

GOVERNOR DOUGLAS: Thank you very much.

I'd like to invite our first two speakers to come up to the table and I'll introduce them to the Alliance and to everyone else who is with us today.

Jodi Daniel is with the Office of the

National Coordinator, and Mark Leavitt is with the Certification Commission for Health Information Technology. Thank you so much and welcome to the Alliance meeting.

If you're agreeable, I'd like to defer questions and discussions until after both speakers have concluded their remarks, and then we'll have, as Phil said, time for interaction.

Our first speaker is Jodi Daniel, the Director of the Office of the National Coordinator's Office of Policy and Research. That's a lot to put on a business card, but, thank you, Jodi, for being with us.

Her responsibilities, as Director, are: Considering the health policy implications of key information technology activities; coordinating health information policy discussions within the Department of HHS.

Her responsibilities include leading health information technology research efforts to inform policy decisions.

We asked Jodi to come this morning with

some description of federal activity in the context of our discussions at our meeting a couple of months ago, as well as some further information on the work of the Federal Advisory Committee that Secretary Leavitt has formed on health IT.

So, Jodi, thank you for coming and joining us again.

(Slides.)

MS. DANIEL: Thank you. It's a pleasure to be here this morning. Good morning to everyone on the State Alliance.

I'm going to talk a little bit more about the American Health Information Community, some of the recommendations that have come out of that advisory body, as well as talk about some of our federal activities and where there may be some opportunities for the State Alliance to look at issues that are complementary to the work that the Office of the National Coordinator is doing and that AHIC is looking at.

I really see that there needs to be a

really close partnership between the states and the

Federal Government. There are a lot of issues in health IT that require nationwide approaches, so that information can be shared across the country in an interoperable way.

But there are also a lot of issues that the states have control over, because there are legal issues that are reserved to the states, because they require some grass roots efforts, and it really does require a partnership between the Federal Government activities and the state government activities, and I hope to bring some of those out today.

To just give a brief overview of some of our collaborative activities, the American Health Information Community was mentioned by Dr. Kolodner last time, and this is going to be a little bit of a focus of my presentation, and I'll talk a little bit more about this.

This is the Federal Advisory Committee to HHS and provides us with advice on how to proceed and how to prioritize issues related to health IT.

The Health IT Standards Panel is being

managed by the American National Standards Institute,

and this is really an effort -- it's a public-private collaboration whereby there are many volunteers that come together to look at existing standards that are out there, identify where there may be gaps in standards, and whether there are duplications in standards, trying to harmonize those, so that there are recommended standards that are uniform or harmonized, that everyone can use.

They're also preparing implementation specifications or implementation guidelines to provide further detail regarding those standards, so that, in fact, when two different entities are implementing the standards, they're implementing them in the same way and the information can be shared from one place to another.

This is one of those areas where I think there is a real need for leadership at the nationwide level, because, in order to have information that can flow across jurisdiction, it does require standards that can transfer across all of the states and not just standards within a particular state.

So that's something that we've been

working on. There has been a first set of standards that has been recommended by HITSP. They have gone through the American Health Information Community and have been recommended to the Secretary.

The Secretary has accepted those recommendations, and has said that they will be recognized as the official standards that we endorse by the end of this year, which gives folks a year's time to try to incorporate those standards -- to give vendors time to incorporate those standards into their products.

The Certification Commission for Health IT is looking for certification criteria for electronic health records, and then also will be looking at criteria for the network across which information is shared. I'm not going to spend too much time on that, because Mark Leavitt will be talking about that extensively.

The last one in the top category is the Nationwide Health Information Network. We have just finished our first efforts at Nationwide Health

Information Network prototypes.

We had four consortia of vendors and healthcare providers and others, that worked together to develop prototypes for a network architecture, for designing the functional requirements and how information can be flowing from one organization to another, from one community to another.

The goal of the NIHN is to be able to foster widely-available services; to facilitate accurate, appropriate, and timely exchange of health information that can follow the consumer and support clinical decisionmaking.

One of the things they also did -- and I believe that NGA will be providing some more information for you on this in the near future -- is that they also were required to look at business models to figure out how to -- how a nationwide health information network could be sustainable.

And each of the prototype contractors developed business models looking at services, governance, pricing, and adoption. All of them also said that there was a requirement for an active

government role, and so there's an opportunity there

for looking at state or regional networks for state participation or in nationwide networks, to look at national participation or Federal Government participation.

If members of this Committee would like more information about those business models or a discussion of those, that could be provided at a later time.

And then if you go to the bottom of this slide, there are a couple of state-based activities that we've been involved with, because we do see the importance of the role of the Federal Government and the state governments working closely together, or the Federal Government working with folks at a state level, and even with folks in the private sector.

So we have the Health Information Security and Privacy Collaboration. This is a group of 34 states and territories that are looking at privacy and security issues, particularly at a state level and organizational level, identifying what practices and policies and underlying laws are out there; where

there are variations in those practices and laws, and

where those variations may pose challenges to health information exchange.

They have developed interim solutions so far, and working on implementation plans for how to implement those solutions. They have also had conversations at a regional level and at a national level to talk amongst all of the various states that are participating, to figure out where there are opportunities for collaboration.

And one of the things that we're planning to do as next step, is to try to fund some of those implementation plans at some level, perhaps requiring some matching funds, but providing some funding for that, as well as to focus on some of the interstate collaborative implementation plans.

The state-level Health Information Exchange Initiative is being spearheaded by AHIMA, and they are looking at basically private-sector activities at a state level, so they are looking at state health information exchange activities, focusing primarily on private-sector activities in

various states.

They are looking at some best practices, such as governance, sustainability and health information exchange practices, and there may be some opportunities with that third task force to collaborate with some of the efforts there.

Then, finally, obviously, there is the State Alliance, which we thought was an important piece of this, because there are so many policy issues coming up at a state level, that it's wonderful to have this group put together to try to focus on some of those issues.

So the American Health Information Community, as I mentioned, is a federal advisory committee. It is chaired by Secretary Leavitt. It's the only federal advisory committee that HHS has, I think, out of about 250 advisory committees, that Secretary Leavitt chairs personally himself.

This is one of his most high-priority issues. There are 17 members from both the public and private sectors, representing various stakeholders in the marketplace, as well as some of

the big federal players, to get input and

recommendations on how to make records electronic, how to encourage adoption of records, looking at issues related to standards, looking at issues related to privacy and security policy at a federal level, and the like.

The AHIC also has a number of workgroups that report into them, sort of similar to the task forces that the State Alliance has. There are -- we've had over 120 experts and stakeholders represented on those workgroups, so we're reaching far and wide to get lots of input on some of these very important issues.

The first set of workgroups that were formed, were focused on particular breakthrough opportunities. The first was consumer empowerment, which was looking at how to get information into the hands of consumers, and they were focusing primarily on medication history and registration summary information as the first step.

The second was the Chronic Care Workgroup, which was focusing on how to -- as a first step, how

to make secure messaging viable between doctors and

patients, so that patients and doctors could communicate, or patients and clinicians could communicate electronically when they are not physically present with one another.

The third was originally the Biosurveillance Workgroup, and now the Population Health and Clinical Care Connections Workgroup, which is looking at public health issues, looking at how to connect population health information and incorporate that into clinical care and clinical decisions.

And the fourth is the Electronic Health Records Workgroup, which, as a first step, was looking at how to make laboratory information available to clinicians at the point of care.

Then a couple of other groups were identified, as needed for focus. The first was Confidentiality, Privacy, and Security, similar to the Health Information Protection Task Force that you have.

This Workgroup was formed at the suggestion of the other workgroups who were raising

these issues over and over again in their workgroups,

and decided that there should be a workgroup just focused on these issues across the board, so that there weren't four different discussions, but, really, there was a group of experts who could focus on these really important issues across all of the different areas that they other workgroups were looking at, as well as quality.

Finally, there was a Personalized Medicine or Genomics Workgroup that's been formed to look at making genetic information available in electronic health records.

Just to walk through some of the recommendations -- I'm not going to go through all the recommendations that have come out of the American Health Information Community, but I'm going to focus on some that might be of particular interest to the State Alliance members.

I mentioned the Electronic Health Record Workgroup that was looking at making lab results interoperable and making lab results available to clinicians. They were focusing on a patient-centric

information flow of lab data, so that information

about a patient, the lab results about a patient, can follow the patient wherever they are seeking care.

A couple of the recommendations that I thought might be of interest: They suggested that there may be some concerns or some challenges related to the Clinical Laboratory Improvement Amendments, about making sure that lab data is available to any clinician who needs it to treat the patient, as well as to the patient himself or herself.

There is some -- the CLIA laws have both a federal and a state component, and we're looking at some of the federal issues as to who can receive laboratory results. There are some state laws that also have been identified as potential barriers to a clinician that's treating a patient, who did not order the test results, seeing those lab results, or the patient himself or herself getting those laboratory results, so there is an opportunity there.

The Consumer Empowerment Workgroup also recommended setting the value of populating personal health records with laboratory results, so not just

making them available to the clinicians, but also

making them directly available to patients.

The Chronic Care Workgroup I had mentioned, was focusing on secure messaging, and they have made some recommendations about -- to HHS to monitor the effect on cost, quality, and care, for patient and caregiver satisfaction, and some medical-legal issues, which I know are some issues that are coming up in the Healthcare Practice Task Force.

They were -- some of those issues were related particularly to licensure. One of the recommendations, which I know the Healthcare Practice Task Force is working on now, is to look at how licensure can be streamlined across states, and try to figure out how to deal with licensure issues when you have secure messaging and the provider and the patient may be in a different state, or with respect to telehealth, where the provider and the patient may be in a different state.

The Population Health Workgroup, formerly the Biosurveillance Workgroup, made recommendations for HHS to develop sample data use agreements, to

facilitate sharing of data from healthcare providers

to local, state, and federal public health agencies, as well as to facilitate health information exchange between public health and clinical care.

At this point, many of the health information exchange activities that are going on at a state or regional level, many of them do not involve the public health community, and there's a real opportunity there for the public health authorities to be able to get access to very valuable public health information through health information exchange efforts, including the information that is required to be reported by clinicians.

So, this was a recommendation out of that group, and I know there was some interest at the last State Alliance meeting about public health involvement in health information exchange efforts, and that would be a great opportunity for this group, as well.

And then finally, the Confidentiality, Privacy and Security Workgroup got a little bit of a later start than some of the other workgroups. They

have so far come up with recommendations on patient

identity proofing, coming up with some standard approaches for that.

And one of the other recommendations related to privacy that has come up, is looking at state privacy laws as they relate to personal health records, and, again, there might be an opportunity there for the State Alliance.

The HISPC, the Health Information Security and Privacy Collaboration, was looking at state practices and state laws, but there wasn't too much focus on personal health records, so that's an area where there may be a new opportunity for this group. These personal health records are new to the market and there aren't, as I'm aware, very many, if any laws focused specifically on them, but there may be some law that affect personal health records.

The way that ONC looks at some of these issues, is, we've broken them into four categories: Governance, policy, technology, and adoption. And I'm going to try to focus some of my last few points in these areas.

I'm not going to walk through all of these

in detail. I wanted to provide you a lot of information, but I'm just going to highlight some of the places where there is some opportunities, I think for the State Alliance.

In the area of governance, I mentioned the American Health Information Community. They are trying to focus a lot more now on privacy.

They have so far done some priority-setting, and come up with a lot of recommendations and results. With respect to the regional and state activities, one of the opportunities is looking at paths to financial sustainability for health information exchanges.

This is something that the state-level health information exchange efforts are working on, as well, but there are opportunities to look at that from a state government perspective, as well.

From a policy perspective, I mentioned CLIA. We're working on CLIA guidance at the federal level, and there are opportunities to do that at the state level, as well, to address some of the state

law issues that coordinate with the federal laws.

There are opportunities in state policy to look at Medicaid, public health, and some other public programs that would be collaborative with some of the work that we're doing.

The American Health Information Community is looking at issues of liability, and I had mentioned that they had made recommendations on licensure, and, again, those are issues that are really state-law issues, as opposed to federal law issues, but they've been identified as challenges to health information exchange, and there are some opportunities there.

With respect to policy on privacy and security, I know that's one of the three major focuses of the State Alliance, and I think there are some great opportunities there.

The HISPC, the Health Information Security and Privacy Collaboration, has really been looking within states. And one of the great opportunities, I think, that the Health Information Protection Task Force has, is to look across those state

implementation plans and solutions, to find out

whether there are opportunities to build consensus across states and come up with solutions across those states, and I think that the State Alliance could be very helpful in that regard.

With respect to technology, I had mentioned the Health IT Standards Panel. This is, as I mentioned, a process for identifying standards at a national level.

Their work is continuing. They have an annual cycle where they identify and adopt harmonized, recognize harmonize standards or recommend harmonized standards to the Secretary for recognition.

And this is an area where I really think that the Federal Government or the -- that the efforts really need to take place nationwide, because we need to make sure we don't have stovepipes across the country, but really that the information can be shared from one place to another, from one state to another.

And, with that, I would encourage us, as

you have states looking at some of the health

information exchange activities, to look at the standards that have been developed so far, and try to see where there are opportunities to build those into the state-level efforts, as well.

And with respect to adoption, one of the areas that folks have been focusing on, particularly the American Health Information Community and the Electronic Health Records Workgroup, is some of the medical and legal issues.

The American Health Information Community is considering recommendations on liability related to adoption of electronic health records and health information exchange. There a couple of issues here that we have heard about doctors who are concerned that if they have access to information, but they don't access the information, that they would be held to know what is available through a network, even though they haven't seen that information.

There are some concerns that if a patient sends a message to a doctor after hours and the doctor doesn't respond, and it's an emergency, that

they would be held to know that and to respond

immediately to that information.

So there are a whole host of liability issues that have been coming up, and a lot of those really are state-level issues, as opposed to national or federal issues, and I think there are some real concerns that have really impeded adoption in this area. And work at the State Alliance level to look at some of those liabilities, really can improve the rate of adoption across the country.

And, lastly, on adoption, there are some cultural issues. And this might be some areas where it would be looking at as well, trying to understand what are keeping healthcare providers from adopting electronic health records or from connecting into a health information exchange effort, beyond just some of those liability issues.

There are some workflow issues; there are some cultural issues that come into play, and there are some opportunities there, and it's something we're looking at at federal level, but it might be a great opportunity to partner with state actors in

this area.

So, as I started with, the state and federal partnership, I think there is a great opportunity for the state and Federal Government to work together on advancing health information exchange and health IT adoption.

The work of the State Alliance is key at the state level. As I mentioned, we have the state-level Health Information Exchange Consensus Project, which is really looking at private-sector activities in this area, and coming up with some best practices.

The Health Information Security and Privacy Collaboration, which is the 34 states that have been involved, we do hope to expand the opportunities to go to more than just those 34 states, with further funding.

And then, again, at the federal level, we have the American Health Information Community, which is an advisory committee at the federal level, CCHIT which Mark will be talking; the Health IT Standards Panel, and the NHIN trial implementations, which will be the next phase, where we will be working directly

with health information exchange efforts at a

regional or state level, to try to implement NHIN architecture approaches. I think that's going to be a real great opportunity where we're blending the Federal Government efforts and the state efforts in looking at how a nationwide health information network could really work within a state and across the country.

And, with that, I would welcome your questions, your comments, and I turn it over to Mark.

GOVERNOR DOUGLAS: Thank you very much, Jodi, for that update on the activities in various forms around the country, and also identifying some areas of opportunity for us to work with other partners. I think I'm going to give the Alliance members a quiz on acronyms before the day is over.

(Laughter.)

GOVERNOR DOUGLAS: But we'll work our way through that. Thank you so much.

I want to introduce Mark Leavitt, who is with us, as well. Mark is the Chair of the Certification Commission for Healthcare Information

Technology.

That's an independent, nonprofit organization whose mission is to accelerate the adoption of robust, interoperable health information technology. It's working under a three-year contract to the Department of Health and Human Services, and it's the recognized authority for electronic health record certification in the United States.

Of course, Mark gets a lot of jokes about if he changed his name when he started working with HHS, but he's a real -- I guess people didn't get that, Mark.

(Laughter.)

GOVERNOR DOUGLAS: We really appreciate your work in this important area, and thank you for being with us today. We look forward to learning more about CCHIT's efforts in the e-health arena, so thanks again for joining us.

(Slides.)

MR. LEAVITT: Thank you for inviting me. When Michelle invited me, I actually set a personal record for the interval time between being asked and

saying yes to be speak.

(Laughter.)

MR. LEAVITT: I said, absolutely, I want to be there, because you are such important -- I'm going to use the word, "customer". Stakeholder is the right term in the public sector, but I was in the commercial sector for most of my career, so, customers/stakeholders, you're really important to us, so I'm really glad to be here.

But I also sense that we're a little behind schedule, so I'm going to be very concise, because your questions are important. I want to answer five questions for you today, and they're up on the board.

But I'm looking forward to your questions, because that's probably the most valuable part of the talk.

So, who are we? Why certify health IT? How do we operate? Are we having an impact? And, finally, what can we do for you? What value do we have for state e-health efforts?

And maybe I will get in there, what can

you do for us? What are the things you might do that

would help us help you?

So, I won't even repeat the mission, because Governor Douglas, you stated it very well and perfectly. I'll just say that CCHIT just -- just always remember to spell that and don't pronounce it.

(Laughter.)

MR. LEAVITT: Some of the five-letter acronyms are pronounceable; ours is one that should only be spelled.

(Laughter.)

MR. LEAVITT: Our history: We've actually been around two and a half years, which is sometimes hard to believe.

We were launched by three health associations that -- when this says "the Alliance," that's not the important big Alliance that we're sitting here at; that's a small other one. That's called the National Alliance for Health Information Technology, but they call themselves, "the Alliance."

So now they have the same problem I have with Secretary Leavitt, sharing the last name, those

two Alliances.

Anyhow, we were founded by them, got funding from eight other organizations, and then after about a year of operation, won that federal contract that we're under. Keep in mind that we're a private-sector nonprofit, working on a federal contract, but one of the key issues in the contract is that we have to become self-sustaining.

And then last year, we started certifying electronic health records, and the first scope of work was ambulatory of office-based, and we certified and announced the first ones in July. In August, we were officially recognized by the Federal Government as a certification body.

This January, we completed our governance transition to be a fully-independent, nonprofit. Our financial transition will take another year or two, as we finish up the contract.

So, then the question I said I would answer about why certified health IT, there are basically four ways, build strong bodies four ways.

Most obviously, certification can reduce

the risk of investing in health IT. I mean,

certification is first and foremost about reducing someone's risk of using someone. That's why you certify using a professional or a product or method.

Equally important, though, is making sure that these electronic records and networks, are going to interoperate. It's very easy for that not to happen, and Betamax and VHS is an example that everyone uses.

So we want to make sure that we have a uniform set of standards, so that we get the benefits of connecting electronic health systems.

The third is to make available, adoption incentives and regulatory relief. I'm sure you've heard that there is an adoption issue with electronic records, because most of the savings flow to the purchasers of healthcare, not the providers who buy the systems.

Well, many times, purchasers are willing to share some of the benefits, but they need to be sure that these systems that they are incentivizing or rewarding, are actually doing the job and

delivering quality, so that's a key benefit.

Finally, and not least important, making sure that privacy is protected. When you start passing information from the doctor's office through the network to the hospital, through the network to the nursing home, through the network to the patient's family, there's a lot of links in that chain, and when you talk about security and privacy, you always have to worry about the weakest link, and certification can set sort of a baseline, a floor, to make sure that you don't have a link so weak that privacy is compromised. That's very important.

I have a little different picture than the one Jodi showed about the different federal efforts. You always put yourself in the middle, right?

But the key take-away on this, is that we're a coupling mechanism between policy efforts that produce standards, policies, and recommendations, and the rough-and-tumble world of the private sector and competition.

So, our job is to use market mechanisms only. Certification is not mandatory; there's no law

requiring it. We use market mechanisms to help drive

some of these policies and uniform standards into the private sector, at whatever pace it will accept.

So, at every step, we're saying, are we going too fast for the vendors or the purchasers of systems to accept, or are we going too slow, so that they won't get the benefits and we'll end up with incompatible systems. And that's one of the most interesting challenges of being CCHIT.

A little bit about how we operate: We have the three different years in the contract with the three scopes. The first is office-based electronic records, like is used in your doctor's office or clinic; the second year -- that's this year -- to launch certification of hospital EHRs, and we're on our way and planning to launch in August; and the third year, 08, is when we are supposed to launch certification of networks, and we're just getting that started, and that's why it's so important that we're here.

We're also updating the criteria each year for each of those domains. We're now expanding

certification to address additional specialties,

settings, and populations, such as the features needed to care for children safely, what's needed in an emergency room, long-term care, aspects of the system for those who, for example, specialize in cardiology or other specialties.

And I mentioned our obligation to become an independent, self-sustaining entity by the end of the federal contract. I won't go into our governance, because I understand everyone here understands how to run a transparent, expert advisory panel, policy group, whatever it is; you all are familiar.

We've simply adopted the kind of standards that government has to adhere to in terms of openness, transparency, public comment, and internalize those. Reed Tuckson is one of our founding Commissioners, and I'm really glad to see him here.

And if you want to see if I'm telling the truth that we're being very careful about the process we run, rather than me trying to convince you, just

catch Reed later and he'll tell you the truth.

But that is our most important asset, is really the trust of stakeholders, and we treat that as if it's the most important thing we have.

What impact are we having? Well, we've only been certifying ambulatory records, and we've really only been doing that for nine months, but we have exceeded everyone's expectations.

There were 57 products already certified in nine months. You know, there were worries that nobody would come, and, you know, if you build it, will anyone come?

And the other worry was, would certification tilt the playing field so only large companies could succeed, because of the cost and expense of certification? The opposite seems to be the case. It's created a level playing field where small and mid-sized companies can build a good enough product to get certified and become players.

So, if you look at the cross section there, more than half the vendors are small companies with revenues of one to ten million, and a good

handful have revenues under one million, so we're not

excluding small companies, or, I think, limiting innovation in any way.

Also, if you look at the sizes of the practices served by those companies, we were worried, well, will this only be the system that large clinics adopt and not in solo and in small offices? That is a reflection of the distribution of physician practices in the U.S. -- about a third, solo, and two-thirds are in two-to-five-doctor groups, so it seems to reflect the reality.

We've also had good acceptance by providers, and the professional associations of the internists, pediatricians, family physicians, emergency doctors have all endorsed the work.

We're seeing payor incentive programs use certification in Hawaii. The Blue Cross-Blue Shield Plan has a \$50 million incentive program for adopting IT and they have used certification as a qualifier.

State networks and regional networks, we know that several, for example, New York City Medicaid has a project to share prescription

information with doctors and use certification of

EHRs as the qualification for those doctor systems to be secure enough to be able to receive this prescription information, so we think we're helping.

And you are probably aware that because of our federal recognition, certification qualifies an electronic health record system for donation under the Stark and anti-kickback safe harbors that were promulgated in October, that Jodi is the absolute expert on. So, if you have questions on that, I'm sure she can help you.

And, of course, recently, at the last AHIC meeting, they recommended that certification be extended to PHRs, to personal health records.

So, now, let's sum up with what value can we have to the state initiatives? Surprisingly, it's not just about certifying the networks.

I think we could have just as much or more benefit, because of the certification we do of the provider EHRs. So here are ways that it can help:

First of all, we can ensure that provider EHRs are standards-compliant and ready to connect up

with networks. Trying to do that alone in each

state, would be a big job, so we think we can do that.

Second -- and this ties in with that -- making sure that we're progressing toward full portability of the records stored in those electronic health records. It establishes a baseline of technical security capabilities in the provider EHRs, for example, that example I used from New York City Medicaid.

Basically, this is an efficient qualification mechanism. If you're looking to give IT adoption incentives, grants, or loans, it would be a shame for each state to have to invent their own process, invite in 50 vendors. That would be basically be 50 times 50 or 2,500 vendor evaluations going on, and that's kind of inefficient.

So, we encourage you to take advantage of our work. If you want to add additional criteria, build on it; it's not a problem, if you have special requirements in your state, but at least take advantage of the basics. There's 250 criteria right

now that we inspect the ambulatory EHRs against.

Now, what can we do in terms of networks?

We're just launching this, but one of the most important things, is, if the provider EHR is the plug, the network is the socket.

It doesn't do any good if the plugs are all the same, if the sockets are different, so we hope to help make sure that the networks are standards-compliant and can connect to the provider EHRs, or the consumer personal health records.

Then another important point: The networks themselves need to interconnect, so if Tennessee needs to connect to Oregon and Oregon needs to connect to Massachusetts, we don't think you have to create that standard here. It's going to come from the Health Information Technology Standards Panel.

We'll find a way to test the networks to make sure they're compliant, so all you have to do is make sure the networks are certified and those technical issues should be solved.

You have enough governance and policy

issues to worry about, without having to do the

technology. Again, the technical security, now you have a baseline of security, so if it has to pass through Indiana on the way from Vermont to Michigan, you know that that network that's passing information, has the security required.

Finally, if the networks become eligible for federal grants, incentives, and loans, it's possible that certification would be a requirement, a qualifier.

So, just to quickly sum up what's ahead, we're just launching our network certification development, so we'll be calling for members for the workgroup, so you may know people in your state, and whether you or someone that you know, is an expert in this and very interested, encourage them to sign up and volunteer on our workgroups.

Encourage them to comment when we circulate our work for public comment. There will even be openings for new Commissioners in the summer, and, hopefully, by the spring of 08, we will be pilot-testing, and in mid-2008, launching network

certification.

So, that completes my answers, but I look forward to answering some questions that you have. Thanks for having me here.

GOVERNOR DOUGLAS: Mark, thank you very much, as well. We appreciate your explaining the work of the C-C-H-I-T -- I'm being careful --

(Laughter.)

GOVERNOR DOUGLAS: And how it works into the efforts of the Alliance. You alluded very quickly to the fact that some states may have their own standards or criteria that vary somewhat from the norm. I'm curious as to how that works in terms of certification and interoperability.

In other words, there's going to be some uniformity, I assume, in the standards.

MR. LEAVITT: This is one of, I think, the most important things that this group, that your group can do.

It's not an issue if states have different policies. Let's talk about privacy, because that's one of the areas where you get right into, right?

I don't believe there is any hope of all

the states agreeing on the same privacy policies in all states, and I don't believe it's necessary, but you have to build them on the same framework.

So if I might use the example of substance dependency, okay, it would be fine if one state says any record related to substance dependency cannot be released with specific consent. There's an example.

And it's fine if another state says, no, it can be released for treatment without consent, but if another state says it can be released for treatment by a certain specialty, but you have to wait 30 days, now the electronic system goes crash, okay?

So, choose -- you need to set a little menu of policy options that is national, and then your states will choose which of the options you implement, and that's fine. And people who make the software and the hardware for your networks, every system is configurable, so it will be configured differently when it's implemented in different states but if you can't come up with sort of a common set of

possible options, I would use that as an example to

answer your question.

GOVERNOR DOUGLAS: That makes a lot of sense. I was thinking, as you were explaining that, that it's very similar to what states are going through now with respect to the streamlined sales tax project, where we're achieving some level of uniformity, but not necessarily taxing everything at the same rate, but choosing among a menu of options and the definitions are the same, so that does make sense.

Jodi, I wonder if you can react to the certification presentation. One of the opportunities for this Alliance and others looking at e-health initiatives, is addressing liability concerns. Do you think certification can address them to some extent?

MS. DANIEL: I think that could help. I think that there is an opportunity for states to look at the certification criteria for a baseline for liability. I know at least one state is trying to give some liability relief, if, in fact, the doctors

adopt a certain level of technology or in exchange

for adopting that technology.

So I think there might be some opportunities there to consider at a state level. I think that, as Mark had said, one of the important things that they're looking at, is privacy and security of those systems.

And so where there are concerns about a breach of privacy or security, because the information is in electronic format, that might be an opportunity for the states to look at with respect to liability.

GOVERNOR DOUGLAS: Other questions.

Founding Commissioner Tuckson?

MR. TUCKSON: I'm very proud of that, thank you. Jodi and Mark, Jodi, your presentation was extremely complete and thorough. There was one area that you didn't have to time to highlight, and I think that was the -- you had the Quality Committee, and you sort of flew by that one.

The reason why I'd like you to see if you could expand on that a little bit, is that there is

an issue that continues to go on, where most of our

states now are moving forward with state-based, transparency of performance initiatives.

Since we have last met, I have had several more of these state initiatives around evaluating the quality of performance by physicians and hospitals, come across my desk.

What is hard to see, is the connection between the state initiatives and the performance measures that the Quality Committee of AHIC and all of the other national standard-setting activities are trying to establish.

Similarly, it's difficult to see how the data collection at the state level, to populate performance and describe it to the citizens of that state, is going to be done in a way that's consistent across the country, thereby taking away administrative cost and burden.

So, without going further, is there a sense of a relationship between the national effort and support for coordinating -- appropriate support at the state level, so you sort of have efficiencies,

while not stifling local, state-based initiatives?

MS. DANIEL: Sure. Thank you for asking that. The Quality Workgroup, as I had mentioned, has only been up and running for about six months, so it is just in the infancy stages.

They are evaluating right now, various quality measures through other organizations that have been developing those quality measures. This is, as you know, an important area for Secretary Leavitt, looking at making sure that there is quality information about clinical care, that's available to consumers, as well as pricing information.

They are looking across -- in a variety of different markets across the country, as a mechanism for trying to test some of the quality measures, but I think there is -- at this point, it's still very much in the infancy stages and we have to look carefully at where there are those opportunities to bridge the gaps between the federal efforts and the state efforts.

I think it is a great opportunity for collaboration among what is a priority at HHS and

through that workgroup, as well as the state efforts.

I don't have a whole lot of information about the state efforts, to know where there might be those opportunities, but we could come back and provide some more information on that, if that would be helpful.

MR. TUCKSON: Mark, I know that the certification criteria tries to find a way to capture -- as one of its goals, to capture performance measurement that physicians do in their office, to make it easy and convenient for them to populate some of these performance measures, so it doesn't cost them a whole lot of money, as their offices have to go back through paper charts to try to get this information to satisfy the performance measures by state government and federal activities.

Is there much progress in that area now?

MR. LEAVITT: Yes, Dr. Tuckson, I think so. At the last AHIC meeting, Dr. Clancey from AHRQ gave some testimony that spoke right to this, and from what I can see, there actually is an active harmonization of quality measures and quality

measurement standards, that once that is harmonized,

then, actually, certification can require those measures in the products.

We can't require a hundred different measures. That makes the products too complex, but once those are harmonized, they will be required, and then I think we will see the ability to measure quality in a comparable way in different states, and roll up the data to look at our national quality picture.

REPRESENTATIVE CONAWAY: Yes, Mr. Leavitt, you mentioned that the qualification or certification is voluntary, and I wondered, given the particular importance of PHI, personal health information, why that wouldn't be required, why we shouldn't make access to the market in the state, dependent on certification?

If not, then physicians will have to know to check, and, it seems to me, as a consumer protection measure, both for patients and for physicians, this certification ought to be required. Your thoughts?

MR. LEAVITT: It's certainly an option

that any state would have. I believe that the reason to think about it carefully, is, we have a problem with adoption of these products, and mandating it -- I believe that, given that physicians, in many cases, have to go through a rather wrenching change to move from paper to electronic, having them do it voluntarily, based on just market factors -- this is going to save me time; this is going to help me improve quality -- they are more likely to succeed, than if there's a state law that suddenly says you must buy an EHR and it must be certified.

REPRESENTATIVE CONAWAY: Well, I didn't mean requiring you to purchase one, but giving the physician purchaser, protection, that the EHR, EMR that they're purchasing, is actually going to meet standards.

And I'm going to get to the question, with the Chair's permission, and talk about what kind of certification ought to be required in the doctor's office for their servers, for their networks, for their connectivity beyond the office.

I thought you alluded to that and that's

where you were heading.

MR. LEAVITT: Yes.

REPRESENTATIVE CONAWAY: I think that's very important, to protect that information in the office, and I guess hospitals are going to have to -- are going through the same kind of a process?

MR. LEAVITT: Yes.

REPRESENTATIVE CONAWAY: And, last, if I may, this might not be right on your plate, but one of the things that we know happens, and I see that, are that you have -- and by the way, there are plenty of EMRs out there.

I don't think that we're going to take the market and destroy our market by making people adhere to certification standards, but what happens when you have someone in the marketplace that then goes out of business or, you know, they're not available to service the product?

You now have records that are potentially locked up in an office, you have offices now that can't function because the support personnel for the

software, is not there.

My own thought on this, by the way, is that there should be some instrumentality in the government to store in a protected way, the codes, the security codes, the sort of back access keys to these programs, so that in the event that there's a failure or some demonstrated lack of performance in terms of support, the EMR program, given its importance to the personal health of patients, that there needs to be a way for the government to go in and grab those keys and make them available so that the physician can use -- continue to use a program in the event that his vendor fails to survive in the marketplace.

MR. LEAVITT: You've raised a couple of very interesting points there. You obviously thought about this a lot.

In terms of the vendor failure, I believe that the most direct solution for that right now, is, as soon as interoperability includes the ability to export a record in a portable format, you relieve the problem, because if your product is no longer

supported, you could export all the records in the

standard format, and whatever system you migrate to, could be imported, so you wouldn't lose data.

Now, you would lose money. That's a completely separate issue. You wouldn't lose the data, though, and the records backup -- you've raised a very interesting question.

There is probably a need for a utility that backs up records, because a small office -- and let's turn to Louisiana for a moment and think about if anyone is using an EHR, there's a fair chance it's backed up on tapes that are in the office, that you can lose, along with the system.

If there's a utility for backing up offsite, securely, encrypted, so that no one can get at the records, except the doctor or a very special circumstance like the doctor died in a flood -- now we'd have a circumstance. That's a valuable service, I think, that might be provided and might be very interesting and useful.

REPRESENTATIVE CONAWAY: Was that among your 250 criteria?

MR. LEAVITT: Backup is required. We

haven't reached the level of sophistication to say you have to get the backup at least 100 miles away, but backup is required. We test and make sure that they are able to backup.

But, you know, the criteria can escalate and be enhanced each year, so we hope that we'll make sure that there are no incidents of records being lost when they're on EHRs.

GOVERNOR DOUGLAS: Yes, Representative Harrell?

REPRESENTATIVE HARRELL: Thank you very much. It's a delight to be here, and I apologize for my plane being late and my not being here for the beginning of the meeting. I'm sorry I missed Ms. Daniel's presentation.

In Florida, we are moving rapidly along with the establishment of RHIOs, and we have legislation pending right before my committee now, and, in fact, it has passed my committee and hopefully will go to the floor, to start the Florida Health Information Network.

I am concerned about the networks and the

linkage and those standards. We have ten different RHIOs in the process of various stages of establishment.

When are you going to have those standards established, that we can -- we're really looking to you for some leadership on this. We don't want ten different RHIOs doing ten different things, trying to connect into a FIN, so we really -- when do you think you are going to be at the stage where you can impart some wisdom to us in Florida?

MR. LEAVITT: Well, in terms of imparting a wisdom, that's a question, but in terms of being ready to certify, the contract calls for us to begin certification in 2008, and I'm guessing that it will be mid-Fall, because it's quite a challenge.

I think the key here is to build in a requirement that a network gain certification within some amount of time after certification becomes available.

This same question came up a year or two ago when people said, well, should I wait to buy my

electronic record, because certification is coming?

And rather than freeze the market, we suggested that they just put in the purchase contract. The vendor has to agree that when certification does become available, they will get certified.

And then there's some incentive, a final payment or something to tie that in, so there's a way to tie it in without certification yet being finished and ready, so that you can look forward. And you want that anyway, because certification is going to be incremental.

I mean, the first version will not have all kinds of interoperability; it will be basics. And then it will evolve over the years, so what you want, is for the system to become certified and stay certified and keep up with the standards.

GOVERNOR DOUGLAS: Joy?

MS. PRITTS: Yes, you mentioned that you're still looking into certifying PHRs, personal health records?

MR. LEAVITT: We're about to be asked to

look into it, I think.

MS. PRITTS: Okay, I'm curious as to what criteria you use in the certification process, particularly with respect to PHRs. They're kind of a new concept.

MR. LEAVITT: Well, you've tapped into the controversy that came up at the AHIC meeting. And, actually, I had dinner with the leader of the dissenting opinion here in Washington, which was really good, and we figured out what a lot of the dissent was.

Instead of using the term, PHR, I'd like to talk about a personal health information platform and personal health applications. The personal health information platform is network and infrastructure and security, so you know that the information is kept secure, and there's interoperability.

The application kind of sits on that, so, for example, when you use the web to buy something and you see that little lock in your browser, that's a secure platform for doing business on the web.

And we don't have that in healthcare and

we need it, so, the first thing to certify, is the secured interoperability, and you don't have to certify the applications, because we still don't know.

We think, well, one application is the retail aspect. The point is that it's obvious that there may be ones that still need to be invented, that will help people behave in ways that improve their health.

If you certify too soon, you might stifle that. So it's really the platform underlying personal health applications, that should be certified first. So that's my best thinking on it as of today.

MS. PRITTS: And if I may, the decision of the American Health Information Community was not to recommend any criteria for functionality, because it is such a new market, but they wanted -- they did recommend that there be at least minimum privacy and security standards set forth, as well as minimum interoperability specifications set forth, where

those were available, so that as the market is

developing, they're at least building in minimum criteria for protections, as well as for interoperability.

But I understand that from a consumer perspective, what they see on their computer screen, they're interacting with the application, not with the platform, right?

MR. LEAVITT: Right. They don't even want to have to know about the platform.

MS. PRITTS: So that raises a question with me as to what the certification does, how that information is communicated to them and what it means to them, whether they're thinking that that's going to be -- I guess this doesn't have to be answered right now, but, you know, what a consumer sees, if they see certification, they're thinking what they're dealing with, the application, has been certified, and that's not going to be the case.

MR. LEAVITT: There is some education needed. Whenever I try to buy something on the web, I look in the right corner of the browser and I see

the lock. I'm not sure everyone does that, and it

could be that there may be some consumer education needed.

You need something very simple, obviously. It might be a seal or something that they are taught to look for, so that they understand that they are using something which is on this secure basis and not possibly something that's going to compromise their privacy.

So it's not an easy problem to solve. There is a lot of education needed and a lot of thinking.

GOVERNOR DOUGLAS: We started 15 or 20 minutes late and we're still there, but is there a final question? Steve?

MR. PALMER: Thank you very much. I'd like you all to maybe speak to the issue of potential state roles in the standards process. I know, Jodi, you mentioned that that was something that should really be done at the federal level, but in response to Representative Conaway's question, Mark said that there are some of these key issues like being able to

transfer a whole record, that is not -- has not been

done and has not been approached by CCHIT.

And the in the AHIMA report that was sent out with our meeting materials, one of the responses from some of the interviewees, seemed to indicate that the particular standard sets that were tackled by HITSP, were not the necessarily the most pressing or most useful. Can you just kind of address that set of things, particularly in light of states potentially wanting to get out there and fill some of those gaps?

MS. DANIEL: I think that those are very fair points. The HITSP process is definitely an incremental process, just like the CCHIT process is an incremental process.

We have the same questions coming up at the federal level. We have public health authorities at the federal level who need access to information, and there may not be any standards out there for a particular piece of information or a particular transfer of information.

What I would recommend, is that -- that

states engage in the HITSP process, either to

encourage them to put something on their radar screen, or, if, in fact, there is a standard that the state is using to inform HITSP so that they're aware of what's out there already, so that as they do look at those issues, they can take that into account, particularly if, for instance, if Texas is a leader in a particular area in developing a standard and there is no other standard out there, then that may serve as a basis for their deliberation on the topic.

So, what I would encourage, is that states that do either have standards in place for a particular type of information transaction or that are developing those because of a particular need, to engage in the HITSP process to make sure that when HITSP takes on that issue, they don't go in a different direction that's incompatible or can't be harmonized with what you're currently doing.

So that would be my suggestion of how to incorporate those efforts.

GOVERNOR DOUGLAS: Jim, last question?

MR. GERINGER: Mr. Chairman, this might,

at least for my purposes and perhaps for the

committee, help focus on where we can go with each of these presentations.

It seems like we bounce a lot between policy and process, and I'm very interested in how things get done, not just what needs to be done. But that confuses me, too.

I look at the CCHIT as an example of how, if you let someone go, how a lot of things can happen, so I like their approach, where they're incremental. Would it be advisable for each presenter to let us know, in a policy sense, what the states, Governors, and legislators, could look at as policy-in-common; in other words, model legislation that would set down points of policy that could be implemented, then those things that could be done on an incremental or optional basis.

Then let something work. For instance, CCHIT is operating on the basis of incentives, regulatory relief, and reduced administrative burden. It would help me if each of the presenters would say, now, from the state's perspective -- and I'm looking

at it, that the Federal Government only indirectly

provides healthcare.

They are not the primary or the first-line responsible party; the states are. So, everything that's going to be done, is going to be done through state legislation.

The Federal Government will be doing it through it's incentivizing or disincentives, in this case, through Medicaid compatibility, let' say. So, if we could at least separate the thoughts, then we could pull something together in the year's time that Governor Bredesen is talking about, that would enable us to say, here are the policy options that the states ought to consider; here are the things that we feel ought to be in common, and not just wait for one federal mandate to come down, because, as soon as that happens, we'll be squawking about federal unfunded mandates.

Why did I say that? I don't know.

(Laughter.)

MR. GERINGER: I couldn't help it. Those are some thoughts. If we could at least separate

these terms and where we have responsibility and

where we can enable others to do the work, they can take off and do it on their own.

GOVERNOR DOUGLAS: Those are good concerns, Jim. I think, a little later, when we get reports from our task forces, we'll have some clarity and some direction in terms of model legislation or policy directives that might begin to inform our deliberations.

MR. GERINGER: What I'm looking for, is that each presenter makes a presentation and what should we be taking as the summary, moving it along and taking action on it, or just saying, that's great, I'm glad to know you're making progress.

GOVERNOR DOUGLAS: Well, Jodi very specifically identified areas for opportunity in the slides that she presented, which I think will be very helpful to us.

We really should move along, in fairness to our other presenters, so, thank you, Jodi and Mark, for your very helpful presentations this morning. Thank you.

(Applause.)

GOVERNOR BREDESEN: And, Governor, I'd only like to suggest a change from squawking about unfunded mandates, into correctly identifying problems relating to unfunded mandates, if you want to accept that.

(Laughter.)

MR. GERINGER: No need be always so diplomatic.

(Laughter.)