Health IT Policy Committee



A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

HIT Policy Committee Interoperability & Health Information Exchange Workgroup Listening Session Governance Subgroup Transcript August 22, 2014

Presentation

Operator

All lines are bridged with the public.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thank you. Good morning everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Interoperability and HIE Workgroup, and this is a Governance Subgroup meeting. This is also the second of two listening sessions that we're holding. This is public call and there will be time for public comment at the end of today's meeting. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. Also, as a reminder, please keep yourself muted when you are not the person speaking. I'll now take roll. Carol Robinson?

<u>Carol Robinson – Principal – Robinson & Associates Consulting</u> Here.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Hi Carol. Chris Lehmann?

<u>Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine</u>

Good morning, Michelle.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> Coordinator for Health Information Technology

Hi Chris. Anil Jain? Anjum Khurshid?

<u>Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health</u> Institute

Yes.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Hi Anjum. Anne Castro?

<u>Anne Castro – Vice President, Chief Design Architect – BlueCross BlueShield of South Carolina</u> I'm here.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> Coordinator for Health Information Technology

Hi Anne. Barclay Butler?

Barclay P. Butler, PhD – Defense Health Agency

Present.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Good morning. Beth Morrow?

<u>Beth Morrow, JD – Director, Health Initiatives – The Children's Partnership</u>

Present.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Hi Beth. David Sharp? Deanna Wise? Elaine Hunolt?

<u>Elaine Hunolt, FACHE, PMP, CPHIMS – Health Acting Program Manager, Health Interoperability</u> <u>Service, Virtual Lifetime Electronic Record (VLER) – Veterans Health Administration/Department of Defense</u>

I'm here, thanks.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> Coordinator for Health Information Technology

Hi Elaine. Jitin Asnaani?

<u>Jitin Asnaani, MBA – Director, Product Innovation - AthenaHealth</u>

Here.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Good morning.

<u>Jitin Asnaani, MBA – Director, Product Innovation – athenahealth</u>

Good morning.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

John Blair? John Lumpkin? Mariann Yeager?

<u>Mariann Yeager, MBA – Executive Director – Healtheway, Inc.</u>

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

I know Mariann...oh, hi Mariann. Melissa Goldstein? Tim Pletcher? Tony Gilman?

<u>Tony Gilman – Chief Executive Officer – Texas Health Services Authority</u> Here.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> Coordinator for Health Information Technology

Hi Tony. And from ONC do we have Kate Black?

<u>Kate Black, JD – Health Privacy Attorney - Office of the National Coordinator for Health Information</u> Technology

Hey Michelle.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Hi Kate. Kory Mertz?

<u>Kory Mertz – Challenge Grant Director – Office of the National Coordinator for Health Information</u> <u>Technology</u>

Here.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

And Kim Wilson?

<u>Kim Wilson – Health Communications Specialist – Center for Disease Control and Prevention – Department of Health & Human Services</u>

Here.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

And with that I will turn it to you Carol and Chris to kick us off.

<u>Carol Robinson – Principal – Robinson & Associates Consulting</u>

Thank you so much Michelle and thank you very much Chris Lehmann as my Co-Chair I will just welcome everyone back again. It just seems like a very short week ago that we were here for our first listening session and I want to thank everyone who is joining us today for a 3 hour session to again really hear perspectives from across the healthcare ecosystem about the issues that they're confronting in their own spheres on the...around HIE and then to consider a potential roadmap of solutions for governance on HIE with the goal essentially to improve both the quantity of data that's being exchanged electronically across the country and the quality of that HIE as well in terms of privacy and security.

And so I will kick it over to you Chris for your comments, but I just want to thank everyone again who participated in a robust conversation last Friday and we're very, very much looking forward to hearing all the comments today, have been looking through the materials and I know a lot of people have spent a tremendous amount of time on some very thoughtful responses so thanks. And let's get started. Chris?

<u>Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine</u>

Thank you, Carol. Good morning everybody first let me thank my Co-Chair Carol Robinson for kicking us off and Michelle, and the ONC staff for putting together a very interesting program today. The goal for us today is to sit back and listen and to take in what you have to tell us about what works and what doesn't work when it comes to exchange of information, what the obstacles are and where you think governance can reduce barriers and facilitate the exchange of information.

Last week we heard from the patient perspective, we heard from providers and we heard from vendors and this week we are anticipating to hear from people who are actually at the heart of the exchange, we are planning to hear from state and federal participants as well as from government entities.

The goal for information exchange is ultimately a very high and noble one. We want to make care more efficient, we want to make it better, safer, provide more value for the dollar we spend on healthcare, and having the right information available at the right time is something that I don't have to sell to anybody, the importance is clear to everybody.

But it's very obvious that the obstacles are quite impressive and that there are many different potential solutions, and that there is a need to bring in some clarification and a common roadmap to this challenge. So, I am looking forward today to receive your ideas, your complaints about what is currently wrong and what needs to be done to fix it. And I am looking forward to be educated. So, without further ado I'm going to turn it back to Michelle for kicking us off.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thank you both Carol and Chris. Just a reminder to everybody just a few logistics before we get started. To all of our panelists just a reminder that your testimony will be limited to five minutes, after each panelist on your panel has presented we'll then open it up to the Workgroup for questions. A reminder to the Workgroup if you could please use the hand raising feature within the webinar that will put you in the queue to ask questions and then we'll open it up to questions for you to ask the panelists.

So, if we're ready, let's get started with our first panel which is state and federal perspectives. On our first panel we have Gail Graham from the Department of Veterans Affairs, David Minch from the California Association of Health Information Exchanges, Tony Gilman from the Texas Health Services Authority, Jennifer Fritz from the Minnesota Department of Health and Karen Guice from the Department of Defense.

I don't believe we have Karen on the phone yet but hopefully, she is our last panelist, so hopefully we'll find her before we get started. So, if you are ready Gail please go ahead.

<u>Gail L. Graham – Assistant Deputy Under Secretary for Health (ADUSH) for Informatics & Analysis – Department of Veterans Affairs</u>

Okay, thank you very much. I thank everyone for the opportunity. So, I'm just going to walk through kind of the questions as they were posed. So, of course for VA we have, traditionally had a large coordination, care coordination role considering that many of our veterans receive care from other sources they may be retired from Department of Defense or they may be receiving care from a private sector provider and this is increasing for us now with recent legislation that even increases the amount of what we call Non-VA Care or Purchase-Care. So, this need, while it's always been pressing is even more pressing today as the legislation actually requires that we incorporate this information back into our system. So, certainly care coordination and continuity of care are of utmost importance to us.

Over the last year we've introduced kind of a different partner and that's collaborations with retail pharmacies as we had noticed that some of our influenza and other vaccination, immunization numbers had tended to look like they were decreasing but I think for most of us we thought veterans are no different than we are that it's then made more convenient in our local pharmacies, our local just stores of all kinds where vaccines are offered.

So, we've had a pilot over the last year with a retail pharmacist, pharmacy to bring in immunization information and it's been very successful and we'll go nationwide with that in the fall. And the important thing there for us on the level of what do you do with that information when you get it is we did incorporate that information back into our electronic health record and actually it appears in the clinician workflow, it's not a separate thing that I retrieve and look at the information separately so that's been an area where we've tried to do more and more of how we incorporate this information into our workflow and that...I'll mention it a little bit later, also steps up the need for adherence to standards and the information that we send and receive because that's only enabled by receiving good quality data in a standard format and then using standards for the content of the information.

So, some of the challenges, VA uniquely has a challenge that we, because of the existence of the Privacy Act of 1974, we have to have patient consent for providing the information to other providers and so this then necessitated a process being put in place for obtaining patient consent and we've, you know, over time worked that from a paper process to an electronic process.

The other is, related to that, is just this need for consistency of consent processes across states. We find in some instances where an opt in consent is used that can be cumbersome at times. Some of the other challenges we have are this whole aspect of patient identification or patient matching.

We struggle with patients that are opted in and they're known to us and they're known to the other provider, but still making that correlation between systems. And I think if there was...if somebody asked me to put what's number one, you know, thing to be resolved and addressed it would be patient identification and number two I think would be standards, the information and standards and adherence to those standards.

So we continue to work the patient identification with each individual partner that we join with. We are unique in the fact, in some ways, that we still...social security number is still the information that we use. We are fine with moving away from that in matching. We know that that's not commonly used outside of the government entities but we think agreeing at least on the traits that are to be matched on and further clarification and work in patient identification is needed.

And then more communication is needed to accelerate veteran's enrollment. So, it's more that the veterans have heard about this in their communities or commonly have knowledge of it rather than receiving just the letters from VA.

So, in the areas of provider adoption we see a great variation in the richness of data. Many of the organizations that we're receiving data from are not fully populating the CCD.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> <u>Coordinator for Health Information Technology</u>

Thirty seconds.

<u>Gail L. Graham – Assistant Deputy Under Secretary for Health (ADUSH) for Informatics & Analysis – Department of Veterans Affairs</u>

Yes?

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thirty seconds.

<u>Gail L. Graham – Assistant Deputy Under Secretary for Health (ADUSH) for Informatics & Analysis – Department of Veterans Affairs</u>

Okay. Okay. So, this whole issue of lack of semantic interoperability and so we...you know, I think if you could address some of these areas we would be grateful in many ways. But, thank you for the opportunity. I look forward to the questions.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thank you Gail. David Minch if you're ready?

<u>David A. Minch, GS, FHIMSS – President & Chief Operating Officer – HealthShare Bay Area</u> I am ready.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Please go ahead.

David A. Minch, GS, FHIMSS - President & Chief Operating Officer - HealthShare Bay Area

All right, thank you. Good morning I'm speaking to you today as the President and Board Chair of the California Association of Health Information Exchanges, what we call CAHIE. CAHIE is not a state or other government entity rather CAHIE is a voluntary collaboration of many stakeholders all of whom are interested in promoting and extending health data exchange throughout California.

CAHIE has developed the California version of the Federal DURSA which is the common trust agreement that all California participant trading partners sign which allows access after testing and certification to the California Trusted Exchange Network.

The Cal DURSA works in concert with the California developed model modular participation agreement which we advise all participants to use that assures trust flows down to all participant users. The Governance Subgroup has posed several interesting and substantive questions which I have responded more fully to in written form. During this short presentation I would like to focus on one specific question which I feel is at the heart of moving interoperability forward both in California and nationally.

Specifically the question I will address is what factors are limiting the exchange of health information? Next slide. Oh, we don't have the slides up? That's all right.

To begin the discussion let me briefly relay part of the dialogue from yesterday's national HIMSS HIE roundtable which was attended by many HIEs throughout the country. One participant described how they achieved their Meaningful Use 2 goals and they admitted that most of the organizations in the region use the same EHR vendor and that they leveraged that vendor's private implementation of a HISP to communicate using Direct to the other providers.

The participant was asked if he could have achieved Meaningful Use 2 had his trading area participants not all been using the same vendor and without hesitation he said "no." That single question sparked a dialogue which consumed the remainder of the roundtable's timeslot.

Most of the dialogue dealt with Direct capital "D" and many organizations complaining that Direct messages that they send could not be received by other HISPs and that messages sent to them would be rejected by their Meaningful Use 2 certified software.

My take on the dialogue is that there is a fundamental disconnect between what ONC had originally intended for Direct and what the vendors have implemented. In most cases when folks complain about Direct messages being rejected it's not because of a failing of the protocol it's because there is no nationally standardized reference implementation that all vendors must follow. Consequently, each EHR vendor is free to make the implementation unique and not interoperable with implementations of other vendors without significant one-off work and costs.

Direct, capital "D" as it was initially conceived and developed was essentially replacement for the fax, send anything you want the fax just prints it. Then Meaningful Use came along and the requirement to move CCDs and now C-CDAs and then the EHR certification criteria was established.

The vendors took a look at their EHR certification criteria and each addressed it individually since there wasn't a prescribed reference implementation that provided for both structured and non-structured content. To be very clear it is not in the best interests of any vendor to be interoperable with others because it ultimately limits their ability to sell more of their product.

Vendors will find a way, anyway possible, to make more work and cost to the providers to enable their interoperability and this situation is not at all limited to Direct, exchange is virtually crippled because of its extensive dialogue requiring trading partners once they are on the same network to spend weeks or months of testing and often additional bilateral agreements are required.

I believe that this is not the interoperability that ONC had set out to achieve and I believe that there is a relatively simple and straightforward solution to this continuing problem and that solution is development and implementation of a computable interoperability taxonomy that addresses trust and service capabilities. Next slide.

I ask you to imagine a point, in the hopefully near future, when an organization in California which is a CTEN participant can without any prior contracting or testing exchange trust and service capability attributes with a member of New York's network such that each can understand the relevant trust concerns and service abilities of the other and can make a decision to send data or a request data based on the national director exchange standards, again to be clear, without any prior one-off coding, testing or special side agreements.

We proposed to trust taxonomy during the NeHC Governance Committee work which was published last year and I urge the ONC to considered development of such a computable capable taxonomy combined with service capabilities and more uniform participation agreement template such as the California MMPA to make interoperability real for the US healthcare industry.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>
Thirty seconds.

<u>David A. Minch, GS, FHIMSS – President & Chief Operating Officer – HealthShare Bay Area</u> Thank you.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>
Oh, sorry.

<u>David A. Minch, GS, FHIMSS – President & Chief Operating Officer – HealthShare Bay Area</u> No, I'm good, thank you.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thank you. Tony Gilman?

<u>Tony Gilman – Chief Executive Officer – Texas Health Services Authority</u>

Good morning. I am Tony Gilman the CEO for the Texas Health Services Authority, a Non-Profit Corporation charged by the Texas legislature to facilitate and coordinate the development of HIE in Texas.

It's important for my discussion to explain that Texas is implementing a federated network of network's model for HIE. Local HIE networks will be connected together in two other gateways such as the National eHealth Exchange and data sources such as those maintained by our state agencies in Texas through the THSA's thin layer of shared services called HIETexas.

With that context I was asked to discuss what Texas is doing through the use of accreditation and certification to build confidence and trust in HIE. I will note that what I'm going to talk about today is just two elements of kind of a broader strategy to build confidence, trust and interoperability in Texas. Next slide.

Through the Texas HIE accreditation program public and private HIE organizations operating in the state will be recognized for meeting and maintaining accepted in uniform standards and the handling of protected health information.

The accreditation program is designed to increase trust in HIE efforts and improve interoperability within the state. Ultimately, we believe trust will increase the number of physicians and other practitioners, hospitals and patients participating in HIE.

To administer the accreditation program the THSA partnered with the Electronic Healthcare Network Accreditation Commission or otherwise known as EHNAC. THSA and EHNAC worked collaboratively to develop a program based on existing criteria and processes from EHNAC's existing HIE accreditation program while ensuring that it aligned with Texas law and relevant guidance from ONC.

Through this program EHNAC and THSA will review technical performance, business processes, resource management and other relevant information to ensure that accredited HIEs within Texas are interoperable with state and federal programs and provide the private, secure and proper exchange of health information in accordance with established laws and public policies.

Although the program is voluntary only accredited HIEs will be allowed to connect to HIETexas our state shared services network. Two local HIEs completed a beta of this program in July and the program just recently went live. Next slide.

The second program, which is the first state program of its kind, focuses on compliance with federal, state and medical privacy and security laws and regulations. SECURETexas health information privacy and security certification is designed to improve the protection of health information for Texas residents by certifying that those who use and disclose PHI are in compliance with laws such as HIPAA and the Texas Medical Records Privacy Act. The program looks beyond HIE organizations and focuses on any organization that touches protected health information or PHI. This is important because HIE from our perspective is only as strong as the weakest link connected to an HIE network.

Organizations participating in the program will be able to show that they have met state and federal privacy and security standards in order to manage risk and increase confidence in how they protect health information.

The THSA is partnering with the health information trust alliance, otherwise known as HITRUST to implement SECURETexas. HITRUST utilizes its common security framework to validate the compliance of organizations with various steps toward and regulatory requirements, industry standards and best practices.

HITRUST common security framework is the most widely adopted security framework in the US healthcare industry with over 85% of hospitals, health plans, PBMs and pharmacies using the security framework.

THSA and HITRUST have worked together to ensure that SECURETexas criteria include all relevant federal and state privacy and security laws, and regulations.

Covered entities as determined defined under Texas law can undergo any assessment...can undergo an assessment using the security framework assessor organization to analyze their adherence to the relevant controls. The Texas covered entity definition includes not just HIPAA covered entities but also business associates and others. If the assessment shows sufficient compliance with the criteria HITRUST will recommend to THSA that the entity receive certification. Smaller entities will be able to request certification by conducting a remote assessment that would then be submitted to HITRUST for review.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thirty seconds.

Tony Gilman – Chief Executive Officer – Texas Health Services Authority

SECURETexas is...I guess the next slide, quickly, organizations that have obtained this certification importantly will have some advantages under a state law mitigation that protects them from penalties and it also affords them some protection under HIPAA as well should they violate HIPAA or have a breach.

SECURETexas is live with one hospital receiving certification and several other hospitals and health plans pursuing certification now. If you go to the next slide there are several links to the HIE Texas website as well as more information on SECURETexas and the HIE accreditation program. Thank you.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> <u>Coordinator for Health Information Technology</u>

Thanks, Tony. Jennifer Fritz?

<u>Jennifer Fritz, MPH – Deputy Director, Office of Health Information Technology – Minnesota</u> Department of Health

Yes, good morning. Thank you for the opportunity to present on behalf of the Minnesota Department of Health. If you could proceed to the next slide, please?

Minnesota's HIE governance approach is authorized by legislation as you can see the reference there on the slide. Minnesota supports a market-based approach to health information exchange with government playing an oversight role to ensure that entities provide HIE services in the market.

Currently our state certified health information exchange service providers provide the full range of clinical Meaningful Use transactions as well as additional emerging transactions such as those necessary for health reform.

Currently one of the challenges that we see is the lack of nationally agreed-upon standards for exchanging with a range of health and healthcare providers such as behavioral health and local public health.

One of the advantages to Minnesota's market-based approach to health information exchange is that the state alone isn't required to advance the market innovation but allows companies that provide HIE services nationally as well in Minnesota to foster innovation. Yet the model in Minnesota assures that some level of government oversight is there to ensure a level playing field as well as to offer protection for both providers and consumers.

We also know our law was passed in 2009. We know that our law needs to be updated and we've been working through a public process to make recommendations to align our law with the emerging activities happening nationally. Next slide, please.

As part of our oversight process all entities seeking certification are required to attest to a list...I'm sorry required to attest to a list of requirements including various policies and governance mechanisms. In addition health information organizations, which is one of the entities in Minnesota, must seek the full EHNAC HIE accreditation, while not required, in part because their law was established before these activities took place, HIE service providers who provide direct capabilities are encouraged to become members of DirectTrust and all HIE service providers in Minnesota have become members or are undergoing the process to become EHNAC certified for Direct.

Another optional requirement that has been so far agreed to by all in Minnesota is to participate in Minnesota's statewide shared HIE services, which basically provides three things the ability to look up a Direct address, a mechanism for recording opt out of record locator services statewide and then the ability to query across record locator services.

One other requirement in statute is actually the establishment of a reciprocal agreement to ensure that HIE service providers are willing to route Meaningful Use transactions across the network.

For entities that have been certified they also receive an order from the state with clear expectations and dates with follow up from our staff. They also complete quarterly reports and an annual recertification so that we can update things as needed. Next slide, please.

We know in Minnesota there is a lot of HIE happening so this slide is meant to reflect the different types of HIE happening in Minnesota and the ones with the stars are covered by our oversight. Much of the HIE that's happening in Minnesota is not through our oversight process however, so such as EHR vendor facilitated exchange or peer to peer.

So what we see in Minnesota is that we have a little bit more of silos of data versus lack of HIE happening. And in Minnesota it seems like there are several reasons for this, one is we have the presence of large EHR vendors that provide HIE services and quite frankly that refuse to seek state certification. Plus the lack of certified EHR technologies and agreed upon standards to support use cases in important priority settings such as behavioral health, long-term care and others.

In Minnesota we also have stricter privacy laws so we struggle there in terms of recording consent appropriately.

Because there is often confusion about various state and federal laws around privacy and security there is a strong need for governance structures. And the term governance itself can be confusing and what the components of a good governance structure should be clearer. Next slide, please.

At the national level it would be helpful to develop a common set of, I guess, taxonomy as a previous presenter mentioned and this slide is really meant to reflect some of the things that in Minnesota we would see valuable. So, a common definition component and minimum standards for a strong governance structure from different perspectives, so what if you're a provider or consumer, or an intermediary, common core sets of HIE services and standards that support health reform. Standards for interoperability...

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thirty seconds.

<u>Jennifer Fritz, MPH – Deputy Director, Office of Health Information Technology – Minnesota</u> Department of Health

Across services. And then I'll move onto the next. ONC could play a role in helping to shape the common model for data governance. The states in the private sector have to be active in shaping what it looks like in an effort to meet the interoperability of new healthcare models.

And I guess, you know, one last thought is one possible mechanism would be that maybe ONC could develop some type of a voluntary registration process for entities that are in the HIE space and learn over time working with states and HIE service providers about what type of regulation ONC may be able to play into the future. Thank you very much.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thank you, Jennifer. I think we have a last minute change to the agenda instead of Karen we're going to have Barclay Butler.

Barclay P. Butler, PhD - Director of Health Standards & Interoperability - Department of Defense

Yes, thank you very much, good morning; I'm Dr. Barclay Butler the Director of Health Standards and Interoperability for the DoD. Dr. Guice offers her regrets in not being able to participate and share her perspectives on interoperability of healthcare data in the Department of Defense and she has asked me to provide that perspective from the DoD and the Defense Health Agency.

Interoperability in the Department of Defense, the Defense Health Agency really falls into three main categories. First it's the exchange and use of healthcare data amongst our hundred plus hospital host electronic health record systems where our data is mapped to national standards and then is stored centrally that enables the access to patient records really from anywhere on the planet.

Second, is the interoperability of healthcare data supporting our referral management process where we send upwards of 60% of our care out to an external network of providers and this is most commonly facilitated by our managed care support contractors. This concept similarly applies to the exchange and use of healthcare data for our service members that are treated in the Veterans Affairs Hospitals which are supporting our dual use patients.

The third category is the consolidation of a career long Service Treatment Record, an STR, for sharing with the VA as our service member's transition from military service to veteran status. This service treatment record is a consolidated record of all of the care provided to that service member regardless of the location of receiving that care. For example it could include documentation of civilian care, as a result of referrals anywhere in the country, anywhere around the globe. As well as the treatment record from our direct care system or that system provided by the DoD.

In terms of security, being a founding member of the eHealth Exchange we rely on the Data Use and Reciprocal Use Agreements, the DURSAs and we certainly rely on the HIPAA business associate agreements with our managed-care support contractors and our network providers in the civilian sector.

There are two emerging efforts with regards to health information technology interoperability of healthcare data that we are driving towards. First, we're in the process of procuring a new electronic health record system that will replace our legacy outpatient, inpatient, ancillary systems.

And secondly, we are updating our managed-care support contracts in 2017 and would like to include interoperability in support of that referral management process at the very least. To support these efforts we need clarity and policy guidance for the support of that interoperability.

We want to be interoperable with our civilian network providers, which include hospital systems, group practices, independent providers and yes even remote providers who may only have Internet access and that means we need interoperability among all of the EHRs that out there and that leads to what you even heard today, standards-based interoperability exchanging use of data to include web-based access by those very remote providers.

Interoperability for us includes all of those scenarios where achieving interoperability continues to support access to care while it improves our Quadruple Aim. Quadruple Aim for us is the Triple Aim plus readiness.

As we move forward in the healthcare interoperability space our concerns mirror many of the concerns that have already been raised in this forum. For example, we're concerned about the scalability of the HIE, is the HIE the right architecture for a national or global healthcare provider? Can it scale or is a centralized health data bank the right model with a push model into a centralized storage.

Is there an HIE to HIE exchange model to support multiple local or regional exchanges leading to a national exchange? Is the HIE business model a viable model? Are the HIE fees and interface development fees too high? Is a provider identifier or phonebook coming soon? Will there be reliable ways to identify patients? And can we reach agreement on an inexpensive and viable trust authority?

These questions and more are what really drives us in participating in the interoperability governance, our standards development efforts, transport messaging framework, the security and trust, and patient empowerment and it's through these means that we hope to continue to improve in our Quadruple Aim. Thank you very much.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> <u>Coordinator for Health Information Technology</u>

Thank you, so just a reminder to our Workgroup members we're now going to the question portion. If you have a question can you please use the hand raising feature within the webinar and that will put you in the queue for questions. As of now we don't have any questions so I'm going to turn it over to Chris and Carol to kick us off with our first question.

<u>Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine</u>

Okay, I'm going to go ahead and get started Michelle. Thank you to all the presenters. You know one of the things that I noticed at last week's listening session is that we have so many different entities that are involved in the exchange or have a stake in the exchange that it becomes, for me, it becomes difficult to look at what's been said and come up with some unifying themes that are worthwhile addressing.

However, today's session I noticed something that came up over and over again and I want to follow up on that and because multiple of you addressed this, this is really a question that goes to the group. There was a discussion of the need for standards in the space of exchange of data and there were varying standards that were addressed there was the computable interoperability, taxonomy, there were standards for the actual clinical data being exchanged.

My question to this group now is that assuming the ONC takes on the task of developing a standard, what recommendations would you have to get people to adopt these standards? What kind of incentives or barrier reduction approaches would you recommend for us to drive the implementation of those standards?

And, you know, I heard some of you "complaining" about the incentives that vendors have not to adhere to the standards. So what tools do you think are available to us to drive implementation not only the development but then the implementation of standards?

David A. Minch, GS, FHIMSS - President & Chief Operating Officer - HealthShare Bay Area

Well this is Dave Minch and I'll kick it off since I was one of the "complaining folks." And I want to be really clear about the distinction between standards and reference implementation. I mean, we have a number of what I think are very good standards, what we seem to lack or have not spent enough time on is a specific reference implementation that crosses a very broad reach of use cases that the standard can be used for.

And consequently when vendors take a look at this they can customize their designs towards a very specific use case that they're interested in and that essentially creates a deviation in the marketplace. Some vendors restrict content for Direct; some vendors have a very unique implementation of the structured content.

And many vendors have not implemented an HPD+ type of directories and are not capable of or do not easily share their directories and this makes Direct itself very difficult as a protocol to...the Direct standard as a protocol to implement.

So, our recommendation is really to look at a very broad set of functional capability for both Direct and exchange and then reduce that to essentially capability elements.

We proposed, and this was written up in the NeHC work last year, the beginnings of and a methodology for development of a trust taxonomy, I think we called it a framework in that work, and I would add to that a functional capability set of attributes which really describe how a particular implementation has used the elements to customize what can be sent and received.

Once we have a good taxonomy, a computable taxonomy it becomes fairly straightforward to then be able to create a posting process where organizations can exchange that taxonomy with each other and learn and understand without prior agreements what the trust elements are and what the functional capabilities are of a potential data trading partner and then make decisions that ultimately allows data to flow.

<u>Gail L. Graham – Assistant Deputy Under Secretary for Health (ADUSH) for Informatics & Analysis – Department of Veterans Affairs</u>

This is Gail; I'd just like to add, Gail Graham, three points. We think that the standards currently focus mainly on primary care which makes sense but there is a need to expand these into the clinical specialties, cardiology, ophthalmology, etcetera and maybe enlisting the assistance of those specialty organizations that support the profession.

We also believe that ONC should continue to concentrate on standards development and facilitating communications between all parties involved in the exchange and the suggestion that monitoring scoring data quality would help improve HIEs over time and that data quality could potentially be a Meaningful Use Stage 3 criteria. That's it, thank you.

Tony Gilman - Chief Executive Officer - Texas Health Services Authority

Hi, this is Tony Gilman; I'd like to also just, you know, talk a little bit about something positive that I think ONC did last year, and it may come up on the next panel, on governance. But ONC really took a leadership effort last year in convening through the EHR HIE Interoperability Workgroup a number of stakeholders, including the eHealth Exchange, some standards organizations, NATE from the west coast to advance work on federated provider directory standards and I think that was a positive exercise and as a result, you know, the work that was done has been incorporated and is being balloted through HIE International right now.

And really the next step is to provide, you know, for I think...from my perspective is for ONC to provide, you know, more clear guidance or pointing to that as, you know, the standard to help us on the provider directory challenges that we face with Direct but could also benefit states on query-based exchange as well.

So, you know, I think that's a positive example of where ONC played a strong role in convening organizations to address a problem.

<u>Jennifer Fritz, MPH – Deputy Director, Office of Health Information Technology – Minnesota Department of Health</u>

And this is Jennifer Fritz I'd just like to add two comments. I agree with all of the previous comments the first which is I think that ONC actually has an opportunity to build upon the existing EHR certification process and I know ONC is looking at expanding for other settings such as behavior health and others. In Minnesota we actually have a mandate by 2015 for all providers across the entire continuum of care to have an electronic health record that we point to ONC in our statute for having a certified EHR, but as we all know most settings don't have certified EHRs available.

And the second thing, which is...you know, of course we've recently, in the last two years, have been focus a lot on Meaningful Use but what we're seeing in a lot of states and particularly in Minnesota is many providers are really wanting to move beyond that into more of the accountable care health reform space.

So, things such as data aggregation models are starting to emerge and more repository-based architectures and it seems that we don't even have agreed-upon standards about basic core data elements that would be needed in order for better data aggregation. So, just a couple of comments there.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thanks, Jennifer. I'm going to go to our next question from Beth Morrow.

Beth Morrow, JD - Director, Health Initiatives - The Children's Partnership

Hello, this is Beth Morrow and I wanted to follow up on something Jennifer said, but many others might have answers as well. I may have missed something, but you recommended that ONC develop voluntary HIE certification as a means for establishing a common governance framework, but I'm wondering how this would differ or accomplish more than what Minnesota has tried since I thought you were saying that despite your efforts to address this through certification and oversight, you were having limited effect because large vendors were not participating?

<u>Jennifer Fritz, MPH – Deputy Director, Office of Health Information Technology – Minnesota Department of Health</u>

Sure, actually thank you for that question. I think what we hear from large vendors, and quite frankly some of the large vendors have participated in Minnesota such as companies like Surescripts and Emdeon and some other larger companies, but because we're only one state some of the larger vendors don't want to have to, you know, do 50 different requirements for, you know, 50 different states.

And similar, I guess the analogy is similar to maybe telecommunications, it seems that there needs to be some type of a national way to at least know what's happening in the market and whether you call it regulation or accreditation or registration, I'm not sure what the term is, but it seems like HIE does cross state borders obviously and there would be value in having some type of a picture at a national level about what's happening in this space.

Beth Morrow, JD – Director, Health Initiatives – The Children's Partnership

Okay, I see, so you feel it's an important strategy but that it needs to be a national approach rather than state-by-state?

<u>Jennifer Fritz, MPH – Deputy Director, Office of Health Information Technology – Minnesota</u> Department of Health

I do and I could see cases such as in Minnesota where we have stricter privacy laws, you know, there certainly might be certain things that have to happen state by state but some of the core pieces that hopefully cross all state borders should be common across all state borders and it would be helpful, at least to us, if there was a national model for that.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> Coordinator for Health Information Technology

Do other panelists have comments? Okay, I'm...

David A. Minch, GS, FHIMSS - President & Chief Operating Officer - HealthShare Bay Area

This is Dave Minch, I guess one thing I would just caution is the concept of certification and I think certification to some extent unless you have truly a standardized set of attributes to certify to it becomes a...you know, it could become a two edged sword driving people away from interoperability as much as bringing them to it.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> <u>Coordinator for Health Information Technology</u>

Okay, Anjum has a question.

<u>Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health</u> Institute

Yes, thank you and thank you for the presentation. I was actually very interested in the concept of using market mechanisms to increase the trust for exchange of information and both Tony and Jennifer mentioned using EHNAC criterion. So I would like to know what was the...what is the general feedback they are getting from providers for whom this will be an additional cost and how do they see ROIs on increasing requirements for exchange of information?

Tony Gilman – Chief Executive Officer – Texas Health Services Authority

So, this is Tony Gilman and in terms of our HIE accreditation we're requiring that of organizations that want to participate in statewide exchange and utilize our state shared services network, HIETexas, and so it's limited to those types of HIE organizations that intend to on board with HIETexas. So, it's not necessarily provider organizations directly.

But what we hear from providers through our stakeholder process, physicians, hospitals and others is that they want kind of a gold seal of approval from the state that the organizations that they're working with are legitimate businesses, that they are maintaining good business practices, that they have a governance structure that's representative of the community and that they are building their HIE operations in a way that's interoperable with other HIE operators and in a way that would allow them to exchange information with state agencies in Texas. And so, hearing that fairly often during our process really led us to put an accreditation program in.

The other kind of core reason we put that in as well is that there is some concern that legislative bodies, including the Texas legislator, may want to regulate in this space and by having a self-regulatory framework so to speak through an accreditation program such as the one we've implemented we feel like that's an important step to try to stave off efforts to potentially regulate HIE too soon because it's such an immature market and there is so much potential for innovation having anything in statute would really prevent us from, I think, advancing in a way that we would like here in Texas.

<u>Jennifer Fritz, MPH – Deputy Director, Office of Health Information Technology – Minnesota Department of Health</u>

And this is Jennifer, I can add from Minnesota's perspective, we use EHNAC in two ways, one is called out in our statute and that was back when our first oversight law passed EHNAC seemed to be the only body around nationally that was accrediting HIE service providers and so that was spelled out specifically in statue for our HIOs which provide more robust HIE services.

What we hear not so much from healthcare providers but from our HIE service providers that have participated in that is that it has really strengthened them as an organization particularly around their internal policies and procedures and in particular around security.

However, we've also heard from them that the cost for going through the process is quite expensive not only in terms of the fee but in terms of their internal resources and it's quite a rigorous process. So, it has strengthened them but it's also been a challenge.

And then the second is the EHNAC accreditation for Direct or for HISPs which I believe many states are using and seems to be sort of the current model for entities that want to provide Direct services. Thank you.

<u>Anjum Khurshid, PhD, MPAff, MBBS – Director Health Systems Division – Louisiana Public Health</u> Institute

Okay, thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Carol did you have a question or did you change your mind?

<u>Carol Robinson – Principal – Robinson & Associates Consulting</u>

No actually I didn't change my mind I have a number of specific questions but I don't want to prevent other members of the Sub-Workgroup from asking if there are others waiting.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> <u>Coordinator for Health Information Technology</u>

No, so we've gone through the queue so you're up.

Carol Robinson - Principal - Robinson & Associates Consulting

Okay, excellent. I'll try to go through these really quickly, for Jennifer, your slide shows that you are developing standards for query across record locator systems and then the requirements for I think cataloging an opt out and I'm curious about the standards that you're thinking about querying. Are you thinking about requiring a response for those queries or just...because right now I think that there is not necessarily always a required response?

<u>Jennifer Fritz, MPH – Deputy Director, Office of Health Information Technology – Minnesota</u> Department of Health

That's a good question, I don't know if I know, from a technical stand-point, the answer. I do know that for the query part we did use the IHE profile for query across HIE service providers but I'm not sure if I know the answer to the specific question that you have.

Carol Robinson - Principal - Robinson & Associates Consulting

Okay, thank you. My question for Barclay is about your RC and certainly has a lot of press out there so in terms of the interoperability standards that you're including for the procurement of the new DoD EHR record system; do you have anything that you're pointing vendors to that you will be evaluating those proposals on?

Barclay P. Butler, PhD - Director of Health Standards & Interoperability - Department of Defense

Yes, certainly there is a whole list of them and they cross a number of clinical domains. We currently have got seven domains that we have identified and are sharing using national standards very specifically with the VA and are extending that out into the private sector with our network providers. That list will continue to expand almost in a dynamic way between now and the procurement and even through the procurement upwards to, oh gosh, I would think maybe high 30s or low 40s in the domains and we seek the use of the national standards in every case. Where those standards don't exist we look for the areas where there is the most consensus and then use that as potentially a springboard for an SDO to create a standard and propose a standard.

So, the answer, the very short answer is absolutely national standards based on clinical domains.

Carol Robinson - Principal - Robinson & Associates Consulting

Thank you very much for that answer. And my final questions are for Tony and so I'll ask both of them at the same time because I know we only have a couple of minutes for the answer.

The first one Tony is about the cost and burden of the HITRUST certification for small organizations and the response that you're getting from covered entities for that and the second one is if you could, very briefly, explain how the federated access to eHealth Exchange is going to work from Texas HIE?

<u>Tony Gilman – Chief Executive Officer – Texas Health Services Authority</u>

Sure with respect to the HITRUST certification, so privacy and security for covered entities, it's primarily being used by large health care organizations right now hospitals, PBMs, health plans and pharmacies. We are working in collaboration with HITRUST to have an alternative pricing structure for smaller organizations and we're doing so in collaborations with organizations like the Texas Medical Association to get their input on a pricing structure that would be more in alignment and more affordable for small physician organizations in Texas. So, that's something we recognize as a challenge and it's something we're working on collaboratively with HITRUST and provider organizations here in Texas.

And then in terms of our interaction with the eHealth Exchange, we really view the eHealth Exchange as a strong partner for Texas. We modeled our architecture after the eHealth Exchange architecture. We're using the same IHE standards for exchange. We also are leveraging the federal DURSA and have a state level trust agreement model after the DURSA which serves as a central component of our legal trust framework for Texas and ensures trust across Texas...exchange of information as trusted across Texas as well as across the nation.

And we're leveraging our model to make it easier for our HIE organizations to connect to the eHealth Exchange so we've built a...are technically connected to the eHealth Exchange and we've...as we on board our HIE organizations onto HIE Texas they will be able to connect to other states and federal agencies through the eHealth Exchange and they will be able to do so at a lower cost because they won't each have to go through the on boarding testing and pay the fees associated with on boarding to eHealth Exchange we've done that through the HIE Texas.

And I just want to reiterate we are viewing the eHealth Exchange as our primary mechanism of connecting to federal agencies in other states. So, we're in the interoperability testing with both the VA and the Social Security Administration and we're in a dialogue with a large hospital system in New Mexico with the States of Kansas, Michigan, Florida and other states that are connected through the eHealth Exchange and that's our way of supporting interstate exchange as kind of the next phase once we begin to ...as we begin to look beyond exchange within Texas.

Carol Robinson - Principal - Robinson & Associates Consulting

Thanks so much for all those answers. Michelle, I think I'll turn it back to you.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thanks, Carol. I think we're ready for the next panel. So, let me just go through each panelist and then we'll get started. So, this panel is about governance entities and we have David Kibbe from DirectTrust, Kitt Winter from HealtheWay, Aaron Seib from National Association for Trusted Exchange, Nick Knowlton from CommonWell Health Alliance and Dave Whitlinger from the EHR/HIE Interoperability Workgroup. So, David if you are ready if you could kick us off?

David C. Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians

Yes, I'm ready. So, good morning everybody and thank you for the opportunity to speak on this panel. DirectTrust is a vibrant, diverse and collaborative organization of 145 members that has strong ties to ONC both because DirectTrust grew out of the Direct Projects Rules of the Road Workgroup and because DirectTrust is engaged in a cooperative agreement with ONC under the exemplar HIE Governance Program. This was first awarded in March of 2013 and then extended for another year in March of 2014.

DirectTrust is organized as a Non-Profit competitively neutral and self-governing entity with a goal to develop, promote and as necessary help enforce the rules and best practices necessary to maintain privacy, security and trust and identity controls within the Direct community with the important secondary goal of fostering widespread public confidence in Direct because of the security and trust elements.

Among our primary deliverables under the terms of the cooperative agreement with ONC has been one to establish and maintain a national program of accreditation and audit for Direct service providers namely HISPs, CAs and RAs, and we launched that in spring of 2013 in partnership with EHNAC to help assure that EHR to EHR interoperability via Direct gets off to a good start primarily through interoperability testing and to demonstrate Direct exchange progress with the federal agencies.

Now, I'm among the optimists who sees a great amount of progress has been made towards the goal of interoperable health information exchange during just the last two years and I want to describe that to you briefly, but first I'd like to correct for the record several statements that have been made about DirectTrust during these hearing which I think are in error.

DirectTrust and its members are focused on practical and the affordable. Both DirectTrust and EHNAC are Non-Profits acting for the public benefit and our member fees and the accreditation fees are both on a sliding scale allowing even quite small organizations and startups to participate fully.

Accreditation and audits doesn't cost "hundreds of thousands of dollars" as was claimed last week. And the fact that 20 HISPs have reached full accreditation and another 28 are in candidate status soon to reach full accreditation speaks to the openness and availability of these programs particularly compared with the alternative of dependence on one-off legal contracts for trust relationships among dozens of HISPs DirectTrust members are fully convinced that accreditation and audit is efficient and able to create a network of scalable trust at a reasonable cost.

Secondly, we found that generally speaking health care provider organizations do not desire to build and operate their own HISPs rather they would prefer to be dependent on their EHR vendors or their EHR vendor's partners to source the quite sophisticated and specialized roles and responsibilities carried out by HISPs and in some cases relying on a partnership between the EHR vendor and state or local HIEs who operate a HISP.

So, why am I optimistic? Well, the answer has been speaking to you and will continue to speak to you during these hearings due in large part to the responsible actions, guidance of funding by ONC, we now have robust network for both Direct exchange and for eHealth Exchange connect protocols in this country.

DirectTrust member HISPs now serve over 200 certified EHRs, provide direct service to over 28,000 healthcare organizations and have provisioned over 420,000 Direct accounts for these organizations largely in just the last year and you'll hear similar growth has occurred among HealtheWay's members and users I'm sure. These are protocols that are in demand now because they are useful.

Aside from Direct and Connect there are several places in the country where HIEs are thriving and offering their members interoperability through several types of connectivity arrangements often as a matter of course including Direct and Connect.

And finally, we've seen dramatic growth in the interoperability available through large EHR vendors such as Epic through their proprietary yet ever expanding connectivity solutions such as Epic Everywhere and through the VA's efforts with My HealtheVet and Blue Button Plus.

Let me point out that these several communities of trusted exchange are all national in scope. They're competing with one another to see which can grow the fastest, provide the best services most reliably and which can innovate the most nimbly.

We think this is a grand experiment and that ONC, CMS and NIST should be given the credit due them for encouraging private sector growth and interoperability almost against all odds.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>
Thirty seconds.

<u>David C. Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians</u>

We encourage them to stay the course, follow through and continue to lead. I would also like to say that I would be...in my written testimony I address some of the issues that David Minch brought up with the local policies and practices that are being implemented by some electronic health record vendors. Thank you very much.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> Coordinator for Health Information Technology

Thank you. Kitt Winter?

Kitt Winter, MBA - Director, Health IT Program Office - Social Security Administration

Good morning, thank you for providing me with the opportunity to testify regarding our governance and interoperability experiences with the eHealth Exchange, HealtheWay and Carequality. I'm Kitt Winter, currently the Director of Health IT Program Office at the Social Security Administration but I'm providing this testimony in my role as Chair of the eHealth Exchange Coordinating Committee a governmental liaison to the HealtheWay Board of Directors and the federal agency representative to the Carequality Steering Committee. We have submitted written testimony to complement the verbal testimony.

In the interest of time I will focus my remarks on three key areas, first we believe interoperability is not an elusive goal it exists now. The eHealth Exchange and other large-scale nationwide initiatives provide evidence that interoperability and a good sustainable government model exist today.

We encourage ONC and the industry to learn from our experiences over the past five years specifically the Meaningful Use Stage 3 rules provide ONC with an excellent opportunity to advance the goal of interoperability. While developing requirements ONC should align with the capabilities of the IT systems already implemented on a large scale.

Second, the eHealth Exchange is a flexible, adaptable governance model that supports rapid growth and innovation. The eHealth Exchange has exceeded our greatest expectations in terms of its growth and the vitality of a proven flexible and adaptable governance model.

In 2012 there were 23 participating organizations in the eHealth Exchange, today there are 77 with another 30 preparing to go into production. Once we reach 100 participants the eHealth Exchange will represent more than 30% of US hospitals, 10,000 physician practices and 100 million Americans.

The governance model implemented in the eHealth Exchange was fostered by ONC and formed and guided by its leadership and continues to work extraordinarily well with the ability to quickly adapt and evolve as the industry and use cases change.

The eHealth Exchange governance model includes six essential elements including eligibility criteria, testing, compliance obligation, self-policing, formal dispute resolution and enforcement. A more in depth description of each is outlined in the written testimony.

Interoperable exchange of health information occurs every day across approximately 30 different technology platforms. Our experience demonstrates that interoperability needs to grow organically by learning and adapting, this works by having a flexible adaptable governance model that can respond to rapidly changing industry dynamics within weeks or months rather than years. We believe the following governing characteristics have led to the success.

The flexibility, governance approach supports a multitude of use cases and can quickly change as needs arise. It's efficient; it's a mature high functioning governance process that enables rapid response with limited overhead to maintain. It's been adaptable. It's nimbleness and has enabled the eHealth Exchange and its governance in a rapidly evolving environment.

The final key area is collaboration versus regulation. The eHealth Exchange began as a ONC initiative in 2007. To build on this success we believe ONC should continue to collaborate with industry and actively participate with the eHealth Exchange Coordinating Committee, HealtheWay Board of Directors and now Careguality.

Carequality's focus is to enable query for information between and among networks, having ONC's active engagement and guiding and providing input to that work would shape the future outcomes of Carequality.

ONC's active participation in industry driven public/private initiatives continues to be invaluable. A recent example is how ONC collaborated with industry and standard development organizations to gain consensus on a standard for provider directories.

We encourage ONC to continue to share information, provide guidance and lessons learned and to engage with industry as a partner in this rapidly evolving space. In addition, it would be beneficial to have industry voluntarily report their interoperability statistics to ONC and to educate ONC and others about the current state of interoperability in the country.

Finally, we recommend that prior to adopting new standards and architectural approaches ONC enable industry to implement new approaches in production for a sufficient period of time to gain practical experience regarding how these capabilities work. The eHealth Exchange has the luxury of learning from the trial implementations and blossom into a highly successful nationwide network.

In closing we applaud ONC's thoughtfulness around the use of rulemaking to avoid burdening this developing market with regulations. While challenges certainly exist we believe the best solution is to continue the public/private collaboration that ONC has successfully pursued.

The new Carequality Initiative is an excellent opportunity for the private sector, government and the public to come together to discuss some of the complex technical and policy issues that have delayed the complete interoperability of Health IT systems. Thank you.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thank you, Kitt. Aaron if you're ready?

<u>Caitlin Collins – Junior Project Manager – Altarum Institute</u>

Aaron if you're speaking you're on mute.

Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)

I'm sorry about that I was on mute. I'm ready.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Okay, please go ahead.

Aaron Seib - Chief Executive Officer - National Association for Trusted Exchange (NATE)

Thank you for inviting me to participate as a member of this guest panel. It is humbling to be associated with so many successful HIE governance efforts and the people who have been so critical to their organization's results.

My name is Aaron Seib the CEO of the National Association for Trusted Exchange and it's a privilege to be the one that gets to convey some of NATE's experiences with regards to governance on behalf of our membership.

I hope that you find that NATE's written testimony is responsive to all of the questions posed by the panelists, to the panelists but recognizing that each panel member only has a few minutes to speak I will be limiting my spoken testimony to talking about what I think is the key charter of this governance subgroup.

Specifically, I will be talking to you about what role the ONC can play to help address the governance challenges that are inhibiting broader adoption of HIE in our nation today. Before I can get to that, I would like to share some of the context of our experiences that have helped create and inform these thoughts. Next slide, please.

What I've learned about governing HIE. Governing HIE is tough, we are still learning. One size does not fit all. In many cases depending on the use case a plethora of authorities influence the disclosure decision. There is applicable federal law, applicable state law, applicable local policy considerations, applicable preferences of the caregiver, applicable privacy preferences of the individual, applicable laws of the market, applicable financial policies and that is just with regards to the primary uses of the data.

Some of the governance heuristics that we have found useful and how to recognize bad governance is when you have the fewer of these authorities that influence disclosure decisions involved the worse the governance that results.

How to recognize good governance? Support...good governance supports options that allow local policy decision makers, the most local being the individuals themselves, to choose who they trust. Next slide, please.

When I think about how the various governance efforts I have been involved in have emerged I can look back on all of them and recognize that in the beginning there was a stage where I thought we had a simple path forward to encouraging HIE governance that maximizes appropriate exchange. Next slide, please.

Looking back on all of them I can report that with the best of intentions on the part of everyone, establishing governance is always a challenge. I've been working in HIE for what feels like forever, it isn't a simple enterprise integration problem. All of the technology is necessary but not sufficient to get data to flow. It is really tempting to believe that technology will make the hard stuff go away, but in fact we think about...when we think about other industries that have had to balance the differences between ensuring safety and adoption we can come up with cautionary examples that illustrate the risk of relying too much on technology when governing domains that touch all Americans.

The natural inclination that we all have is to make exchange bulletproof and to do whatever we can to minimize risks in exchanging PHI. After all when we think about what could go wrong an awful lot of us get the same feeling that we get when we think about car wrecks. Next slide, please.

So, a simple question that I thought about when I was preparing for this talk was could governance eliminate injury due to traffic accidents? Next slide, please.

I believe sure we could eliminate traffic accidents if we required everyone to drive one of these cars at 15 miles per hour. Thankfully, there hasn't been anyone with so much hubris to think they know what everyone should be driving. Some of us drive Volvo's and others like two seat sports cars, and yes some of us get our groceries in a Humvee. For some of us...for some use cases some of us unfortunately have to drive vehicles like this to work. To date the ONC has refrained from establishing what vehicle each of us must use to govern HIE and that has led to where we are today. Next slide, please.

To provide some context I've prepared an abstraction of the various governance models and tried to isolate specifically were the ONC, this Subgroup's recommendations to the ONC, would help optimize the use of governance and optimize the appropriate amount of exchange that occurs in the country.

Meaningful Use of emerging governance entities, in my abstraction I assume that there are only three governance entities, four HIOs, 10 local policy decision-makers and assume that some local policy decision-makers may belong to more than one HIO. Next slide.

Just to build this up real quick, relationships between local policy decision-makers, those people who go at risk when they join our governance and rely...become relying parties on what entities like NATE and others do, typically join a single HIO which offers services to many local policy decision-makers. Some local policy decision-makers are part of multiple HIOs; some HIOs are local policy decision-makers in and of themselves. Next slide, please.

Multiple HIOs may belong to more than one governance entity; we know this is true for many of the states offerings both of them belonging to NATE and DirectTrust as example. Some HIOs are eligible to be part of only one governance entity, while others are eligible to belong to many. Next slide, please.

Creating a landscape that looks like the following. Next slide, please.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

If you could please wrap us.

<u> Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)</u>

Sorry. Where the ONC can be very helpful to local policy decision-makers is helping them make sense of this landscape. In the abstraction a new local policy decision maker comes to the environment and needs to make some decisions about which governance entities align with their priorities. Next slide please.

Typically decisions about who to exchange with are driven by many factors including geographical, distal and use case specific activities creating a target such as the following. Next slide, please. Which is overlapped with multiple governance entities. Next slide, please.

What role should ONC play? ONC should make it easier for local policy decision-makers including patients to discover which governance entities can I rely on to meet or exceed my local policy decision maker's requirements? Help me understand...

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> Coordinator for Health Information Technology

Aaron I'm going to have to ask that we move onto our next panelist, I'm sorry.

<u>Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)</u>
Sure.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> <u>Coordinator for Health Information Technology</u>

Hopefully there will be time in the Q&A to finish up. Is Nick available?

<u>Nick Knowlton – Senior Director, Strategic Initiatives – Greenway Health</u> Yes I am.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Please proceed.

Nick Knowlton – Senior Director, Strategic Initiatives – Greenway Health

Good day my name is Nick Knowlton and I work for Greenway Health. I'm here to represent CommonWell Health Alliance today as I serve the alliance as both a board member and the chair of the membership committee. In addition to this role of CommonWell I work with dozens of public and private health information exchange initiatives and I lead Greenway's efforts with Carequality, HealtheWay and eHealth Exchange.

As CommonWell is a bit of a different animal compared to traditional HIEs I want to give you some background to frame our views on governance issues. The CommonWell Health Alliance is an independent not-for-profit trade organization devoted to the simple vision that health data should be available to individual patients and providers regardless of where care occurs. We believe that provider access to this data must be built into Health IT at a reasonable cost for use by a broad range of healthcare providers and the people that they serve.

The alliance currently consists of 12 health technology vendors who collectively represent more than 40% of the acute EHR and 20% of the ambulatory EHR markets, as well as participants in laboratory, pharmacy and post-acute care markets.

The alliance is in the process of defining and promoting a national infrastructure with common standards and policies. The early core components of this infrastructure include identity management services to accurately identify patients as they transition through care facilities, record locator services to help providers locate and access their patient records regardless of where the encounter occurred, consent management services to deliver a patient authorized means to simplify management of data sharing consents and authorizations, trusted data access to provide authentication and auditing services that facilitate trusted data sharing among member systems.

We believe that our approach will help solve the long-standing industry problem of interoperability among a sometimes fragmented Health IT landscape enabling a patient's data to be available in a secure trusted manner to the patient and the patient's care providers. This approach can improve care quality and foster innovation by creating an open vendor neutral platform to break down the technological and process barriers that currently inhibit effective health care data exchange.

With specific regard to our governance model it is driven by the member organizations in an open and transparent manner. We have published bylaws and membership agreements for the vendors who comprise the alliance. Our appointed board of directors approves use cases and service models and these approved interoperability policies are passed down to our participating provider organizations and recommendations from those organizations are carried up to the board.

As stated, we have started with the use case and service model that a patient consented into the alliance network will have the ability to have their record located and retrieved by their provider at the point of care regardless of setting, at a reasonable cost and aligned with the provider's natural workflow as much as is reasonably possible.

Our requirements and specifications address consent, trust, security, audit, patient identity, transport and content issues related to improving health information exchange. We do have these policy flow downs to participants that stipulate allowed access requirements. We also have auditing policy and technology to ensure compliance.

The CommonWell Health Alliance was formed in part due to lack of national patient identity policy and associated record locator service infrastructure. In the past year we have proven that the HIT industry is willing, dedicated and capable enough to solve these issues.

As founding members who compete with one another vigorously in the marketplace we were able to identify common ground and how the alliance would operate, what use cases would be initially supported and what technology services would be provided all within the first six month period postformation. We launched the service four months later. This is incredibly fast given the size of the problems we decided to solve on behalf of the healthcare industry.

In the eyes of the alliance the proper role for all federal, state and local government entities is to collaborate on issues that hinder interoperability not to regulate, not to dictate technical specifications and not to state for required interoperability intermediaries.

Interoperability is best served by a government structure that removes roadblocks and supports the private sector. Opportunities exist to help advise and collaborate on trust and security issues. For any interoperability scenario you must have standards and vision alignment of the member organizations and vendors.

Business reasons sometimes discourage provider organizations in HIEs from actively exchanging information. We aim to remove as many of the roadblocks as is reasonably possible but we as vendors do not control all of the variables.

In our eyes the ONC's best role is monitoring the landscape and reporting on findings as an effective method to both encourage interoperability and educate all stakeholders for healthcare in the country that interoperability is not only possible, but it has taken hold and it is here to stay. Thank you very much for your time.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thank you Nick. Dave Whitlinger?

<u>David Whitlinger – Executive Director - New York eHealth Collaborative</u>

Good morning, my name is Dave Whitlinger I'm the Executive Director of the New York eHealth Collaborative, we're an organization that is responsible for operating the Statewide Health Information Network of New York in partnership with both the Department of Health and with the 10 Regional Health Information Organizations or RHIOs across the state.

The SHIN-NY, as we call it, the Statewide Health Information Network of New York, has its governance within the New York eHealth Collaborative or NYeC, as we pronounce the acronym, and we also have a certification program embedded in that which is regulated through regulation from the state that ensures trust and confidence in the network and the operators of the network.

But today I'm here to talk more about a different organization that we formed in response to demand for interoperability and that is the EHR HIE Interoperability Workgroup. As the State of New York is a highly fragmented healthcare system over 150 EHR vendors are represented across the landscape in about 20,000 individual EHR systems that are now in existence in the state that need to be connected in order for us to support both query-based exchange and Directed exchange and as we're seeing more demand for both those services as well as automated alerts, patient access and in the future care plan management.

All of this is being driven largely by the enormous transformation of the healthcare system through Medicaid redesign and other payment reform systems. HIE growth and demand is growing rapidly and the lack of interoperability is one of the significant barriers.

That lack of interoperability can cost as much as \$30,000 for interfaces in order to connect to an HIE to enable Directed exchange, query-based exchange and other forms of HIE services. So, from that we developed the Interoperability Workgroup, it at this point is comprised of 19 states that also recognized the similar problems that we were facing. Those 19 states represent more than 50% of the population. We also have roughly 47 different EHR and HIE vendors who have participated.

The principal goal of this group was to get to what we call and what the other tech industries call is plugand-play standardization. What that really means is that you've achieved a level of standardization in the software such that two products can work out of the box without engineers getting involved in between and having to cost an inordinate amount of money in order to make things work. We did that with query-based exchange, Directed exchange as well as some of the standards involved in the record itself.

From that then we a built a test tool and this is the gold standard test tool such that vendors can now test against this tool, it's an automated test tool, there are roughly 1000 test cases for full compliance such that these products could now be proven to be plug-and-play in a gold seal, it's actually a green seal, it could be affixed to the products to prove that both the vendor community who are looking for similar interoperability as well as the customers, the purchasers of these products. That set of standards we think being plug-and-play is vital for us to overcome the significant adoption of HIE.

This organization was modeled after other successful organizations, the USB Alliance, the Wi-Fi Alliance, the Bluetooth Sig, very much similar as industry alliance in the form of governance that was used in order to develop these standards.

At this point we have the test tool now available in the marketplace and as of last week we launched a large group purchasing program with one of the large group purchasing organizations in the country in order to encourage the EHR vendors to be compliant to these standards in order to participate and that group purchasing is at this point covering several states representing roughly 15,000 acute providers and roughly about \$1 billion worth of purchasing opportunity for the EHR vendors that are compliant to these standards and therefore plug-and-play compatible with the local HIEs or the networks that those providers may connect with.

A couple of things that we would encourage here, the role of ONC really shouldn't be in the development of the standards that really industry can do more effectively, it requires engineers and commitment on both sides in order to be able to make that successful and it really is market-driven.

So, at the end of the day with the purchasing changing through the Medicaid reformation that is really what's driven demand for HIE. The vendor industry that's responding to that can now put together the vendor-driven responses to that and an industry alliance that partners both the provider community or the purchasing community with that set of engineers is very much achievable at this time.

So, the success that we've seen in other industries such as USB, Bluetooth, Wi-Fi is that partnering of both the purchasers or the buyers of these systems with the vendor community strong test cases that actually achieve plug-and-play or achieve a market promise of plug-and-play, the ability to test that such that you achieve the market promise and then the ability to market that such that both the purchasers and the providers are receiving the benefit of that and that's been done time and time again in other industries.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Dave, if you could please wrap up, that would be wonderful, thank you.

David Whitlinger – Executive Director - New York eHealth Collaborative

Sure. And so at this point we would like to see that the ONC perhaps becomes an organization that selects an industry group or set of industry groups that have that role and that resolves the logjam in some of the interoperability that we're seeing today.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thank you and thank you to all of our panelists from panel four. We are now going to go to questions from the Workgroup members. As a reminder, if you could please raise your hand to put yourself in the queue and we'll go in the order of how people raised their hand. I don't see any questions yet so again I'm going to defer to Chris who has his hand raised. Thank you, Chris.

<u>Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine</u>

No worries. Thank you. Thank you again to the panel. I have a series of questions and I'm just going to start with one and then yield to the group, but David Kibbe, I have a quick follow-up question on something that I would like to ask you about.

I heard Kitt talk about the number of organizations and an estimate of the exchange activity supported I was wondering if you could tell me for DirectTrust, you know, how many health organizations you've provided services to? What does that translate into accounts and actresses and if you have an estimate about the total exchange activity?

<u>David C. Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American</u> Academy of Family Physicians

Yeah, sure, Chris, we've just done our July 31st reporting so I have that information. With 35 HISPs reporting, these are the HISPs that are actually in production and in the trust anchor bundle, they are supporting now over 200 certified electronic health record products. They have...they are working with and providing service to 28,000, over 28,000 healthcare organizations, these are hospitals, medical practices, clinics and they have provisioned over 420,000 Direct addresses.

We also have some preliminary information from just July with only 10 HISPs reporting the activity for support of transitions of care. That's about half a million transactions from those 10 HISPs have been with a Direct message plus a CCD message going to a referral partner or to a discharge endpoint in support of the numerator for the transitions of care objective and metric. So, I hope that gives you some idea.

<u>Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine</u>

Thank you. Michelle are there other questions? If not then I will just continue.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> <u>Coordinator for Health Information Technology</u>

There are other questions but why don't you continue because they're from Carol.

<u>Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine</u>

Okay, all right. So the next question that I have is to Nick, you know, so CommonWell is a very different model than we do in exchange where a lot of exchange is being conducted. The exchange for interoperability of electronic health records cuts off a lot of the middle man.

One of the things that you said is that the exchange happens at a reasonable cost and I was wondering if you could give us an understanding of what reasonable cost means and what the business model is that you are working with at this point?

Nick Knowlton - Senior Director, Strategic Initiatives - Greenway Health

Okay, very good question. So, the concept of reasonable cost was discussed during the formative process of the alliance well over a year ago. It was really one of the founding principles that if we as vendors were committed to making interoperability as widespread as we wanted it to the services were going to have to be provided at a reasonable cost, you know, no numbers were ever discussed on that and, you know, furthermore, the alliance is comprised of vendors who compete very much head to head in the open market.

So there are obviously some very important legal restrictions about talking amongst ourselves on anything regarding our own commercialization models. So we have never gotten into what the member organizations would do to price the services out of the customer base simply because it is not permissible for us to discuss it.

The basic model of the alliance, just to explain that further, is the alliance collaborates on providing the common services to manage patient identity and move records from system to system. At that point the alliance members are free to make their own decisions as to how they choose to commercialize those services and you would have to talk to each alliance member individually to find out exactly how they define reasonable cost.

<u>Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine</u>

Thank you, I might follow-up but who is the one who is ultimately paying? You said customer. Who do you define as a customer?

Nick Knowlton - Senior Director, Strategic Initiatives - Greenway Health

Well, those could be the provider organizations, but, you know, there is no set requirement that first of all the alliance members would have to even charge their customers or any set requirements as to what those fees would be. It is just, you know, an agreement informing the alliance that we're going to make sure that this is done at a reasonable cost to avoid some of the problems that have been stated already on this panel regarding the high cost of historical interoperability.

<u>Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine</u>

Thank you.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thank you. Jitin?

Jitin Asnaani, MBA – Director, Product Innovation – athenahealth

Hi, thanks. So I think every panelist alluded at some point to the opportunities ONC has to help foster and drive innovation and interoperability. What I would love to hear sort of, you know, taking yourself out of the context of this panel and the mandate to ONC, I'd love to know, for each of the panelists or at least where it is applicable, what are the most important factors that are affecting adoption of the interoperability services today whether they're technical, you know, policy related or operational? What is that...what are the barriers where they're moved or incentives where they are there that would really foster the adoption of your services across the board?

<u>David C. Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians</u>

This is David Kibbe, I'd be glad to start. I think Dave Whitlinger hit a very important point and that is that payment reform that rewards quality over quantity and specifically focuses in on the value of care coordination is really a significant driver and I think that as we see the payment reform occur the organizations respond then they start to remove the barriers themselves. They put pressure for example on the electronic health record vendors to make it work and to make the security as good as it can possibly be so that would be my major comment on that.

David Whitlinger – Executive Director - New York eHealth Collaborative

If I could build on David's response, this is Dave Whitlinger. Yeah payment reform definitely is a driver and I think that ONC and HHS are doing a tremendous job. I think that there is a little bit of a stall going on right now in the overall interoperability because there is this Meaningful Use effort that could apply some pressure, it's unknown where, you know, whether that's going to lead or is going to have a different effect and so these other industry organizations are cropping up in order to meet customer demand or the healthcare system demand for interoperability.

I think at some point there is going to be additional stalling, Direct aside, simply because there are too many options, you know, the options of interoperability make it more difficult and so picking a winner, so to speak, has the direction is going to be at some point necessary in to order to move the market forward.

Kitt Winter, MBA - Director, Health IT Program Office - Social Security Administration

So, this is Kitt Winter, for us early on we recognized that the barriers to interoperability were not just technical but also included that legal policy implementation as well and to address those barriers and to really focus on the trusted, the trust that was needed I think the Data Use and Reciprocal Support Agreement, the DURSA, was specifically set forward to help address a lot of that barrier.

If we also look...I mean for HealtheWay and for the eHealth Exchange, as I said earlier, it really has had tremendous growth. I think for several states it has successfully transitioned from the federal funding and are developing sustainability business technical models for that state-level and that has also helped for the scalability and moving forward.

I would only add I think that focusing also from Carequality perspective, since I'm really speaking to the three different areas, I think that will help expand it because Carequality is focusing on bridging the connectivity among the current networks that are out there. We can facilitate the agreement on the common national level, business policy and technical requirements that will enable providers to access patient data from many different groups very much the way the bank customers did as we moved to the ATM ACH Network where I think that movement of having the universal strong base of the policy and standards that the different networks can talk to will help move that forward as well. Did that answer your question?

<u>Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine</u>

Yes, that helps, thank you.

<u>Kitt Winter, MBA – Director, Health IT Program Office – Social Security Administration</u> Okay.

<u> Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)</u>

Jitin, this is Aaron, I think, you know, your specific question about what are the barriers, you know, taking ourselves aside from all of this, I think we're being very successful as Dr. Kibbe and Kitt have indicated on exchange related to some use cases but not all use cases.

I think that, you know, if we start to look at the next round of, you know, moving beyond replacing a fax machine and moving beyond exchanging structured data between two providers and start looking at, you know, some of the folks that we've excluded traditionally in HIE to date, I believe that we have some opportunities going forward that hopefully as part of payment reform will get addressed, specifically examples include, including behavioral health, substance abuse and so forth.

And actually for payment reform to be successful I think everyone would agree that patient engagement is a critical element which to date has been just in the very nascent stage.

<u>David C. Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American</u> Academy of Family Physicians

This is David again, if I could add one more thing. I think that one of the things ONC is getting right is the tendency to separate transport and its certification from content and its certification. Many of the problems that are occurring right now with respect to Direct do not have to do with the interoperability between HISPs but they have to do with the ability of the actual users, the healthcare providers and their organizations to understand each other's C-CDAs and that's a very important thing to understand that there are problems that are very specific to content and there are other problems that are very specific to transport regardless of what the transport protocol is.

Aaron Seib - Chief Executive Officer - National Association for Trusted Exchange (NATE)

I completely agree with what David is saying, you know, being able to use the structured data and rely on the structured data for both the sender and receiver to enforce, you know, to execute on policy enforcement points is really what's going to turn the ROI, you know, we'll be able to realize a lot more ROI once we've achieved that.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thank you. Elaine?

Elaine Hunolt, FACHE, PMP, CPHIMS – Health Acting Program Manager, Health Interoperability Service, Virtual Lifetime Electronic Record (VLER) – Veterans Health Administration/Department of Defense

Hi, this is Elaine Hunolt, Department of Veterans Affairs and my question is...you've answered a lot of questions today there is obviously a lot of work going on and a lot of effort to reach out and connect areas that are not connected now.

But how do you address those 40% of individual providers out there who have not adopted an EHR yet, certified or not, or those providers who have adopted and are using a certified EHR but are not using the HIE capabilities that are included in the EHR?

<u>David C. Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American</u> Academy of Family Physicians

Again let me start this is David, because one of the things we're doing is addressing that exact problem around the country of small providers in rural areas and ancillary or affiliated organizations like long-term care who are logical endpoints along with home care and hospice. But what's happening is that, first of all many of those organizations are adopting electronic health records. They are not certified necessarily but they are some form of EHR.

Secondly, we are finding that hospitals around the country are providing web-based Direct applications to those long-term care facilities for example or to those medical practices that are not using EHRs that are certified. It is not a perfect workflow problem solution because you'd like to have the Direct exchange capability enough to integrate it into the product but it's very easy to provide and it's very inexpensive to provide.

<u>David Whitlinger – Executive Director - New York eHealth Collaborative</u>

This is David Whitlinger. In New York we operate the Regional Extension Centers so we've been on this journey of getting physicians to adopt from paper and now adopt the HIE and, you know, that last 40% of the EHR adoption we're seeing is rapidly falling and, you know, we're rapidly getting to the place where it's the physician community that says, you know, I'm going to retire actually instead of, you know, we're rapidly getting to those folks.

With regards to the HIE adoption it comes back to the payment reform. There isn't really a justification for these services outside of the need for care coordination and team-based care and that's where the HIE shines and becomes a necessary technology component for that collaboration. And as payment reform drives more of that team-based care model the demand for our services goes up.

Nick Knowlton - Senior Director, Strategic Initiatives - Greenway Health

This is Nick, I'll second that last statement, payment reform and the Triple Aim are definitely driving the need for interoperability. Getting providers to use interoperability functionality that is contained within their systems of choice involves a lot of different factors, but as the healthcare delivery landscape shifts to more of a value-based reimbursement model there will definitely be a strong driver that will continue to encourage providers to use interoperability capabilities of their given products.

Kitt Winter, MBA – Director, Health IT Program Office – Social Security Administration

And this is Kitt Winter, just to step out of the role that I'm in for the Carequality and talk about from the SSA approach, one of the things that we do is really message out to organizations our value proposition, the benefits of being able to exchange the information and use that part of their EHR capability to also bring them onto the eHealth Exchange and coordinating committee. I think getting that message out across the board from both HIEs and other kinds of healthcare providers is critical to showing that the success and the value that they can obtain by using those features within their electronic health record.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thanks, Kitt. Last question to Carol.

Carol Robinson - Principal - Robinson & Associates Consulting

Thanks, Michele. My question is a combined question to, well I'll say the David's maybe. So, in terms of the, you know, I'll say very strong work that DirectTrust has done in creating an interoperability playing field for HISP to HISP exchange, I would like to follow-up on some of the previous comments that we've heard from last week and again from today in terms of, you know, what you're seeing in the field for these EHR implementations of Direct and their capability or lack of capability and what I heard you say, David Kibbe, was that it was a matter of, in some ways, the clinical data in, you know, the C-CDA formats, but I would even want to get down a little bit deeper in terms of, you know, attachments being very constrained...

<u>David C. Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians</u>

Right.

Carol Robinson - Principal - Robinson & Associates Consulting

Use cases being very constrained, etcetera. Thanks.

<u>David C. Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American</u> Academy of Family Physicians

Yeah, so first of all, you know, the great majority of the HISPs and the EHRs that they work with want this to work seamlessly and understand that an ultimate approach to the messages and the attachments is a good thing. In other words you shouldn't have to have a particular kind of attachment in order for a message to go through. You might be just sending a message without an attachment at all.

But there are a few EHRs that don't see it that way and the reason this is a problem is that, you know, the HISPs can receive the message and then forwards it to the electronic health record but the electronic health record says it doesn't have the attachment that our local policy requires and then they dump that message now that becomes potentially a safety hazard because the sender may not even know that the message wasn't received by the intended receiver.

And I think we are making progress and bringing this problem...you know, the engineers are working on this hundreds and hundreds of times every day. There's a lot of pain around this but I think we are making progress and trying to convince those EHRs that have created these constraints that it's not just about them and their customers it's also about a larger community of people who want to send and receive to them. Does that answer your question?

<u>Carol Robinson – Principal – Robinson & Associates Consulting</u>

Thanks, David, that's very, very helpful, I was curious if anybody else had comments and their own experience on this, Aaron or...

<u>David Whitlinger – Executive Director - New York eHealth Collaborative</u>

As one of the certified HISPs, this is Dave Whitlinger, the New York eHealth Collaborative does operate one the certified HISPs and our HISP to HISP testing and communication, as David commented, is not where the problems lie it's when we are pushing a CCD from our HISP to an EHR and what it does with it and the inconsistency with how the vendors deal with receipt is problematic.

<u>David C. Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians</u>

This is what David Minch was referring to I think earlier too. And everywhere I go in the country I hear the same problems over and over again.

<u>David Whitlinger – Executive Director - New York eHealth Collaborative</u> Yeah.

<u> Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)</u>

And, you know, I guess Carol I would share that's when HIE occurs, right, the transport between two endpoints that results in someone not being able to consume it whether it's because they don't have the ability to constrain for re-disclosure or they don't have an EHR that is able to handle it is producing some dichotomy between that haves and the have-nots.

And the folks that are in the most need of these kind of services that would benefit the most in, you know, health reform being dependent on our ability to not just get 80% of the data but to get 100% of the data exchanged for all of people is really the long-term governance outcome that we should have our eye on.

I believe fully, as the other panelists have said, the market and different mechanisms of governance can assure transport but for at least the last 10 years we've been ignoring some of the heavier policy side that is preventing the actual return on investment from being able to exchange.

<u>David C. Kibbe, MD, MBA – President & CEO – DirectTrust.org, Inc.; Senior Advisor – American Academy of Family Physicians</u>

This is David again, I think that we are pretty confident that this problem is going to be worked out because as the use cases for Direct exchange multiply it becomes more and more important for the vendors to see this as a secure messaging capability not just a particular transport protocol.

The other thing that's even more worrisome that we're starting to see is that some HISPs are at least considering charging other HISPs transaction fees and I really do think that there's a role for ONC to prohibit that from occurring, you know, this is sort of a net neutrality within the DirectTrust world, you know, that the federation agreement and the federation services agreement require the prohibition of that practice, but there are people outside who are instituting it.

<u> Aaron Seib – Chief Executive Officer – National Association for Trusted Exchange (NATE)</u>

I agree with David's optimism that this problem is so important that we have to work on it, you know, I think its independent or complementary to trust and transport and, you know, of course net neutrality is going to be a barrier if we can't address it.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Okay, well, thank you, everyone. We're going to move onto our next panel. So, our last panel is other governance approaches. We have Janice, Janet, I'm sorry, Estep from NACHA, Devin Jopp from the Workgroup for Electronic Data Interchange, Thomas Spavins from FCC and Carolina Rossini from Public Knowledge. Janet, if you are ready, please go ahead.

<u>Janet O. Estep – President & Chief Executive Officer – National Automated Clearing House Association</u> (NACHA)

Okay, thank you very much and thank you for inviting me to share my thoughts with you today. I'll have you turn to the first page of the presentation that has a diagram shown on the left. For 40 years NACHA, the Electronic Payments Association, has served as what we call trustee for the ACH network and we are responsible for managing the development, the administration and the operating rules for the financial network that universally connects all 12,000 financial institutions across the US.

So the diagram on the left shows that NACHA's primary responsibility is to create rules that can enhance the quality, the integrity or the value of the ACH network. But in addition to being a rule writing organization we also enforce the rules. We provide education. We create venues for dialogue for many different types of organizations to be heard and to learn from others.

In addition, I'll call out on the right side of this slide you see that not just core competency and creating operating rules has really been leveraged by many other types of organizations whose goal is to bring diverse parties together.

We have written and administered the Quest Operating Rules for Electronic Benefit Transfer or EBT. We support various types of collaboration between government and industry, opt in programs for child support, social security enrollment, death notifications, interoperability for protective key infrastructure models, identity management and we are the standards organization for the Healthcare EFT standard.

So as we move to the next page it's just a slide to show you what the ACH network is. It began 40 years ago best known for direct deposit and direct payment via ACH, 87 million transactions every day passing between 12,000 financial institutions and their millions of customers.

And although it started to support delivery of payroll instead of paper checks, it's really evolved over the years in many different forms and we'll talk about that in a couple of slides. So, I'll move to the next slide that gives you a picture of the NACHA operating rules, they are the legal framework for all ACH transactions and all participants of the network are required to follow the rules.

So, by entering into an agreement to comply with the rules the network participants also become subject to network rules enforcement mechanisms primarily our national system of fines, which is the enforcement mechanism that allows financial institutions to report and resolve alleged violations of the rules and potentially for fines to be imposed if they are appropriate. So, as a result this reduces exception processing for financial institutions and really maintains the integrity and the reputation of the network.

Each month an industry panel meets to review alleged violations and they are really the final arbiter as it pertains to a violation of the rules. And I call that out here because the rules do include a definition of roles and responsibilities as well as standards for formatting and so the national system of fines actually helps to enforce uniformity in all of these areas.

So, let's move to the next slide for just a minute and this shows you the timeline of the 40 years of the ACH network. Through our collaborative and self-governing model NACHA has really facilitated the expansion and the diversification of all types of electronic payments on the network over 40 years supporting these many different types of payment as shown here and it really has been in a state of kind of continuous change adapting the changes in technology, regulations and needs of the network.

So, as we move to the next page you see a high-level definition of the operating rules for the ACH network that in fact encompass both operating rules and standards and I believe it's this interweaving of the standards and the rules that has allowed for more fluid change in the ACH network over time.

So, as I said a while ago, the operating rules established the roles, the rights, the responsibilities of parties in the network, they also often prescribe the process to enable how a transaction is initiated, how it's processed and completed, error resolution, liability apportionment and the rules also define the data formats when specific consistent data is required from all network participants. So, those are the standard SEC codes as we call them in the ACH network.

In addition to the data format standards for the ACH transactions themselves we can also incorporate standards from other organizations to create formatting for payment related information and so to give you an example that is explicit to healthcare, the NACHA operating rules currently support healthcare related payments and information and over the years we've utilized X12 835 and 820 transaction sets that allow payments and related information to flow through the network.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thirty seconds.

<u>Janet O. Estep – President & Chief Executive Officer – National Automated Clearing House Association</u> (NACHA)

We also support other government related purposes and mandates that require information to flow with the transaction. So, the next page calls out the NACHA rulemaking process and I'll just speak to that at the highest level because the important things here are that it's a deliberative and inclusive process such as federal agencies use. It's not brief but it's flexible. We engage many different parties and key to making sure that the rules are understood and adapted is the education that is provided in the end.

So, the last page speaks to the benefits of private sector rulemaking as we've seen over the years and that is that we think it's important to really make sure that they're flexible to allow for innovation, efficiency, interoperability thereby creating value for all.

And the very last page then speaks to the lessons learned and that is that in addition to the operating rules having a perspective that balance and adaptability are important, rigid timelines and processes may not be the most efficient if you allow for more flexible evolution you need to be adaptive and as I said earlier, inclusiveness and education is very important also so that business practices can be adapted over time.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> <u>Coordinator for Health Information Technology</u>

Thank you, Janet. Devin?

<u>Devin Jopp, Ed.D. – President & Chief Executive Officer – Workgroup for Electronic Data Interchange</u> (WEDI)

Hi, this is Devin Jopp thanks so much for the opportunity to be able to present today I really appreciate it. I serve as President and CEO of WEDI and it's a pleasure to provide testimony on behalf of WEDI today regarding other governance mechanisms and interoperability and we greatly appreciate the collaboration of the Office of National Health IT Coordinator.

I want to briefly run through some of the questions that were asked about WEDI. We are currently...our acronym, WEDI, stands for the Workgroup Electronic Data Interchange and we serve as the leading authority on the use of Health IT to improve healthcare information exchange in order to enhance the quality of care, improve efficiency and reduce cost to the American Healthcare System.

We were formed in 1991 by Secretary of HHS, Dr. Louis Sullivan, with the idea of trying to create a blueprint by which the healthcare industry could use Health IT to improve the exchange of health information.

Our report formed the basis of the 1996 HIPAA Law where we actually were named as an advisor to the Secretary of HHS on matters regarding healthcare information exchange and we continue to serve that role today.

We really serve as a public and private industry solution to critical healthcare problems in our coalition of healthcare stakeholders ranging from doctors to vendors, to health plans as well as federal and state government agencies.

We're a little bit of a different bend than some of the other groups that you might hear from today. WEDI itself is not a standard setting organization save one exception to that, WEDI does manage the implementation guide for the benefit cards that are probably in many of your wallets, it's called our Health ID Card Implementation Guide, it's used by many payers across the healthcare industry.

Another example of what we have done in this space is we've also partnered with EHNAC, which is an accreditation organization and development accreditation program for practice management vendors. So, much of my remarks are going to focus around how do we really use private industry innovation and voluntary adoption and some other mechanisms to consider as policy levers.

The Health ID Card Implementation Guide was developed by industry stakeholders and government reps and later adopted, much later adopted by Medicare and the purpose has enabled an automated interoperable identification using a standardized machine-readable health identification card. It is currently being used by about 100 million cards are now issued by providers, health plans and government programs.

While we do not enforce the compliance with the Health ID Card Program, you know, one of the interesting things we noted in developing the 2014 WEDI Report, which was a roadmap around the future of healthcare information exchange, is that we also had to come up with programs like this where we can use private sector innovation as we don't see new legislation regulation as, if you will, a driver for new Health IT innovation.

We believe that the regulation and legislation that we have is probably what we're going to have at least in the foreseeable future and that value in our eyes must be a primary driver in order to engage private industry around these initiatives.

In terms of how we manage the evolution of policy and technology requirements as an example of this WEDI and EHNAC have a Workgroup that's made up of key stakeholders from across the industry that could set criteria for practice management system accreditation. We are rolling those standards out new this year and we do anticipate that there will be ongoing work to actually examine those to make sure that they meet and at some level drive market needs towards where we want to move the industry together so it's actually flexible and incremental at the same time.

WEDI itself is served as a 501(c)(6) organization, we have about 450 member organizations that participate in approximately 30 different Workgroups and so in this case WEDI and EHNAC and some of the programs that we have like around accreditation are RFC-based and there are revenue shares that WEDI and EHNAC both share for actually supporting those organizations and those initiatives.

I want to focus on some of the lessons learned that we've had in the over 20 years since WEDI's founding as we've really help provide guidance to the Secretary in matters of this area. One of them is we believe that you need to start with collaboration and look for win/win/win alternatives. An example right now is WEDI is about to partner with its 501(c)(3) organization, the Sullivan Institute for Healthcare Innovation, on trying to team up Blue Button standards for personal health records with the WEDI Health IT Implementation Card which has been the benefit card that I mentioned that's in your pocket most likely.

We see an opportunity to actually create a new way where we can actually solve automating eligibility, getting patient records in the hands of the individuals presenting at the doctor's office and also reducing cost at the same time, that's an example of a win/win/win.

We believe that voluntary adoption is going to be a primary driver like we've done with the WEDI Health ID Card and while there may be future opportunities where regulation may be useful in that area we do believe that in the short-term the business cases will be derived through the private industry to resolve some of the key data exchange challenges. We also believe there is new...

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thirty seconds.

<u>Devin Jopp, Ed.D. – President & Chief Executive Officer – Workgroup for Electronic Data Interchange</u> (WEDI)

Yes, we also believe there are new models for flexibility and focus on metadata and we're very excited about some of that data link opportunities where we're focusing on the data rather than on the actual...syntax.

Finally, one of the things that WEDI really feels is important is we've got to focus on something that's winnable and achievable, how do we...and we think that's getting rid of the clipboard, it's in the 2013 WEDI Report, we think we can create and essential substantive healthcare information that we can get in the hands of the patients in order to really begin solving this.

And finally, we think leveraging private industries pilots is really critical to helping to demonstrate how this can really be done and WEDI does stand ready to partner with ONC in these matters. So we greatly appreciate the opportunity to provide testimony today and happy to answer any questions.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thank you, Devin. Tom Spavins?

Thomas C. Spavins – Senior Economist – Federal Communications Commission

Good afternoon, I'm Tom Spavins and I'm from the Federal Communications Commission. My talk will tell you and be focused on what the Federal Communications Commission does which is a little bit different from most of the discussion this morning, that's great. Our goal is that what we do should be invisible to people who are solving the types of problems you deal with.

Who is the FCC? We are an independent regulatory agency. We were established by the Communications Act of 1934. There were predecessor agencies on both the wired and the wireless side.

The FCC has five Commissioners appointed by the President for five-year terms. The Chairman is selected by the President from among the Commissioners. We have about 1800 employees and a basic budget of about 350 billion dollars. That is about...oh, next slide, please, next slide, please. That is about 0.0008% of the industries we regulate.

Next slide has some budget details we can skip that. We get some money and give out some money for auctions. We are mostly fee supported, but the fees are subject to a hard budgetary cap. We don't get to keep any of the money we collect in fees. We also get substantial revenues from fines and forfeitures but that all goes directly to the treasury. Next slide, please.

Okay, what is our business model? Let's talk about our objectives. We have two major objectives. The first is the efficient use of the electromagnetic spectrum. The spectrum is a resource but its utility depends entirely on the properties of things humans make in terms of transmitters and receivers.

Having transmitters and receivers work together and at the same time not interfere with each other is our goal of spectrum management. To do that with cooperation of international authorities we engage in something called allocations which is basically spectrum zoning, who can do what, where, and we engage in assignments which are giving people the right to use individuals and businesses the right to use licenses in individual areas.

We also care about universal service. We want, because the media is an extension of the human senses, people to have access to telecommunications services that has a geographic dimension, it has a dimension of populations within service areas, it has a dimension of strategic users who we're particularly concerned about schools, libraries, hospitals, police departments are among others.

Finally, we care about what we call the virtuous cycle. We like to think our networks are developed more when people are encouraged to use them, when they can connect with other people, when they can develop applications on top of them and we feel very strongly that we have to encourage the virtuous cycle so that people recognize that this openness benefits everyone in the long run even if some business models may not be maximized in the short term. Okay, next slide, please.

How do we enforce things? Well, once an FCC rule is enacted it has the force of law. Our major tool with our rules is self-compliance. Self-compliance is the primary way all laws get obeyed. To do that you first have to encourage broad participation in the creation of the rules, people who participate in rules are much more willing to obey them than if they seem to be imposed on the outside. The public also...

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u> Thirty seconds.

<u>Thomas C. Spavins – Senior Economist – Federal Communications Commission</u> Thirty seconds?

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>
Yes.

<u>Thomas C. Spavins – Senior Economist – Federal Communications Commission</u>

Okay. The public also has to understand the purpose of the rules. We have some other mechanisms which are outlined on the next page which begin from audits and end with sending people to jail.

Managing technology policy, we're a very small part of a large industry. We have to be sure most changes come from outside the industry. Our role is basically to design a process such that new ideas get generated. We respect and make use of standards bodies in our rules and for sources of information. We have the power to use our ability as a matter of chair to create new groups when they are needed.

What are some lessons for health care? Quickly, incentives matter a lot, modularity in design and organizational decomposition are essential, what appears to be a technical problem is often an organizational problem as well and diversity in the generation of solution options is something we wish to encourage. Thank you.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thank you very much, Tom. Carolina? Carolina if you're on the line you are on mute.

<u>Carolina Rossini, LLM, MBS, MA, JD – Vice President for International Policy– Public Knowledge</u> Hi, sorry, can you hear me now?

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

We can hear you.

<u>Carolina Rossini, LLM, MBS, MA, JD – Vice President for International Policy – Public Knowledge</u> Okay, good, thank you. So, thank you for inviting me to speak...hello?

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Please go ahead.

<u>Carolina Rossini, LLM, MBS, MA, JD – Vice President for International Policy – Public Knowledge</u> Okay, I'm going to go ahead, can you hear me?

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Yes, please go ahead.

<u>Carolina Rossini, LLM, MBS, MA, JD – Vice President for International Policy – Public Knowledge</u>
Okay, thank you for inviting me to speak on the other governance approach kind of at this listening session at the HIT Policy Committee on interoperability and health information exchange. I will submit testimony in its written form later today with a series of additional resources that might be of your interest.

My name is Carolina Rossini and I'm the Vice President for International Policy and Strategy at Public Knowledge. Our organization that preserves the openness of the Internet and the public access to knowledge promotes creativity through balanced copyright and upholds and protects the rights of consumers to use a novelty technology loftily.

We work at the intersection of copyright telecommunications and Internet law at a time when disputes are converging. Public Knowledge's experience in these three areas puts us in an ideal position to advocate for policies that preserve and serve the public interest.

Internet governance is a continued development and implementation of principles, policies and decision making processes that impact the Internet. It includes both the technical elements that define the connection of digital networks and the political processes that are touched by them.

While the term Internet governance became more popular in the early 2000s after the UN held the World Summit on Information Society, WSIS, the idea of developing a way to efficiently manage the Internet is almost as old as the Internet itself.

In the 80s known governmental organization emerged to manage technical and policy functions of the Internet including the Internet Engineering Task Force. The late 1990s were marked by the creation of a California-based Non-Profit called, ICANN, the Internet Corporation for Assigned Names and Numbers, which coordinates the Internet's naming system.

Internet governance has grown to power of a variety of issues and involves a number of actors. The issues break into a multitude of categories including access, security, openness, diversity and management of critical Internet resources, but the centering of the Internet's daily life around the world means that it also includes constituting developing countries, intellectual property rights, cyber security, human rights and so on. With so many topics covered by Internet governance I find it helpful to break down these topics according to four layers of the Internet infrastructure, obligations, content and the social layer.

The infrastructure layer is a set of wires, cables, hardware, software, data links and protocols that serve as the backbone of all the layers of the Internet. Subjects related to the layers includes Internet penetration, Internet speed and infrastructure development.

The application layer is reserved for communication protocols and methods designed for process to process communications across the Internet protocol computer network. Internet governance topics at the application layer include policy on information flow and cyber security for example.

The content layer of the Internet is made up of communication information, knowledge produced, published, distributed and received by all Internet users. When thinking of the content layer you may think of such as mass generated or user generated content sites such as CNN or Wikipedia. When talking about the content layer in Internet governance you may hear freedom of expression and other human rights principles and intellectual property rights.

The fourth layer of Internet that is often identified in Internet governance is the social layer. The social layer of Internet represents the behavior of actors and stakeholders on line and the policies that impact their behavior this includes privacy, surveillance and open data.

In the past few years you may have heard people in the news or the Internet governance community talk about Internet governance along the term multi-stakeholder. The multi-stakeholder model of Internet governance is the organizational framework in which all the stakeholders including civil society, the technical community, the private sector, academia and government can participate, cooperate and assist in a consensus-based and transparent decision-making process not only that, but the multi-stakeholder model strives to place the stakeholders on a relatively equal footing with each other. This equal footing idea comes from the Tunis Agenda on the consensus statements from the 2005 WSIS Conference I mentioned earlier.

The Tunis Agenda thought it was too controversial today emphasizing the need for multi-stakeholder Internet governance and specified these roles for all stakeholders. When talking about multi-stakeholder model and Internet governance the groups I mentioned above civil society, private sector, technical community, academia and government are the many actors in this space. Members of all these groups have embraced the idea of multi-stakeholders, but there is a constant struggle between balance and multi-stakeholder industry versus multi-laterally as well as varying degrees of participation from different stakeholders.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thirty seconds.

<u>Carolina Rossini, LLM, MBS, MA, JD – Vice President for International Policy – Public Knowledge</u>
Yes. Today, Internet governance isn't all multi-stakeholder and further can be broken into multiple categories including UN processes, the WSIS processes, the ITU Forum, the IGF forum and other series of technical forums.

The issues of government engaging is definitely integrated in public/private networks governance that has ranged from deeply technical to deeply personal. The Internet itself shapes the market that uses the Internet and in terms at least some of the governance of those markets.

If we are looking for systems that are generative that create an expected value and economic and social benefits over time the Internet is a deeply competing model but it requires a commitment to decentralization, to standards setting and consensus to engagement with all the stakeholders. Thank you.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> Coordinator for Health Information Technology

Thank you Carolina and thank you to all of our panelists, just a reminder please use the hand raising feature to put yourself in the queue. I believe Jodi Daniel from ONC has a few comments to make before we go to the question portion so while Jodi is speaking if you could think of some questions that would be wonderful.

<u>Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology</u>

I could wait until the end of our discussion while we have these folks here although I do have a question, if I may? It was actually for Janet about NACHA, because since you all have been established for such a long period of time my question is how did you all get started and how did you get...how did the organization form and how does the industry participants agree to vest authority in this organization just a little bit of the history on the foundation of the organization would be helpful?

<u>Janet O. Estep – President & Chief Executive Officer – National Automated Clearing House Association</u> (NACHA)

Okay, very good question. As electronic means to replace paper checks were evolving throughout the country there were actually a relatively large number of regional groups of banks that came together to start moving to electronic and so that happened before the creation of NACHA and before the creation of the ACH network but specifically because the federal government was, and actually still currently is, the largest user of the ACH network it was pretty rapidly acknowledged that a national not a regional system would really provide the greatest efficiencies and so the idea of an umbrella organization with rulemaking capabilities that would represent all financial institutions across the country was agreed to primarily by those regional groups that were coming up. So because there were individual organizations they collectively could decide then to create an umbrella organization for the nation.

One thing that I should add is that the funding of the organization has changed over the years. It has always been a nonprofit association. It was originally funded by just direct members and it was an option to be a member or not. But everyone really was able to achieve the benefits by everyone being connected so a number of years ago we moved to a structure where every single financial institution that is connected to the network pays a very small annual fee and then a per transaction fee to support the rulemaking, the governance, the enforcement, the network development and again that's agreed to by all and it's done on a breakeven stand-point in order to sustain that value for all. Did that answer your question?

<u>Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology</u>

Yes, thank you very much.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Thanks, Janet. Chris Lehmann?

<u>Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine</u>

Yeah, I'd like to follow-up on that question. Janet, one of the things that occurred to me is that obviously somebody's managing an address book of all your financial institutions, can you talk a little bit about this, how that is done and how you got started on that one and how the address book is maintained?

<u>Janet O. Estep – President & Chief Executive Officer – National Automated Clearing House Association</u> (NACHA)

Yes and I'll try to be precise in my answer so that it's not too confusing. There is actually not an address book or a directory that has a look up in it and in fact that's something that we believe would be of benefit if in fact it was available to businesses as well as their financial institutions in order to be able to direct payments to another organization and have a lookup to be able to do that. So, I would start with what is not there, but perhaps to anticipate that this is what you assume is there as you asked your question but it's actually something the industry is working on right now.

So the next question may be if you don't have a directory then what do you have? And the structure today is what we call two ACH operators. All banks in the country are connected to either one or two of those and then all the businesses and consumers really millions of entities are connected to the banks via their bank account numbers.

So it is through the interoperability through the two operators and the banks, and then other solution providers, processors, entities of many different kinds that all the rest of the connections are made. So the key infrastructure right now is the two operators that exchange the information and the payments multiple times per day to really make that technical connection. If you have a follow up question to that if I confused you please ask again?

<u>Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine</u>

That was very intuitive of you to see my puzzled face cross the phone line. So, I'm sorry for obviously being a little dense there, so the...so how do these...who knows that I want to send money from Bank A to Bank B, how to direct this? Is this...does everybody keep a directory of all the other members of the network with them? I mean, how does it practically go?

<u>Janet O. Estep – President & Chief Executive Officer – National Automated Clearing House Association</u> (NACHA)

Yeah, so the item that really directs the payment and the information is what we call the routing number and the bank account number. So, because you have a bank account at a specific bank that bank has a routing number you have an account number within that, that information essentially gives the direction as to where to send the payment.

So, you know, again, I said the most commonly used mechanism of the ACH network is either payroll or bill payment. So, you tell your employer what bank and what account number you're at, that information starts as they format a transaction, it goes through a payroll process or it goes to a bank, it goes to your bank and ends up in your account, right, so what we call the routing number and the DDA number are the key identifiers that allow for that without having a central directory because nobody has to have in one place your account number, that's known by the bank, but the entities that are either paying each other or directing a payment, you know, are the parties that need to know that as the transaction begins and that directs it to the end party.

<u>Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine</u>

Got you so the sending party, it's the sending party's responsibility to know what the routing number and the account number is, I've got it now.

<u>Janet O. Estep – President & Chief Executive Officer – National Automated Clearing House Association</u> (NACHA)

That is right.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> Coordinator for Health Information Technology

There are...I'm sorry, Melissa Goldstein.

<u>Melissa M. Goldstein, JD – Associate Professor Department of Health Policy – George Washington</u> University

Hi, can you hear me? Can you hear me now?

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> Coordinator for Health Information Technology

We can hear you.

<u>Melissa M. Goldstein, JD – Associate Professor Department of Health Policy – George Washington</u> University

Okay. This is a follow-up question. You mentioned just now that there were two operators who are I guess the groups in charge of managing the transactions. How are those operators chosen?

<u>Janet O. Estep – President & Chief Executive Officer – National Automated Clearing House Association</u> (NACHA)

Yeah and here a little bit of history is also helpful. There used to be many more operators so the network is not exclusive to only two and our operating rules actually call out the obligations of the operators and the way the transactions are uniform it really says there could be many different hub points so they aren't actually chosen they are organizations that have decided to play the role of an operator and again many years ago there were several more operators throughout the United States.

At this point in time there are two, one is actually what we call a public-sector operator, it is technology that is run by the federal reserve of Atlanta out of what they call the retail product office. The other operator is one that has been paying this role for many years and it is called the Clearinghouse, but it is another type of nonprofit organization but it is funded by many of the largest banks in the country.

Both those organizations run the technology and NACHA as an organization outlines the rules that then those operators essentially abide by. The rules are actually passed via contract law to all entities that pass the transactions through them so they actually essentially help to support the adherence to the rules.

<u>Melissa M. Goldstein, JD – Associate Professor Department of Health Policy – George Washington University</u>

Okay so just to follow-up on enforcement. If it's contract law so then enforcing...if something bad happened enforcement would mean a breach of contract suit right, there is no...is there a government enforcement role there or a legal enforcement on the part of the government or is it only contract law?

<u>Janet O. Estep – President & Chief Executive Officer – National Automated Clearing House Association</u> (NACHA)

Well the right to transmit a transaction into the ACH network essentially says that you will abide by the NACHA operating rules, so I mentioned our national system of fines so that is the key enforcement area.

What we have done over the years though is try to accommodate other regulations into the NACHA operating rules where they intersect and try not to duplicate regulations but those are things and I'm going to speak alphabet soup here, but things such as Regulation E that give consumer protections they do that for the ACH network as well as for credit cards and debit cards. Those regulations align but they don't really have anything to do with the NACHA operating rules.

So there is no other government entity that enforces the obligations on the ACH network other than that NACHA organization in our national system of fines.

Melissa M. Goldstein, JD – Associate Professor Department of Health Policy – George Washington University

Thank you, that was very helpful.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> Coordinator for Health Information Technology

Thank you. We don't have any other questions in the queue maybe Carol is waiting until the end because Carol seems to always have questions, but...

Carol Robinson - Principal - Robinson & Associates Consulting

I'm going to pass this time Michelle, but thank you.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

Okay. Well, since we have no other questions in the queue I think I am going to turn it back over to Jodi Daniel before we wrap up.

<u>Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health</u> Information Technology

Great, thank you. So, thanks to all the testifiers as well as to the subcommittee members this was a fabulous listening session and really great discussion and I think you all have a tough charge in front of you, the Workgroup members, to try to digest all this diverse and thorough information that we've received in the conversations that we've had over the past listening sessions.

I would like to encourage you all, and maybe we can talk about this at the next committee meeting, to try to think about some of what we heard in light of the framework that we started with at our first meeting that ONC put forward because we would love your feedback on that because that does reflect some of our current thinking and trying to take some of this information that you've now had a little bit of time to process and think about particularly some the stuff we just talked about in this last panel how that might affect your thinking and how it should affect our thinking on a path forward to support health information exchange and the role of governance in doing that and where the federal government has a role to play or where there may be others that have a role to play in supporting that effort.

So, you know, I wanted to thank our presenters for your time today and for engaging us in this discussion and look forward to future conversations with the Workgroup members.

<u>Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine</u>

Michelle, is it too late to ask one more question?

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology</u>

No, of course.

<u>Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine</u>

And I'm sorry for going back to Janet and my question to you is, you know, most of the transactions that you were describing are push transactions somebody is interested in paying somebody else and pushes money out.

What are the opportunities for pull transactions in your network? So, in other words me giving authority to let's say my landlord to pull my monthly rent from my account once...what are the opportunities and how do you regulate that?

<u>Janet O. Estep – President & Chief Executive Officer – National Automated Clearing House Association</u> (NACHA)

Yeah, very good question. To translate your question to ACH-ease a push transaction is an ACH credit and a pull transaction is an ACH debit.

Currently, perhaps contrary to what you think, 58% of transactions in the network are debit or pull, 42% of those are push or ACH credit transactions. So, over half are debit where you're giving someone else the authority to take money from you and when we define the rules and the standards based on how those transactions occur we create the roles of responsibilities around how to get that authorization, what it means, what the rights and responsibilities and guarantees are when either a push or a pull occurs and as you might surmise those are different situations so the rules speak to the very different roles, responsibilities, warranties and guarantees that come with that, the rights of return, the rights of guarantees and I say that because the network is involving financial transactions, money, funds, you know, to the tune of trillions of dollars that pass across the network the financial institutions really have to stand behind the integrity of the payment and for that reason they are the ones that actually approve and fund the association and are responsible for those transactions ultimately.

<u>Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine</u>

Thank you.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> Coordinator for Health Information Technology

Thanks again, Janet and to all of our panelist. Before we go to public comment Chris or Carol do you have any final comments?

Carol Robinson - Principal - Robinson & Associates Consulting

Only the, you know, continued gratitude that we have for everyone's time and very, very thoughtful and well prepared comments today. It was incredibly helpful I think to all of the Sub-Workgroup members and I just urge as we move very quickly through these next few weeks in terms of trying to develop this roadmap that we take a few lessons out of, you know, the...I guess I'll say one of my current reads which is think like a freak, so out of the freakonomics book I'm looking at the comments of have fun, think small, don't fear the obvious.

And when I'm thinking about what our challenges are here right now that, you know, the problems we're hearing are quite large and so when we have been considering iterative stakes that's along the way and we go back to our public meetings starting next week that we really continue to have fun with this discussion, that we consider small and incremental steps if that's necessary and that we don't fear the obvious or ignore the obvious problems or elephants in the room. So, those are my comment, thanks, Michelle.

<u>Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine</u>

I just wanted to follow Carol and thank everybody for their testimony. It was very educational. One thing that today's listening session has done for me is that it has made me take a step back in looking at exchange at the level that we have been talking about earlier and look at potential other models that are used in other industries and domains. So, this was very educational, it was a lot of fun and I appreciate everybody's effort and attendance today.

Public Comment

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> Coordinator for Health Information Technology

Thanks Carol and Chris and one final thank you to all of our panelists and to Kate, Kory and Kim for helping us put together today's session. With that I'm going to go open the lines. Operator can you please open the lines?

<u>Caitlin Collins – Junior Project Manager – Altarum Institute</u>

If you are listening via your computer speakers you may dial 1-877-705-6006 and press *1 to be placed in the comment queue. If you are on the phone and would like to make a public comment please press *1 at this time.

<u>Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National</u> Coordinator for Health Information Technology

It looks like we have no public comment. So, thank you again everyone for your time and we'll touch base again soon. Have a wonderful weekend.

Public Comments Submitted

- 1. As a member of panels at the design level of the ACA and then EHR creations through Meaningful Use Stage 1, I have comments about what I perceive to be a significant shortfall in the current systems in use here in North Carolina. Checking my Medicare account, after receiving notice of my annual physical, I discovered there were no services listed as covered during the exam. This creates an opening for all number of challenges. My provider did not know what would be paid for and what not paid for and for what amount could Medicare be billed. That puts the financial onerous back on the patient. This defeats the purpose of open disclosure of cost of care services. Also, when conducting a chat online atMyMedicare.gov, the phrase 'if the provider accepts the assignment' of a Medicare patient, opening the door to discrimination and inappropriate billing issues. At the close of the physical that only included height, weight, blood pressure, auditory exam, an offer of a CBC was made, for which I may have to pay unknown \$\$.
- 2. I fully agree with David Minch's perception of the broken communication as a result of individualization of what was to be a universal communication system.
- 3. With the onset of ICD10 codification this may be a timely matter to design and implement just such a system as Mr. Minch envisioned.
- 4. As soon as it is defined by a state i.e. Texas HIE, there is a crack in the data system and since the American consumer is migratory, especially during these days in which jobs are just returning to the economy.
- 5. Now with programs such as Telemedicine, these unseen state boundaries will become blurred and data lost or mismanaged.

- 6. Those nationally agreed upon standard are generally expected to be met via Diagnostic codification which again, will change with the implementation of ICD10.
- 7. Why do we hear of some many unmet medical needs of Veterans, despite whole world data system?
- 8. When you speak using the term 'provider' are we including acupuncturist, chiropractors, nutritionists?
- 9. Place a contest on Challenges.com in order to create incentive to implement a single data driver system.
- 10. And of course the World Health Organization. World Bank, etc are all in support of using ICD Codification and the USA is far behind the rest of the world in this model. Can we catch up?
- 11. Also, there are new mathematical models being used for the statistics that are supporting worldwide health. These are referred to as Quality of Life. Has this been considered at the ONC? How so?
- 12. What role can the patient's right of access to health information play in broad HIE?
- 13. How is Net Neutrality affecting the cost and accessibility of EHR and PHRs? How the cost to consumer being managed?
- 14. Through creating allocation, a block is created where pricing can and is being increased without other competition to drive the cost down. How are you addressing these monopolies?
- 15. Historically, self-compliance has been subject to greed, gaft and other power negatives, that was why Public Utilities were initiated at one time. How are you addressing these natural occurrences?
- 16. Was there cost involved to become an operator? How is it credentialed?