur, as opposed to having to actually go through some of the software demonstration process on alerts. It's the same criteria, but it might be just a different way to demonstrate that you've got it.

**Unidentified Man**

I think the keyword might be—we're trying to look for a certification process that would scale from "This software only runs in one place; it's just got a few users" to "runs in thousands of places; it's commercially sold." And right now, we felt the process didn't support scaling. And we were putting out some straw horses, if you will, on how we might be able to scale it.

**David Blumenthal – HHS – National Coordinator for Health IT**

There is, I noticed—the last bullet in Recommendation 1 is, the recommendation to the Office of the National Coordinators encouraged to explore critical aspects of the EHR for certification material—may not exist today—usability and improved models for a system and data architecture. I think the usability—and the Holy Grail of usability is, in some ways, what we're talking about when we try to think of things that are more along the line that Christine was talking about, which is the endpoint that everyone wants to be assured about. And we are talking with NIST about usability models and the feasibility of that. And you know, we'll see what we can learn. There is—there should, ideally, also be a market for information about the usability of alternative software products that is part of any market—should be part of any market.

I'd like—in the interest of time, I'd like to bring us back to the high-level recommendations that you made and to the transition recommendations and see, first of all, how much comfort there is within the group with the five overall recommendations that you've laid before us. [Pause] Silence could be comfort or discomfort.

**Unidentified Man**

We'll go with comfort.

**David Blumenthal – HHS – National Coordinator for Health IT**

Does anybody have any recom—any objections to these particular recommendations? Obviously, there is some—the details matter, but they’re also statements of—they do have content. The focus on meaningful use is an important assertion. The commitment to security and privacy and interoperability expresses a set of priorities. Objectivity and transparency is, I think, something that the community might find reassuring to know that we’re concerned about. And the expansion of certification is also something that would be a change in past practice. And the need for a short-term transition plan is also an observation about the kinds of issues that Gayle was raising about the need for timeliness. So even though there isn’t a lot of detail, there is content to those recommendations.

Yes, Neil?

**Neil Calman – Institute for Family Health – President & Co-Founder**

I’m just very concerned about how this is going to play in the public at a time when we’re really trying to say, “Here’s the road; we know where we’re going; here’s where we’re headed; get in right now; 2011 is the time to get in; there’s a short time frame,” and at the same time sending a message. We’re redoing the certification process. The people that currently certify you are not going to probably be the people certifying you going forward. There’s going to be a new set of standards. And we’re sending out those messages simultaneously. And I just think that’s going to—you know, it runs the potential of just freezing people in place, because up until now, the certification is the one thing that people who know very little about electronic health records sort of depend upon to at least think that they’re—you know, that they’re getting a product that meets certain standards.

So I think the education around how we put this information out is going to be critical. And my concrete recommendation would be that we define dates immediately upon which the things are going to get laid out. And even with that, I think you run the chance of people just freezing in place right now the minute that they hear that the current certifications that they’ve been depending upon and that people have been advertising and all the rest of that are sort of going to fall by the wayside. So I’m concerned about that.

And the other thing that we didn’t really talk about that we’ve talked about before in more detail was the question that people have when they’re buying: Like, so what does it mean that the certifications are going to change year by year as the meaningful use criteria change year by year? That’s another education message that we—I kept hearing back from people, so what does it mean now? Even before people heard that there might be a new certification process, people were saying, “So what does it mean right now that certification is only certification for this year? And what happens if the vendor that I’m buying a certified product from this year doesn’t keep up with the certification, so I’m a meaningful user this year but not 2 years from now?” So there’s a ready-enough concern out there, and I just think we need to be really careful about how we put this message out on the street.

**David Blumenthal – HHS – National Coordinator for Health IT**

Deven?

**Deven McGraw – Center for Democracy & Technology – Director**

I don’t disagree that certainty is desirable here, but I don’t think we did anything today to make this marketplace any less—any more certain. I mean, even with res—even with the progress that we made on what we want to recommend with respect to the meaningful use criteria, those don’t get settled until the rulemaking process goes through. So we’re several months away from certainty. So we’re going to be frozen, and we’re going to need to know that the products that have certification are going to enable providers to meet the meaningful use requirements. In my view, that is more critical than anything and is one of the reasons why I think this is a good set of recommendations—don’t disagree at all that the education standpoint—getting a little more data on what criteria do we have in place right now through the CCHIT process that match up well with meaningful use so we have a better idea of where those gaps are. And you know, I think you guys have more information on this than the rest of us do, but my sense is that—I don’t know how you not at least tweak the existing process to make it work for the new set of criteria that involves spending \$46 million in taxpayer dollars and knowing that we got what we paid for.

**David Blumenthal – HHS – National Coordinator for Health IT**

Gayle?

**Gayle Harrell – Florida – Former State Legislator**

Thank you. I agree with you, Deven. I think the market is in such a state right now. This is supposed to be part of a stimulus bill, and what I see happening in the market is that the whole health care EMR market is dead. Nobody's buying anything. Everybody is frozen in fear, because they are extremely concerned that—

**Unidentified Man**

Judy's in big trouble [laugh].

**Gayle Harrell – Florida – Former State Legislator**

I—this—all the providers I know are frozen. They do—now, they want to know what is going to happen, and nobody wants to put down a penny until they find out what's going to happen. So I think this needs to be expedited. If we can—this is a priority issue. If we go down that road, is there any way to expedite this particular element—the rulemaking section of it; get some concrete dates so that people can move forward with some confidence; and that we can open up the whole market, get things moving, and help move the process along?

**David Blumenthal – HHS – National Coordinator for Health IT**

Let's see—Paul and then Judy.

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

I'll make an attempt to thaw a little bit of this [laugh]. I think this—so this is an advisory group, yet it has been a very open and thoughtful process by a lot of people who have a lot of experience. And I think what—the consensus around a lot of the thoughts—have been presented do signal the market, I think, in a very important way. So if you just look at, let's say, whether it's the objectives in the meaningful use criteria or the approach that's being prop—either was proposed by HIE and by certification, those are very strong signals. And I don't know that people would be lost on either the goal that has been set out there or even the roadmap to get there. So I think, with that information, there's certainly intelligent, reasonable steps anyone could take, even beginning today.

What I heard—and correct me if I'm wrong, let's say, with this last group—is that there is a gap, and we want to make sure that we match up the certification with the objectives that have been laid out, let's say, in the meaningful use matrix. You said that CCHIT could have it done by Labor Day and that—your initial proposal was that the existing certified folks with the gap—the additional gap certification would be deemed certified for the purpose of this statute. I mean, I think those are very concrete things that would allow the thawing of the frozen actions. And so, while that's no guarantee, because it is an advisory group and we have the NPRN process, it's not necessarily, in my mind, a way—a reason—or very thoughtful reason to stop where you are and wait because the direction's been set. That would be my thought on that.

**Unidentified Man**

[Inaudible] Recommendation 5 that basically makes it sound like CCHIT is temporary. And that—I think that's where my concern really comes—is that message.

**Unidentified Man**

First of all, I mean, that's not at all of what was intended by that. And—I mean, fundamentally...

**Unidentified Man**

It says, "Until another process is established, CCHIT should continue to perform this." The implicit message is that it's something else—going to happen.

**Unidentified Man**

[Inaudible] Our organization continues to survive the current process. It doesn't—I mean, I would be very surprised if—how this all turns out—CCHIT isn't deeply involved with this thing going forward. You know, I

mean, basically, they're the ones that know how to do it, and they'll be doing it—plus this whole idea of the advisory service. There's a lot of demand for that, and I'm sure they will continue to do that also.

And I also want to say, CCHIT—the people who've done work there—they've done terrific work. I don't want anyone to get any impression at all that there's any intention here to criticize the people at CCHIT or anything that's happened. They've done terrific work. We just have to remember they were formulated under, like, a totally different sort of legal administrative process than what we have here with meaningful use—total different concept, and that's why there has to be a change.

**David Blumenthal – HHS – National Coordinator for Health IT**

So my sense is that we probably need more discussion before we adopt these recommendations, even the high-level ones. And I wanted specifically to separate the high-level recommendations from the specifics, so the transition—not to adopt the transition plan per se, but just the first—the high-level recommendations. If you're comfortable with that, I think it would be a useful statement to the community that we are moving forward. If you're not comfortable with that, then I think we will need to revisit this in—but I would think that if we get that on paper, it at least gives our working group some more direction that they are taking us in—the way we want to go, but we want to revisit the details. I see Neil nodding.

**Gayle Harrell – Florida – Former State Legislator**

If I'm hearing you correctly [laugh], we are not going to adopt, at this point, the high-level recommendations.

**David Blumenthal – HHS – National Coordinator for Health IT**

No, we are.

**Gayle Harrell – Florida – Former State Legislator**

Oh, we are. Okay.

**David Blumenthal – HHS – National Coordinator for Health IT**

So as I'm in the middle of a sentence, I looked around the table, and the body language had changed. So [laugh] I reversed the sentence, but—from being pessimistic about the high-level recommendations to being more optimistic. But I'm waiting for your comments, Gayle [laugh].

**Gayle Harrell – Florida – Former State Legislator**

I believe that we need to move forward and accept the high-level recommendations. There—tweaking of the specifics that absolutely needs to happen, but I think we need to get the message out there that we have got to move forward. We need to expedite the movement of this whole process as soon as possible and really move the thing along. We are under such time frames—I keep harping on time, I know. You don't want to hear me again, I'm sure. But I think it's very, very important that this happen: that we let the community know that these are the high-level recommendations that we are moving forward as rapidly as possible.

**David Blumenthal – HHS – National Coordinator for Health IT**

So the ticking I hear all of the time is a bomb, Gayle [laugh]?

So without objection, I will suggest that we adopt the high-level recommendations by consensus and ask the committee—the workgroup to make any changes that they may think more useful in light of this conversation. They may, for example, want to make some more specific recommendations around the timing of the transition and that we bring those up at the next meeting of the work—of the policy committee.

Yes, Paul.

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

And we also want to publish it in the *Federal Register* and encourage public comment so that we can respond to that also.

**David Blumenthal – HHS – National Coordinator for Health IT**

Okay. That requires some preparation, and we'll have to get back to you on how that can happen.

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

Okay [laugh].

**David Blumenthal – HHS – National Coordinator for Health IT**

It is—we—in order to do the meaningful use, we actually had to notify the public in the *Federal Register* 2 weeks before the meeting that we were going to take comments. Yeah. So we haven't done that for this. We—you know, we were still focused—so focused on meaningful use that we didn't get to that point. We could, though I need to talk to—you know, I'm just a primary care doctor; I don't know this lawyer stuff [laugh]. But we need to talk to our counsel about how we would go about getting public comment. I do want to make the point—well, never mind. So I just have to—I would have to get back to you on that.

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

Okay.

**David Blumenthal – HHS – National Coordinator for Health IT**

So thank you very much. I—we're going to have—we have another couple of panels, and I think we're going to run over. I apologize to the members of the committee about that, because we also do have to have public comment—a public comment period. I want to thank the members of the standard committee for their patience in sitting through these comments. And I think we're going to start with Jamie Ferguson.

**Jamie Ferguson – Kaiser Permanente – Nat'l Director for Health IT Strategy & Policy**

Thank you very much for having this here. So first of all, why are we here? Well, our relationship to this committee is that, by statute, the Health IT Standards Committee is charged with specifying the standards and certification criteria, specifically for health information exchange and the use of health IT to implement the policies that are developed and determined here by the policy committee.

So how are we doing that? We have three workgroups. I'll be reporting on the Clinical Operations Workgroup. We start with—we're starting with the meaningful use objectives and measures, and we started with an initial focus on the proposed quality measures. After reviewing those objectives and measures, we go through a process of identifying the standards and then the feasibility of implementing those standards by different dates. We start with the existing standards that have been adopted, recognized, and accepted by the department. We also look at other widely recognized and widely deployed standards. Then we identify standards gaps for each of the measures.

After we go through the—so we segregate the standards identification process from our assessment of the feasibility of widespread implementation of those standards by 2011 or 2013 or beyond. And then we take a formal step of doing what we call a reality check, and we just make notes about—and we go away and come back and think about what it is that we didn't consider, in terms of the implementation feasibility for widespread use of these standards and EHRs.

Now, once we specify the standards for each measure in the Clinical Workgroup, then the Quality Workgroup has the responsibility to direct the measure stewards to define the specific code values—the specific list of codes that would be used to calculate the numerator and denominator, for example, of each of the measures. And I think Janet Corrigan will go into that in some additional detail.

I have two examples of our process. And I'm not going to go through the details of this. It is in the materials. I'd be happy to take questions. But in general, the existing standards for the quality measures,

such as those from NQF or those that are used in CMS, are not geared to EHRs, and so they need to be reworked for EHRs.

As we look at the standards that have already been adopted and consider the existing standards, we're typically reusing standards for purposes other than those for which they were originally adopted. One exception is SNOMED CT, which was adopted for clinical documentation in the consolidated Health Informatics Standards prior to HITSP coming into existence. But many of the other standards that we're identifying were recognized for EHR interoperability, but now we're recommending that they be used for quality measurement.

So in the interest of time, as I said, I'm not going to go through these examples in detail. But I do want to point out that we've identified some gaps in the adopted standards that may affect the fundamental scope of each of the measures. As an example, here in this measure, we're talking about the percent of lab results that are incorporated in a coded format where we've identified gaps. One gap is documentation of surgical pathology results, and the text that's used for that is not standardized, so that may affect our ability to define standards for calculation of the measure.

Our status is, we've completed a first draft of the EHR standards identification for all the quality measures that were in the previous set of meaningful use criteria before those that were released today. We've also done a first draft of the widespread implementation feasibility assessment for 2011 and 2013 for most of the quality measures. Now, many of these same EHR standards are going to be useful for measures other than those for quality assessment and quality improvement. For example, standards for the continuity of care documents may be selected by the standards committee for health information exchange, for continuity of care, or for patients to receive summaries of their care. But right now, we're only—we've only looked at the quality measures so far.

In terms of our next steps, then, within the workgroup, we will complete the identification of the existing standards, and we'll have cross-workgroup discussion on that as well as the implementation feasibility of using these standards for 2011 versus 2013 and beyond. We then want to take a step to harmonize the standards recommendations across all the different objectives and measures so that, if we're using a standard for one purpose, it might be used for other purposes in the same implementation year. And then we'll develop the standards committee recommendations for the implementation of meaningful use.

And so, I tried to be brief to—in the interest of time here. I'd be happy to take questions. Otherwise, I'll pass it off to Janet.

**Janet Corrigan – National Quality Forum – President, CEO**

Thanks, Paul. I want to first just really commend the policy committee for coming up with a wonderful starting point, really, for us in terms of the quality measure descriptions for 2011/2013. What we have done in the Clinical Quality Workgroup is to identify the specific standardized measures that currently exist and, for the most part, are in use that apply to each of those quality measure descriptors that you've provided.

And I've given you a handout today—a two-page handout, which you should have, that's a brief listing. And I want to be very clear: This is a work-in-progress. What our Quality Measure Workgroup did was to look at each of your quality measure descriptors—so, for example, percent diabetics with hemoglobin A1c under control—and we then crosswalked over to an existing standardized performance measure that is endorsed by NQF.

And for those of you who may not be familiar with the National Quality Forum, we're the organization that evaluates performance measures and then selects the best in class as the standardized performance measure. We have about 500 performance measures—standardized performance measures that have been endorsed by NQF. It's the largest repository of measures and the measures of first choice by CMS, private purchasers, and others.

So what we did is, we went into the repository—that database, and we identified where we had a performance measure that was well-specified, vetted with numerator, denominator, exclusionary criteria.... And as I said, for the most part, it's typically in use. That's really been our first step—is the identification of the measures. We then essentially hand those measures off to Jamie's workgroup, which then takes them into identifying what the appropriate HIT standards are.

Now, the good news is that, for the most part—for the majority of 2011—the quality measures that were identified by the policy committee, we do have an NQF-endorsed standardized performance measure. And most of them are pretty good matches for your quality measures. There's a few that divert a little bit. And of course, there's a few holes.

The challenge, though, in moving forwarding—and I think Jamie alluded to this—is that these quality measures—these standardized performance measures were developed by many different measure stewards. And these measures were not developed for use with EHRs, for the most part. So they now need to be retooled to be able to actually run off of EHRs. As soon as we've reached agreement, as a community or various committees, on exactly which measures will be selected, that retooling process will begin very, very quickly so that, hopefully, the measures will actually be retooled by the end of the calendar year—that's the goal here—so that we have—once it can be rolled out.

Now, there's a variety of challenges in that process. Since the measures were not developed to run off of electronic health records, they probably would be specified quite differently. So, for example, you'll find that many of these measures have a denominator population that is perhaps identified by ICD 10 codes—ICD 9 or ICD 10 codes. And of course, if you have the full richness—clinical richness of an electronic health record, you probably would use other information to identify that denominator population, and you would come up with a more all-encompassing, accurate estimate of the patients who actually belong in the denominator population. So an example there would be that you could identify patients with heart failure using a diagnostic code, but if you had ejection fraction, you'd probably get a much better estimate of the patients who actually belong in that denominator. So that's one of the challenges that we have going forward.

There's also going to be some challenges in terms of certain types of data that need to be captured for some of these measures, which could be difficult in 2011. And our particular workgroup, for example, has identified body mass index and vital signs as ones that it's probably going to be tough to capture in 2011. So we're taking a close look, for each of these measures, what types of data do need to be captured. And a lot of that builds on the work of HITEP, the Health Information Technology Expert Panel, that Paul chairs for NQF, which has already essentially taken each of the measures in the NQF database and traced them down to the types of data that need to be captured to be able to then generate the particular performance measure.

For some of the measures, we don't have—for some of the policy committee quality measures, we do not have—currently have an NQF-endorsed standardized measure. And probably, we'll have to rely on attestation, at least for 2011. But hopefully, as we move into the later years of 2013 and '15, we wouldn't have that anymore. Probably a good example there is the percent of laboratory results that were submitted electronically.

Some of these measures, too—as we look in greater detail at them, there will be fairly significant cost implications for capturing the necessary data and having it reflected in 2011, and that will be another consideration. Lipid profiles is perhaps an example there of one that would perhaps be quite costly.

And last but not least, the performance measurement community—for those of you who aren't familiar with how performance measures are developed for quality measurement and reporting purposes, there are many different measure stewards that develop measures—dozens of them. And these measures typically have been developed in silos. So, for example, we may have a body mass index measure for the hospital environment. We have another one for ambulatory environments—probably also have them for the long-term care community. And there are different conventions that have been followed by the various measure stewards. So moving forward, we want to use this as very real opportunity here to encourage harmonization and the development of what we call patient-centered measures. Essentially, the body mass index should be the same regardless of what environment that patient just happens to be in, and regardless of what type of provider's treating that patient.

So this will be a bit of a moving target over time, because there's a huge amount of work here to redo and retool these measures in order to get to measures that actually are harmonized across various settings. You'll also find that there's inconsistencies depending upon whether the measure applies to a pediatric population or an adult population. And once again, that's because we've had measure development occurring in silos of pediatric community developing their measures and then the adult community developing measures for adults. So all these are things that we will have to kind of work through going forward.

Now, the Quality Workgroup over the next few weeks—what we're going to be doing is to start to work on a framework for classifying each of the NQF-endorsed performance measures according to two dimensions, one being sort of a degree of readiness for implementation in 2011 and in what form; and then the second one to begin to take a look at some potential recommendations that we can make to both the standards committee, and presumably also to the policy committee at some point, about setting thresholds for those various years, depending upon the degree of readiness for implementation in each of the years going forward.

Then I guess the last point I would make that is, in terms of timing, we think we're getting pretty close to a list of performance measures at this point, and we'll be delivering our recommendations to the standards committee next week for them to weigh in on it at that stage. The overall framework for the thresholds and sort of degree of readiness will be in the very early part of August. I'd be glad to answer any questions you have.

And I should acknowledge my colleague, Floyd Eisenberg, who has done just extraordinary work and, really, this mapping of the endorsed performance measures over to the policy committee's quality measurement listing, which was a huge amount of work. Thanks.

**David Blumenthal – HHS – National Coordinator for Health IT**

Thank you, Janet. Any questions for Janet? Yeah.

**Unidentified Woman**

Can you give us an indication when those harmonized measures would be available and when they would become part of the 2011 project that we have to have ready for the vendors and the market?

**Janet Corrigan – National Quality Forum – President, CEO**

It'll be a mixed bag for 2011, as you might imagine. As we—as the Quality Workgroup dives in deeply into the individual measures, I think what we'll find is that we do identify some aspects of harmonization that the measure stewards can respond to in their retooling between now and the end of the year. But then there's going to be a variety of other aspects of harmonization—that frankly, it becomes—it's closer to a new measure than it is to the existing measure. So we're making a distinction between modifications to the existing measure that probably had more to do with the underlying data source—maybe more minor tweaking. If that harmonization really requires a very significant change in the measure, then it's really more of a new measure, and you're looking at 2013.

#### **Unidentified Man**

[Inaudible] question. And I don't know if this is for Jamie or for Janet, but we heard discussions on the Certification Workgroup regarding a lot of the specialty practices, particularly from one oncology group, where just tumor classification varies setting to setting, hospital-hospital. Are there standards in place for some of these specialty practices that can start to be incorporated or looked at?

#### **Jamie Ferguson – Kaiser Permanente – Nat'l Director for Health IT Strategy & Policy**

Well, I'll just say, from the standpoint of our workgroup, we are identifying a number of gaps in HHS-adopted standards, where there may be a variety of standards both nationally and internationally that they could potentially be used. They haven't been through the public comment and vetting and selection process. And so, we're identifying those as gaps, and we're going to have to figure out how to deal with those. But I also think that, in some areas, there may be either partial standards or no standards that would affect the scope to which the measure could potentially apply.

#### **David Blumenthal – HHS – National Coordinator for Health IT**

Let's move on now to Dixie. Okay, last question. Go.

#### **Unidentified Woman**

Do you know when you might have the required—list of required fields available? Because that would be extremely helpful, even though I realize you're in the middle of changing some of the measures, which would change some of the fields. But having a notion of the space or the fields would be very helpful as we move forward in trying to understand privacy issues and things like that on the secondary use of the data. Do you have a time frame? [Pause]

#### **David Blumenthal – Department of HSS – National Coordinator for Health IT**

Guess not [laugh].

#### **Jamie Ferguson – Kaiser Permanente – Nat'l Director for Health IT Strategy & Policy**

I don't think we have firm dates yet.

#### **David Blumenthal – Department of HSS – National Coordinator for Health IT**

Okay. Let's—Dixie, please.

#### **Dixie Baker – Science Applications International Corporation – Senior VP, Chief Scientist**

Okay. I appreciate you inviting us all to report our status back to you today. I'm Dixie Baker, and I'm the Chair of the Security and Privacy—Privacy and Security Workgroup of the standards committee.

Basically, it—and I credit Jodi Daniel for making this very clear to us—is that in order to get reimbursement for adopting an HER, an eligible provider must meet two separate requirements. First, they must show that they've acquired a certified product or certified service. And secondly, they have to demonstrate that they are using that product and service—or service meaningfully. So the standards

committee really needs to recommend two things—two sets of criteria: one set of criteria to be used in the certification of products, and the other to be used in the—in demonstrating that the applicant is using that acquired product or service meaningfully.

In the case of privacy and security, this distinction is particularly relevant and important. Because certification of a defined function or service has been implemented in the product does not imply that the user is necessarily using it meaningfully or, in fact, even that the user is using it at all. And I'll give you two good examples of this. One is the case of audit. I am absolutely sure that the capability to audit user actions will be part of our criteria for certifying of an EHR product. But everybody knows that when auditing is implemented in systems, it can be turned off, and you can audit different actions. Another example is encryption. You know, you may have the capability to encrypt, but depending on your policy, depending on your use case, depending on your environment, you may or may not use that encryption capability. So it's really important that the Privacy and Security Working Group make this distinction.

And what we've done is adopted an approach that addresses both the certification of products and the demonstration that a user is using the certified product meaningfully. And I'm going to show you today how that comes out.

Okay, this first slide here—what we did is, we went back to the ARRA eight priority areas of focus. And in those eight priority areas, we extracted those priority areas that have implications for privacy and security and can be used to derive privacy and security criteria, which is what we did. We identified the privacy and security services that are implied or directly required by the ARRA 8, as we affectionately call them. Then, once we had that list of privacy and security services, we looked at the available sources of standards, those being the CCHIT certification criteria and the HITSP construct. And we mapped those available standards into the privacy and security services. Now, what really happened is that, you know, in the case of HITSP, a lot of HITSP uses IHE profiles. So we went to—we identified the IHE profiles, and then we went to the IHE profiles and extracted the technology standards that those profiles depend upon.

So the next step is to really map that into the meaningful use demonstration. First of all, we will—we believe that there will be a subset of all the product certification criteria that will be part of the meaningful use criteria in particular. And then in—then above and beyond that subset of certification features are things like the IT infrastructure—things that really are derived from the HIPAA requirement for meaningful use. And so, the combination of the required services—you know, this list of services must be configured if your—you know, your application is deployed on a laptop, for example, that's carried around or between hospitals or something like that. That will have a different set of configuration requirements than one that sits in a very secured area.

Then we'll add the secure IT infrastructure and secure operations. In particular, we want a current risk assessment and a current contingency plan. The contingency plan—those are—both of those are HIPAA requirements, but both of those are really important to meaningful use, particularly contingency plans, to show that they—as they acquire this EHR technology, they have assurance—they have processes and procedures and operational rules that assure that they—that the information and the services that they need will be available when they need them. And we haven't finished that list, and I doubt we do by Monday, but [laugh] there's a list of additional things that we—criteria that will become part of dem—the demonstration of meaningful use.

Okay, this is—in these next two slides, I just show you what—the criteria that we derive—the policy—privacy and security services that we derive from the ARRA priority areas of focus. As I mentioned, there are eight areas of focus. Here you see the first four. And on the right, you see the services that we identified that—the first ARRA priority area is jam packed full of security requirements, security criteria,

identity management, authentication, access control.... And in fact, it implies two types of access control. It implies user-based, identity-based, or a role-based as well as label-based when it gets into the segmentations category—consent management in encryption. The second one, the NHIN—we've been told that it's—that in all probability, most of the health exchange requirements are likely to come in in 2011, with some exceptions. And my workgroup would very much like to talk to your workgroup on the HIE about what those are likely to be—pardon?

**Unidentified Woman**

I was just thinking that.

**Dixie Baker – Science Applications International Corporation – Senior VP, Chief Scientist**

Yes—what those are likely to be so we know what—which of the exchange capabilities we need to include in 2011 versus 2013. And then the fourth one, technologies that are part of the accounting of disclosures—everybody knows that's in ARRA. And these are the kinds of security services: auditing, consistent time, inner-enterprise traceability, and nonrepudiation.

This slide shows the Priority Areas 5 through 8. And you can see #5—some of you may not consider #5 a security priority area. But in our view, and certainly in my opinion, I believe, you know, security is important not only to protect privacy, but also to assure the integrity of data and that critical services and information are available when they're needed. And that's why we stated the #5—the use of certified EHRs to improve the quality of care—those two functions of security, protecting the integrity of data and the assurance that services and information are available when they're needed, I believe, will make or break EHR adoption, because if we have systems that are able to perform the clinical functions that we need at that particular clinic or that particular hospital, but the doctors soon learn that they can't depend on the integrity of the data and they can't depend on the services and the avail—and the information being available when they need it, they will not continue with that adoption. So we believe that that is very important.

You look like you're ready to say something.

**David Blumenthal – HHS – National Coordinator for Health IT**

I'm only paying attention to time, so...

**Dixie Baker – Science Applications International Corporation – Senior VP, Chief Scientist**

Okay. These—this is the last slide, and these were the concerns that we sent to the policy committee when we reviewed the goals and the objective and measures. We—our committee did have some feedback on that. One, we were concerned that it was—that the privacy and security was focused exclusively on privacy and confidentiality. We believe that the security functions to protect data integrity and service availability are equally important. I—you already mentioned—I saw in your slide that you mentioned HIPAA compliance. Our people felt—our workgroup felt that HIPAA compliance's already required by law, so it may not make sense as a measure for meaningful use. We also felt that public health should be addressed and that the measures that we put in place—and criteria we put in place need to accommodate both small clinics as well as large hospitals and integrated delivery networks.

**David Blumenthal – HHS – National Coordinator for Health IT**

Thank you very, very much. Thanks to all three of our panelists. We are so pressed for time that I'm going to use the Chair's prerogative to ask you to step off the panel. We're not going to take any additional questions, I'm sorry to say. But that doesn't mean you won't get questions later. And I think we've benefited from the opportunity to coordinate and learn about what you're doing, and I'm sure that this exchange will continue.

I think that we've now reached the point on the agenda where we are going to open the floor for public comment. And Judy, are you going to manage this part of the process?

**Judy Sparrow – ONC – Executive Director**

Those in the room, if you wish to make a comment, please step to the microphone. Let me remind you that—make those comments short and noncommercial, and we'll check in on the phone periodically. We have about 10 or 15 minutes for comments.

**Chris Weaver**

[Instructions]

**Kathleen Connor – Microsoft Corporation**

Hi, this—my name is Kathleen Connor with Microsoft Corporation, and I'm also—participate in HITSP and the Security Privacy and Interoperability Workgroup; HL7; and, to some extent, in IHE. I would like to—I think that IHE and HITSP specifications are great for the [inaudible] EHRs. I would just like to ask that the committee consider whether those are appropriate for some of the modular component technologies that are now being looked at for meaningful use implementation. I think, in some situations, they are not, specifically around the security standards. And the IT standards are more for enterprise systems and are not particularly helpful for privacy protection. Thanks. [Inaudible]

**Dmitry Novak – Professional**

My name's Dmitry Novak. I don't represent Microsoft or some other company; I represent myself, so... I'm professional. Behind me, 55 years in information science; technology application, in particular pharmaceutical needs as x-ray imaging—all the sorts—x-ray, chemical analysis, CT, and MRI. I'm professional, period. But my remarks will be from professional point of view, but mainly from the commonsense point of view, because what we don't see is, we don't see forest among the trees.

So five comments, very shortly. I'm professional in data compression, so I'll compress as much as I can my comments. So first of all, these numbers—2009, 2015—it's too long time from 2009 to 2015. It's more than the term of Presidents. It's unbelievable. If you cannot do anything for 6 years we need to wait, maybe don't do this.

Second comment about numbers: 10 processes and—this and this and this—it reminds me—very simple anecdote, where you describe separation really eloquently. Man came to **old doctor** and asked, "What will the product—2x2?" And so doctor said to me, "What do you need?"

So this time frame—2011, 2013, 2012—it's nothing behind this. It's—and again, why you measure time in years, not in months?

**Judy Sparrow – ONC – Executive Director**

Sir, thank you. We've got a line behind you.

**Dmitry Novak – Professional**

I'm—it's only short comments. I spent most—

**Judy Sparrow – ONC – Executive Director**

I'm sorry; we have people behind you. If you could just make it a lot shorter, thank you.

**Dmitry Novak – Professional**

So what, I can speak or no?

**Judy Sparrow – ONC – Executive Director**

You can, but just please speed it—make it shorter.

**Dmitry Novak – Professional**

I—as short as I can. I compress tremendously. Comments about meaningful use—ladies and gentlemen, if you are in doubt, don't play with what we just heard. What kind of use can be as meaningful? Is this—and by the way, you established 48 criteria of meaningful use.

**Judy Sparrow – ONC – Executive Director**

I'm sorry, sir; I'm going to have to ask you to—if you want to submit written comments to me, that'll be fine. I'll put it in the—

**Dmitry Novak – Professional**

I'm sorry?

**Judy Sparrow – ONC – Executive Director**

We have people waiting; I'm sorry. I appreciate what you've said, but we're going to have to let other people have a moment.

**Dmitry Novak – Professional**

Okay, if you don't permit me to speak, I explain to—

**Judy Sparrow – ONC – Executive Director**

I think you have been speaking. Thank you very much.

**Robert Kapler – America's Blood Centers – Director Government Relations**

Good afternoon. I'm Robert Kapler. I'm Director of Government Relations with America's Blood Centers. We represent 75-plus centers across the Nation that collect about half the blood annually. I—and one—we are one of the organizations that submitted meaningful use comments. And I first, just want to thank everyone here for allowing us to submit the comments for the transparency that you've shown and your willingness to include the viewpoints of all stakeholders. I'm not going to reiterate my comments, but I just want to point out a couple of things: that blood centers were included in the Stimulus Act under Title 8 and that we are part of the National Response Plan, which means we are part of the critical infrastructure of this country and, as such, along with EMTs.

I was at the CONNECT seminar, and I heard Dr. Blumenthal speak. And an EMT got up and said, "Where can we fit into this process?" And he said, "Well, basically, this is geared toward the Medicare bill—Medicare and Medicaid billers, the physicians and hospitals." I submit that blood centers are—should be part of this process. And I ask you, where can we fit in? I looked at the meaningful use matrix, and by the way, we endorse most of the measures and objectives of meaningful use matrix, and we think this process is being done correctly. But we believe transfusion should be part of the matrix. Thank you.

**Judy Sparrow – ONC – Executive Director**

Thank you. Let me just put a 2-minute limit on everybody else so we can get as many people as possible. Sir, go ahead.

**Rick Blake – Strategic Health Resources**

Rick Blake, Strategic Health Resources. The GAO this week released its report on DoD and VA—the challenges that they face harmonizing their clinical data. And since veterans use both VA and non-VA facilities on a community level, I was wondering whether this committee has, as a goal or an objective—as to meshing with the DoD and VA EHRs?

**Judy Sparrow – ONC – Executive Director**

Let's take a caller on the phone now, please.

**Operator**

Our first comment from the phone comes from the line of Jean Vagan—Fagan.

**Jean Fagan – Wheaton Franciscan Healthcare – VP Operations**

Hi, yes, this is Jean Fagan. I'm the Vice President of Operations here, responsible for the implementation of electronic health record at Wheaton Franciscan Healthcare in Wisconsin.

One of the comments I wanted to make was around the 10 percent of all orders entered into CPOE. We've just completed a 3-year project—or finishing a 3-year project of implementing 22 applications that will comprise our health record. We've implemented in nine hospitals across two States. CPOE is not, as I believe—I think it was Gayle, and I don't want to misquote her—said it's an aggressive timeline and it's challenging. I think one of our approaches to implementing CPOE is to stratify the implementation, where we're concentrating on the hospital side of implementing it first to all the hospitalists, intensivists, RN population—because we feel, again, trying to apply that 80/20 rule of getting the—at least 60–70 percent of all our orders for the inpatient world are addressed to those clinicians.

So I just further suggest, maybe, is that something that the panel could look at as they're looking at that 10 percent of all orders? Does that apply to the inpatient world? Does that apply to all of the hospitals? And maybe you look at—in 2013, going—you know, start with the inpatient world—certain population and then expand it to all of the clinics and outpatient areas, etc. That's my comment. Thank you.

**Judy Sparrow – ONC – Executive Director**

Thank you. And in the room, please.

**Richard Eaton – Medical Imaging and Technology Alliance**

I'm Richard Eaton from the Medical Imaging and Technology Alliance. We submitted comments on meaningful use, and I won't go into them in depth at all. I just want to emphasize a couple points, and—basically along the theme of why imaging—why it's important to include both diagnostic images and imaging information into the EHR. The meaningful use matrix states that providing clinical decision support at the point of care and exchanging clinical information among providers are key goals. We know, secondly, that medical imaging provides pivotal diagnostic information from any clinical decisions and is a valuable clinical decision support tool. Thirdly, one of the primary purposes of the ARRA and the underlying important purpose of EHR is to make delivery of medical care more efficient and to save costs through reduction in unnecessary or duplicate imaging scans. However—but if a practitioner is unable to access imaging information, this fuels the growth of duplicate imaging. So that is something that needs to be remedied. Therefore, I think that both diagnostic images and imaging information ultimately must be a part of EHR. Thank you.

**Judy Sparrow – ONC – Executive Director**

Thank you, Richard. And let me do one more on the phone. We're losing our committee here. Thank you very much.

**Operator**

Our next comment from the phone comes through Donna Robinson with Caption Colorado.

**Donna Robinson – Caption Colorado**

Yes, this is for deaf, hearing, and hard-of-hearing persons. My public comments are as follows: I have not heard much about the patient in all of this. I hope the committee will make sure the development of an electronic health record includes accessibility to the disabled, including sight/hearing impaired. Also I hope that the committee will consider a patient-centered EHR that provides clear health data rights for patients who control their own health data. Thank you very much.

**Judy Sparrow – ONC – Executive Director**

Thank you. Do you want to make one quick comment?

**Sarah Nicholls-Sharp – American Physical Therapy Association**

Yes. Hello, my name is Sarah Nicholls-Sharp for the American Physical Therapy Association. We wanted to comment specifically on meaningful use, as we iterated in our comments submitted last month. We think that meaningful use is severely limited without the inclusion of all health care providers. Physical therapists and other nonphysician health care providers play a crucial role in delivery of care to patients. And a goal of quality, efficient, safe, and cooperative care cannot be met if they are excluded from initiatives that are designed to foster the adoption of meaningful use of health information technology. We would encourage you to consider the limitations of HIT, as a physical therapist or other nonphysician health care provider is unable to exchange information with a physician or vice versa.

And so, therefore, we would urge you to put together a recommendation to ensure the inclusion of nonphysician providers in the definition of meaningful use and the work that is taking place. We are prepared to assist you in any way possible in developing criteria that are inclusive of physical therapists and their vital role in delivering quality care. Thank you very much.

**Judy Sparrow – ONC – Executive Director**

Thank you. And I—we've gone over now almost 30 minutes, so I think we need to adjourn.

**David Blumenthal – Department of HS – National Coordinator for Health IT**

I appreciate that and appreciate all the folks who have taken the time to both submit comments—they're extraordinarily helpful, and you saw that it played an important role in the deliberations of all the workgroups in the committee. And at this late stage, I want to—is there any other urgent business on the part of the committee? [Pause] Hearing none, we'll stand adjourned. Thank you.

## HIT Policy Committee Meeting – July 16, 2009: Public Comments

1. While the HIE discussion was enlightening and well presented, the Committee did not directly address the additional costs a HIE places upon the clinician. There is common agreement that there is a disconnect between who receives the value and who pays for the services of an HIE. It is hoped that the cost issue will be addressed and that HIE will not just be one more cost that must be borne by the provider community.
2. The 2011 reporting requirements for physicians should reward those that have implemented EMRs that are capable of capturing the data needed, rather than require the actual reporting; defer actual reporting to 2013; by doing this, physicians will have time to redesign their processes and work flows to better accommodate the reporting requirement; the effort and time to implement the EMR is a great enough stretch for 2011
3. Am I correct in that there will be several certifying bodies focused on just MU certification?
4. Will the HHS MU criteria be a Superset of the CCHIT 2009 criteria?
5. How many of the board members have a provider who uses an EMR now?
6. Under the current fee-for-service payment model, providers don't seem to see much of a benefit from either sharing their data, or using somebody else's data. Which means that there is little push on their part towards HIE, and the market simply doesn't exist. But HIE is absolutely crucial with regard to public health, biosurveillance, early epidemics discovery and collecting diagnosis-treatment-outcome statistics. I believe the Government will have to be the driving force behind HIE.
7. certification based on MU criteria is great, however why should there be a second "comprehensive" certification -- it costly and distracting
8. Does that mean that the new HHS criteria will be a SUPERSET of the current CCHIT criterion? Or a different set
9. The only way you will solve HIE is by mandating 1 master IHE per state - in a standard format - those HIEs out there now would actually like this b/c since they collect the data already they could then just transmit it to the state exchange. Every provider subject to meaningful use should be on the hook to comply with transmitting the data to (1) either a middleman already collecting the data who could charge a fee or (2) directly to the exchange. This would encourage innovation & the free market. Plus you can then, from a national level, run queries showing people at risk of heart attacks and make sure they are on meds. This will lower overall medical / hospital costs.
10. How would we do medical network connectivity for care coordination, medical homes, multi entity registries and other multi path communications to support new way medicine if we go to MARKET Based solutions or proprietary approaches of labs and pharmacies? The claims clearing houses are way different than HIO/HIEs. The claims transactions must be delivered from individual providers to ONE end point, a claims processor in order to get paid! This does not exist with clinical data in any way, does it? The big barrier is that competitors in a market do not want to collaborate and share, but to compete on a most wired, most advanced, and gaining physician lock in basis.
11. Do the penalties for 2015 remain in place for 2015 to occur in 2015 for both hospitals and docs or are they pushed back under meaningful use recom?
12. What do we do if we approach this exchange at the transaction level of orders and results how do we keep from fragmentation which makes consolidating a patients record for a patient centric view? The market based approach may result in aggregation of data and control of patient level

13. On HIE what about Edge Server model? How will patient be uniquely identified? Name and DOB not sufficient. Address not reliable. SSN forbidden.
14. What does the opt-out refer to ? Opt out of the inclusion of their information in the entities EMR/EHR, or that orders or results cannot be communicated electronically (exchange) through inter entity communication, or that their history would not be included in any multi entity CDR, or registry without their consent. Of course there are many other areas or environments; however one should document and explore each of them relative to a patient's ability or option to opt out. The answers to these types of questions will or would have tremendous implications to the whole effort. An example might include a patient's ability to opt out of the HIE HealthBridge for all orders and result delivery of transactions directed by the patients physicians with the patients implied consent. Will the eRX Surescripts connect to and through EHRs hubs, through state wide hubs and or through regional HIOs or HIEs? If so under what circumstances?
15. Excellent idea to apply 2011 standards even for late comers. Who will monitor and measure?
16. My concerns are really more of a policy issue than a definition one, and apply to the direction signaled by the Policy Committee in yesterday's meeting.
17. I support Charles Kennedy's observations relating to the need for transactional data to be transformed into views that provide decision support for physicians and patients. In a presentation this spring, Dr. Kennedy mentioned ontologies as tools for understanding the relationship of concepts in health care. Axiologies could be used as tools for understanding values in health care. An example of an axiom is: "The whole is greater than the sum of its parts." From a patient's perspective, a Health IT (HIT) axiology would be a view showing the value to a person's health that would be greater than the sum of the transactional data parts.



## **ABC Urges Health IT Policy Committee to Include Exchange of Blood Transfusion Data in Definition of Meaningful Use**

America's Blood Centers (ABC), the national association of non-profit community blood centers, whose members provide half the nation's volunteer blood supply, urges the Office of the National Coordinator of Health IT, Health IT Policy Committee to add the language "record and generate blood donor infectious disease test results, track blood to the right recipient, and monitor blood recipient transfusion data" to the definition of meaningful use.

Specifically, ABC asks that those words be added to the 2011 Objectives of the Meaningful Use Matrix in the "Health Outcomes Policy Priorities" row: "Improve quality, safety, efficiency, and reduce health disparities" as part of the definition of meaningful use.

ABC members are actively working to implement IT systems, improvements, and processes to track blood from donor to patient to reduce the number of transfusion errors (i.e., "right patient, right blood") and transfusion-transmitted infections in the hospital setting. In addition, ABC members are working with partner hospitals to monitor blood use to assure patients get the blood they need (i.e., appropriate blood use). For example, IT systems being implemented include: those based on radio frequency identification and bar-coded labeling for tracking blood from donor to recipient; use of data miners and a data warehouse to help hospitals benchmark blood use with other hospitals; and nationally monitoring disease markers in blood donors as early warnings of trends. In addition, efforts to establish an interface standard will allow data exchanges in the blood center environment and between blood centers and hospitals. The number of deaths caused by incorrect blood component transfusions already has decreased in recent years with the requirement for automated-readable information on container labels.<sup>1</sup> With the full implementation of health IT systems between blood centers and hospital transfusion centers, transfusion-associated adverse events and inappropriate transfusions will continue to fall.

The American Recovery and Reinvestment Act (ARRA) includes several health information technology (HIT) grant programs for which America's Blood Centers (ABC) members should be eligible to apply. Title XIII of the legislation, "Health Information Technology," contains the health IT provisions, including grant programs, technical assistance, and hospital and eligible provider incentives. Blood centers are included in Section 13101 under the definition of "health care provider" for the purposes of Title XIII. However, the eligible recipients and the application process for the majority of the grant programs in the HIT sections of ARRA are unclear. Thus, blood centers have been stymied in applying for HIT funding.

ABC is North America's largest network of community-based blood centers. Recognized by the U.S. Congress for its critical work in patient care and disaster preparedness and response, this federation of 76

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<sup>1</sup> Citation: Vamvakas EC, Blajchman MA. [Transfusion-related mortality: the ongoing risks of allogeneic blood transfusion and available strategies for their prevention](#). *Blood*. 2009 Feb 2. [Epub ahead of print]

blood centers together operates more than 600 collection sites in 45 U.S. states and Canada, providing half of the U.S. and half of the Canadian volunteer donor blood supply.

Congress' intent was clear: Blood centers are stakeholders in any electronic health records network and should have access to HIT funding. Thus, any definition of "meaningful use" should encompass the critical work that independent, community blood centers are doing to enhance or create systems that better track life-saving blood products from donor to patient, and to help ensure that the right patient gets the right blood.

Specifically, HIT funding under ARRA would allow:

- **Implementation of Sophisticated Tracking and Coding Systems:** IT grant funding will enable blood centers to strengthen blood product tracking and records interoperability with the hospitals and other transfusion services they supply. The ABC HL7 Special Interest Group has been formed with the long-term goal of developing a data structure and messaging standard that will facilitate system-to-system interface in blood center environments and, eventually, between systems in blood centers and hospital transfusion services. The new HL7 standard will enable blood centers and transfusion medicine entities and operations to exchange data between systems in the same facility and systems in multiple facilities. The enhanced messaging will include the transmission of donor and donor-related information not currently included in the HL7 Standard, which is already used by hospitals. The enhanced messaging will utilize specific blood product/transfusion-related messaging structures.
- **Implementation of Appropriate Blood Inventory Management.** ABC recently began providing blood centers with a tool to help hospitals and physicians better manage the available blood supply while lowering the risk of transfusion complication and the cost of blood transfusions and increasing the local blood supply. Using an enhancement of software developed by the UK's National Health Services Blood and Transplant (NHSBT), a consortium of ABC centers is beta testing a blood inventory management program called AIM, short for Appropriate Inventory Management. Phase One of the project is a Web-based data management system to be operational in the summer 2009 that will collect from and provide data to blood services and hospitals regarding individual and community-wide blood inventory; benchmark and trend blood center and hospital performance against a national database; and help hospitals comply with current and emerging industry standards on monitoring blood usage. In eight years of use, NHSBT experienced a 16 percent decrease in the quantity of red blood cells distributed of over 16 percent, a 45 percent reduction in wastage and an average five-day increase in the freshness of red blood cells distributed.
- **Secure Data Collection and Storage:** IT funding will help blood centers ensure a level of system redundancy necessary to preserve and maintain access to vital data about blood supplies, blood products, blood samples, donor histories and blood test results, especially during domestic emergencies. A 2006 survey found a significant number of blood centers without IT redundancy.
- **Improved Identification of Infectious Diseases:** Blood centers are in a unique position to identify infectious diseases across a broad demographic of the population and provide that data in a timely fashion to local, state, and federal health authorities. Most blood centers perform nine different disease marker tests to identify hepatitis B and C, HIV, syphilis and West Nile infections. A growing number of blood centers have begun using electronic donor questionnaire forms, which provide data about the risk factors and habits of millions of Americans. Grant funding could be used to provide donor data (with full security and privacy precautions in place) to health-care and government database systems. In conjunction with emerging electronic blood tracking systems and testing data,

donor questionnaire data could be used for state and regional hemovigilance systems that would help governments assure the adequacy and safety of the blood supply.

For all the reasons stated in this submission, community blood centers need access to federal grant funding for health IT initiatives. Adding language that includes transfusion safety in the definition of meaningful use not only will ensure that transfusion safety is considered a part of the national HIT initiative objectives but will be a valuable first step to helping blood centers obtain the resources they need for HIT projects.

Submitted by,

Jim MacPherson  
CEO  
America's Blood Centers  
725 15<sup>th</sup> Street, NW, Suite 700  
Washington, DC 20005  
(202) 654-2902