Health IT Advisory Committee

Transcript
January 18, 2018
In-person Meeting

Operator
The lines are now bridged.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Thank you. Good morning and welcome, everyone, to the inaugural Health Information Technology Advisory Committee. My name is Lauren Richie. I am the designated federal officer. I would like to thank everyone for their time here today. I am going to officially call the meeting to order. I will start with a brief role call, and then I will turn it over to our national coordinator. Michael Adcock?

Michael Adcock, MS, RN, FACHE - Executive Director - Center for Telehealth, Univ. of Mississippi Medical Center
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Christina Caraballo?

Christina Caraballo, MBA - Senior Health Care Strategist - Get Real Health
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Tina Esposito?

Tina Esposito, MBA, RHIA, FACHE - Vice Pres., Information & Tech. Innovation - Advocate Health Care
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Cynthia Fisher?

Cynthia Fisher - Founder and Managing Director - WaterRev LLC
Yes, here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Brad Gescheider.

Brad Gescheider, MBA - Senior Director, Provider & Payer Solutions
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Valerie Grey.

Valerie Grey - Executive Director - New York eHealth Collaborative
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Anil Jain.

Anil Jain - VP and Chief Health Informatics Officer - IBM Watson Health
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
John Kansky.

John Kansky, MBA, MSE - President & CEO - Indiana Health Information Exchange (IHIE)
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Kensaku Kawamoto.

Kensaku Kawamoto, MD, PhD, MHS - Assoc. Chief Medical Information Officer - Univ. of Utah
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Steven Lane.

Steven Lane, MD - Clinical Informatics Physician Director - Sutter Health
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Leslie Lenert?

Leslie Lenert, MD - Chief Research Information Officer - Medical University of South Carolina
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Arian Malec.

Arien Malec - Vice President for the Data Platform Solution Line - RelayHealth
Good morning.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Denni McColm.

Denni McColm, MBA - Chief Information Officer - Citizens Memorial Hospital
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Clement McDonald.

Clement McDonald, MD – Director - National Library of Medicine
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Aaron Miri.

Aaron Miri - Chief Information Officer & VP Government Relations - Imprivata
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Brett Oliver.

Brett Oliver, MD - Chief Medical Info. Officer - Baptist Health
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health

Information Technology
Terrence O'Malley.

Terrence O'Malley, MD Geriatrician - Massachusetts General Hospital
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Carolyn Petersen.

Carolyn Petersen, MBI, MS - Senior Editor - Mayo Clinic Global Business Solutions
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Raj Ratwani.

Raj Ratwani, MA, PhD - Scientific Director - Natl Center for Human Factors in Healthcare, within MedStar Health
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Steve Ready.

Steve Ready - System Vice President and Chief Information Officer - Norton Healthcare
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Patrick Soon-Shiong.

Patrick Soon-Shiong, MD - Chairman & CEO - Nanthealth
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Sasha TerMaat

Sasha TerMaat – Director - EPIC
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Andy Truscott?

Andy Truscott - Managing Director, Health & Public Service - Accenture LLP
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Sheryl Turney?

Sheryl Turney, Med - Senior Director, APCD Analytics & Data Policy & Administration - Anthem Blue Cross Blue Shield
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Robert Wah.

Robert Wah, MD - Global Chief Medical Officer - DXC Technology
Present.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
And Denise Webb.

Denise Webb, MA - Chief Information Officer - Marshfield Clinic Health System
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
I will also ask for our federal representatives to acknowledge themselves. Lauren Thompson.

Lauren Thompson
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Kate **Goodrich**.

Kate Goodrich
Here.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Chesley Richards. **Ram Turum**. Okay, thank you. And now we turn it over to our national

coordinator, Dr. Donald Rucker.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

Welcome, everyone. Thank you very much for attending. And so, this is our kickoff meeting for the HITAC group. And as I think probably everybody here knows, HITAC is the advisory committee to advise the United States, to advise the country on some of the key modern questions as we move to electronic health records. So, those key questions are how do we get closer to interoperability? How, with privacy and security, do we really make medical data available to patients? That is the charge of the committee, and we have a very great set of members elected through a complicated set of mechanisms. Welcome, everybody. Just for the record, we had a just administrative on how to be a member on a FACA committee yesterday. I know there was some speculation on that. But that was yesterday's agenda. This is the substantive agenda today. And we look forward – we have a lot of folks here today. We look forward to getting the committee's work and thoughts on interoperability.

The Cures Act, passed almost unanimously by Congress, calls out for open application programming interfaces without special effort, as folks can know and imagine, there's a lot of detail in making those things so they're fully responsive to the American public, both on the individual patient level and on the collective level that we need for being smart buyers of healthcare, learning healthcare systems, and all of modern technology. We in the administration are extremely doubled down on doing interoperability well. We have – many of the HHS senior staff are involved in this. **Sema Roma** at CMS heavily involved in this. Kate Goodrich from the Quality Group. Maybe Kate, if you can just raise your hand. Heavily involved as well. Chesley Richards from CDC. We have Lauren Thompson, who's on the other side, shepherding the daunting task of the DOD and VA operability.

And most importantly, let me introduce, as an expression of the president, and the White House team, and HHS's senior team, interest in interoperability, our Acting Secretary of Health and Human Services, Eric Hargan, who's next to me. Eric, as you might imagine, for this kind of position has a distinguished and long CV. The things I found most interesting is that he actually has a ton of experience in exactly this space. He was acting deputy secretary. He's currently the confirmed by the Senate deputy secretary. And he was deputy counsel and head of all regulatory policy for HHS in a somewhat prior life. So, with all of that, let me turn it over to Secretary Hargan.

Eric Hargan – Acting Secretary of Health and Human Services

Thank you. Thank you, Dr. Rucker, for that kind introduction and for all the work you've been doing, hard work you've been doing at ONC. And that's absolutely right. We want to make sure that everyone here understands what a focus this is at HHS. That's part of the reason that I'm here, is to make sure that that's well understood. But thank you for joining us on this important occasion. In particular, all of those of you who have agreed to serve on HITAC, we are grateful for the commitment that you've made and look forward to working with you to make these recommendations and contributions a reality. The establishment of HITAC by the 21st Century Cures Act was a major step forward for American health IT policy by replacing the Health IT Policy Committee and the Health IT Standards Committee with a single committee. We now have a single body that can make expert recommendations to advance our work.

The composition of the committee, too, is, I believe, both telling and important. Your immense collective experience in healthcare and technology will be an important asset in helping us to set a strategic direction for the country's health IT systems. This body, we expect, will have a key role in achieving ONC's goals and the goals that we have set out for health IT under this administration, particularly achieving interoperability within health IT and improving the usability of health IT for providers, patients, and all other stakeholders.

HITAC in particular, as you know, is charged with making recommendations for the national coordinator relating to the implementation of national and local health IT infrastructure, focusing on the following target areas. Number one, achieving health IT infrastructure that allows for the electronic access, exchange, and use of health information. For example, allowing the easy exchange of clinical information between providers, including among our federal partners like the VA and the Department of Defense; promoting and protecting the privacy and security of health information in health IT, because we know that cyber threats around healthcare data are ever increasing; facilitating individuals' secure access to their protected health information, because we know Americans want control of their information and to be able to easily access it. Nearly everyone has a smart phone now, with which they ought to be able to access information and security, and of course, considering any other area that the HITAC identifies as appropriate. Now, I want to emphasize that we understand that these are lofty goals. Significant efforts have been made in this area before, and yet, we still have a long way to go.

Like many of you, in fact, I can personally attest to how difficult those challenges can be. In my time as Acting Deputy Secretary at HHS during the Bush administration, Secretary Mike Levitt made health IT a top priority, and I am going to say probably personally speaking, that was probably his top priority. The amount of time that he spent on that was an immense amount of time. It was an immense amount, too, of personal time, and that's pretty much the sort of highest coin a department can pay, is having the secretary work personally on those issues. And yet, as many of you, as in any ambitious enterprise, some of those efforts came up short, while other important ideas never got off the ground. And again, that's in spite of that much effort being put. It was an ambitious undertaking, but we couldn't get everything done. But we have many reasons to be more optimistic today. For one, we've made huge progress in terms of the use of electronic health records. This has exponentially increased the potential returns to making these records more interoperable and more usable. The 21st Century Cures Act, as we've talked about, also gives us new tools and authorities for advancing interoperability, including provisions that should increase market competition, we think, allowing new entrants to design software applications and tools that will help solve complex challenges.

Meanwhile, technology as we know has advanced by leaps and bounds in terms of our ability to harness big data through artificial intelligence and machine learning; in terms of our ability to store and share data through the cloud; most important, in terms of ordinary Americans' ability to access and use their own health data. One of the main goals we have today is to make health data more accessible through peoples' smart phones. This is something that just wasn't possible for most Americans in 2008, when just 11 percent of Americans had smart phones at the time. But as of 2016, that number is up over 81 percent of all Americans who have their own smart phones. Now, this leads to the possibility of advancement, but also the expectation of performance. That 81-plus percent of Americans – probably over that at this point – at some point, they're gonna wonder why they can't use their phone to access their own health data and their own health records. So, it's not just HHS. It's not just stakeholders in the health IT

community, us gathered here today, who are eager to see progress on this front.

The high priority placed on interoperability and the promise of health IT runs straight to the top of this administration. I can personally tell you that the White House is deeply committed to this effort. I've been on multiple meetings at the White House on this very topic already. But just as important, the demand for advancing health IT is also coming from the ground up. So, you're working for a goal that will serve all Americans by advancing the quality, the affordability, and the accessibility of our health system. Your work will serve to directly empower individuals. Anyone who's dealt with a complicated medical issue knows the feeling of powerlessness that can beset you during a difficult diagnosis or a decision point. And nearly all of us have been frustrated at some point by the opacity of our health system's pricing and quality measures, which produce not only frustration, but also cost inflation. We cannot solve these problems solely through better technology and better technology standards, but we can certainly ensure that technology and standards are working to solve the problem, rather than being part of the problem itself.

So, thank you for your dedication to this work, and I wish you the very best on a personal note, because I have been through this before at HHS and outside. But we believe, definitely, that the rewards will be worth it. So, thank you again, and now I'll hand you back to Dr. Rucker.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

Well, Secretary Hargan, thank you very much for your interest. And I think it's one thing to come to this kind of event, but I'm just gonna say, throughout the entire administration, and when your team has, behind the scenes in the evenings and when the work actually gets done on this stuff have been very steadfast in helping getting these goals, and obviously, this is a hardworking group here as well. So, we appreciate it. Thank you very much.

Eric Hargan – Acting Secretary of Health and Human Services

Thank you.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

Thank you very much. Thanks. A round of applause.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Okay. And with –

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

So, we have just a couple more things I'd like to mention in that spirit. First of all, one of the charges of the HITAC Committee is on privacy, and I just want to highlight that ONC has announced Catherine Marchasenie as our Chief Privacy Officer. You can look up her credentials, which are quite impressive. She's an attorney. She has a lot of experience in this space and has been a longtime senior contributor to ONC, and we think that we have a great team in place to work on privacy, and we do a lot of work with the Office of Civil Rights there jointly on that. The

other thing that's sort of a housekeeping is the FACA committees sort of run with co-chairs, so we're asking members of HITAC who might be interested in this, and we will be appointing co-chairs, and we'll have those names for you before the next meeting. So, I think with that, I'm gonna turn it over to Lauren Richie, who is the acting chair of the committee.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

For today. Thank you, Dr. Rucker. And I will actually turn it over to Elise Sweeney Anthony to give us an overview of the 21st Century Cures Act.

Elise Sweeney Anthony – Director of the Office of Policy - Office of the National Coordinator for Health Information Technology

Good morning, everyone. Welcome to HITAC. One of the things I wanted to do before I started was just to say thank you. I think you've heard it a couple of times today, but particularly on behalf of my team, who you will be working very closely with on your work on the committee. We really appreciate you taking the time to kind of lead this effort on behalf of kind of the advisory committee and the work that Congress has called for us to do here. We recognize that you have day jobs, so we know it's a huge commitment. And our goal is to help support that effort as much as we can. So, we look forward to getting started. And we thought a good way to do that would be for myself, as well as Steve Posnak, who is the head of the Office of Standards in Technology, to provide some updates on some of the work that's underway at ONC. So, I'll start with talking a little bit about some of that work, and then I'll give a little bit of an overview of Title IV of the Cures Act, which is where much of ONC's work sits.

So, with that, let's go ahead and get started. So, we'll start with the updates first. So, one of the things that we want to highlight is the 2015 edition. Now, many of you, from your day jobs, are pretty familiar with how the certification program operates at ONC. We maintain an ONC certification program that is responsible for certifying products related to health IT. And some of those certification criteria, as we call them, relate to technical specifications. Some of them relate to more functional specifications. Anything from demographics to the means in which information travels across from provider to provider or system to system, all the way to things like patient capture of information, and which is a functional criteria around the ability of the technology to be able to do that. The program is a modular program, which means that you can be certified to some of the criteria or all of the criteria, depending on what the product that you are putting together needs to do to service the patients, providers, and other users who use it.

So, one of the things that we aim to do is we recognize that regulatory documents such as our rules can be pretty heavy reads. And while we encourage everyone to read the rules and definitely participate in the public comment process that's associated with a notice for proposed rule-making, for example, we wanted to make a resource that could be used by the community to quickly see what the addition does. So, for the 2015 edition we've posted online, and this has been up for some time. And we're hoping that it becomes a really good kind of quick way to look at what the program does. But the goal of this is as an infographic, and it's navigable. So, what you can do is you can take a look at those little circles at the top. We call it "the wheel" affectionately at ONC. But it highlights the key areas that are covered by the different certification criteria. And if you click on those online, you're able to go through and look at different components of the program in terms of the certification criteria. The main ones, because it's a little bit hard to see on the slide, are clinical processes, care coordination, clinical

quality measurement, privacy and security, patient engagement, public health, health IT design and performance, and electronic exchange. Within each one of those little circles, there's more information on the criteria.

And it's designed to give you as much or as little information as you need, so you can start at a pretty high level in terms of what the criteria does, but you can also dig really deep into some of the guidance that we have related to what we call the certification companion guide, which gives you a full look at the criteria implementation specifications. And then you can also find the reference to the rule as well. So, we hope that this is a good resource, but we are definitely open to feedback on how it's used and how it works for you.

So, in addition to "the wheel," as we call it, there are also some interactive PDFs that we've included online, and these relate to specific areas that the certification program is designed to support. We've said it before, but interoperability definitely includes the clinical space and tends to be where a lot of our focus is. But there's also the other setting environments that are important to move information. So, that is covered in the "Supporting Care Across the Continuum" PDF, as well as we have a second one that focuses on access and exchange. And again, our hope is that these are easy references to provide some general information on what the program covers and how it can help you, either as a provider, a developer, or a patient.

Okay. So, one of the other pieces that – a slight update, as many folks know, that we updated the model privacy notice. The original version was from 2011 and focused then on personal health records, right, as they were called at the time. As technology has evolved and the concept of health IT and where information is stored has evolved as well, we wanted to update the model privacy notice. So, what is it, first? The goal of the model privacy notice is to provide developers with a means of providing quick information to the users of that product regarding the privacy and security of that product. It's not a replacement for a more in-depth look at the privacy and security pieces or a notice of some sort, but just a quick reference. We heard from stakeholders that this was a needed component in the industry, and we hoped it would provide that.

So, the 2011 edition was updated last year. Well, 2016, actually. And when we released it, we released it for feedback. After that, we led a challenge that allowed for development based upon the draft that we released. The challenge was successful. We got some great feedback. And from there, we updated the model privacy notice to what's now called the 2018 version. And that is available online as well. Again, the goal for it is to be a quick resource. So, just looking at this here, which is extremely small, but again, some slides, I just include so that you can have an easy reference for later reading. But this provides kind of the snapshot of the questions that are asked. And you'll see there are some questions in there related to HIPAA, compliance with HIPAA. But the goal of that is that you can turn kind of this information into something that's an easy template or navigable system for the user who's doing it. It doesn't have to be displayed in this way, but these are the questions that would be captured. One note on this is that we did work with different communities, including patients, to identify what words or phrases worked for them in terms of understanding some pieces around the privacy and security element. And that's some additional information.

All right. So, public health updates. We wanted to provide an overview of some of the work that we've been doing in the public health arena. Again, there are health IT components that help us

address as a country some of the problems that come about when there is a national emergency. Whether it's a communicable disease, whether it's Zika or Ebola, both efforts that we assisted HHS in addressing, as well as states and so forth, when Ebola, for example, was present. Same with Zika. We're doing work with CDC and our partners to think about what are the means that health IT can help support the needs, whether it's **syndromic** surveillance, whether it's case reporting, whether it's clinical decision support and turning clinical guidelines from CDC into clinical decision support into EHR systems. Those are some of the resources that we aim to provide.

One additional note here is I think another piece of this is thinking about the standards that support the environment for responding to disasters. So, for example, with Zika and our response to Zika, the previous **taskforce** advisory committees on health IT looked at Zika response, along with CDC's request. One of the things that they identified was the importance of pregnancy standard and standard status, and the interoperability of that information. Since that time, we have updated the interoperability standard advisory to include that information, and that was one of the recommendations of the taskforce under the previous committees. So, I think that's an example of how you can see, as your work starts to occur, how we are able to take some of the feedback and the recommendations and figure out ways to incorporate that into existing and moving items at ONC, or identify new opportunities where the need exists.

One of the other areas related to disaster preparedness and response – and unfortunately, we saw this very clearly with the hurricanes that occurred in the previous season – the Patient Unified Lookup System for Emergencies, or PULSE, as we call it, was really part of one of the innovation pieces at HHS and at ONC in thinking about how to get information to first responders more easily and to make that information available for querying regarding patient documents. Once that effort was set up, we then worked with California to identify how that could be integrated into their health IT systems across the state. And some of this has occurred already. We're looking forward to kind of the best practices that we've learned from California to inform the work across other states. And we're seeing some interest in that as well. This is a project that I think puts front and center the importance of health IT and how important it is to the front lines. So, the PULSE system is something that we hope will continue to pick up some interest. And we're seeing some positive benefit from California and some of the implementations that they have done in certain areas.

Last, in terms of public health, the hurricane season not only included some of the work around how we were addressing things or engaging with states like California around wildfires and so forth, but looking more south, to Florida, for example, working with the states to identify where they were having some problems with health IT, thinking proactively before the hurricane hit in terms of reaching out and making sure there was engagement was an important part of the work that we were doing, and it's something that we work very closely with the Preparedness and Response teams at HHS to make sure that that's happening. And that includes things like electronic surveillance systems and working with the public health agencies. So, that's one of the things that requires us to have good relationships, and making sure that we're serving at the federal level as a resource to states and to public health agencies. So, even though that's something that we don't see as much on a daily basis, it's something that's a really important part of our job. And we make sure that we are engaging with them, and not only identifying the needs during the present disaster by identifying where opportunities are for us to help in the future occurrences can exist.

All right. Next slide is our playbook. So, one of the resources that we have available – many folks know it by now – is our playbook. And it's a resource for providers and others to identify, learn a little bit about health IT, how it can help them in their daily practice. Provides information on everything from patient engagement to more specific information about how the certification program operates. We, from time to time, have updated it with new resources that we think would be helpful to the community. One of those is the Patient Demographic Data Quality Framework and Ambulatory Guide. A long phrase. We call it PDDQ, because acronyms are our favorite thing in the government. But the PDDQ resource, the goal is really to provide a resource for healthcare practices and systems in assessing, measuring, and improving patient demographic data quality. For those frontline practice professionals who are taking in information from patients who are inputting it into the system, we know that that's an important part of making sure that that information lives in an accurate way once it is actually in the system. And we all know that that's an important part of kind of what we do here.

So, the PDDQ resource is designed to provide that practice level input and support. There's an ambulatory one as well, and the goal of that is to be – and similar to the wheel that I mentioned earlier in terms of the infographics for the certification program, for you to be able to dig deep. So, you can start at a high level, identify some best practices that would be helpful to you; but you can also go through and kind of take a look at how you are operating at a deeper level in terms of your standard operating procedures, for example. We worked on the development of this with an organization called CMMI, who has been very involved in this type of data governance. And the idea, again, which I think you will see the theme across ONC's work, is that, one, we can't do it alone. Two, there's a lot of best practices and work that has been done not only for our sector, but across industries, that can be useful in terms of what we're doing here at ONC.

Another resource, and this is all about resources because we are aiming to make some of our work a little bit more accessible as we move forward – we have two modules that we've put together. And I talked a little bit earlier about setting support and thinking about interoperability not just in terms of the traditional ways that we've thought about it, but other settings that benefit from and can use health IT. Now, those settings may be at different phases of health IT adoption across their sector. Behavioral health is one example. And what we wanted to do for both behavioral health and LTPAC providers, long-term post-acute care providers, is provide a resource that can identify how health IT can be useful, some of the technologies that can be useful in that particular setting, and do it in a way that recognizes that providers' first order of business is to provide care. So, doing it in an easily accessible and hopefully quick format.

So, we created these two modules for that purpose, the behavioral health module, and you'll see on the following slides one for LTPAC providers. We worked with our SMEs here at ONC, who we actually have folks who what they do is they focus on behavioral health, as well as long-term care and post-acute settings. But we also tried to identify where the shortfalls were. So, we worked to identify with our contractor on what they were hearing from the sector, and identifying that and including it in these two resources.

Last on the kind of resource side of the equation, we wanted to know – one of the reports that we issued – and this was based around some research we did in terms of patient's ability to access health records and the process for that occurring. So, we talked to not only to the

community of patients, but we also talked to others in the sector who are involved, whether it's administrators and such, and identified some of the things we learned, and we included it in a resource available online. And I think this is part of our ongoing effort to understand what is happening in the field so we can help inform our work as we go forward into different areas of cures and general operation of the program.

So, now we turn to the Cures Act. So, a couple of kind of comments on the front end of this, which I always tend to have to say. But one, some of this involves ongoing policy development and regulatory work, which means there are some limits on what I can answer in terms of where we are in the development of some of these pieces. But I did want to give an overview generally of what's included in Title IV. Now, as you all know, Cures is a very large piece of law that is being implemented by a number of different HHS arms, including FDA, CMS, for example. There is a title in there, Title IV, which focuses on ONC's work. And as you can see, I've listed here the sections in particular that have a fair amount of ONC involvement and responsibilities for us to implement. As we go forward with this, we have been working on a rule, which I'll talk about a little bit later, that's included in the administration's unified agenda for publication, and it focuses on some of these pieces as well. So, you'll hear me mention that throughout, but I'll also come back to it at the end.

So, 4001. And I should note that each section includes a number of different provisions, some related, some not as much, but all important, obviously, to health IT advancement. 4001 focuses on burden reduction – or 4001-A focuses on burden reduction, specifically on identifying what some of the burdens that attach to providers, for example, when it comes to documentation or EHR use. Some of the areas specifically noted for development of a strategy by HHS that Congress noted are around some of the CMS programs, such as the alternative payment models, merit-based incentives, payment systems, also public health, health IT certification, individual access, alignment and simplification of quality measures, and privacy and security. Now, this is a good point for me to mention that what we've tried to include here are highlights of Title IV, but we definitely encourage the committee to take a full look particularly at Title IV, but Cures more generally, because there are a fair amount of sections around the provisions that we're highlighting here.

What we've been doing here is working very closely with our HHS partners, in particular with Kate Goodrich and her team, as well as others at CMS, to identify what opportunities there might be to address and develop the strategy around the burden reduction. So, this is an ongoing work stream that is occurring at ONC. It's something that I think you've heard is a top priority, not only for us at ONC, but also for CMS, in identifying some of these areas. And we look forward to putting together this strategy. We've been working with stakeholders and meeting with stakeholders to understand what they are seeing from their perspective in the industry that can help inform our work going forward. And CMS equally has been very involved in outreach to the community across the country in this vein.

In addition to the burden reduction provision in 4001-A, Section 4001 also includes a provision related to pediatrics and identifying the health IT for purposes of certification that can be supportive to the pediatric community. What we're doing now is we are identifying what those opportunities might be where there is a need that exists in the community, and identifying how we can help with that and where it would be appropriate for us to do that. That's one of the things that we will be including in the proposed rules for public comment.

Next, I wanted to talk about 4002, which includes a couple of different provisions. There's a provision on conditions of certification, and those are one of the areas that we plan to include in our upcoming rule. And this focuses on identifying not just what we have done in the past, which has been around the technical criteria for purposes of health information exchange and health information technology generally, but also identifies that there are some roadblocks to interoperability that exist that go beyond the technical specifications. So, Congress things such as information blocking and concerns around that for purposes of the conditions, as well as real world testing, for example, and other commercial components. So, these are things that we're looking at and identifying what the opportunities are and how to implement this provision to best address Congressional interests and Congressional goals outlined in 4002.

The second provision is the EHR reporting program. This provision revolves around more information being available to the community around the operation of products themselves and identifying reporting criteria that could be helpful for that purpose, to identify how the products are operating, etc. There's a fair amount in the development of the reporting criteria that's identified in this section. This is one of the sections that I think you heard Dr. John White mention at the October hearing that there are some elements of this that are related to our ability to operationalize this provision considering budget. So, these are things that we are looking at on an ongoing basis.

All right. And Section 4003. Now, this is where I'm gonna be pretty short on this section, only because Genevieve **Morris** will be presenting on this section in a more in-depth fashion later this afternoon. But a couple of highlights that I will mention. One, just note the timeline. This document has been released – as you know, Committee, you've been given the draft trusted exchange framework that has been released, along with the associated U.S. core data for interoperability document. So, that will be the subject of a conversation later today, so I won't spend too much time mentioning it here.

In addition, in 4003, there is a provision related to a digital provider directory and the responsibility to create that and establish the means for doing so, whatever that will look like once it's finalized. CMS is actually responsible for implementing this provision. ONC is providing technical support related to the technology that might be available, technical specifications, implementation specifications related to this. So, this is an ongoing work product. As more updates are available, we'll be sure to follow up with the committee and make them aware of that work.

4003, you probably know this section pretty well by now, because this is where the House Information Technology Advisory Committee sits, also known as HITAC. So, this is the provision that actually stood up the committee, and this is a good opportunity for me to publicly recognize my team for the work that they've done to stand up the committee. It is a fair amount of work to do this, so huge appreciation to Lauren Richie, to Michael Baker, to Mitch **Caw**, to Jennifer Brown for the work that they've done to make sure that all of this has been stood up. But also, another part of this provision was actually to wind down the previous two committees. So, as folks know, the Health Information Technology Policy Committee and the Health Information Technology Standards Committee, which were stood up through HITECH, the HITECH Act, the Cures Act called for those to be sunset.

So, we went through the process to do that. And that was the first phase of us implementing this provision, was to actually work with those two committees to complete the products that were already underway, the existing charges, which we did; close out those committees, which we did this summer in June; and then begin the process for standing up this committee. And that takes a fair amount of work as well, including setting up a charter, the standard operating procedures, and working with GAO once their members came in in terms of who they were appointing, Congress, and then ourselves. All of that has led to today, so, welcome.

So, a couple of other things I wanted to note in terms of 4003 are the priority target areas and some of the additional provisions here. Now, again, this is obviously an important provision for you, so we are definitely open to additional questions you have once you take a look, if you haven't already, to the full section here in terms of what is called for. But we will pretty much start going on this immediately, because there's a number of things that are related to other work streams that ONC is responsible for in Title IV. So, Congress identifies priority target areas. And these are areas that Congress has asked that the HITAC focus its work on. And they include areas around – and I'm paraphrasing here, but definitely, there's much more text behind these provisions in Cures itself. But related to access exchange and use of information, privacy and security, as well as related to patient access of the information.

As ONC worked to charge the committee with areas that we are working on and are looking forward to having committee feedback on, we are definitely cognizant of these target areas. And I think a lot of the work that we'll talk about a little bit later that will be upcoming aligns with these three areas. For example, the first charge that we are planning to present to the HITAC will be around the trusted exchange framework, which, as you can imagine, hits on a number of these pieces based upon just the draft that you've seen. So, we recognize kind of what Congress has called for you to do, and that there is definitely a synergy established regarding what ONC is working on under Title IV as well. In addition to the target priority areas, there are some additional target areas that are identified in the statute as well. And some of those relate to healthcare coordination and continuity, children's needs, collection of patient demographic information, as well as telemedicine, home health, remote monitoring, and related issues.

I think the key thing to note here – oh, and here's some additional areas as well related to health information and the management thereof, and then even certified health information technology. One of the things to note here is that there is a process set forth that Congress would like us to work on for a consideration of additional target areas. And I think that's the indication that Congress really is looking for a focus to exist on those, the priority target areas, as we've called them, which is in that first section I talked about. So, as I said, you'll see that there's a number of things coming down the pipe. One is, as I said, around the trusted exchange framework and that being a key area for comment and feedback. Other areas that we anticipate that the advisory committee would look at in this upcoming year are around, one, the USCDI, which is the U.S. core data for interoperability, which is the complementary document to the TEFCA. And Steve **Posnak**, along with Genevieve Morris, will be discussing that later this afternoon as well.

Once the proposed rule is released, and our expectation date for that is April, is what we're aiming for, we plan to bring that also to the committee for feedback and input. So, that would be the third item as well that they would be focusing on. And then there's another provision in the HITAC section in 4003 that focused on standard use cases and calls for the committee to begin

work on that area within six months of their first meeting, which is today. So, we are working as well on that component to support the committee in their work. Once the chairs have been named, then we will go forward and work with them on thinking of these pieces, as well as publication of the schedule, which is called for by Cures as well, and that relates to the timing of review of the areas to be charged. And that will be published in the federal register as well.

All right. So, Section 4004, information blocking. And I have to say, if there's one area that I get a lot of questions on as we give these presentations, it's on information blocking, and for good reason. Because I think you can see by the amount of – the number of provisions and the references across Title IV to information blocking, including in the conditions of certification area, that Congress has identified this as a key area. That very much aligns with ONC's thinking, as you can imagine, based upon your publication of the information blocking report earlier before the publication of Cures – I think two years before, if I have my dates right. But don't quote me on that.

So, the information blocking report was a look to see, because we were hearing a lot about information blocking being a concern, and it impeding the flow of information. So, we looked at information blocking in that report and identified the different types that could occur and what we were hearing about. And that was a report to Congress that was requested by Congress. So, now, having this information blocking provision, Section 4004, it's a continuation of, I think, Congress's kind of interest in this area. Information blocking itself is defined in the statute, and it defines it in two constructs, in terms of healthcare providers, as well as health information technology developers, exchanges, networks. And so, there's two different constructs for the definition. What Congress has asked us to do is to think about what are the exceptions, as we're calling them, that would relate to the information blocking provision – so, where information blocking is not okay. Are there situations where it has happened for a reasonable reason? And that's part of what we're looking at.

And we recognize that there are different views on information blocking, and how it happens, and where it happens, and what it looks like when it happens. So, what we've been doing is meeting with a range of stakeholders since Cures was passed, enacted, to learn more about what's happening on the ground. And that's from diverse stakeholders, whether it's patient groups, whether it's developers, whether it's associations, providers – just across the health IT gamut. And we've been doing that in conjunction with OIG. And that's the other key component of 4004. And OIG obviously is responsible for enforcement of some of these provisions around when information blocking is occurring. And I'm gonna try to use less acronyms. OIG, Office of the Inspector General at HHS, would be responsible for some of these provisions and implementation thereof. So, we've been working with them and meeting with stakeholders so that we all understand what the environment looks like and what we're seeing. And this provision or implementation of those exceptions as I identified would be included in the upcoming rule.

4005 includes a couple of provisions I wanted to note. One is around registries and identification of the capabilities for transmitting information through the registries, and applicable certification opportunities that could exist. This is a provision that we continue to look forward to hearing from stakeholders about as we consider what implementation would be effective. And as there's updates on this provision as well, we'll be sure to come back to the committee. 4005-C also includes a reference to how developers are treated with respect to patient safety organizations

and with respect to associated reporting. We are working with **ARC** in implementation of this provision. And again, once there's more updates on this, we'll be sure to update the committee as this moves forward.

4006 references empowerment of patients, improving patient access to their electronic health information, and means for providing that information to the patient community. For this provision, are working very closely with OCR, Office of Civil Rights, at HHS, as well as ONC on implementation of this. This is, I think, a provision that, as all of the provision in Title IV, is an ongoing work stream that we have been thinking about at ONC. And this is identified through some of the resources we released even before the Cures Act was enacted around making more information available to the patient and the provider community about how HIPAA, for example, can be used as an enabler of information access by patients, as opposed to some of the misconceptions that were appearing to exist in the community about HIPAA not allowing certain types of access. And OCR released a fair amount of information on this.

And then we worked with OCR as well on turning some of the informational resources into easy to use guides, including quick videos that could be used, as well as sector-specific information around public health, for example, and access to information, in particular, public health circumstances. And then also, quick little one-pagers that could be used by patient providers and communities for that purpose. This is one where I think we all have our particular story about where we tried to, as patients, access our information, and that wasn't possible, and why that wasn't possible. So, resources like this can really be helpful to the community. And we look forward to continuing to work with OCR on how to implement this provision towards those goals.

So, 4007 and 4008 are not actually our provisions, but they are important for the community to be aware of. And when I say that they're not our provisions, these are actually where Congress has asked GAO to move forward with studies related to two particular issues. One is patient matching and the other is patient access to health information. So, our role as ONC in terms of these sections are to be supportive of GAO's work, so that where there are questions or they're interested in the background that we have done on these particular areas, that we are providing that to them. So, that is our goal, is to make sure that we are providing GAO with the resources they need as they move forward with these two studies. As the information becomes available from GAO, we'll be sure to keep the committee apprised of that as well.

So, besides information blocking, this is probably the other most often question that I get asked, is about the upcoming rule. The interoperability and certification enhancements proposed rule is underway. We are working now – Michael Pinsky, who's the head of regulatory affairs at ONC, is diligently working, probably as we speak, on thinking through the policies and making sure that we are putting them down on paper in a way that is useful for purposes of comments for the proposed rule. Our goal is April 2018 for release of the proposed rule. And as I mentioned, but I'll just go over them really quickly again, some of the areas that we expect to be addressed are the conditions of certification and maintenance of certification for health information technology developers or entities; voluntary certification of health IT for use by pediatric health providers; health information networks attestation.

Now, this is an interesting one that I just want to spend a little bit of time on. Genevieve later today will talk about the trusted exchange framework, which is a document we released for

public comment, which is part of our commitment to really having a transparent process for moving forward with the trusted exchange framework and ultimately the common agreement. It is not going to sit in a regulation, as it were. The goal is for that to be a document that is available and updated as needed. We will publish it in the federal register, as per Congressional requirements. The part that does sit in a rule that Congress has specifically said to include in the rule is around the process for attestation. So, the process for an entity to sign onto what will be the common agreement. So, we expect to include that process in the proposed rule. Last is the information blocking, and specifically the reasonable and necessary activities that do not constitute information blocking, which many in the community have deemed exceptions, as it were. But yes, so this is the actual term that is identified in Cures.

So, these are the four sections that we expect to be included. And I just want to note, one of our leadership's commitment, as well as mine, is to make sure that we are developing policy in a way that allows for the important feedback of the community. So, the folks who live not just health IT, but healthcare every day from the patient community, so that we can hear about how what we are proposing or what we plan to put in place impacts the community on a day-to-day basis on the ground. And that's really important to us. And it's something that has always been important to our work. Even with the 2015 edition rule, when we released the proposed rule, what we put out in the proposed rule was actually more than what was finalized. And that's because we heard feedback on certain areas that maybe something is not ready. Maybe additional thought needed to be included in that. And I think that's across the government in terms of how we think through the development of proposed rules and also other policy documents that we are releasing.

So, we really look forward to public comment once the proposed rule is released, and equally so on the trusted exchange framework, which is actually out for public comment now. With that, I'm going to leave some time for questions. As I said, there are some things that I won't be able to answer, so don't get mad at me. But we are required not to talk about certain elements of the rule-making process. But with that, let me open up for questions and see if folks have any thoughts.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

And just to remind members to please use your **Tint** cards to acknowledge your question or comment, and to please state your name prior to your comment.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

Can I just make one semi-administrative comment on this? So, Elise, the slide deck you've just given is going to be on healthIT.gov?

Elise Sweeney Anthony – Director of the Office of Policy - Office of the National Coordinator for Health Information Technology

Yes. It will be on the FACA page, in particular.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

Okay. So that anybody on either the committee or in the public – because you've obviously gone through a lot of things here. I would just make one observation before we get into the questions. For the folks who have spent a lot of time in the Congressional landscape, this, I think, when you look at it from a distance, reflects an extraordinary interest in Congress in doing all of this, right? This is a lot of language, a daunting amount of language, and reflects a deep Congressional interest, which when Congress is interested probably meant that almost every member of Congress heard complaints about this in their offices. And so, as we sort of think about this, it's worth just keeping in the background how much communication had to be given by the public to Congress to end up with this end result. I mean, John Fleming, who is our Deputy Assistant for Health IT, can just say one word about that. John is a family practice doc who, unlike most family practice docs, was also a four-term member of the U.S. Congress and an EMR pioneer going back a long ways. Maybe John, I think you voted for the Cures Act. Can you say a couple words here?

John Fleming

Okay, thank you, John. Yes, I voted for the 21st Century Cures Act. But it was a massive bill, and to be honest with you, there are a lot of pieces of legislation that have come through the last couple of decades that have not always been that good for healthcare in general or technology related to it. I would say 21st Century Cures Act comes as close as I've ever seen to being really on target to addressing the real problems and the forward-moving issues. So, I really think not only did Congress get it right this time – and I'm a huge critic of Congress. I haven't been there for eight years – but also, the staff that we have, our leadership staff, both career and appointed at ONC, I think, is perfectly qualified to make this go forward. So, I think we're in an excellent place, and I've seen some of the resumes, the Faulkner Group here today, and I know you'll be an excellent resource to help us in going forward. Thank you, Don.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

So, Elise, you're ready to answer questions?

Elise Sweeney Anthony – Director of the Office of Policy - Office of the National Coordinator for Health Information Technology

I am. If there are any. Raj?

Raj Ratwani, MA, PhD - Scientific Director - Natl Center for Human Factors in Healthcare, within MedStar Health

Thank you. So, my name's Raj Ratwani with Medstar Health. Thank you for the concise overview. I have a general question about information blocking and the language in 21st Century Cures Act around information blocking. So, when we hear information blocking, we naturally think about the exchange of health information. The language in there also hints towards things like that blocking of information around the assessment of usability of EHRs and the security of EHRs. Can you elaborate on that point, and whether that falls under information blocking?

Elise Sweeney Anthony – Director of the Office of Policy - Office of the National Coordinator for Health Information Technology

So, I cannot, unfortunately. I think this falls into an area that we would look forward to receiving comment on whatever is included in the proposed rule, and then from there would consider it. But I can't comment right now in terms of the interpretation.

Male Speaker

So, I want to applaud the ONC staff for the continual release of really useful background information in the playbook. I was literally, two days ago, at a meeting talking about some of the data governance issue associated with patient matching, and the importance for health systems to get their upstream data governance house in order in order to facilitate downstream patient matching in order to enable things like where we're going with TEFCA. It's one of the sleeper areas that ONC does. So, I first of all really want to applaud ONC, but also just point out that it was a little bit of a surprise to me that this information was out there. I'm sure that ONC's done a great job of promoting it through the Twitter feeds and the blog, but there's a huge resource of information available at ONC, and I'm not sure that people appreciate how much is there and how much depth is there, and maybe ask you what we can do to better promote some of this information.

Elise Sweeney Anthony – Director of the Office of Policy - Office of the National Coordinator for Health Information Technology

Yeah, I definitely appreciate this question, and it's something that we continually seek to find new ways to get information out there. Some of this information has been out for some time, but you'll probably see me present it over and over and over again, and that's in the hopes and recognition that sometimes people are not listening to every single presentation we do. So, we try to continually try to get this information out to be useful. I think if there are organizations, trade associations, meetings, forums – any opportunities for us, or my team, or Steve's team, or leadership to present on these types of issues or to make the resources available, we are absolutely open to it. We recognize that we do not know every organization out there, and are but a sliver of the kind of healthcare pie, as it were. So, any resources that you guys have in terms of how to reach out, we are happy to do those and to bring those back to our public affairs team.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Any other questions or comments? Okay. Hearing none. Oh, wait, one more. Clem? And if you could state your name, please?

Clement McDonald – Director - National Library of Medicine

I'm Clem McDonald, and I wondered if you could – the Cures Act says something like interoperate all clinical data. And I haven't cited it correctly. And are there any thoughts about what we start to bite off? Because all is a big number.

Elise Sweeney Anthony – Director of the Office of Policy - Office of the National Coordinator for Health Information Technology

Yes. So, I think this is one of the things that we are looking at. I think part of the presentation this afternoon will touch on some of the ways that we are identifying data classes, or hope to identify data classes of information over time. What's currently available, what makes sense now, what do we need to think about for the future. And that's captured in some of the U.S. core data for interoperability document that was released, but I'll let Steve or Genevieve jump in if there's more they want to add now If not, I'm sure it'll be covered this afternoon. Okay.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

I'm sorry, I can't see that. Terry?

Terrence O'Malley, MD Geriatrician - Massachusetts General Hospital

Yes. Hi, Terry O'Malley, **Partner South Care**, Boston. Just a question, the flip side of Clem's question where he's seeking to scope it down, I'm gonna seek to scope it up. What is the process for adding other target areas, which is a nice elastic phrase?

Elise Sweeney Anthony – Director of the Office of Policy - Office of the National Coordinator for Health Information Technology

Yeah. So, I have to say, you guy are quite on point, because that's one of the things that we plan to share with the committee this afternoon as part of that presentation. But I mentioned that there would be a taskforce developed on the trusted exchange framework. I probably neglected to mention that there will also be a taskforce developed around the U.S. core data for interoperability document. So, one is a little bit more on the policy side of what needs to happen for health information exchange, and the other more on the standards and technical capabilities side of that same equation. And the USCDI taskforce, one of the things that we really want feedback on is what that process looks like, and whether we've hit the right targets, and how we start to think about it. Right now, it's around the current and then candidate data classes, and then emerging data classes. But we definitely look forward to feedback on whether that is the right way to think about it and affords the right timeline for what we need for interoperability.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

I think it's worth noting – Don Rucker. I think it's worth noting as we think about the data, and how much data we're gonna do in what format, that for this data, we're talking about structured data here, for the most part. You also have to think of it in the context of what are the payload standards? There's a lot of detail that goes into that question. So, as we have the considerations, I think what makes it hard is it's not just the choice of data, but it's really the status of the standards and the fitness of those standards over time, and getting them at least somewhat right. I mean, there's always iteration on things. And all of that then has to be programmed by developers and installed in complex enterprise systems that many of you have worked on. But I think sometimes when we sort of look at the life of data, we are sort of forgetting the entire stack of stuff. I think that's not any news to anybody on the HITAC. But I think for folks out in the public who are listening, that's a very important consideration, think about that entire timeline and what the end result is in terms of the quality and usability of the data.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Thank you. Patrick?

Patrick Soon-Shiong - Chairman & CEO - Nanthealth

Just a comment on –

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

And if you could state your name, please.

Patrick Soon-Shiong - Chairman & CEO - Nanthealth

Sorry. Dr. Patrick Shoon-Shiong. A comment and then a question. I think, if I understand, one of the real goals of this interoperability issue is really to understand how we can improve outcomes. If you want to improve outcomes, I think one of the issues is how do you get real time data of real time patients, the right time, right place? So, my question is, is the ONC, as it moves forward, going to readopt some of the convergence of technology that is available today, and look forward, in fact, to things like cloud computing, block chain, artificial intelligence, 5G, that's coming? And not just data interoperability, but process interoperability, so we can get real time data. Is that going to be a charge of this committee or this program at this point in time? Because I think if you look at the Cures Act, it's to accelerate some of these, including that clinical trial.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

Let me answer that. The answer is yes. So, we're absolutely interested, and I think the whole point of the Cures Act around open APIs without special effort, right, when you dig into what does that mean computationally, is sort of modern standards. I think as a practical matter when you look at that, some of those are gonna be modern **restful** web standards. That's really the currency of the trade out there. You have to look at – and I think this bifurcates. Some of this is gonna be machine learning and relatively unstructured data that is coming. There are amazing technologies with AI, machine learning, natural language processing. I mean, I was reading some stuff last night on automatic translation, which is machine learning. So, I think there is a stack of technologies there. There are obviously a whole bunch of use cases that require structured data, as we envision it now, and all of the structured data requires a lot of standards. Clem has worked on putting out the length standards on all of the lab information for many decades. NLM has **Rx Norm**. So, there's a stack of standards.

But I think this committee's work on open APIs, and what is transmitted, and all of the potential uses of that, are absolutely critical. And we're very interested in some of the new technology. Steve **Grube** has done some work in exploring block chain, which he can maybe talk about a little bit. But absolutely, we are interested in that. A very important technical part of that and what we're working on is making sure that the transmission of data is not just one patient at a time, right? So, let's say the classic provider to provider, but that we actually leverage these technologies to be able to look at populations, right? So that we can actually look at some collective data. And the population level resources, there's not a lot of work that's been done on that. That is largely today one-off scripting things, where you sort of have a negotiation. Let's say the classic one is between an insurer and a large institutional provider on a script. Those are very one-off things. And we've gotten a lot of feedback that we need to really work in that area to facilitate exactly what you're asking for.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

And I see a comment from Ken?

Kensaku Kawamoto, MD, PhD, MHS - Assoc. Chief Medical Information Officer - Univ. of Utah

Hi, Ken Kawamoto, University of Utah. I just wanted to comment in support of two of the

comments that just came out. So, with regard to what Patrick said, I totally support it, and in particular, I do think the interoperability of knowledge is really executable. Knowledge is really important, whether it's in **[inaudible] [01:05:32]** support of a quality measurement. And in support of what Don was saying, I really do think there's this important life cycle of standards and data that we really need to consider. So, I think establishing standards is just the first step. So, how is it implemented in the system so that the data can be collected? Even if it can be collected, is it just gonna be extra documentation effort on the part of providers that's not being collected? Even if it is documented and there's an interface or not being up to standard codes, if we're using local codes in our local systems, what's the processes that we make sure that not 80 percent, not 90 percent, but 100 percent of the data gets encoded and translated? So, I think that's a really important aspect, and I think it's something we should focus on as well.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

So, seeing no other comments or questions, thank you, Elise. We will now turn it over to Steve Posnak, our Director of the Office of Standards and Technology at ONC.

Steve Posnak

All right. So, is my charge gonna be to tap dance until 11:30? All right, yes. All right, great. I'm usually between – I usually follow Elise and I'm between a meal, so I'm used to this position. Good morning. My name's Steve Posnak. I'm the Director of the Office of Standards and Technology at ONC. I want to welcome you. I want to thank you for your service. This is the first of many meetings. Typically, once we get a few meetings under our belt, we usually announce the meeting number, as some of our past advisory committee members will recall. After eight years of meetings, you have a lot of meetings, so the numbers will get quite high. I am privileged to be the person in front of you today, having often been behind many other ONC leaders, in support of our mission and activities. I now have a great team of experts that work with me. And my colleague Elise, who is my partner in health policy – health IT policy, I guess you could say – to run the day-to-day operations here at ONC and the activities that you'll hear about. I have now – I guess you're on my fourth advisory committee, so I want to thank you for that, having started first through the American Health Information Committee with Robert Wah on there, and then the two Health IT Standards and Policy Committees, and now the HITAC, which I think I'm – I don't want to say personally responsible for having the pronunciation of the acronym, but I think I was beating up everybody in the office to go in that direction, so thank you for your tolerance of that.

I only have one slide. And I'm gonna talk quite a bit to it. So, you'll just have to sit and listen. The one thing that I wanted to orient you toward first, which you'll hear quite a bit about, and you'll hear it a little bit from Elise, is with respect to the ONC Health IT Certification Program. This was an outgrowth from the HITECH Act from 2009. As part of the stimulus bill, there was now, I think, world-renowned, the Meaningful Use program, otherwise known as the EHR Incentive program. And as part of that, that program largely dealt with incentives to healthcare providers, the behavior change that Congress wanted to see from a health IT use perspective. We had a corresponding responsibility to establish a certification program and the certification criteria for the health IT products that providers would be incentivized to adopt. And we stood up, through various regulatory activities, a health IT certification program. That now includes, to fast-forward you to today, authorized testing laboratories, authorized certification bodies, and ONC as kind of the oversight organization for those.

So, we have a split process, testing first, then certification. Testing really focuses on the purely quantitative aspects of health IT testing. So, standards of conformance, demonstration – I like to call it show and tell. Are these functionalities present in the product? Are they working in conformance with the certification criteria and technical outcomes that we've expressed in our regulations? And are the standards being implemented in a conformative manner, inclusive of either the content or vocabulary expectations that we've set? We require that the testing laboratories and certification bodies be accredited. So, there are ISO standards for the various competencies associated with testing and certification. The accreditation organizations for our program, one is run by NIS, which is called the National Voluntary Laboratory Accreditation Program, and then the other is run by ANCE, which handles the certification side. So, both of those, insofar as we have organizations that come to get authorized by us to certify and test, need to be first accredited for their respective competencies.

The other thing that is perhaps misunderstood at times is that the authorized testing and certification bodies that we have are not paid for by ONC. They are separate third party organizations. They run their own business. They run their own business model. They determine the fees that they charge for performing testing and certification underneath our program. That being said, there are a certain number of obligations that we have delegated to them to perform on our behalf at a first level, and some of those include many of the oversight responsibilities. Do the products perform in the field appropriately? We kind of colloquially refer to this as surveillance. So, we have post-certification surveillance. We have a kind of robust approach for healthcare providers and other stakeholders in the field to submit complaints or reports to both ONC, as well the ONC certification body, and then we follow up to identify if there are any issues that are associated with those products. If there are, a corrective action plan approach is instituted, which is kind of common in many of these situations. Our interest primarily is to get the product fixed as fast as possible, as safely as possible, with the appropriate remediation, and to make sure that the product is up to conformance with the program standards.

So, that's kind of a rough overview of the ONCLIC certification program, its constituent parts, the bits and pieces that fit together. And there are a number of different rules that really inform this regulatory architecture that we have now after eight years. We have the overall program rules that establish a process, how we engage with the certification bodies, how they can apply, how we oversee them, etc. We also have implemented various what we call "additions" of certification criteria. We're currently actively managing in parallel two additions of certification criteria, the 2014 edition and the 2015 edition. The 2014 edition is as result of a rule that we published in 2012. As with everything we have learned through maturity and cycles about naming convention and branding, and how to be better communicators, originally the 2014 edition was set to convey the compliance timeline by which providers needed to have that technology. At that point in time in 2012, it made a whole lot of sense, up until the point in time when the compliance timeline got delayed, and it no longer kind of married with the communication ability that we had set forward.

That being said, the 2014 edition is roughly six years old now at this point. In 2015, since we learned our lesson, we decided to publish the name of the edition by the year in which the rule was published to kind of keep things simple. So, we have a 2015 edition, which was published in 2015. That is commensurate and tied to the EHR incentive program policies and now the quality payment program policies, if you're in the ambulatory space. Both of those by statute, or

organizations, hospitals, and eligible clinicians, as they are now referred, have to adopt what's called certified EHR technology, which, since we're in the Washington, DC space, we define everything. So, that is a specific definition that CMS administers. It relates to certain requirements that Congress set forward for us in the HITECH Act, which established certain baseline capabilities that all certified EHR technology needs to include. So, as that kind of works its way upstream or downstream to healthcare providers, we have certain certification criteria that all healthcare providers must have as part of their certified EHR technology. We refer to that as a base EHR definition. It's kind of a rough subset of a dozen or so criteria, if I remember my math correctly. And those are a basic functionality that Congress said needs to be included. So, it includes demographics, medication information, problems with information, the ability to exchange certain health information data, and deal with relevant quality information as well.

So, we have specific certification criteria that we've assigned to them. The 2015 edition is put into life by our colleagues at CMS or any other colleagues, be it state or federal, that choose to reference it. But by the triangulation of the statutes as they exist, when it comes to provider compliance and their participation in the various Medicare and Medicaid programs, they are the ones that are required to adopt certified EHR technology that's certified under our program. CMS sets those compliance deadlines, just to reference them as an example. And so, as we're looking to 2018, 2019, that's in the 2015 edition we expect to get picked up in a more kind of compliance adoption and really hit its stride. That will be, just for context, four years after we have put those criteria out in a rule. And so, as we've discussed and some conversation that we were having yesterday, as we talk about some of the more substantive matters that we have in front of us today, it's important to kind of keep in mind our aspirations and the timeline by which we've seen them practically been implemented. We have had very aggressive regulatory schedules before in the past when we look to the HITECH Act and the EHR incentive program, and as the rubber hit the road, we had to make adjustments.

And so, similarly, I think we'll have a bit of history and precedent to inform us about the next steps that we want to take. But we have a good deal – bit of, I think, experience at this point to help guide some of those conversations. We're often tugged, to some of the earlier comments that were just made, between the bleeding edge of where we want to lead the industry and the fact that some healthcare providers still don't have a dial tone. They still can't connect. They still can't exchange. And this is particularly acute in the ambulatory space, where we're still trying to get them, having just adopted products in the past two or three years, to get to a place where they have the same baseline technological capabilities as a large hospital system. And that's really the diverse world. Not to mention and not to leave out organizations that still haven't adopted a full suite of health IT capabilities, be it long-term post-acute care, behavioral health, mental health – the real care continuum that we are focused on and charged with enabling interoperability for.

So, that's a bit of a segue out of the certification program. One of the other things that we do administer on behalf of the certification program is what we call the certified health IT product list. So, as products go through the testing and certification process, we have three certification bodies that perform those duties right now. All those products that as they get certified, they get listed. And so, we maintain a single listing. This is another acronym that we pronounce. We refer to it as the CHPL. It's the C-H-P-L. And so, all product information associated with the certification program, including all the data exhaust that comes about as a result of the program, are now made available as part of the certified health IT product list. So, you can find that at chpl.healthIT.gov. There's everything you'd want to know about that product vis-a-vis the

certification process. We require certain transparency and disclosures that health IT developers need to make.

The 2015 edition included, for the first time, application programming interface certification criteria to help advance that technology. And there are various information that health IT developers need to make available, especially where there are APIs. They also need to make available certain information about their products in terms of additional fees or other types of limitations. I colloquially refer to those as the "batteries not included" provisions, so that you kind of have a sense of if there are other things that healthcare providers need to be aware of, you can find those types of things about the product in those types of disclosures. All that information is made available on, again, the certified health IT product list.

The other thing that we do support in concert with our colleagues at CMS, for any of you that have participated in the EHR incentive program, you know you need to get the CMS EHR ID number. As we worked to implement the original incentive programs, we realized that healthcare providers often have multiple technology solutions that they're implementing in their environment. This is especially true in the hospital setting. And so, what we wanted to do is enable a way for healthcare providers to pick off the health IT certification product list the various products that they have, and then kind of homogenize them into a single ID that they could then report to CMS. So, that functionality is also built into the certified health IT product list.

Just as a public service announcement for anyone's the interested in the data that's available, we do make this available in an open data format. We have APIs that are part of the CHPL. If anyone wants programmatic access to all that data, it's all there built in, and you're certainly welcome to contact my team if you'd like more information about it. The other thing that we do in terms of overall programmatic support for the program, we support a number of electronic testing tools for standards of conformance. We've done this for the past eight years in collaboration with our colleagues at **NIST**. They have developed and supported several of the tools that we operate for the program. We have the ePrescribing testing tools, we have direct testing tools, we have consolidated CDA testing tools, and so on. So, many of those testing tools are supported through our program.

We also, as a public service announcement, have been ramping up the awareness that we are open to approving alternatives to the government to produce testing methods that we have. And last year was a banner year for us in that we had two organizations step forward to get their alternative testing methods approved. One was NCQA, related to electronic clinical quality measures. The other was the **HIMS** immunization program for immunization-related testing. And so, those provide alternative testing methodologies that we can provide a form of reciprocity under our program. And so, what we'd like to see from a health IT developer perspective is that as many times as possible from an efficiency perspective, they can get tested once and use those test results for multiple purposes. And if the purpose that they're going in to get tested is principally to work with NCQA, those test results would similarly be useful for the purposes of our program insofar as they're equivalent in their scope. So, if there's anyone else out there who's interested in pursuing those types of opportunities, just again, wanted to make sure that everyone is aware that we are certainly open to that.

The other thing that we do is, for the program overall, it's what I like to call a citizen service. It's one of the public-facing things that we run as a program day-to-day. It's one of the heartbeats of

ONC. And as we release an edition, there is a corresponding long tail of what I would refer to as customer support. In this case, health IT developers mostly, but other groups that engage with our certification program. And we have produced, as I think was mentioned by Elise both yesterday and this morning, we produced what are called certification companion guides. So, for each of our certification criteria, there is a world of interpretation. What did we mean by this? And we tried to head off a lot of those in the past in the preamble of the regulations, which explains in some cases the length of the regulations and adding additional guidance upfront in response to comments. The other aspect is that sometimes, we aren't able to predict the scenario that a particular health IT developer may have, or that a particular novel approach that they may be interested in pursuing. And they come to us for guidance in terms of how we can make the rules work, which is often our job and our duty in a general way, is not to say no, but to make the rules work in a way that's both win/win for our policy interests and for the health IT developer.

So, we maintain these certification companion guides. They are living documents updated on a weekly to monthly basis, depending on the inquiries that we get. On average, we get an inquiry pretty much every day of the week, so that adds up, right? So, we're kind of in the 300s mark for last year in terms of the amount of inquiries that we get. Some are relatively simple questions. Others require detailed weeks' worth of interpretive analysis, conversations with our general counsel, etc. And those are the ones that are both the most intriguing and painful at times. But ultimately, our job is to get an answer and get back out. And we know, as we're in an edition cycle, every week that goes by for a health IT developer that they are waiting for an answer is time not spent getting certified. So, it's certainly in the minds of our team and our leadership.

So, that's about it on the certification program. The next body of work that I wanted to take on and give you a primer on was the activities that we lead in general from a standards in technology perspective. And the kind of conceptual model that we use to frame this is what we refer to internally as the ONC tech lab. And so, we're gonna break our thinking out into four different areas. My staff works across all four of these different areas, depending on the type of work that they're taking on. But it really helps to organize and communicate the type of work that we do on behalf of all of you for health IT.

So, when we talk about pilots, often we know that it's really important to – and the most experience that we get is probably forgetting a Stan Huff, is he's listening – the first hour of work that we have in production is more learning than we ever imagined when we're actually doing the tabletop exercises or theoretical thinking about the work that we've got. So, often, whether it be pilots that we're able to administer through funding that ONC has available, and we've done that in the past through two programs. One was called the High Impact Pilot Awards. The other was called the Standards Exploration Awards. Those are two different cooperative agreements that we had pilots for. Many of you may have been recipients or participants as part of prior work that we did through the HITECH Act, either through regional extension centers, through the state HIE program, through some of the Sharp work that led to some of the technologies that we're now really excited about today, vis-a-vis APIs and the smart teams work. So, those are various different areas where we were working from a pilot perspective.

We also have contracts at times. Our colleagues at the Assistant Secretary for Planning and Evaluation, ASPE, to spell out acronyms first, have run the Patient-Centered Outcomes Research Trust Fund for a number of years. And we have been the recipient of certain rounds of funding

through our colleagues at ASPE to work on Patient-Centered Outcomes Research data infrastructure work. So, for those of you that have operated in that space, we had a number of different PCOR projects that we've administered that have led to pilots and other types of industry engagement to help advance that data infrastructure.

And then we also get ourselves into public/private initiatives, which are often the most exciting and rewarding for our team. Relatively low-cost in terms of expenditure, but mostly staff allocated with the various experts that we have on our teams. And one example would be just at the end of the last administration, we engaged many of you on a comprehensive medication list pilot project, which was really trying to forward the idea of using **Fire**-based APIs to help patients get a comprehensive medication list from their various healthcare providers. And so, I know a number of you participated in that project. That was a public/private initiative that we helped kind of be the booster rocket for, and then sent it on its way, really. And those are really the most fun and rewarding activities, again, that we are equipped to do insofar as there is an industry need for coordination, which, as you know, is in our middle name. And that's one of the things that we like to do just in general.

So, that really wraps up most of our pilot activities. The one other thing that I would note, which I think many of you experienced and will probably be shared throughout your time as part of HITAC, everyone is working on cool stuff. And often, to one of the points that Arien made earlier, it's hard to make everyone else aware of the cool stuff that we're working on. We've all probably attended numerous HIMS conference, numerous **AMIA** conferences, numerous other conferences. You talk to a colleague, and you're like, "I've never heard about this activity. I'm so glad you shared it with me. Who else needs to know about it?" And there aren't really very good mechanisms to share that information. So, one of the things that we stood up was a collaborative web-based platform, which we call the Interoperability Proving Ground. And so, it's a place where people can share, learn, be inspired by other projects that are happening across the nation. And it's very easy. You just kind of go in there, pop in your information about your project, and it's publicly available to everybody. And some of the cool things that we were able to do, since we knew the kind of collaboration that we wanted to enable, was we let people tag their projects with particular keywords, and then you can subscribe to those, as well as particular states.

So, if you're in New York and you want to know what's going on in New York, you could search by all the projects that are happening in New York. If you're working on Fire and you want to know what's going on with everybody working on Fire, then you can search by that particular tag. Equally, if you want to be prompted when someone adds a new Fire project, you can get that subscription and get that notification pushed to you if you're interested in that as well. And so, it's a lightweight way to collaborate without a kind of heavyweight infrastructure to kind of force people to pay attention all the time. We have over 280 active projects that are listed. We just crossed over the 400-project submission mark recently. So, for the past couple of years, we've really engendered a lot of interest. And we started to link it to one of the other resources that I'm about to talk about as part of our standards coordination activities.

So, when it comes to standards coordination, really, we go where our priorities are and where the industry wants to take us in a lot of cases, and where the action is. So, for the past few years, we've had a cooperative agreement with **HL7** that's largely focused on the consolidated CDA, improving implementation guidance for it, additional conformance testing tools, and the like.

We've also had investments in Fire in general, how it's organized, any of the other underlying support so that the actual people doing the work can get that done knowing that they'll be able to make available certain resources to the community that are necessary for its overall organization, so that under the hype that many of us have heard associated with it, it doesn't get crushed with some of the just general bureaucratic needs of standing up a new standards infrastructure. So, we have investments along those lines.

We also, as Dr. Rucker mentioned, this year have been investing in some forward-looking aspects related to Fire, population services, and how we can help that specification have additional consistency and support for going beyond just the single get request for a patient. Looking forward to population level services that can be supported via a **RESL** API. So, we have worked with HL7. That's ongoing. We also have cooperative work with NCPDP, who many of you may be familiar with from an ePrescribing standpoint, around testing infrastructure for the script standard, as well as work where, from an opioid perspective, implementation guide for how to interact with the prescription drug monitoring programs that states have. There's a bit of a triangular relationship in terms of control. An opioid gets prescribed, gets sent over the to the pharmacy. Pharmacy reports it out to the Prescription Drug Monitoring Program. And that third leg of the triangle there has really been a place where there hasn't been a lot of technical specification in terms of how you get that interconnectivity between the EHR and the PDMP, how you build that into workflow.

Because we know, just like with many other activities, if it's in a separate webpage, or portal, or other type of thing that you need to get out of your normal workflow to get into, it just impacts the amount of use that we see devoted to it. So, when we're thinking about the opioid epidemic and the work that we do, a lot of our work in collaboration with our colleagues at **SAMSA** around substance abuse and mental health has been dedicated to the EHR optimization and connectivity to prescription drug monitoring programs. While I just mentioned our colleagues at SAMSA, one of the other components that is often behind the scenes work that ONC does from a standards perspective is both providing leadership and consultative support to our colleagues throughout HHS and federal government at large. So, when it comes to many of the other agencies with which we interact, CMS is probably our biggest sister agency. Many of the components, be it the other CMMI that would be referenced in terms of innovation, be it our quality-related programs, Medicare and the like, there's a lot of work that we do with our colleagues at CMS, DOD, DA, Agency for Healthcare Research and Quality, AHRQ, SAMSA, HRSA for rural health and the like, OIG, which will be more of a partner related to our information blocking-related activities, now that we're joined at the hip from that perspective. We've previously worked with them on **[inaudible] t [01:34:01]** kickback-related activities. You may be familiar with the EHR Exception and Safe Harbor for Donations of EHR Technology, which really dates back to the Bush administration 2006 time period when we first worked on those rules. So, we've had a long history of working with OIG on various policy activities related to health IT as well.

The other work that we do, which is, I would say, central to our standards of coordination activity is what's called the Interoperability Standards Advisory. Colloquially, again, I refer to this as the Standardsopedia. It's a web infrastructure that we have available on healthIT.gov. It represents the collective wisdom of our entire community. And again, one of the things that we realized as we were working on our interoperability roadmap several years ago was that every time we wanted to talk about a particular interoperability need or a particular set of business cases that we wanted to address, we had to recreate a set of resources. All right, what are the HL7 specifications that are available? What are the IEC profiles that are available? What else is

going on? What are the terminologies that we need? And it became an inefficient process. And so, what we wanted to do was find a way to engage with industry to make available a resource for all stakeholders that could include, here's an interoperability need that we are aware of. Here are the standards and specifications that are associated with it. And here's some information that you may want to know about where that kind of standard is. Does it for purpose? Has it been pilot tested? Is it in production? How many people may be using it? Does it cost money to get that standard? Are there testing tools available for it?

And so, we provide all that information through the Interoperability Standards Advisory, which has gone through about three iterations now at this point. Some of you, I recognized and wanted to express my thanks for participating on previous advisory committee taskforces that informed its structure. And right now, at the end of December of last year, we published what's called the 2018 reference edition, which was really a snapshot of everything that's in the Standards Advisory for folks that like to print out or have that PDF handy. That being said, one of the evolutions that we made in moving it from a PDF to an online experience is that it's updated real time, rolling, 24/7, insofar as we get that feedback. So, now we have a more formal ongoing relationship with HL7 and other organizations, that as new specifications come out, we pair them with the appropriate interoperability need as it's been identified, and we also identify – over time, it starts to show the history, trajectory, and the kind of family tree of particular specifications as they're released. And so, we can start to see a progression where things move from emerging from a standards perspective to something that is employed in production. And that's something that we help to facilitate via transparency with the Standards Advisory.

So, we are looking always for ways to improve it. As another public service announcement, when I mentioned the Interoperability Proving Ground earlier, we now link projects that are focused on particular standards that are out there that people have submitted in pilots with the particular standard as it's listed in the Interoperability Standards Advisory. So, if there's a group of people that are working on transitions of care and need references to consolidated CDA standards, you can click on the link that will bring you to projects working on consolidated CDA. So, you can kind of connect the theory and practice of the theory of the standards and their business needs that they're associated with, and the actual people putting those into practice, and figure out what's going on. So, we started to link those two together, and I think there's been rewarding feedback that we got from our advisory committee in terms of the work that we have thus far.

The other thing that I would note in terms of our standards of coordination activities, last summer, which some of you may have attended, we held a technical interoperability forum. Those are other types of activities that we do in terms of gathering groups of stakeholders together to talk about tough issues and the type of work that we have ahead of us.

I'm gonna move on to our testing and utilities activities. So, we run, as part of our certification program support, electronic testing tools. We also make them publicly available for general use, not just in the context of health IT developers getting tested and certified. So, that infrastructure is available through our standards implementation and testing environment. We also have, in the past couple of years, produced specific utilities that are designed to either support how the key developer implementation, or, in a kind of post-deployment implementation world, for healthcare providers. And so, I'll touch on these two really quickly. The consolidated CDA has largely been the body of our work since its reference in the 2014 edition. And as much as there

are plenty of rough edges with it, it has been substantially improved over time. And one of the things that we wanted to do, building on some earlier work by Josh Mandel and others at the SMART team was to make a valuable tool that could give people more quantitative feedback about conformance issues with the consolidated CDA. So, we put out a CCDA scorecard, which you can use to give yourself a checkup on how your CCDA is constructed. And so, this can be used by health IT developers. It can also be used by various health information exchange organizations, registries. Anyone that's using CCDA, you can run one through it, and it'll give you its conformance score.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

Steve, can you just say what the CCDA is, just to make sure that everybody's on the same page?

Steve Posnak

Yeah. For Consolidated Clinical Document Architecture. As long as I don't get my history wrong, if anyone can correct me. Prior to document templates that HL7 managed in various separate implementation guides, they were all based on the CDA clinical document architecture standard as a whole, kind of the parent standard. All of those at some point in time were consolidated, hence the word consolidated, to a single implementation guide. So, the one that people are most familiar with is generally referred to in acronym speak is the CCD, which is the continuity of care document. That is but one of many document templates that exists in the consolidated CDA's library. There are others for discharge summary, care plan, and so on. And so, there are various different documents that exist. So, our testing tool is meant to look through the conformance-related requirements of the CCDA document and judge them, and kind of give you score, give you feedback from an implementation perspective. It's an XML-based specification, if anyone wanted that level of detail as well.

So, we have the CCDA scorecard. It can be downloaded, the tool, as well, so if people wanted to locally install it in their infrastructure as opposed to using our upload tool, you're welcome to do that. Likely, you might want to run your own PHI through it. And so, that is available for you. And we are enhancing that tool as we're able to and as we get feedback relative to particular needs. The other thing that we did recently was to pair one of the testing tools that we had as part of our certification program and really flip it around 180 degrees, and make it available for healthcare providers. So, the way I orient everybody is generally, you've probably done an Internet speed test. You've clicked on one of those links to say, am I really getting what I paid for with the particular Internet service provider – I won't name names – that I've signed up for, and how do I know? And so, it gives you a rough quantitative look at your bandwidth, upload/download. And as we were looking at the availability of utilities for healthcare providers of putting their products into production, it's hard for them to have a sense of what is it that my product is shooting out into the wire to the next healthcare provider?

So, the tool that we built was leveraging the infrastructure that we knew that healthcare providers already had in place. Everybody already had in place the capability to send direct messages, effectively through secure email, encrypted email. The direct infrastructure, paired with the CCDA, allowed for effectively a full loop of a transmission. So, if I'm a healthcare provider, and I want to know how the CCDA that I have and my product is conforming to the particular standard, if my colleagues are complaining to me that they're having trouble with it, maybe it's on my end. Maybe it's on their end. But I now have the opportunity and the

availability through this tool to send a direct message to scorecard@direct.hhs.gov, and we unpack it, we score it, we erase it, and we send it back to the healthcare provider with the score for their CCDA. And this happens in a matter of minutes, so they get their information back in a full loop. So, not only does it test that your direct dial phone is working, because we're in active production using a direct trust accredited HISP, which is a health information service provider – sorry direct speak – that the message routes through, but we also score the CCDA that's in production.

One of the unique things about the health IT certification program is that when it comes to oversight of health information technology, it's considered a health oversight program in the context of the HIPAA privacy rule. And so, for this particular context, insofar as surveillance is being performed and associated with certified EHR technology, health providers are allowed to send the PHI to ONC, and were disclosed effectively in the HIPAA parlance. And we're allowed to receive that and have it for that brief moment, and then we scrub everything else and erase all our data. But for the regulatory purposes, we work through with our prior colleague at OCR, if she's listening, Devon McGraw, on the kind of mechanics behind how all that would work from a regulatory standpoint. So, that utility, we call the one-click score, because effectively, you type in scorecard@direct.hhs.gov, and then you get your secure message back from us again in a minute or two. We also work with our colleagues at CMS related to clinical quality measure testing. There's a tool called Cypress. But as many of you know, if you're in this space, there are electronically specified clinical quality measures, and there's a whole process and infrastructure around assessing the electronic clinical quality measures. And so, we support the tooling with our colleagues at CMS on that type of work.

Okay. So, innovation as our last category. Perhaps I'll fill more time. We look across various different areas for work that's going on. Block chain was one of those a couple years ago. Had reached a certain level of interest among everyone. We ran an ideation challenge for whitepapers. We got over 70 submitted, and then we collaborated with our colleagues at NIS to run a workshop about block chain and healthcare. And so, if you go to our innovation section on the tech lab as part of our website, you can go through and find all of those whitepapers, which I'm sure are still pretty fresh relative to the idea. So, that's some of the areas that we go. We also manage interoperability and action webinars. So, as we produce particular activities, like some of the patient matching resources that were just discussed earlier, we make available, in a half day kind of web session, a way to expose everyone to the various information that would be available to different stakeholders and their particular interests.

Other things that we do relative to innovation, insofar as we have the resources available, we run prize competitions. So, there's the America Competes Act, as it's been reauthorized, allows federal agencies to do various different prize competitions. And we received a particular kind of acute need for some focus. We worked with industry to develop a prize competition in various different areas. So, right now, we have one around API security, specifically Fire, which we call the Secure API Server Showdown Challenge. We have another one focused on data provenance, which is Dr. Seuss-inspired and termed the Oh, the Places Data Goes challenge, if you're familiar with that book as a parent of young children. And we've also done one more recently on patient matching algorithms, which just finished. And so, we had a webinar on that recently. So, that's a pretty, I guess, comprehensive rundown of everything that we've got going on. Our technical capacity, as well as our expertise, that we'll be able to bring toward the various work that you all have to look forward to. Thanks.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

Thanks, Steve. That was very helpful. For the HITAC Committee members, obviously, that's sort of a bit of a laundry list of things. But hopefully, that gives you a sense of the control surface of things that we've done that you can sort of give advice on reflecting what's not working, what should be done differently, to have a little bit of that sense, because I think that's an important part of the committee's work, is to actually give us feedback on those things. So, I just wanted to make that observation before turning it over to Lauren for questions and comments.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Thank you. So, I see the first comment from Arien.

Arien Malec - Vice President for the Data Platform Solution Line - RelayHealth

There we go. Elise, are you gonna shut me down if I ask what the future of the certification program is?

Elise

No, I will not shut you down.

Arien Malec - Vice President for the Data Platform Solution Line - RelayHealth

I thought you were gonna say it depends.

Elise

No. I think – and Steve, feel free to jump in, or obviously, Don – the certification program is a really important piece of the standardization. And that floor that we generally talk about in terms of the interoperability pieces that we are developing in support of Cure, such as trusted exchange framework, all of those work together, and they're important pieces of the overall interoperability puzzle. The certification program is important not only from our perspective in terms of implementing as per HITECH Act, which continues to be a requirement, but also in terms of CMS, for example, and the programs that they provide, ensuring that that technology is available and is operating as providers believe they should.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

Yeah. Obviously, I think everybody knows there have been issues with sort of the way that that has all played out. And it hasn't played out in the way that maybe the way everybody sort of hoped or thought, or many people hoped or thought. I think the focus of Congress and the Cures Act has been pretty clear, to sort of double down on interoperability and usability. And I think that really is the focus. And I think what you're going to see in the future is really a focus on those areas. That's where we think there's value added. What might happen down the road, it is worth noting, there are some specific legislative provisions in Cures on things that meaningful use requires that maybe have been solved. I think when you sort of look at it from a national perspective that are still in the law in terms of what has to be done. But I think certainly, the intent of meaningful use is really going to be through interoperability and the broader work on making sure that the entire stack of federal activities is efficient from a provider point of view.

And I think we've obviously had major challenges when you look at where providers are spending their time.

Arien Malec - Vice President for the Data Platform Solution Line - RelayHealth

Just to follow up on that question – so, thank you for that. Just to follow up on that question, we have the upcoming presentations on TEFCA, on the U.S. core data for interoperability. We've had, since the 2015 edition, a lot of work on refining the API requirements that were functional certification only. And we now have much better implementation guidance on SMART on Fire that's relevant for those APIs. But right now, that work seems to be divorced from MIPS, which is MIPS and the ACO program, and the other APN programs at CMS, in terms of requiring those capabilities as a floor capability. So, I'm not sure if this is a question for Steve, or Elise, or Kate, but I'm just trying to puzzle through, if I'm an EHR developer thinking over the next couple of years, am I thinking, am I anticipating that there's another sort of occasion – a 2018 or a 2019 rule coming down – that will then get incorporated into or a vision to MIPS or to APN program that'll drive development activity? And these kinds of forward-looking activities, if you're an EHR developer, are really important to start planning your roadmap cycles.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

I'm gonna hand it over to Kate Goodrich, who runs the quality group, in a second. But I think, Arien, your point is spot on. Obviously, we have to make sure that not just the private sector but the federal sector use on interoperability standards are in sync. I think that's a central point where this committee can, I think, be very helpful in delineating that. But let me ask Kate Goodrich, who is one of the directors of one of the very, very large functional areas of the Center for Medicare and Medicaid Services, to give her thoughts on this.

Kate Goodrich

Yeah, it's a really important question, and something we have been – well, for years, have close collaboration and conversations with ONC, with the meaningful use program, as well as with QPP, the Quality Payment Program, on how we can stay aligned. We very much understand the need from the provider and vendor communities in particular to have that predictability, to understand what the roadmap is ahead of time for the reasons that you just cited. And so, as I think folks here may or may not know, within our regulations for the programs that require the use of certified EHR technology, we do of course point to the certification standards that ONC puts forward. So, anything that ONC may do in the future regarding certification standards, it is our collective responsibility to be sure that we are collaborating and in lock step with that, so that through our regulations, we would continue to point to that as those standards would get updated. And that we are also working together to understand what not only the development cycles are for the new standards and when they're ready for putting into national programs. They'd obviously have to be ready for that. But to also be hearing together from the provider and vendor community, from this body, but also through other mechanisms that we share collectively to hear our stakeholders about what the needs are, so that we can again work together through our parallel regulatory cycles to be sure that ONC and CMS are aligned on this.

So, we've already started to have conversations about what that will look like over the next several years in terms of those kind of cycle times. So, definitely very much on our minds as well.

Donald Rucker - National Coordinator for Health Information Technology - Office of the

National Coordinator for Health IT (ONC)
Thank you.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Thanks, Kate. So, we may have time for just one more comment before we open up the public comment period. We will have additional time for a Q&A later at the end of the day. So, I will acknowledge John Kansky.

John Kansky, MBA, MSE - President & CEO - Indiana Health Information Exchange (IHIE) John **Kansky**, Indiana Health Information Exchange. I think it's a quick question, Lauren. Steve, you mentioned the three third party independent certifying bodies. Does ONC have any role in regulating the prices that they charge, or is it completely determined by the market?

Steve Posnak
It's completely determined by the markets.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Okay, that was a quick one. All right, maybe one more. Ken, I believe you had a comment or question, a quick one?

Kensaku Kawamoto, MD, PhD, MHS - Assoc. Chief Medical Information Officer - Univ. of Utah
I keep pushing the wrong button. Sorry. So, Steve, I just wanted to resonate and emphasize what you mentioned in your presentation about it always takes longer than you think. And I think that's just the theme here. So, I think it's really important for us to balance not letting the perfect get in the way of the good, but also being realistic, because I think sometimes we'll get farther if we really consider being thoughtful about not rushing forward with things that we're not quite ready for. So, I think all of us are aware of it. But I think sometimes, we'll go farther if we go a little bit slower and more methodically through this.

Steve Posnak
Everyone heeded your warning, to be sure. So, it's up to you, Lauren.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
That's okay. Maybe we have time for one more quick comment. I believe Aaron Mary is on the line. He may have a question. Are you there, Aaron? If not, we can come back after lunch today. So, at this point, we will open up our public comment period. For those individuals in the room, we will ask that you come to the center table here. You will be provided with three minutes to provide your comments to the committee. And if time allows, we will open to comments on the phone. So, at this point, Operator, can you please open the line for public comments? And we have one comment in the room so far.

Larry Wolf
So, hi, Larry **Wolf**. I'm with Matrix Care. I'm the Chief Transformation Officer there. Our message

is about integrated care and better outcomes. Our mission is to leverage technology to improve the qualities of lives for seniors. Our customers are primarily providers that support seniors; CCRCs, like planned communities, assisted independent living facilities, home health services, so the broad spectrum of many different kinds of care providers. We've been ranked best in class for long-term care software for 2017. We'd like to think that we're actually out there doing good and trying to address many of the issues that were raised here this morning. As a longstanding member of the health IT community going back into the mid-'70s, we've really come a long way. It's pretty amazing, actually. There's been, in many ways, a consistent vision by many people in the industry for connected care across an individual's lifetime that engages them as an individual, as well as engaging, clearly, their care providers. We've accomplished a lot, and there's a lot more to do, and I think we heard that today in the fire hose of things that Elise and Steve both summarized.

I'd like to point out, though, that it's not just about technology. It's also really about culture and organizational capabilities, that health and healthcare is a very human activity. And so, we have to actually move beyond just having good standards to the ways in which they get used, the ways in which they actually tie into the workflow. So, this has come up in some of the usability discussions, and I think there's a good guideline there about you want to make the right thing to do the easy thing to do. So, we really want to bake into the workflow, into the activities of care, the things that are really gonna accomplish this vision. And in doing that, and this is really why I feel like it's my personal charge, is to go find the pockets of where the future is now. Where are there already individuals and organizations, technology accomplishing the things we want to do in life was to work at the Interoperability Proving Ground to really put a spotlight on those activities to understand they're scalable, what prevents them from being scalable, to build the human community around it as well as the technical community infrastructure to make those things work and take them nationally.

We've talked about the access to information. I'd like to suggest we also need to equally focus on how we then present that information. We've really unleashed, if you will, the waterfall of information that's out there. And often, providers say, there's just too much there for me to deal with. I feel too exposed. I don't even know how to think about dealing with this. I'm so used to working as just a solo practitioner, even if I'm in a big practice or a big hospital system, I see the patient in front of me. I know about their care. I focus on what I'm doing. The whole context of what's going on, I really need their tools to help me.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Your three minutes is up.

Larry Wolf

Thank you.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Do we have another comment in the room? Yes, you can come forward.

Grace Collins

Is this on?

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Yeah, it's on.

Grace Collins
My name is Grace Collins, and I founded TeleCaregivers. It's a curriculum and a compendium app that helps train home healthcare workers about the latest in telemetric services from the homecare setting. And it's basically a workforce development project. What I've done is, over the four-and-a-half years that I've been working this, have realized that this telemedicine has changed and evolved so much, and been acceptable as a word that people are starting to understand, and the concept that 90 percent of people want to stay at home as long as possible. That a lot of the regulations have prohibited me to advance. But now, with Fitbit and all these self-tracking devices, regulations have been freed up. So, in my business plan, I've already put in, on a grander scale, ONC. And I commend you for all the work that you've done, because that's part of my goal, is interoperability and usability, from someone who's at a lower level, but is actually the person who's spending most of their time with the patient. That's not the doctor, it's not the nurse.

So, I think when you're building a business plan or a company, you have to build a better mousetrap. And so, you've done all the work. You've built in the standards and everything. I just need help and advisement as to put it together to where you're at now, because where it was years ago, it wasn't developed. So, it's a constant moving thing, and I appreciate a chance to be here and to tell you more about my project. And I hope CMS and other places will adopt this on a federal level. Thank you.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Thank you for your comment. Do we have any other comments from the room? And Operator, just to confirm, are there any comments on the phone? Okay, so it doesn't look like we have any comments from the phone. So, with that, we will break for lunch. We will return promptly at 12:30. Thank you.

Okay. We're gonna go ahead and get started. Operator, if you can please open the line again.

Operator
The lines are bridged.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Operator, do we have our line open?

Operator
Yes, the lines are bridged.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Great, thank you. Okay. Welcome back. I hope everyone had a great lunch. I just want to pause and do a quick audio check for one of our members on the line. Aaron, are you able to hear us now? And more importantly, are you able to speak? Okay. We will check in again with Aaron in a few minutes. Okay, with that, I am going to turn it over to Genevieve Morris to give us an overview of the trusted exchange framework – we highly anticipate it – as well as Steve Posnak on the U.S. core data for interoperability. Genevieve?

Genevieve Morris

I'm not sure what you mean by highly anticipated. So, this is Genevieve Morris, principal **WU** National Coordinator. You all came back from lunch like right on time, so clearly this is what's up on the docket. So, what we're gonna do, just as a slight modification from the agenda, so you're all aware, we're gonna go over the trusted exchange framework first and then pause for questions there, and then go over the U.S. core data for interoperability glide path, and pause for questions again, so that way, you don't have to listen to us for a full hour. It gives you an opportunity to sort of interject what questions you might have. So, first things first, on some just administrative things around the Trusted exchange Framework Taskforce. So, particularly for the public who weren't here for the administrative meeting, we will be putting together a Trusted exchange Framework Taskforce to actually develop the comments and feedback and recommendations that will come up to the committee for review and then come to ONC.

And so, the timeline that we're working on, we released the framework on January 5th, which was, I think, now two weeks ago. Today is our first official meeting. And then public comments are due February 20th. For anyone listening, we did change the date by two days, because it was a Sunday, and then there's a holiday, so February 20th by 12:00 PM, I think it is, comments have to be in. But because the HITAC folks and the taskforce have day jobs and need to do both that and their work on the taskforce, we are giving a little bit longer to the taskforce and the HITAC to actually get together the recommendations for ONC. And so, by March 19th, we expect to have recommendations from you all. Just as a point of order, the full committee meeting is March 21st, and so the comments will be coming to us, I think, on a Friday. And then on the 21st, those would be publicly presented during the full committee meeting. April 18th is the date for the U.S. Core Data for Interoperability Taskforce comments, so again, we're forming a taskforce around that too. And we're giving a little bit longer, just because of the nature of the USCDI, we have a little bit more time, whereas on the Trusted exchange Framework, because we need to move quickly on some subsequent stuff, we don't have quite as much time.

And then towards the end of this year, it says December there, we would have the HITAC final report that you all are working on for Congress. And hopefully around that same time, we would be releasing the final TEFCA. And I'll explain a little bit about the framework versus the common agreement once we get into the content. For the Draft Trusted exchange Framework Taskforce, we have drafted up an overarching charge as well as a detailed charge for you all. So, as you're thinking about wanting to volunteer to be on the taskforce, whether you're on the HITAC or not. These are the things that we're gonna be asking you to look at. So, for the overarching charge, we are looking for the taskforce to develop advanced recommendations on both parts A and part B of the Draft Trusted exchange Framework, which would inform the development of both the final Trusted exchange Framework and the common agreement, which we collectively call TEFCA together. The detailed charge has some very specific recommendations on part B. And again, I'll

get into what part B covers in a few minutes. But we're looking for recommendations around the recognized coordinating entity, the definition and requirements of a qualified health information network, as well as the health information network; permitted uses and disclosures; and a number of the privacy and security items that are included in part B.

These slides will be up on the taskforce website once that is set up, which I believe is going to be tomorrow at the earliest. So, if you are interested in the taskforce, either tomorrow or on Monday, go ahead and take a look at the taskforce webpage. Take a look at the detailed charge that you all are being given. Let us know if you have feedback on that charge, as well as if you're interested in being on that taskforce.

And now, onto the more interesting, perhaps, non-administrative-y kind of things. So, what is the Draft Trusted exchange Framework? So, it is broken into two parts, part A and part B. Part A is general principles for trusted exchange. So, we think of these as the guardrails, things that qualified health information networks should do just as good practice to ensure trust amongst folks who are exchanging data. And we've broken it into six different principles, which folks have seen. These are the same six principles we ask people to submit public comment to us on during our first public comment period. There really weren't a lot of changes there, aside from adding in security and privacy to the principle number four. Part B is a set of minimum required terms and conditions. And so, these are actual legal terms and conditions that are set out across the six principles, so we tried to keep some of the same organizational structure in part A and part B. It also includes a very long list of definitions. I will tell you, one key for reading the framework, when you are reading through part A, if something is capitalized, that means that it is an actual formal definition in part B, and you should pay attention to what that part B definition is, because that impacts who part A might be applicable to.

So, the way that we have thought that this would work, and we will certainly be getting comment on whether this is how we should make it work, the Trusted Exchange Framework is part A and part B. So, once we've received all of the public comments, we will go through and update part A and part B, and that will continue to be the Trusted Exchange Framework. We would then work with an industry-based organization called a recognized coordinating entity, which I'll describe more in a bit, who would develop the full common agreement. So, part B does not in any way contain all of the terms and conditions you would need as part of a participation agreement to enable exchange. We worked very diligently to focus only on the areas where there are variations or gaps between current networks that prevent them from being able to exchange data. And when I say we worked diligently, I mean we actually had meetings where we discussed it and said, is this your preference, or is this something we really need to do because it's a problem?

And so, we tried to narrow down what is in part B, but certainly, there are many other legal terms that you need in order to exchange data. And that would become the full common agreement, all those other legal terms plus the set of minimum required terms and conditions. So, over time, what ONC would keep up to date is the Trusted Exchange Framework, because we would anticipate that the minimum bar might need to be raised, particularly when you think about security requirements. So, we would keep that part up to date, and then the common agreement would have to mirror any updates that are made to part B on the minimum required terms and conditions. Happy to take questions on that when we get to the question period. But the full TEFCA is what would then be posted in the federal register at the end of the year.

As we developed the framework, there were five goals that really led our thinking around what we were going to do, the first and foremost of which is building on existing work done in the industry. And this is where I get to give you all kudos and props for the progress that we've made. We would be disingenuous if we did not say that we have certainly made progress in the last five to six years. We've made pretty significant progress in many different ways, but technologically, as well as from a policy perspective and a connectivity perspective. And so, we made every effort to use work done in the industry, including using existing standards that health information networks use now, building off of some of the ways that folks are sharing data now into what's in part B.

The second goal is to provide a single onramp to interoperability. And so, this is just the concept that right now, people have to join multiple networks, and they really, really don't like that, nor can they afford it. And it is just not really great for scalability, which I'll get to in a second. We think that health information exchange should work a lot more like cell phone networks, where it doesn't really matter which you are on and which one I'm on. We can still exchange text messages and phone calls. I can take my phone number with me if I choose to move off of Verizon to T-Mobile. That's kind of the way we think this should work, so that providers can pick the network they want to pick, join it, and be able to get access to the data that they need, and be able to exchange data with the folks they need to exchange with, including third party vendors that they might want to work with, or folks like qualified clinical data registries.

Goal three is that in all of this, we have to be scalable to support nationwide exchange. And this is where I think we all need to be a little bit realistic about where we are right now. So, we by and large have a lot of the health systems in the country connected and sharing data. But when you move into the ambulatory space – and that includes primary care specialists, long-term care behavioral health – we just do not have significant levels of connectivity from a query perspective. Certainly, a lot of those folks are using direct messaging to send messages, but being able to discover patient data if you're in that ambulatory setting is still just not there. And the way that I think we need to think about this is if we actually get to a nationwide exchange, the number of messages being exchanged every day is billions upon trillions of messages. And so, as we build out the framework, we have to think about being scalable to handle the number of broadcast queries every single day by providers who need to discover patient data in real time. And so, that was a very large consideration for us in how we scoped out the part B requirements.

The fourth goals is to build a competitive market. So, I think right now, there's a lot of providers who might want to work with third party vendors. There's a lot of third party vendors who have really cool, innovative products, but they cannot get the data to actually make those products work. And so, we want a marketplace that is not based on hoarding the data and selling the data, but is based on the data services that you can provide. And we think that that starts to affect some of the usability pieces. If we have more innovative technologies, more hooks into EHR systems, more sharing with third parties that providers want to use to do things like clinical quality measures, that gets them better usability. And so, we think it's important to sort of even out the market that right now is not very competitive in those spaces.

And then fifth, of course, is long-term sustainability. This has been a struggle of health information exchange for years. The word sustainability is instantly a bit of a dirty word that we

don't like to use, but we need that for nationwide exchange, because at the end of the day, we need to be able to exchange data not just today, but for many, many years to come.

So, who can use the Trusted Exchange Framework? From a stakeholder perspective, we tried to be quite parsimonious in who we thought might want to use the framework for exchanging data. And so, certainly health information networks are at the top there. But we tried to think about sort of all the different folks, if you're really trying to build a single onramp where providers and patients and other folks only have to join one network, that kind of means that all these other stakeholders have to be available to them via the networks. And so, as we were building out part B, we tried to keep in mind who would need to use it.

So, a couple of terms. There is term "health information networks" and "qualified health information networks." So, if you read through the Cures legislation and the statute, it says that we are, to developer support, a trusted exchange framework and common agreement to connect together health information networks. So, we have defined health information networks in part B in the definition section, which I will show you in a second. And we've also defined something called qualified health information networks. So, health information networks, this is a very broad definition, somewhat purposefully so, because there's a lot of organizations who fit into this. It also means that we're renaming some organizations, so apologies. We have to follow what statute says. And so, certainly, health information exchanges fit into the definition of health information networks. Some of the EHR vendor networks also fit into this definition. And there's a pretty wide range of folks who might be considered a health information network. And then we have a concept of qualified health information network, or qualified HIN.

And so, one, you have to be a HIN first in order to be a qualified HIN, but then there's an additional set of requirements around being able to locate what we're calling electronic health information, which is a new definition. So, again, check that out and give us comments. They have to have mechanisms in place to be able to enforce some of the minimum core obligations in some of the flow-down clauses that are into part B into their own participation agreements. They have something called a connectivity broker service, which I'll cover a bit later; be participant neutral; and I think kind of key, have participants who are actually actively exchanging data. So, in other words, if you are a network who's net new and you have no users or anyone actually live in production, then you would not be a qualified HIN, which I think is kind of important for making sure that we have folks signing on who can actually support what we need to be able to actually support.

So, how will this all work? So, I mentioned earlier something called the recognized coordinating entity, which is a new acronym, RCE. I will try not to use the acronym today as much as possible. But we are looking for an industry-based organization to partner with us to be the recognized coordinating entity. We at ONC understand that there are limitations to what we can do as a federal agency. There are limits to what we should do as a federal agency. And so, there are things around governance and day-to-day oversight and operationalization of the Trusted Exchange Framework that are really just not our core capabilities or things that we should be responsible for. And so, we want to work with the industry to find someone who has some experience with doing this, who's creative participation agreements and knows what needs to be in them, who knows how to bring stakeholders to the table to deal with areas of disconnect between what some stakeholders might want and others might not want, and then someone who has some experience doing that on a pretty broad basis. And so, we are planning to do a

cooperative agreement.

If you are familiar with the work of ONC under the state HIE Cooperative Agreement Program, it's the same type of vehicle, which allows us to work very closely in partnership with the organization versus doing a straight-out contract. We would be releasing – so, assuming public comment agrees that this is the approach we should take, we would be releasing a funding opportunity announcement for an open and competitive and transparent bid. Around the April to May timeframe is what we're timing for if all goes our way, with the goal of having the RCE actually in place no later than August so that we can get to work with them on the common agreement.

By opening a competitive process, what I mean, for those of you who are not familiar with how our contracting process works, the FOA gives you – I think it'll probably be 30 days for folks to come in and submit a bid into us to be the RCE. There will be some money attached to the cooperative agreement. It will be a multi-year cooperative agreement. I think we're aiming for three years right now. They can submit their bids into us. We have an objective panel who are not ONC staff, but are from the industry, do a review of all of the bids that we get, and they make the selection. And so, we're anticipating a couple of organizations will have interest in fulfilling this role within the industry. And they would have oversight enforcement general governance responsibilities. So, a structure of a qualified health information network, and I'm gonna go into more detail here than we have in the webinar. So, the concept of a qualified HIN is that they would have this connectivity broker service, which basically facilitates the ability to do broadcast queries. And I will get in a minute to the definition of what that means. We think broadcast queries are really important to being able to actually support nationwide interoperability, because at the end of the day, I don't really remember all of my doctor's names.

So, I'm maybe your test case. In six years, I move six times, which means I had six different PCPs, six different specialists, probably. And I'm really bad at names, so I actually didn't remember who any of them were. And so, directed queries that work based on my zip code or on me knowing the name would be totally inefficient for actually getting all of the data on me, and that's just not – and I think a lot of people actually fall into that same bucket. Probably it can't just be me. So, broadcast queries where you don't actually have to know who you're asking for the data from are really important to support – to actually get us towards nationwide interoperability that works. And so, some of the services that we've set up as part of the connectivity broker are meant to facilitate being able to do broadcast queries without having to have centralized infrastructure. And that's a pretty important component. Again, we'd love to get comment on this. Our feeling on centralized infrastructure of an NPI or record locator service is that that opens you to some pretty large security concerns, and that might just not be what folks want. But certainly, give us your feedback on that.

And then you have participants and end users. So, sometimes end users can also be participants. It's going to depend on sort of the type of network the qualified HIN is. We are trying our best not to specify the type of participants that any qualified HIN might have. There are certainly a lot of different amalgamations that any different network could have that's gonna be based on the user cases that they support and the services they want to provide. And we don't really want to dictate that. However, because we 've been asked a lot of questions about who is and isn't a qualified HIN, we wanted to give a little bit more detail about how we could see some of the amalgamations working. And I would say that these are just examples. But the first one there,

and this is not something that actually exists today, would be a qualified HIN that has a bunch of payers who've agreed to follow the terms and conditions of the Trusted Exchange Framework, where they're gonna facilitate and allow for broadcast queries into their network. And so, the qualified HIN would be brokering those queries and for all the payers.

A second example is a qualified HIN that's somewhat vendor-based, and so, they have EHR vendors. They have health IT developers who might be analytics products or care management platforms, or all of the different health IT vendors that are out there, or it might be even an HIE in the mix as well. Third example would be a qualified HIN that has federal agencies and health systems and maybe HIEs all in it together. A fourth example could be a network of just all regional HIEs. I think part of what we want to explain here is that a regional HIE on its own would likely not be a qualified health information network. There could be some chances that would happen, but likely, they would not. A regional HIE that has regionalized, and so they're in actually different states with different infrastructures set up could be a qualified HIN if everyone agrees to the terms and conditions and sets up a connectivity broker.

Likewise, a single EHR vendor health information network would not be a qualified HIN based on the participant neutral requirements. A single health system would likely not be a qualified HIN based on the participant neutral requirements. And so, we want to try and make that clear. To give a little bit of the intent of what we're thinking there, again, this goes back to lack of centralized infrastructure. If you're going to support broadcast query, at the end of the day, you need a fairly small number of qualified HINs, because otherwise, you're sending out thousands of broadcast queries. And if you multiply that by the number of queries that you could get in a day, there's just not enough bandwidth to do something like that. And so, what we're aiming for is a smaller number of qualified HINs that can handle the broadcast query nature of things that we're requiring. So, one of the terms I've actually heard tossed around is we're suggesting a network of networks of networks, just to make it more complex. And I'm sure you all will have questions on that when we get to Q&A.

So, overarching picture of how all this works, the regional – sorry, recognized coordinating entity – I almost looked up to REEC there. My bad. The RCE listed at the top is an umbrella organization working closely with ONC. And then they would have oversight of the qualified HNS. And so, what we're anticipating is, at the end of the year, when we post in the federal register the Trusted Exchange Framework and common agreement, the common agreement is an actual legal agreement that folks would "sign onto" and agree to abide by. I put "sign onto" in quotes because there's a lot of different ways you could actually do that without requiring someone to put a signature on something. But that would – they would agree to the common agreement. The RCE would then have oversight of them. Broadcast query would work in the sense that if I have an end user who wants the go fish method of I want all the data on Genevieve Morris, I as the end user would send that query up through my participants. So, let's say it's Dr. Smith. He would send it up through his EHR vendor. It would go to the qualified HIN, who would need to send that query out to all the other qualified HINs, who would likewise need to figure out how to do the broadcast query inside their own internal network, return the data back to that qualified HIN in some sort of coordinate fashion so that you're not actually getting 20 million different queries sent back to you, but you're getting one sent back to you from each of the qualified HINs.

And so, what we've done is set up some standards, some technical standards that the qualified

HINs would have to use between each other. We did not specify internal standards a qualified HIN would have to use. So, if you want to use **Fayer** or IHE or whatever you want inside your qualified HIN, you're more than welcome to do that. Between qualified HINs, we have set out the requirement that you be able to support both IHE, **XPS.b** specs, as well as the Fire specs. And particularly for the population Level Fire spec, when that becomes available in two to three years, it becomes a requirement for the qualified HINs to be able to support that as well.

So, just some clarifications. And I'm gonna be real honest that I'm struggling to read this from back here. So, this is a little bit from memory, perhaps. But we wanted to clarify sort of what's included versus not included. From an included perspective, there are terms and conditions that apply to the qualified HIN, and there are some that apply to the qualified HIN's participants and end users. Again, we try to be very careful about what would pass down to participants and end users, and focused only on items that would basically make the qualified HIN not function if you didn't pass them down. So, for example, if the qualified HIN has to support all six permitted purposes, but their participants only support two permitted purposes, the qualified HINs actually can't do what they're supposed to do. And so, those types of terms and conditions, we did flow down, so that's included. We also included a set of technical and standards requirements between qualified HINs. But like I said, tried to exclude what they do internal to their own networks.

And then another sort of important point is that we're covering a fairly broad use case of broadcast and directed query for the set of permitted purposes that I'll get to in a minute, but at the end of the day, it doesn't prohibit you from setting up other agreements for things that fall outside of those use cases. So, what we would anticipate is that the qualified HINs will want to offer other services to their participants. And we want to allow room for that innovation to actually take place and for them to be able to sustain themselves because they have other services they're offering. So, you are welcome to set up other agreements for services that fall outside of those use cases, so long as it's obviously not impacting the ability of those use cases to be able to function in accordance with the Trusted Exchange Framework and common agreement.

And so, an example that I'll give of something we left off the table, one of the reasons – well, there's two reasons, really, that we didn't include push messaging in our minimum use case. One is that we actually felt like that market has done a really good job of figuring out the trust issues, thanks to some of the work by Direct Trust. HINs communicate all the time and have no significant issues with it. But the second is that some of the innovative services that we think folks are gonna want to offer, like notification services or sending a risk score, those are all push-based services. And we wanted to ensure that people could innovate on those types of services and be able to recoup funds so that they can continue to make their networks work. And so, those were some of our thinking around that. I'm sure we'll get comments on that.

So, the use cases that are covered, so we have six permitted purposes, treatment payment, and healthcare operations, which are all the HIPAA definitions of those three things. And then we've added a couple additional permitted purposes based on, honestly stakeholder feedback, where we talked to health information networks, and they told us, these are the areas where we struggle to get agreement to share. So, public health is its own specific permitted purpose, which includes public health reporting to state and local and federal agencies. Benefits determination is non-healthcare related benefits. So, that honestly is meant to meet some of the needs of the

federal agencies, like SSA, or Social Security Administration, who need to do non-healthcare benefits determination, and individual access, which we think obviously is an important permitted purpose.

I will say on the individual access use case, we tried to set up part B so that if a qualified HIN doesn't themselves want to offer patient access, they don't have to. So, there's a number of reasons why I can think of a qualified HIN not wanting to offer direct patient access. Some is the identity proofing and authentication pieces. But if you get a query for the individual access use case – so, let's say that there's a personal health record vendor who's a member of a qualified HIN, and a patient close into that PHR and says, I want all of my data, no matter it exists. That PHR sends the data up through their qualified HIN they're a member of. If you receive that query and it's for the individual access use case, you have to respond to it. Even if you're directly not giving the patient access, you need to respond with the data because it's for the individual access permitted purpose. That is actually true for all of the permitted purposes that we have up on the screen. If you receive a query for any of these six, as a qualified HIN, you would need to respond back with the data if you have the data.

And then the three use cases that we have, two of which are out the door use cases – the third one is a future use case, in some senses. The broadcast query, which is, again, the go fish method, to steal Steve's terminology he gave me yesterday, of I just want to know – I want all the data on this patient, no matter where it exists, because either I don't know where it all exists, or I want to make sure that I'm not missing something, or I'm trying to do some type of population health analysis. So, that is sending it out to everyone, getting the data back in. But there's also times where a directed query is what's necessary, where I know exactly the doctor that you went to. And I don't actually want all of your data from across the healthcare system, I just want to know about that one hospital visit that you had. And so, directed query is a targeted query based on geographic location, the name of the physician, name of the health system, a number of other different ways that you can do a directed query. Under part B, qualified HINs have to be able to support both of these. So, you can't just support directed query. You have to be able to actually respond to both broadcasts and directed queries. Certainly, you're going to initiate them based on what your users want. So, if your users are never initiating a broadcast query, that's fine. You still have to be able to respond to one.

And then the future use case, and this is based on when standards become available, is population level data. And so, this is under the permitted purposes we have, which means you have to have some type of relationship with the patient, being able to query and retrieve multiple patient records in a single query. And I do want to clarify, this is talking about based on a patient panel, right? So, this is I have my list of 100 patients and patient names, and I'm gonna query and get their data back. This isn't a fishing expedition because I just want every patient who has diabetes that might be in every healthcare system, right? That's not what we're talking about with population level data. This is being able to exchange large amounts of data for particular purposes. That use case would be enacted once the Fire specification that we are working on with HL7 and the SMART on Fire folks is available. I think we put in a timeline of when you would have to adopt that. I'm sure you all will tell us if that timeline is reasonable.

Privacy and security protection, and then I'm close to almost done for questions, which hopefully we're doing okay on time. We did include some identity proofing and authentication requirements. And we are really hoping to get feedback on this because it is actually new

requirements in some senses. We decided to use the new **NIST** 800-63 publication. For those of you who are not super familiar with this world, the current NIST publication has levels of assurance, LOA, and it's levels one, two, three, and four. And that covers both identity and authentication, which can often be confusing because they're actually in the same spec, and **[inaudible] [02:35:10]** folks have struggled a little bit with that. NIST, based on the new security threats that we face, based on the number of breaches that we have had in the last two to three years, undertook a fairly significant process to update to a new identity assurance level and authentication assurance level requirement. So, they're now two separate things. It's IAL and AAL, and it is three levels, one, two, and three.

Basically, for those of you who are familiar with the old LOAs, LOA-2 is gone. LOA-3 is now basically IAL-2 and AAL-3. It's a lot of acronyms, guys. I'm sorry. So, what we did is because of the security risks and because we understand that this is fairly large amounts of data flowing around, we aligned to the new NIST publication. And so, what we included in part B is that identity proofing has to be performed at IAL-2. So, that means that you're giving fairly strong pieces of identity proofing with photo IDs, and those are being verified against some sources. Because of the way that they set it up with verification having to be at the same level as the number of IDs that you need to give – so, in other words, in level two, if I'm using my state driver's license as my ID proof, technically you're supposed to actually verify that against the DMV records. But because for patients in particular, that's going to be potentially very difficult and could prevent them from getting access to their data, we worked with NIST to create some exceptions.

And so, for the individual only, not for other folks, we have a concept of a trusted referee, an authoritative source. Instead of having to check the DMV registry, if you have gone to a physician practice and they've looked at your ID, and by looked, I mean they've actually looked at the hologram and made sure that it's a legit ID and that you look like your picture, they can act as an authoritative source and say, I'm acting like the DMV would act, and I'm saying that this is a valid person who should have access. We also built in the concept of an antecedent event. So, in other words, if I had my encounter five months ago and you did that verification, and now I want access to my data, that former verification that you did can count. I don't have to come back into your office and do that verification again. I will say this is still a little bit clunky. We are very aware of that. We are very much hoping folks are going to give us feedback on this and give us ideas of how we could build this out better, because this is a bit of new territory, I think, for everyone.

The cool thing about what NIST has done in the new publications, though, is incorporated some of the new technology pieces, like being able to use your smart phone for some of the identity proofing and authentication. And so, we're excited about some of those technology pieces that could be brought to bear, but we also need to figure out how that works in our industry. And so, we are very closely monitoring some of the efforts going on right now by non-federal organizations to deal with the individual identity proofing and authentication piece. We are quite hopeful that some of the work they do this year would actually be able to be built into the final Trusted Exchange Framework. It just really wasn't ready at this point to put it in here, but we're hoping to get good comment on that.

And then authentication of end users and participants is AAL-2 as well, so that is multifactor authentication. Again, based on the number of breaches that we have had, you need a fairly high level of identity proofing and authentication to make sure that the right people are getting

access to the data, particularly when you're doing things like broadcast query. And so, we tried to be quite security conscious on that, but certainly are looking for feedback.

I'm gonna pause there and take some questions before we get to the USCDI. I don't know how long I just took there. Hopefully, we're on track, but.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Yes, no, we are good on time. So, just as a reminder to please state your name before your question or comment. I also just want to acknowledge that prior to lunch, we had a couple of questions from Christina and Leslie prior to the break for Steve's presentation, so I just want to check to see if your question has been answered.

Leslie Lenert – Chief Research Information Officer – Medical University of South Carolina
It hasn't, but it's off subject now.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
I'm sorry, say that again?

Leslie Lenert – Chief Research Information Officer – Medical University of South Carolina
No, this is Leslie Leonard. Yeah, no, my question wasn't answered, it's just off subject now. My question was, based on the policies we've implemented here over the last eight years, what's your evaluation strategy for the things that you're doing, and how is that built into the standards and the policy generation activities you have now? What's the feedback loop for them? Now, that question might take some time to answer and might distract from our present conversation, but.

Elise Sweeney Anthony – Director of the Office of Policy - Office of the National Coordinator for Health Information Technology
Well, I can answer quickly, or at least give an overview. So, within ONC, besides Steve's team and my team, there are a number of other teams that work on kind of the operations of ONC. One of them is a team that's led by **[inaudible] [02:40:23]**, who's actually here, that focuses on evaluation and analytics, and focuses on that exact question, of how what we are doing is being measured across kind of different spaces. So, for example, on the standards and technology side, looking at things like uptake of certain criteria and products and so forth, as well as where things stand in terms of interoperability. Those types of activities will continue going forward and help us to kind of inform our policy going forward.

There's also kind of, I think, an inherent feedback loop that we try to build in. There's a lot of stakeholder engagement, as Dr. Rucker mentioned earlier, that we use that provides feedback into what we're doing, makes sure we're hitting the right marks. And then the last thing I would add is we always try to build in these new opportunity, these new efforts that we're doing, opportunity for public comment and public engagement and feedback, so that we're doing it in an iterative fashion. We're releasing a draft, we get some feedback, and then we release the final. Then once the final is released, we still go back and take in feedback we've learned from the operationalization of that project. One example would be the model privacy notice, where

we released a draft, the 16 drafts. We did a challenge to get some more feedback on how it would look once it's out there, and then took that feedback and built into the 2018 in addition.

Leslie Lenert – Chief Research Information Officer – Medical University of South Carolina
Give me an example of an unintended consequence you've identified, and what you're doing in the future to prevent such an unintended consequence from happening again through the policy that you've created?

Elise Sweeney Anthony – Director of the Office of Policy - Office of the National Coordinator for Health Information Technology
Well, let's see. Unintended consequences that we've identified. I think one of the things that we've identified, at least for me as we were putting together policies, is making sure that the policy we're putting together doesn't just touch one particular stakeholder community. And I think it's a little bit to Arien's question earlier, is identifying ways to make the policies that we're putting in place, that Congress has called for us to put in place, that the administration has identified as priorities, that they are understandable and accessible to different populations. So, we've identified that, I would say, earlier in the process. Like when we were working on the 2015 edition, something we did different after feedback saying, hey, I don't really quite understand what's in the rule, or how does it affect this population or another, is we did simple one-pagers that provided information – quick access information for stakeholders to understand what was in the rule and how it could be helpful to them, depending upon where they sat in the health IT ecosystem.

We're building upon that knowledge, and we're doing more so now in terms of making the resource applicable and available to different groups. Likewise with the playbook, that also happened, where we learned that, hey, people are saying we don't quite understand what ONC is doing in this space or how this is applicable to my practice. And the playbook turned out to be a really helpful resource to help address that unintended consequence of doing what we think is great work in trying to help the industry and the environment where they need to be for health IT, but making sure that it's available for the population so that they understand and can benefit from it.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Okay. So, there are – Christina, did you have a prior question?

Christina
Yes. Mine had to do with – in reference to Steve's presentation on some of the standards that we have. ONC's done a tremendous amount of work, especially over the past year, on the interoperability standard advisory. And it's really become interactive and an extremely valuable resource to the community. While the ISA is really well positioned to continue to grow and evolve, I think it is extremely important to continue to educate diverse groups and stakeholders to continue to drive adoption and our knowledge of the gaps in standards that do exist. So, I was wondering what ONC's plans are to ensure that we continue to educate folks outside of our normal kind of dialogue and conversation to help inform the ISA's growth?

Steve Posnak

Sure, thanks for the kind words. As I think was referenced earlier this morning, perhaps by Arien's comments, how we effectively communicate is sometimes is 80 percent of the job in terms of getting out the quality of the product that we've produced. So, the standard stuff isn't sexy, and the presentation that Genevieve just gave is gonna be way more interesting than three slides about data. But garnering that interest and identifying some of the gaps in it, I think incidentally, just from a human behavior perspective, if we see something that's missing that's important to us, it's a way to help initiate that engagement. And so, I think to your point, if there are areas where different stakeholder groups we've worked with, consumer advocacy groups and the like, to get more of their interests reflected in the interoperability standards advisory, same now from a precision medicine perspective. Those are some of the newer areas that we've added more recently, where those particular groups have said, include me here, I'm here. And we very much encourage that continued collaboration.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Okay. So, not to delay the **test** comments any longer. I will start with Steven Lane and then Arien.

Steven Lane - Clinical Informatics Physician Director - Sutter Health

Thank you. Steven Lane from Sutter Health. Genevieve, I had a specific question. You were talking about the population level data being queries based on a patient panel, and then you gave an example of what it wasn't, referencing a group of patients, all the diabetics looking for data. I was trying to fully understand what you were saying wasn't a population health query.

Genevieve Morris

Yeah. So, I think the clarification we were trying to make is that we weren't intending for the population level query to be, I would like to know all of the patients that have diabetes in the United States. Let me send out a query for all diabetics. That, I think, gets towards use of data and what you might be using it for, which folks may not be comfortable with. But also, and you can correct me if I'm wrong, from a technical standpoint, the **[inaudible] [02:46:41]** that's being built out is not being built to query based on things like problems and conditions. It's being based on querying patient demographic information, basically.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

Let me clarify with a positive case as opposed to a negative case, which is I think, Steve, what you're asking for. So, the feedback we have gotten from stakeholders is that there's a lot of provider to provider, the classic interoperability. And a lot of discussion on that. But what has been missing are standards on if I want to – for example, I'm gonna give you a couple of the key use cases. If I'm a payer, right, pick your payer group, do I have any standards to, from a large provider, for example, get data with any standards? Right now, those discussions are pretty much individual negotiations, individual scripts it's built. I can say I worked at one midsize provider. We had 190 different outbound payer scripts of data for what was ultimately a small, midsize company type of thing. So, can we get some standards around that, and at the same time, leverage all the work, and Fire, and the **[inaudible] [02:48:06]** standards, and **Jason**, and all of this modern stuff, so that every one of these things is not a script, an individual one-off script.

So, there are a couple very important use cases. Probably the biggest one is ultimately, most of our care is paid for and purchased by large payers. That's just a fact of the world. And how do

those people who are buying care, right – because ultimately, ONC represents the citizens – how do they computationally look at this? If you look at all the discussion that's been had over, let's say, the last half dozen years on **a learning** healthcare system, how do you get, for example, machine learning into these datasets without lots and lots of commotion. CDC, I don't know if they're on the line, but massive reporting requirements on public health that are there. There is a whole ecosystem of population health vendors who also have a lot of these things. So, what we're trying to do is to leverage the same standards that we're building for these other cases to that use case. It is important to understand what I think Genevieve was getting at. These are not just – and you could use this. Let's say if Sutter wanted to do an individual query and be more efficient about it, absolutely, you could do it. So, not a general fishing expedition of just sort of research type of thing without IRBs and all that.

Very importantly, this does not expand the permitted uses beyond HIPAA, right? So, all of these types of queries are things that are already happening today inefficiently and expensively, and what we're trying to do, as part of building this network of interoperability, is make the same permitted queries efficient. Hopefully, a couple of the positive cases give a little bit of a sense. And there's extraordinary excitement about this. I mean, if you look at all of these modern computer science technologies that are out there, I mean, why is it – let's just take a little bit of a thought thing – why is it that Amazon can use more machine learning to decide whatever crap I bought allows them to sell me some more stuff when I don't have a computational way of knowing whether somebody with the same medical problems I have, whether that treatment worked nationally? And even for large sites, I think there are gonna be collaboratives and rollups and stuff like that. So, we're really trying to have that pathway to modern computing at scale. And that's what that is about.

Steven Lane - Clinical Informatics Physician Director - Sutter Health Thank you, Don. Just a comment back. You mentioned the challenges of payers requesting data from provider organizations, and how those end up being one-off arrangements. In my experience, it's often based on which attorney gets assigned to look at that transaction. And the concerns that inevitably come up around payer access to data – is the payer performing treatment? Are they doing operations? Is it just purely for payment? I know that a year or so ago, ONC offered a lot of guidance around what does HIPAA really say about individual access? It would be very helpful, I think, if there were clearer guidance about what HIPAA says about payer access for these different use cases, because of course, payers aren't just paying anymore. They're doing so much more in our ecosystem. And that would be very helpful, I think.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

Thanks for your feedback. Thanks, that's great feedback. Obviously, there's, as we all know, a lot of confusion about the nuances of what HIPAA actually says.

Genevieve Morris

Yeah. So, just one note on that. OCR did put out guidance on operations. I think ONC worked with OCR on it, I think about a year-and-a-half ago at this point, which we can dig up and share with you all, that clarified particularly when we say operations and care coordination, what does that actually mean. Yeah.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health

Information Technology

Okay. So, we have a number of comments lined up. Arien?

Arien Malec - Vice President for the Data Platform Solution Line - RelayHealth

Thank you. Arien Malec, **[inaudible] [02:52:30]** Healthcare. I'd also point out Lucia Savage did a set of blog posts detailing HIPAA, and went in depth in treatment and operations. I'm not sure she went into depth on payment in those contexts. So, I obviously have a lot of detailed comments on TEFCA, which I will refrain from getting into in this session. But I will endeavor to participate in the taskforce. So, some big stuff. So, first of all, I applaud ONC. I think establishing a norm, a baseline floor norm for the ability of all participants in the healthcare system, patients, small practices, as well as large institutions, to have an equal playing field with regard to access to information for treatment for individual access and for other permitted purposes is incredibly useful. And I think some of the fundamentals from a policy perspective that ONC's put out, I think, are significant advances in that area.

One editorial comment. I think in some cases, the language that the TEFCA uses, when you look at the details, doesn't match, and I think it creates some problematic interpretation. So, for example, these single onramp and qualified HIN, I think you very helpfully noted that there's a lot of HINs that do a lot of different things, many of this TEFCA approach doesn't touch because they're working well. We have ePrescribing networks. We have lab and result networks. We have direct trust and directed exchange networks. So, I think there could be, in the future, a different choice of language and choice of words that makes it more clear what the qualified HIN is or what the qualified HIN is attempting to do.

From a policy perspective, in my experience, ONC's been successful in one of three ways when it establishes standards and policy framework. One is establishing floor standards when there are natural, well tested standards in existence, but where not all participants are using them. And it's very helpful to say, everyone needs to get up to the given floor. In the case of API-based access, when we looked at this for the current generation of standards in certification, we knew that SMART on Fire was the ultimate result, but we also knew that we couldn't pull something off the shelf that was well tested, well shopped, and well maintained, and say everyone needs to get to that. And so, in that case, ONC, I think very helpfully went to a functional certification approach, kicked it to the private sector, and organizations like the Argonaut Project took up that work, worked with HL7, and established more actionable standards that most of the participants have adopted with regard to meeting the API certification requirements. And it puts ONC in a future very helpful position because a lot of that groundwork's been done and tested, and you can start to raise the floor.

In other cases, frankly, there's been a lot of work, enough signals, enough opportunity, and people haven't moved, and there's a market failure. And so, naming a standard is sometimes a way of – even though it's not well tested, even though it's not well defined, is a way of cutting through market failure. There's a lot of places where the TEFCA is very specific in terms of which permitted purposes and uses fall under common carrier requirements versus are seen as value added services. I think there's a floor right now where treatment and patient access are seen as common carrier. And then I think there's other cases like payer-based access for risk adjudication that frankly aren't seen as common carrier requirements. And the TEFCA sort of cuts through that and says, no, no, no, we're gonna count those as common carrier requirements. There's a set of named standards. You went through the identity proofing standards.

And just in the range of policy choices that you had available, I'm wondering why you went to what I would consider to be option three, which is cut through market failure and go name a bunch of stuff, as opposed to sticking with option two, which says some of the stuff isn't worked out, but hey, RCE and purported qualified HINs, here are the policy goals that ONC's established. Why don't you guys go work this out, figure some of this stuff out, and then establish it, and as it gets established, then we'll start to name standards.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

Let me answer part of that, and then I'll turn it over to Genevieve. I think part of it is as we look at this, again, some of this is just, we've gotten a lot of feedback. We've probably met with a hundred stakeholder groups to date. I think some of this was a sense that sort of the current build-out, if you will, which I'm interpreting as your number two item, but maybe that's totally erroneous, interpretation has fairly narrow purposes that are very provider-facing; in many cases, are tamping down economic competition, tamping down new ways of delivery system, and are really more for the convenience of providers than they are for the convenience of patients. I think the fact that all of this got put into law is sort of the Congressional recognition that in fact, these things have not worked for patients. Obviously, Congressional, if you will, rule-making, aka laws, right, so above rule-making, is a little bit of a coarse instrument. And so, we're sort of left with the operational issues of how do we reflect that?

But I think it really – the transition, if you will, from your item two to item three really reflects the broader public recognition that patients are not in control of their data, and are in fact disenfranchised from these conversations, right? I mean, they're simply just not part of it. And so, then the question becomes, we're using as much of what's out there, getting these broader purposes, how do we do them, and there will be, I believe, a work group on this. And we absolutely – you obviously have a vast range of experience on that, and we look forward to getting your and everybody else's thoughts in both the broad and the specifics, because if this were easy, it would have been done.

Genevieve Morris

So, I would counter a bit and say that, in my opinion, option three, if we had done that, would have been us actually writing the entire common agreement, much like the previous ONC did when they dropped **Epidursa**. And so, we think we actually ended up closer to option two by trying very narrowly to focus on cutting through those areas where we see problems based on the analysis that our contractors did of the various participation agreements. And so, I sincerely mean this. We had hours upon hours of conversations to take things off the table that were maybe **[inaudible] [03:00:34]** pet things, that are important, but aren't causing problems. And so, we may not have hit, obviously, totally to option two, but that was what we were actually aiming for. And so, we look forward to comment on if there are areas where we should have been less specific. And there's probably some areas where we should have been more specific, frankly.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Okay, thank you. I'll move on to Clem and then Carolyn.

Clement McDonald – Director - National Library of Medicine

Some of these may be a little reflective of Arien's. But I was struck by some of these things seemed to be more about how to do rather than what you want to get done. Just a few of them. And I don't really understand why you totally forbid a centralized system. I could conceive – actually, I hope some day Medicare will pull in a lot of the clinical data for those people, and it would all get done. It would be a lot less work in the long run. And then the push thing also, I didn't quite get, because the classical way things have worked very well in clinical care – I know it's not the patient – was you say, I want this thing, and you send it back to me, you push it back, you want to get it done. And we could do the same with patients when they check into a clinic. I mean, rather – they won't get their history, but going forward, it just seems maybe so easy. I just described that. You just give me your number as you check in. It's a field. And it goes there whenever it gets done. You don't have to keep looking to see if it's back and all that kind of stuff. Assuming there's a there. And I'm assuming you want a there there. Some kind of medical record thing.

So, that's sort of the big thing. And are you considering any of sort of the general logon mechanisms, or they're not good enough, like Google or Facebook? We see them everywhere. I don't use either of them, but I know you can do big things like your bank accounts and stuff, I think, with those. And they're there, but I don't know if they're any good. So, I just wondered if you're considering them.

Genevieve Morris

A couple of responses. I think on your first point, what we've heard from stakeholders is that they don't really want centralized infrastructure. Certainly, via the comment period, we might hear something very different, but from talking to a lot of technical folks, as well as privacy experts and security experts, a single master patient index that would effectively be for the entire country if all the networks connect and all the providers are using them obviously is a huge target for hacking.

Clement McDonald – Director - National Library of Medicine

Well, if people don't want it, don't do it. But I don't see why we proscribed it. I mean, some governments are doing it very – I mean, Estonia and some other bigger ones are doing it. The VA does it. They've got like a small country. They think it may not work, but just to say you can't try it or you can't use it, it's gonna discourage any sort of invention –

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

Well, there is a parallel with the general accounting office, I think, I believe, in Cures on studying some of the, if you will, global identifier. I think there's also a very interesting question with modern computer technology, what other ways can be used to identify patients.

Clement McDonald – Director - National Library of Medicine

Well, I wasn't talking about identifiers. I was talking about dumping the record in there. It's even worse, probably. But Medicare as 40 million, 60 million now, with all the drugs and all the encounters in it. I'm using it as a researcher. And wouldn't it be nice if patients could poke in there and pull their data out just as easily?

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

I think Medicare is looking at that.

Genevieve Morris

And we would be open to comment on whether that approach would work better. To keep us moving, because I know we have more questions, on the push use case, the main reason we didn't include push is because in talking to stakeholders and looking at the market, particularly with use of direct, that is functioning very well. So, early days of direct, and I did some analysis for ONC as a consultant, HISTs, were not sharing with each other. EHR vendors were not sharing with each other direct messages. And due to the framework that Direct Trust set up, that is functioning very well. I have yet to see a HIST who's on the Direct Trust network who isn't sharing with another HIST. And so, we felt like mission kind of accomplished, industry figured it out, great job. We don't necessarily need to touch that.

On your last question on Google and Facebook logins, we actually have been working on a pilot project with NIST and – it's either Cedar Sinai or Mt. Sinai, I'm blanking on which Sinai it is – to be able to identity proof a patient and then use their Google or Facebook credentials. I would say Google and Facebook don't actually identity proof, and so you still need to have some type of mechanism for identity proofing prior to them being able to use those credentials in your network. But we are – they're actually doing that project against the new NIST publication, and so we are closely monitoring that pilot to see whether there are outcomes that we could also incorporate in.

Clement McDonald – Director - National Library of Medicine

Just to clarify, you're saying that push is already working so well you don't need to do it? Because that's what **ONC** said about lab messages, that we don't have to worry about pushing to the next level because everybody's doing it, but they really weren't.

Genevieve Morris

I would say push from a direct perspective is, I think, functioning fairly well. Now, given now to Steve, there are certainly some workflow issues related to the use of the direct, but from a connectivity perspective of the data moving, that's not problematic. The other point that I would continue to make is that this is a floor, so just because it's not part of our core floor use cases does not mean you could not still use the terms and conditions of the framework to push use cases if you wanted to push lab results or push to public health. So, that certainly is a possibility, where you could do that use case and still use most of the terms and conditions in the framework.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Okay, so we do have a number of additional questions and comments. Carolyn?

Carolyn Petersen, MBI, MS – Senior Editor – Mayo Clinic Global Business Solutions

Okay, thank you. I want to compliment you on the really thorough presentation and the large set of slides and materials to help us better understand this. I had two comments with regard to some of the patient-related aspects of what's been presented. First, with regard to the structure

of the qualified HINs, looking particularly at the examples on slides 49 to 52, these don't show the patient as a participant in terms of the whole process. And of course, I realize today, patients aren't directly controlling their EHR. In some cases, not at all, and in others, in a very, very limited way. However, we do see a number of technologies on the horizon in which patients will be contributing data potentially directly. For example, remote home sensing, the patient-related outcomes measures that are used during things like chemotherapy and follow-up, patient developed and driven technologies, and work being done by patient-powered research networks. So, I'm recommending that the ability to accept data from patients is given as a requirement for these qualified HINs, understanding that at some point in the future, there will be that need, and we won't want to have a lag of some years while the technology catches up to the new need.

Genevieve Morris

Okay, I think that's fair. And I would say, most of the time, we were thinking of the individual as an end user. And so, in my mind, the participant would probably be the app developer or personal health record vendor who is helping facilitate the exchange of that information, with the individual being the end user. And so, it may not work out that way, right? They could potentially directly participate in a qualified HIN. We just don't see a lot of that out there right now, and so we were trying somewhat to be a bit of a mirror of the things we see now. But fair point, yeah.

Carolyn Petersen, MBI, MS – Senior Editor – Mayo Clinic Global Business Solutions

Yup. And we're absolutely at the very beginning. We have the **Niscout** project, and of course, having seen a cascade of other patient-developed technologies. But with FDA's increasing openness to work with patient groups and their guidance to industry to make patient data available to patients through device manufacturers, we can see that might be something on the horizon. My second comment is in a similar vein, having to do with the RCEs, particularly what's shown on slides 47 and 53. I want to recommend that RCEs have some experience with patient collaboration. Perhaps that relates to collection or transmission of patient-generated health data, or some success in terms of implementing patient portals. But again, something that demonstrates that they understand how patients can engage, and are aware of the technical ways that patients do this and where the data needs to flow, so that when we get down the road with more direct patient participation, we don't then have a lag of years while the technology catches up.

Genevieve Morris

Excellent suggestion. As we're developing out the funding opportunity announcement, we will keep that in mind. The one clarification, because I heard you say plural – we are only looking for one RCE. SO, just to make sure everyone's aware, single RCE, not multiple.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Thank you. Ken and then Leslie.

Kensaku Kawamoto, MD, PhD, MHS - Assoc. Chief Medical Information Officer - Univ. of Utah

Hi. Ken Kawamoto, University of Utah. So, I think this is actually really a good direction. One thing that would be really helpful would be for these typical use cases to have end-to-end

examples that you can provide. So, for a patient, for example, Genevieve, I just Google searched you, and all of a sudden, an Australian actress came up, right?

Genevieve Morris
I'm sadly actually aware that there is an Australian actress with the same name.

Kensaku Kawamoto, MD, PhD, MHS - Assoc. Chief Medical Information Officer - Univ. of Utah
You have a fairly unusual name, right?

Genevieve Morris
Yeah.

Kensaku Kawamoto, MD, PhD, MHS - Assoc. Chief Medical Information Officer - Univ. of Utah
So, just to say what information's being sent as these queries, and are you tagging based on a person's last name, date of birth – what is it? What do you do? Who's doing the reconciliation of the data that you're not sure what data's coming in? Examples and what parts are actually standard, what parts might be missing data? I think just having examples, and if an app developer wants to do this, what are the situations where they can have access? If we can have more examples, I think it'll clarify what the issues are and what aren't the issues at all.

Genevieve Morris
No, that would be great. I would say, on the matching piece, we did include, in part B, a requirement that they be able to use this percent, the same demographic information as required in 2015 edition for the matching purposes, which still might not be enough at the end of the day, so we would love to get feedback on whether there should be deeper requirements there. One thing we did not touch was what to do if you come back with multiple records. I know that that is a bit of an area of contention across different networks and how they respond to it, and I'm hoping that folks will actually give us some comment and feedback on that. But good idea on the use cases. We'll work on that.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Okay. Leslie.

Leslie Lenert – Chief Research Information Officer – Medical University of South Carolina
Leslie Lenert, Medical University of South Carolina. I wanted to just congratulate you all on what is an exciting framework that completes the work that was begun so long ago. We have moved from having push operations. Now we're trying to implement pull operations, pulling the data into healthcare providers through our networks, and then with an explicit view towards common carrier principles, which I think is extremely exciting from that perspective.

I do want to make the comment, though, that I think it's important that we focus on not having more regulation than is necessary to achieve the kind of operational system that you're looking to achieve. And to that end, I think it's important that you can document that the tools and the systems that you've put in place are no more than is necessary. So, for example, one question I had was why would a QHIN have to be a vendor neutral organization? If an electronic health

record vendor was the most efficient way to bring all the purchases of their record into a network in a way that still adhered to common carrier principles and access, I'm not sure that that requirement is necessary. So, I would raise that.

The other questions that I had were related to how public health could use the network, and what would be the allowable uses, and whether they would be limited to person level queries, or whether they could do queries by condition to improve their capabilities? And that these kind of pull capabilities at a population level – again, very exciting development – might replace much of the push infrastructure for public health. Last question: are there allowable research uses of this network to follow on to studies like all of us or other large-scale research projects that are enhancing the health of this country, and is that a permitted use?

Genevieve Morris

I'll start with the questions at the end. So, for the population level queries, the way that we've stated it in Section Eight, I believe, is that it has to be for one of the permitted purposes. So, we defined what the public health permitted purpose was, which, I think, is largely the HIPAA definition of it, but I think with a couple of tweaks. So, so long as they were a public health agency, which I believe is the HIPAA requirement, they could do potentially those population level. That's gonna be probably more of a technology piece, if the technology works. But we do think that the public health folks could use this. We're trying to figure out whether the pilot that we have to do under the statue could be around a public use case like case reporting. And so, we would love some feedback around that piece. For the research question, it is not a specific permitted purpose at the moment. We would love to get feedback on whether that should be a permitted purpose. I think with anything like this, we certainly are making some leaps and bounds with the expansion of permitted purposes that we already suggested. And so, we were trying to be somewhat cognizant of moving the industry too quickly. But if folks feel like that is a permitted purpose that should be included, then we would love to get comment on that, or recommendations from you all on it, so.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Thank you. Andy and then Sasha.

Andy Truscott - Managing Director, Health & Public Service - Accenture LLP

Thank you, Madame Chair. I just want to start off. I disagree with Mr. Posnak's statement, standards cannot be sexy. They can. There's nothing better than a finely coordinated concept. It's excellent to see the level of investment, thought leadership, and trendy market awareness that has gone into this framework. It really is reassuring. It's also reassuring to see the level of inquisition that's coming off the floor as well. In this inaugural meeting, we do have a truly understanding and **[inaudible] [03:15:48]** body of people around the table. I just want to follow on to some of the comments that were made by my learned colleague opposite me in one particular area.

The framework does seem to suggest that a QHIN is required to implement a level of authentication and authorization of end users. Using a variety of standards, such as ones provided by a NIST, etc. Has ONC given thought to the potential administrative overheard for a QHIN in this regard, both for authentication and authorization, and the operationalization and management of that? Notwithstanding the varying privacy obligations leveled by both federal

and state legislation and regulation, has consideration been given to a trust framework for end users to accredit their local ITC systems as being satisfactory to assist QHINs in alleviating some of this burden, which frankly, if we look at lessons learned for not just the United States but around the world, has been an issue in adoption of frameworks such as this? I do feel that the framework in its initial form gives us lots of scope for discussion to iron out these issues, and it's good to see that everybody here is actually part of that. Thank you.

Genevieve Morris

Yeah. So, on the ID proofing and authentication, we tried to somewhat hedge on who actually does the ID proofing and authentication. So, if you look at sections nine and ten, which are somewhat – I'm gonna put in quote marks – "slow down" clauses, what we tried to allow for was the QHIN may not actually be the one doing the identity proofing and authentication, right? It might be the health system that the end user is a member of, right? And so, from my point of view, it doesn't necessarily matter who's doing the ID proofing and authentication, so long as it meets a rigorous security standard so we can ensure that the appropriate people have access. So, we did try to write it that way. It's possible that that didn't come through, and that might be an area where we need to clarify or update.

Andy Truscott - Managing Director, Health & Public Service - Accenture LLP

And my suggestion would be that if that's our intent, then we are explicit that that is our intent.

Genevieve Morris

Yeah.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Okay, and just as a reminder to please state your name. We will move to Sasha.

Sasha TerMaat – Director - EPIC

Thanks. This is Sasha TerMaat, and like Arien, I look forward to digging into all the weeds of the proposal in the taskforce. As we visualize this, I'm wondering if I am correctly understanding kind of the role of the connectivity broker. So, tell me if this is maybe a reasonable analogy. It sounds to me like kind of an old school phone tree, so that if I wanted to call all of the members of the HITAC, instead of calling each of them myself, I call one person, and that person calls a few more, and then each of those people call a few others, and so that the question or the notification or whatever that I'm putting out sort of travels through a tree in a distributed fashion, and then in the nature of the trusted framework and the connectivity broker, so it goes back through the tree, so that all of the endpoints are still hit, but through a tree instead of direct communication between each endpoint. Is that kind of a reasonable analogy?

Genevieve Morris

Yeah. I mean, at the end of the day, it's network, right? So, the idea is, I only have to, at the topmost level, hit a small number of networks with my broadcast query, and then they can distribute down the query within their network, right? So, I mean, at the end of the day, it ends up looking like a pyramid or a tree, I guess. Yeah.

Donald Rucker - National Coordinator for Health Information Technology - Office of the

National Coordinator for Health IT (ONC)

Well, I think what we're sort of trying to get at a little bit is sort of the flavor of the modern Internet, which uses various sort of domain naming services and various connectivity nodes on a technical thing. And so, I think it's worth commenting on the broader issue that we're trying to address and get people's thoughts on the broader issue. The broader issue is people don't really know who their provider actually is, right? And this is not just, well, maybe I forgot my doctor's name, which certainly I would cop to as well, having moved around. "Copped to" is not a technical term, I don't believe. But there's that broader issue. And often, it is just, in places where I've practiced, the organizations are so large that I don't even know what – is it the clinic, or is it the hospital, or the ER, or whatever? So, often who the provider is is totally opaque. As an ER doc, I can tell you, patients just rarely seem to know who took care of them. And so, what we're trying to do is have it so that for all of these new business models that empower patients, that there is some automation of that search, right? And as with search in computer science in general, there's probably a whole bunch of ways to do it.

So, we are very interested in exploring whatever the sort of technical options are that would allow that broader identification. I think there are various business entities who have interests in doing that, and from all kinds of points of view. So, I think the top level is really, how do we identify people and get their information in some networked way that does not rely on their memory or their ability to identify specific providers? So, as we think sort of broadly about that, that's, I think, the problem to be solved on the national, right? Because Congress, if you look at the Cures, is really looking at – they want to have all this stuff on an app, right? How do I get my medical record on my app, right? So, you have to put this into consumer convenience. So, what we're trying to do is figure out how would consumer convenience look technically? We're absolutely open if there are better alternative competing versions of that. It sort of reminds me of something that was once taught in school, which is all of computer science is search. So, anyway, I just want to make sure that for everybody, that we got the, I think, what I understood as the top-level question in your comment.

Sasha TerMaat – Director - EPIC

Yes, I appreciate the clarification on the goal, and I think it's a fruitful area to understand that context as we comment on the best technical way to approach it.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

Yeah.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Thank you. Steven Lane, and then Terry.

Steven Lane - Clinical Informatics Physician Director - Sutter Health

Thank you. I wanted to follow up. You made a reference, Genevieve, to the discussions that we've had about push. I have been involved in working with Direct Trust and trying to articulate the challenges that clinicians in particular face utilizing push with direct interoperability. As you say, the wiring is there, the connections have been made. It's built into MU2, but it's not being utilized nearly as comprehensively or routinely as it could be. As a practicing primary care doctor,

it's almost impossible for me to send a push message to a cardiologist who's caring for my patient at another organization. So, having the plumbing done is great, but the workflows and the content issues, and how that has been manifest by the HIT vendors is really still lacking. So, I think to not include that in the Trusted Exchange Framework, and say, well, it's handled, it's taken care of. Check that box. I think that misses the point that there's still a gap there in terms of usability, in terms of functionality, that we should close.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

Steven, I think you're right. One other thing we didn't really discuss on Cures, just because it's so large. But one of the to-dos that is in the domain of CMS is sort of electronic provider directory. So, I think, I don't know, if Kate – I'm not even sure that's in your group, Kate.

Kate Goodrich

No, it's in a different part of the agency, but yes, they are actively working on that.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

But that's what I think Steve is sort of missing, is who you gonna call, to reference a movie of a prior generation.

Steven Lane - Clinical Informatics Physician Director - Sutter Health

Right, so that's clearly part of it. Ghostbusters. The directory's a key part of it. But there's also just a general usability of that functionality. In fact, I'm gonna take the liberty to toss on another question that I had written down perhaps for later. Don, you've said a number of times that interoperability and usability are really the two main foci that we're gonna be narrowing in on, and I know that a lot of work is being done on usability. We've talked a tremendous amount about interoperability, but very little about usability. And if this is a good time, it'd be great to hear from you and from John a little bit about where we're going with that.

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

I think it's a complex – you're spot on. It's a very complex question. I think probably we would, I think, maybe in the constraint of the whole FACA process, we may want to sort of have a separate meeting to go over that and its relation to the Congressional requirements, almost as a separate thing. Because I think it is so nuanced and so complex that I just don't think we're gonna get to it in the next little bit. And I'm very reluctant to give it short shrift because I think it is central. I think the point you made about direct is yet another example of things where there's work needed.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Okay. I think I will give the last question for now to Terry. And I believe Steve just has a few slides for USCDI, and then we'll get back to the Q&A.

Terrence O'Malley, MD Geriatrician - Massachusetts General Hospital

Okay. Thank you. Terry O'Malley, Partners Healthcare. First of all, reecho the kudos. This is a

spectacular piece of work, and it really is groundbreaking, and it's going to provide a floor that will support a very robust structure above it. So, that's great work. I have one concern, and I hate to kick this poor old horse one more time. But it has to do with the difference between authentication and identification of whose data it actually – who is the source of the data, who is the individual. So, it's one thing to know who's getting on your network to do queries. It's another to know that the data at the end of the network actually connects to that person. And I think that's where even the NIST standards are unfortunately still not adequate. And if you don't have a clear identification of who the individual is that belongs to this data, then all the other of the stuff is out the window. And it just means you're gonna have to have some sort of backend reconciliation process, which is huge, which then gets back to that forbidden subject of some sort of general patient identifier.

Genevieve Morris

Fair horse to kick. Obviously, and I've talked about this a little bit, certainly, as someone who knows a lot about patient matching from previous work I've done, I am not unaware of the way that we tune algorithms for geographic and cultural variations across the country. And obviously, talking about broadcasting across the entire nation introduces complexity to tuning those algorithms that we may or may not be prepared for. So, there are sort of two pieces that we currently have in part B that are meant to start to address some of that, but we certainly would very much like recommendations on what more we could do. One is, as I mentioned, they have to use the demographic data in a standardized way that's also included in 2015 edition, and which is a set of, I think, six or seven demographic elements for the matching purposes, which gets us a little bit there, right?

And then the second is the patient demographic data quality framework that Elise mentioned this morning. There is a required that the qualified HINs actually annually do that review of their own internal governance management processes when it comes to demographic data to make sure that they're handling it to a high level so that we can deal with some of the data quality issues that we know are inherent in the demographic data. We would very much like to get recommendations from you all as well as from other folks giving comment on what more we can build into part B to deal with that issue that we are very aware of and concerned about.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Thank you, Genevieve. Steve, we'll hand it over to you.

Steve Posnak

All right. Let's talk about data. So, a little bit of context to set this up. As part of the Trusted Exchange Framework common agreement, there's an accompanying document. If you go to the webpage where all that information is provided, it's the Draft U.S. Core Data for Interoperability and Proposed Expansion Process. This is gonna be the second of the two taskforces charges that I'll be discussing. And to kind of set you up a little bit in terms of statutory orientation, where this is all coming from, Section 4003, which Elise gave you a briefing on this morning, includes the HITAC, and it also includes a number of sections, including TEFCA, Trusted Exchange Framework Common Agreement. It's like the disclaimer at the end of a commercial now at this point, I think. So, the thing upfront to note is that the statue includes, in Section 4003, a definition for interoperability. And that is, as definitions go, gonna guide the rest of our work. It's going to guide the way in which we implement our policy across the Cures Act, the regulatory work that

we have to do. We've been given a definition.

And the definition includes three parts, which are important in the context of what we're trying to accomplish through the Trusted Exchange Framework, what we're trying to accomplish with our subsequent regulatory actions, the policies that we need to consider for information blocking, etc. So, part number one, and this is all from the technology perspective, right? So, part number one talks about that the technology can enable the secure exchange of health information without special effort on the part of the user. So, this is one of the areas in the statue where it specifically identifies a kind of "without special effort" part, which derives also from work that we did as part of the interoperability roadmap and IEEE, etc., etc. The second part of the definition for interoperability is most aligned and important to the U.S. Core Data for Interoperability conversation, is that the technology allows for complete access, exchange, and use for all electronically accessible health information. I could let the mic drop for a second.

So, that's big. And that is part of what we need to consider. Similar language is used as part of the conditions of certification when it's in reference to the API, application programming interface, condition of certification that we have to implement as well with respect to Cures. It talks about all data. And so, in this context, where we have a kind of Congressional mandate, a Congressional expectation, the decades of dissatisfaction, perhaps, of not having enough data electronically accessible. I think you heard in Acting Secretary Hargan's remarks earlier, he referenced the complete access and exchange and use. And access, exchange, and use is a thematic three-fer that is repeated throughout the Cures Act in a lot of places. And so, one of the implementation challenges that we have had is stitching together all of those various references in a coherent manner so that they are consistently applied in each of the statutory sections in which they exist relevant to our policies.

And the third part of the definition for interoperability is that the technology doesn't do things that constitute information blocking. So, it's a little bit a of a mix from a definitional perspective of – it's not the kind of Webster's Dictionary of what interoperability would mean. It's both a mix of kind of policy expectation, context, technical capability. But that's what we have. And when we look at the Trusted Exchange Framework common agreement, and we juxtapose that with the definition of interoperability that we have. And I'm gonna pick up on something that Arien mentioned earlier, is that we have to look at what exists today and where we can meet the market where it is, and where we need to aspire to with a little bit of push vis-a-vis the policies that we've been charged to deliver on via the Cures Act. And so, as we look to the opportunity that the Trusted Exchange Framework and common agreement has given us, I'm gonna take you back on a quick historical journey to shoot us forward here.

When we first started to implement the EHR Incentive Program, there were needs on both sides, especially from a CMS perspective, of relaying a certain baseline set of data that needed to be exchangeable by healthcare providers for certain purposes, including for transitions of care, but equally on patient access. So, for all of you that are familiar with view, download, transmit, VDT, there's a certain amount of data that needed to be accessible to patients. So, we started to create, from a policy perspective, a common dataset, a core dataset, that was a baseline. And that reflected the policy interest at the time, and it was really a minimum floor. In some cases, we saw the market respond by just providing that data. And one could argue that that was not necessarily the intended outcome that we had wanted or expected, but that met the letter of the law and henceforth was okay, but not necessarily the aspirations of some of the policy

intent.

So, for the 2014 edition certification criteria, which again, remember, came out in 2012. So commensurate with meaningful use stage two, original recipe, as I like to call it at this point, we came out with a term of art to reference this kind of collection of data, and we called it the MU Common Dataset. And that was our shorthand to say there's a bunch of data elements. The technology's got to be able to supply it. It's got to be accessible to patients. Here are some standards, vocabularies, terminologies that associate with it. And henceforth, it then became part of the kind of regulatory folklore. As we went to work on the 2015 edition, that was at a point in time where you started to see an interest in making sure that the broader technological infrastructure that was being put in place vis-a-vis certification – Macro was, I think, coming out at the time as well – was available to support many different programs beyond just meaningful use. So, we started to see a little bit of the Velcro kind of separating between ONC and CMS issuing concurrent rules right at the same time. And we decided to rename that bundle of data the Common Clinical Dataset. And that's the acronym, CCDS, that you often see referenced, ad nausea now at this point.

And so, that included various ranges of thing, from a patient's name and their date of birth to vital signs, to lab results, to their goals, and a few other things in between that reflected both, again, some CMS policy interests, as well as our own and across the department. So, as part of the new Common Clinical Dataset that we released as part of the 2015 edition, we included the unique device identifier as a data element that needed to be exchangeable. And that was based on lots of public feedback and the interest in the past administration in advancing UDI. As we reconcile where we are today and the policies that we've recently set with what Cures has given us, that's where we have this opportunity to hop in the time machine, for lack of a better word, and think about how we would advance our policy interests that we set forward into the future. And looking forward, most of the conversations that we have are what is the next – not today and tomorrow look like, but what does three to five years look like from the point that we're at today? And knowing that it will take time for, in some cases, to the point that Ken made earlier, if we just said, I want this data element today, that's not exactly how it works. It needs to be built into product, it needs to be built into workflow, it needs to be part of common agreement. Everyone needs to agree that this is data that we want to be able to exchange, be it structured or unstructured. And certainly, there are challenges with each.

So, we're at the point now where we're looking to make that next evolution. We're adapting the policy that we had originally established to reflect with Cures has given us from a charge to reflect the Trusted Exchange Framework and common agreement, to reflect the work that we need to do going forward to meet the definition of interoperability that I just blew your mind with, and factor in how do we get to all data? And that's, again, an aspirational charge. I think we recognize realistically, there will be an incremental kind of ratio of things that will be structured that are structured now relatively well, things that are somewhere in the middle, things that will probably never be structured, and that's okay, because there'll be way better technology algorithms, machine learning, etc., that can handle that. And so, as we look at the U.S. core data for interoperability, the initial kind of context in which we're approaching this is for the purposes of the Trusted Exchange Framework and common agreement. And that these networks for which there needs to be this common agreement need to be capable of exchanging this data. And so, when we think about – to Don's point earlier, this is really about search, right? What do we want these networks to be capable of handling searches for and access data about?

So, when we look at the data that we're talking about, the data that we have built into the draft USCDI document and proposed expansion process is reflective of today's current state. It's the Common Clinical Dataset with two other little pieces tacked onto them. Yeah, and I can go there first. It's probably a better prop. I threw myself off by having more than one slide. So, this is what we've got. And the last row there are the two elements that are new relative to the current state. Everything else is bait. It's bait. It's part of the 2015 edition's requirements. It's part of what needs to be exchangeable today. It's largely reflective of what was built baked in in 2012. So, there hadn't been a lot of change relative to the dataset that we were kind of incrementally saying, this needs to be accessible for exchange. And so, the Cures Act and the Trusted Exchange Framework really present a unique opportunity to advance this.

And the two elements, just so I don't get too distracted here, are provenance and clinical notes. And I'm sure there are varied opinions on all of these. The one related to clinical notes has to do – we added for comment in that by far, probably the one thing that we have heard since 2012, but also since the 2015 edition's rule in the Common Clinical Dataset was like, give me my notes. I'm not getting notes. And that was the kind of quintessential missing piece that I would say, when we had a lot of meetings with provider organizations and the like that said, all this other stuff is great. I appreciate getting it in a CCDA, but if I'm not wading through all that, I want the notes. And so, from a missing kind of data perspective, we added that in, in a reflection of the past two to five years' worth of comments that we received.

Provenance equally is another area where we've had quite a bit of debate about – there are workgroups and taskforces that date all the way back to probably 2011, 2012. From the past advisory committees that have talked about provenance, for those that need a little initiation, right, it's like the who, what, when, and where of the data, right? The extra metadata that's around the data that describes its authenticity, how you can trust it. And again, it's one of these things where, just like with privacy and security, if we wait until later to build in requirements for supporting provenance, then it could potentially impose more costs on the industry, as opposed to incrementally expanding that capacity from something that gets the job done today to something that could be more robust and comprehensive for additional uses in the future.

So, what we'd like, from the charge to the USCDI Taskforce, is to review and provide feedback on the structure and process associated with the USCDI. And I'm gonna kind of frame this out for you and then give you a little bit more detail on how the USCDI is structured so that you understand how to kind of place all this in context. So, what we're looking for are specific recommendations to the mechanisms and approaches to receive stakeholder feedback; how the proposed categories to which data classes would exist and be promoted – and I'll talk about them in a second – can be reviewed in an objective way for promotion between the categories that we've stated. We will provide you with prior art from a colleague, Dixie Baker, and several of our others that participated in the Health IT Standards Committee. There's a **Jamia** publication that included a methodology for objectively assessing the maturity and adoptability of standards for use in health IT interoperability. And it has a lot of different attributes that may be useful to apply in this context from getting away from a subjective kind of determination. The other aspect of your specific charge would be how do we expand the USCDI, and by how much? So, what's the right cadence? What's the right expansion process? And it may be that it may depend, right? One extra day could be crippling enough in the amount of work that could be required; or the next bolus of data that everyone agrees are really important, right on the cusp

of being technically specified, available, and that would make sense to promote then proper into the USCDI itself as the next version. And then additionally, any other factors that we should consider with the frequency with which it's published.

And that's probably a good segue for me to talk about at least the cycle that we envisioned to have here. Much like many of the other activities that ONC has been involved in, we found from a fruitful perspective, to start things in a non-regulatory space as much as possible, and have them evolve and mature such that when we do need to pull them into a regulatory paradigm, they're ready, and they have some pilot testing around them, and they have – the tires have been kicked in a more substantial fashion than simply plucking them off the shelf and sticking them in a proposed rule, and then crossing our fingers, which has inevitably happened to all of us in various projects that we've been involved in. So, we are following kind of the mantra of good process makes good policy. And what we'd like from this taskforce is to help principally with the policy.

As I noted, the data right now in terms of the draft, it's pretty much what exists today. So, what we really would like your feedback on is how we can best shape the process, especially as we look to 2019, when it would be really the first cycle where we would be looking to expand the USCDI beyond kind of the initial proposal, those extra two data elements. And what is it that makes something ready to move into the USCDI? What is it that makes something ready to move into what would be considered a candidate class? And so, as we note in the USCDI glide pass document, we have these kind of three categories that we've clumped data classes into. I'd generally use a baseball metaphor at this point, so the emerging data classes are AA, the candidate data classes are AAA, and the USCDI is the Major Leagues, right? And so, I think probably the most interesting area for many of us will be the candidate area, where, as we noted the USCDI glide pass document, the data policy that we're trying to identify here, agnostic of technical specifications, is, is this data important enough that networks need to be able to support its exchange for a distributed query, etc. It needs to be made accessible for patient access. It needs to be embedded – capable of being handled in Fire-based or CCDA-based exchange. Other types of purchases like that.

And so, when we talk about candidate data status, it's really seen as the formal kind of ONC policy directive, as we'll be managing the USCDI, that work needs to be done in this area. And so, we could pick a particular social determinant of health and say, this one is really important. Needs to belong. And the candidate status, that's supposed to signify to the industry, everyone agrees this is a policy priority. It's a data policy priority. You want to be able to exchange this data. We want it to be accessible. We want it to be useable. And we know that a little bit more technical work needs to be done. And so, in order to kind of trigger that cadence and that response, from an industry perspective, that's what the candidate data class is supposed to signify. It's supposed to be that – I'm trying to think of the best word to describe it. The indicator to industry that work needs to be done, that we need to prioritize this. And if that work is completed, it will get moved into the next version of the USCDI. And then that will subsequently trigger subsequent support in these various mechanisms, like the Trusted Exchange Framework and common agreement. So, that's pretty much what I wanted to cover in terms of the charge, the kind of look and feel of what we're trying to get after right now. Your work in participating in this taskforce will be the formative aspects of how the USCDI moves forward, and the public comment process and the engagement process, which we expect to be pretty high touch when it comes to the actual work in 2019. Thanks.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Okay. Thanks, Steve. So, just a note, adjustment to the agenda for today. We're gonna open it up now for questions to the committee for both TEF and USCDI. We will still break about 2:30 for public comment, and then we will come back to the committee for additional Q&A. So, I'm going to return to the order in which we left off and start with Sheryl.

Sheryl Turney, Med -Senior Director, APCD Analytics & Data Policy & Administration - Anthem Blue Cross Blue Shield

Hi, Sheryl Turney, representing Anthem, which is a healthcare payer. I had a question that went back to the recognized coordinating entity. I think that the establishment of the current proposal is really excellent and is in the direction where we truly need to go. I was wondering if the governance that you're looking for and the cooperative agreements would include a couple of things. Because from a national payer perspective, it's problematic to have all of these regional health information networks, because they all operate differently. They all have different data requirements. They all have different data use agreements, with also some problematic secondary uses of the data that don't necessarily appear to align with HIPAA allowed uses.

So, with this governance component that we're considering, the RCA would come up with that, would that include potentially a uniform participation agreement or minimum standards for data use, participation? And then also, a participation playbook. Because many people have indicated that not all of the constituents participate. And the challenge is workflow and communication. So, having a playbook that explains what's in it for them oftentimes will be helpful, especially as this reaches out to patients and members, where they could actually see a use case of how they could really for the data would be more likely to use it.

Genevieve Morris

Yes, that's an excellent question. The common agreement that we would work with the RCE to develop would be akin to a participation agreement, and it would be a single **[inaudible] [03:50:44]** agreement, per what Cures actually tasked us with. So, the goal really of the Trusted Exchange Framework and common agreement at the end of the day is to enable not just providers a single onramp, but to enable payers that same single onramp. So, instead of having to connect to a hundred different points of light, you can pick your one point of light and be able to get to the data that you need to get to from the providers who have perhaps chosen a different network. Particularly if you're a national payer and you cross over many states, we know that that has been quite difficult and costly to create all those different interfaces. And so, that's really what we want to cut down on by setting in place the common agreement with the terms that folks have to abide by. And excellent idea on the participation playbook. I've added that to my list of educational type materials that we could do that would help us. Yeah.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Use your microphone, please.

Sheryl Turney, Med -Senior Director, APCD Analytics & Data Policy & Administration - Anthem Blue Cross Blue Shield

Okay. I had one additional question for you, Steve, on the USCDI. Based on the initial list of required data elements, and at least my limited knowledge of patient matching and data identification, there appears to be some data that would be missing to verify that the patient is the patient you're looking for. So, how are you envisioning that patient identification and matching to work?

Steve Posnak

Sure. So, that's some of the feedback that we expect to get. It's a fair acknowledgment and awareness. And that is, again, the opportunity that we have in front of us. So, the curation of the earlier named datasets that we had reflected a dependency on the – I'm trying to not talk in text speak here – the standards with which they would be implemented in. And so, as we looked to see what data we needed to specify in the Common Clinical Dataset as an example, and then how it would be plugged into the consolidated CDA standard, the standard itself picked up other data elements that would be useful in those situations. But when we now look at what we have and abstract that to say, here's data. Let's get agreement on the data and then see how that needs to flow down into the requisite technical specifications. We need to take another look. And that's kind of reconciliation that we're doing between what Cures has given us the opportunity on and what we had in the past. Very fair point.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Thank you. John and then Raj.

John Kansky, MBA, MSE - President & CEO - Indiana Health Information Exchange (IHIE)

So, earlier, Genevieve, during your presentation, the examples were extremely helpful, and I'm trying to develop my intuition, so I had a couple of questions to make sure I understood them. SO, you understood that QHINs will be required to do the six permitted purposes, but they might have participants that are only capable of two. Does that mean that that participant would need to add the four other purposes, or drop out, or what?

Genevieve Morris

Yeah, so it would be somewhat dependent, is what I would say. So, the way to look at it is there are flow down clauses that require users who are allowed to to support the full six permitted purposes. So, for example, a health system should be able to support all six permitted purposes. If you're a public health agency, right, you can probably only support one. And so, we understand that there's a little bit of variability there. And so, we've tried to allow for that in the text. Again, we may not have specified that clearly enough. But the expectation would be that the permitted purposes would flow down to the end users, who legally can support those permitted purposes.

John Kansky, MBA, MSE - President & CEO - Indiana Health Information Exchange (IHIE)

So, don't think this is too deep of a question. If there is an HIE that's a participant that has governance rules currently that prohibit X, that's not prohibited by law. That's prohibited by their governance rules. Are you expecting them to change their governance rules, or would that be a reason that they would be allowed to not participate in this specific permitted purpose?

Genevieve Morris

We understand that the expansion of the permitted purposes and the flow down clauses accompanied with it may require folks to update their participation agreements and business associate agreements. And that is noted, I believe, in the introduction section of the framework.

John Kansky, MBA, MSE - President & CEO - Indiana Health Information Exchange (IHIE)
Okay, and last, a quick related question. You also used an example of the patient access permitted purposes, and you said you could understand why a QHIN wouldn't want to. But did you end up saying but they have to, or?

Genevieve Morris
No, no, I didn't. So, the way the we tried to set it up is not require a qualified HIN to have any particular set of stakeholders. So, if you want to be a network of just payers, you're welcome to do that. If you want to be a network of just individuals as a HIN, you can do that as well. The clarification I made is that if you get a request for a permitted purpose that's one of the six, even if you're not given direct access to the individual, you still need to respond to that query. So, you don't have to allow the individual to be an end user or participant in your qualified HIN, but if another qualified HIN comes to you and asks for the data for that, you have to return it back. And so, we tried to allow for a fairly high level of variability while still making sure that folks have options on networks they can use.

John Kansky, MBA, MSE - President & CEO - Indiana Health Information Exchange (IHIE)
Thank you.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology
Thank you. We'll take maybe one or two more. Raj?

Raj Ratwani, MA, PhD - Scientific Director - Natl Center for Human Factors in Healthcare, within MedStar Health
Thank you. I'm Raj Ratwani with Medstar Health. Genevieve, Steve, thank you both for the great overviews. This is really helpful. So, my question is more of a comment, perhaps. It's around the Trusted Exchange Framework. And in reviewing the five goals, they're all critically important. But one that I'm deeply passionate about is goal four, which was really about enhancing and sparking a competitive marketplace, and doing that through data liquidity, which is I think is critically important. And Genevieve, you had called out usability as one of those key things, which of course I think is a big one. One thing that I think we need to be cognizant of, and part of this is I don't have a deep understanding of the current business models or potential business models for the qualified health information networks. But I think we want to be very careful not to introduce new barriers to innovation and entrepreneurship as we walk through this.

And you also described a limited number of qualified health information networks. So, you could imagine there being the potential for economic barriers that come up, or barriers that take another flavor. So, we're just trading, now, data liquidity for something else. Steve, can you comment on that?

Genevieve Morris
Yeah. So, all in parts. So, first, totally agree that data liquidity is key to opening up a competitive

and innovative market. I mean, that's honestly just part of why we don't have great innovative products at the end of the day. Because I've seen a lot of really cool products, but then when you actually put them into practice in a health system, they don't work. They can't get the data. And then they drop that product, right? So, with the small number of qualified HINs, we are aware that that could cause some market tensions. One of the requirements of a qualified HIN is that they would have to report their fee structures to ONC so that, as part of our job as the government to make sure there isn't price gouging, and there's not unfair practices taking place, we could monitor some of that, particularly in the context of some other things that we monitor. So, we're trying to build in appropriate protection so that folks don't get disenfranchised from an economic perspective. I think having a small number of qualified HINs, I think, is actually okay in the sense that it still gives you options of where you go to for your services. And so, at the end of the day, we talked about a single onramp, but certainly, if you want to be part of multiple networks, you can do that. If there are services that are being offered by different networks that together as a health system just work really well for you, you're more than welcome. We're obviously not presenting that.

But it is certainly an area that we would like to get more comment on, whether there are other market considerations or other protections that we could build in to ensure that we're not hitting a price point that doesn't work for folks. And if you will notice, we did set some fee requirements between qualified HINs to try and keep some competition in the market, but allow qualified HINs to recoup costs so that they can continue to build up their networks. Again, a place where it would be really great to have comment on whether the right level of prescriptiveness on that.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Okay, thank you. And Tina is next.

Tina Esposito, MBA, RHIA, FACHE - Vice Pres., Information & Tech. Innovation - Advocate Health Care

Tina Esposito, Advocate Health Care. And to some extent, this has been somewhat covered with the usability conversation, first from an area that HIEs have not been successful. This has been very just wonderful to hear, and looking forward to seeing this through. I think one of the things that I want to make sure I understand how it's been incorporated is that I applaud the broad definition of use cases, and the fact that we're looking at **pop** health and all of these other areas. But how are we assessing the differences that those queries may have to what has been sort of the traditional HIE use, which is sort of point-to-point clinical care? And the parallel I run to that is that in our world, CCDs, from an analytics perspective, are great for a point of time, but they don't sort of give us sort of the long board history of a patient and their progression – how those lab tests have changed, why are there different meds than there were on the prior CCD? So, I just want to get an understand so I'm clear, how have we incorporated the use – the difference in use of these different queries into the data that we would be collecting, and sort of ultimately the usability, but also how that will be accessed and ultimately useful?

Genevieve Morris

Yes. So, this starts to dovetail, I think, pretty nicely with what we've tried or are trying to do on the U.S. core data for interoperability. So, previous life, worked on a clinical quality measurement tool trying to use CCDAs to generate clinical quality measures for practices. Really,

really hard to do because you don't have all the data that you need. So, I think what we want to do is recognize that out of the gate, you're likely not gonna have all of the data that you need unless a qualified HIN is just amazing and somehow has access to all data that's in an EHR database, right? Which could happen, I suppose. But couple that with the glide path and creating a plan for getting to the larger sets of data. So, part of the prioritization process we went though internally in looking at the candidate class in particular was, what are some of the really big bang for your buck data elements that, if we add them in, actually get us much further on analytics and clinical quality measures? Because I think, while we certainly need more data for treatment, the common clinical dataset, which is now **USCDI**, has a lot of the treatment data in it, particularly once you add clinical notes.

And so, what we are hoping is that the combination of what we're doing on the glide path, coupled with sort of the expansion of the permitted purposes will, over time, next two to three years, allow for some of those other use cases to let a provider be able to work with a third party vendor or a qualified clinical data registry, or QI, whichever one you want to work with, to do some of those services for them. It's not gonna be out of the gate. I think we all kind of have to accept that reality. But I'm hopeful that we're somewhat speeding up some of that process.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Great. Thank you. So, I think we will pause now, and we will open it up for public comment. So, just as a reminder, individuals have three minutes to provide their comments to the committee. We will start with individuals in the room. Please proceed to the table and provide your comments. Just one second. We need to get your mic going.

Grace Collins

Hi. Again, my name is Grace Collins, TeleCaregiver. I'm a patient advocate for myself and also for my mother, who's 91, who has Alzheimer's. And also have a HIPAA IT security and HIPAA healthcare certificate. But I noticed that basically, our HIPAA is being violated all the time. I mean, every time I go to an emergency department, I can hear what's going on in the room next door. And another time, when I went to the hospital, the lady gave me a whole package of other people's information, and I came home with everybody's personal information, Social Security and everything. So, we need to think about the human factor, and we need to think about training of the people who are empowered to get the signatures, to have access to the information, and educate them about HIPAA laws and the degrees of seriousness of this private information.

Machine can only go so far, but we need to look at the human element. I think that that – yesterday, my mother fell, and the nursing home told me that the agency, the hospital, had all the information. I went there. I didn't have her personal ID. I didn't have her ID. I didn't really have even my ID. I rushed over there. And my name was not in the system. Even though it's part of the larger hospital system, it for some reason wasn't over there. So, I was able to talk them into giving me the information, luckily. But at the same time, I thought, boy, this is breach of HIPAA. So, I just wanted to address the fact that we always need to think about the human element, a factor of the people that are trained that have access to the information. Thank you.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Thank you for your comments. Any other comments from the room? Seeing none, Operator, can you please open the line for public comments? Operator, do we have any comments from the phone?

Operator

Your lines are now open.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Okay, thank you. The lines are now open. Okay, just confirming, no comments from the phone. Okay.

Brian Ahare

Hello?

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Yes, the lines are open.

Brian Ahare

Oh, thank you. Yes, this is Brian **Ahare**. I work for Aetna in our **medicity** business, and was just wanting to comment on, within the Trusted Exchange Framework, it talks about recognizing that this would require some updates to participation agreements and health IT capabilities by the QHINs, and I just would like for the committee and ONC in general to consider the costs of updating all of these participation agreements and health IT underlying infrastructure. Thank you.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Thank you for your comment. Operator, any other comments from the phone?

Operator

As a reminder, all lines are live at this time.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Okay. Hearing no other public comments, we realize that we may go over the agenda slightly in time. So, as members are able to stay for additional comments and questions, we certainly welcome that. So, we will ask Steve and Genevieve to return to the hot seat. And I am going to resume the order, starting with Valerie.

Valerie Grey - Executive Director - New York eHealth Collaborative

Hi, thank you. I just want to echo all the compliments. Fantastic work. And in the interest of time, really what I'd like to do is maybe just put two issues sort of on the radar for more discussion in the taskforce. And that is that there are many states that use HIPAA as their standard. But there are also other states that have different rules and laws related to consent.

And I just think – I know it was mentioned in the framework, but it's gonna be an issue that I have found to get very tricky in order to really effectuate some sort of national sharing. So, I'd just put that on the radar.

And then I would also mention that the sustainability issue for HIEs is a big one. It's sort of been broadly mentioned. But the federal and state government have invested significant funds in standing up not for profit regional and state HIEs. And some of that funding is set to expire. I think with HITAC, the enhanced match goes away in 2020 or 2021. And so, I would like us to really think about that impact as we start to talk about sort of the fees that might get charged to support the infrastructure and the pipes that have been built to try and move this information around.

Genevieve Morris

Yeah. On your first comment on the state variation, we obviously are quite aware of said state variation. We are working on an internal analysis on – well, let me rephrase that. We have an analysis already on the consent piece. We are working on a subsequent analysis around some of the states that have actually HIE specific regulations and statutes that govern either their state-designated HIE or all HIEs operating in the state, because it was brought to our attention that some states limit permitted purposes for their state-designated HIE, which obviously could put them at a competitive disadvantage. So, we are working on that analysis, and then are hoping to meet with states around some of that. There are limitations to the authority that ONC has, as well as OCR around that, and so, if folks have suggestions on how we can handle it other than how we currently handle it, which is follow applicable law, which includes state, we are really open to suggestions on that. So far, no one has come to me with anything, but we would love to hear some feedback.

And then on the sustainability front, one of the ways we've thought about the regional HIEs, who certainly fit into this picture – well, there's two ways that we think they fit in quite well. Having worked in the field on connectivity in the ambulatory space to regional HIEs, I know how difficult that has been, taking six to nine months per practice. And that when you multiply that across how many practices we have in the country, obviously, I mean, we're looking at – probably I'd be like a hundred years old by the time we get them connected. And so, what we are hoping the framework actually does it make it significantly easier for them to get access to the ambulatory data to provide value add services like analytics and quality measurement things that a number of them are already focusing on. And then the second piece is that there are some services that are quite local, like community-based social services and some of the state Medicaid services. And so, again, if we can make it easier to get access to the data that community services need and vice versa, community services backend to the network to providers, we think that's also an area where regional HIEs could actually be quite significant in helping us move forward.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Thank you. Next, Andy, and then Clem.

Andy Truscott - Managing Director, Health & Public Service - Accenture LLP

Thank you, Madame Chair. A note. Over the course of the presentation by Ms. Morris and Mr. Posnak, we've moved from three-letter to four-letter and now five-letter acronyms. Facetiousness aside, we do need to demystify this for the patients and the providers that we're

seeking to serve. So, I can only implore that we do actually try and slim down the use of acronyms and come up with nouns, which are meaningful and useful in a **[inaudible] [04:12:12]** use of those two words, to our constituents.

I recognize that other jurisdictions, both home and away, have been through a very similar process to that which we're outlining with data. And we have a history of doing this here in the U.S. over the last 35 years of health IT. And I recognize that this is emergent. I would like to see some kind of distinction between that which is considered core, as you are, and that which is considered summary or essential. And that moving information around does not necessarily need to be core in its entirety, but could be a summary or essential mix. I fear that as we work through this and almost recreate wheels in some regards, we may come up with a subtly different answer to that which is very mature and been used elsewhere. And I fear even more that we may come up with the same answer, where actually, we don't need to go and recreate that. Throughout this process, I haven't yet seen whether there is actually engagement of healthcare professionals and the validation that the answers we're coming up with are relevant to them in how they practice and how they care for their patients. And I think that's something as we go through this process would be useful to sort of bring in to the fold.

And going back to John, your comments as well, with the – and what Sasha was saying, the brokered broadcast query, which does have an intermediary of your TLS or the record locator service, or RLS, sitting as an intermediary, is there a possibility for the persistence of some kind of core data within that, as allowed for within the very sexy standards that exist for such things, Steve?

Genevieve Morris

Yeah. And so, I think we did not get into that level of specificity on the persistence of data within that connectivity broker. I think some systems are always set up that way. I could be wrong, but I believe that's the case. I personally don't necessarily have an issue with the persistence of data. I think it would be very helpful to understand from this committee's perspective whether there are inherent security or privacy concerns that would want to put a limitation on that. But I think, at the root of what we have to be very, very conscious of, is the scale at which we have exchanged data to date is like a fourth of the data that we actually need to exchange when you bring all of the ambulatory space into exchanging data. And so, I would implore the committee, as you are looking at what we've done in the framework and you're coming up with your recommendations, that we have to deal with the scalability issue too, because there are going to be bandwidth problems. And we need to try and avert those as much as we possibly can by planning appropriately.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Thank you. Clem?

Clement McDonald – Director - National Library of Medicine

Thank you. And I want to just comment that I love the comments of everybody, even though I like to talk myself. But I like what everybody's saying. So, my comment is on the items in the list. And I have three different positions. Firstly, doctor's notes. I'm a physician. I practiced for 40 years. I read notes. I only read the discharge summary. It's not possible. So, I think if you're worried about bandwidth, don't send all the notes. Subset them in some fashion. Plus, what I

hear today, they're hateful, because they get 20 pages of nothing saying one note. So, be a little careful about notes. There has been a suggestion about a core note separated out. That might be a solution.

Secondly, I want to – I'm not a radiologist. I never play one on TV. But you gotta get radiology reports higher up. It's a hundred billion dollars a year in 2013. It's probably more now. It's more than laboratory, which we focused on for a long time. I love lab. It's something that injures patients if you do too many CAT scans, so it's really important, don't repeat them. At least ten percent ACR says don't have to be done if you knew what the last one was. So, just please. And there's not much bandwidth because there's a lot of dollars, but the reports aren't big. So, I would just plead to raise the – and maybe EKGs too, because you want to know what they are when you see an ER patient. But anyway, pull up radiology and maybe suppress every single visit note. And I would offer – I think we could get the ACP to do a survey to find out what physicians really want. You may not have a random sample. They did one for me a couple years ago. We could find out what they really think is most important.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Okay. Terry, and then Arien.

Terrence O'Malley, MD Geriatrician - Massachusetts General Hospital

Terry O'Malley, Partners Healthcare. So, let me give the counter-position to Clem. That's a great example of a prioritized list of data elements from the perspective of a clinician. Here, here. I'm all in favor. I'm a geriatrician. I do the same thing Clem does. But you'd actually end up with a very different list if you asked a different part of the all-inclusive spectrum, which remarkably has been included in the universe of stakeholders, including the individual, their direct caregivers, long-term services and supports, post-acute care and all its levels. And then finally, we get to the meaningful use folks, who have been in all the time. So, it's great that it's all-inclusive. But if you asked me to give you a list of prioritized elements from the perspective of the patient and their immediate caregiver, I'd give you a very different list. I'd tell them – I'd say, do you know who I am? Getting back to that sad horse. Do you know what matters most to me? What are my goals of care? And as a subset of that, sort of what are my advanced directives, if I can do that?

But I want the system to know what I feel is most important to me. And then I'll want to know sort of do you know what my list of concerns are and how I prioritize them? It may be my function, it may be my medication, it may be getting to work. But nobody knows, again, what matters most to me. And then do I know who's on my team, and do I know what they're doing? And so, I would – if I worked from the patient perspective, that's the list I would put up. And it would be very different. So, I think one of the challenges we'll have is sort of whose priorities are we following, and what's the process we're gonna put in place for going through that priority list and reconciling what are gonna be conflicting priorities?

Genevieve Morris

Yeah. I think we said yesterday, the easy stuff is done, right? So, we totally agree with you. And I think part of putting together the glide path is that it's, I think, been quite a long time since we've tried to do that type of prioritization process, which I think is what got us to the common clinical dataset, or the first meaningful use core dataset, which led into the CCDS. And so, I think we need to figure out a way to make sure there are all voices at the table, and figure out how we

prioritize in a way that can meet the needs of all stakeholders, while understanding that we're not gonna meet the needs of all stakeholders every time and every year. And so, we would very much help from the taskforce to figure out the right way to prioritize so that we really are taking into account those different viewpoints, because we can't do that ourselves, so.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Can you use your microphone?

Clement McDonald – Director - National Library of Medicine

You got me. There's a difference between data sitting there ripe – all you gotta do is open up the spigot – and stuff you've gotta get people to collect. And I think some of what you've described is ripe, and some of it, you've gotta get people to collect.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Okay, a few more comments here. Arien?

Arien Malec - Vice President for the Data Platform Solution Line – RelayHealth

This will follow on the previous comments on the USCDI. The taskforce charge, I would recommend including some of the comments, Genevieve, that you made and some of the committee members have made, around prioritizing data that wants to be in the USCDI relative to priority areas. So, quality measurement being one. Otherwise, based on future or previous experience, you get a wish list of everybody's private hobbyhorses, as opposed to a prioritized list that's secondary to national priorities. Quite famously, for example, full risk assessment is necessary to adjudicate a number of clinical quality measures, but you can't get it currently out of – or you sort of only inconsistently can get it out of the common core data set and the consolidated CDA. So, if the charge to the taskforce could include that, I think that might be useful in sharpening the recommendations. Thank you.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Thank you. Ken?

Kensaku Kawamoto, MD, PhD, MHS - Assoc. Chief Medical Information Officer - Univ. of Utah

Two quick comments. First, with regard to identifying candidates for adding to the core set, I think one way to look at this is what are vendors and what are healthcare providers already building into their interfaces? So, at our institution, we use Epic. And we have a number of folks who are certified and have built a number of APIs to meet our use cases, like for addressing the opioid crisis. And I think as we build these, I think ONC can provide a coordinating role so that we don't each just do our own thing. And then I think it'll be a natural progression, because we're building it because we actually need it. Second comment is, I'd say that even because a standard exists for how to pull certain data doesn't mean the work is done. So, for example, for labs, if you try to pull data based on **Loink** codes, it depends on how it's been mapped locally, so you might want a glucose. But in our institution, might only pull 90 percent of the glucoses because some others haven't been mapped properly. Or it might be the case that you pull in glucoses that were pulled out of spinal taps because they were mapped incorrectly.

And at the same time, I think it's impossible really to say map everything. Mapping 4,000 labs is a huge task. So, I think beyond just saying, for example, labs and use Loink, there would be a lot of value in saying of the labs, here's the 50 that would be most useful to make sure we communicate properly, like hemoglobin A1Cs, etc., and then to have processes to – if only to encourage local institutions to map them properly so that when you get that data from across – from a different state about the patient's glucose, you're actually getting a blood glucose and not glucose that was in the cerebral spinal fluid.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Thank you. Anil, and then Denni.

Anil Jain - VP and Chief Health Informatics Officer - IBM Watson Health

Anil Jain, IBM Watson Health. I just want to also compliment the team, the ONC, on what I think is a wonderful framework for simplifying exchange. And I think from the perspective of folks who are clients who are producing the data ourselves, our solutions, who are consuming the data, having the unimpeded flow of information is very critical. I think one of the things that I sort of want to comment on is that when you think about the core data and the extension of the core data, the QHINs may be in a unique spot to be able to see what kind of data in the real world is actually beginning to emerge. We may want to think about how do we use the QHINs to get real time data about what's actually happening in the field so we don't repeat the mistakes of the past where we put mandates in place and don't let our colleagues catch up to where we currently are.

Another comment I'll make is that I think it's important for us, when we look – I think it was an initial part of what Steve was talking about – without special effort as part of the thing. I'm not sure exactly what that means. And so, I think we need to in the taskforce spend a little bit of time on what it really means to be able to exchange information with a core dataset without special effort, and what that really means. Thank you.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Thank you. Denni?

Denni McColm, MBA - Chief Information Officer - Citizens Memorial Hospital

So, I have a number of questions. Thank you also for your work. And I just – this is sort of a procedural question, I guess, a FACA question, how the taskforces maybe work. If you're not on a taskforce but you hope they consider certain questions that we don't have time for today, which I'm sure that is many of us, right – is there a way to submit those to the taskforce that you're not on, or do you just wait till it comes back to the full committee for consideration?

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

So, questions specific to the other taskforce, you mean?

Denni

Yeah, another taskforce that maybe you're not on.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Yeah. I think we'll get in place a process for there to be a bilateral communication between the two taskforces.

Steve Posnak

We're happy to have you on any taskforce you want to be on.

Genevieve Morris

But we are limiting numbers on the taskforce, so. But so, everybody can't be on every taskforce, because we do need a small number of folks on the taskforce as compared to the larger committee, so I think we can work out a way for you to make sure that if you have particular questions or things that you want them to consider, that that gets shared with them so it's part of their deliberations. Yeah.

Steve Posnak

And especially for everyone, as we kind of discussed today, about just general mechanics. For those of you that aren't on a particular taskforce, you're obviously welcome to listen into them. But then equally, you're gonna have colleagues here that will be the co-chairs who you can communicate to to make sure your concerns or questions are voiced to the taskforce.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Okay. And we are running short on time, so we're gonna take one or two quick questions, and then we will start to wrap up. Steven Lane?

Steven Lane - Clinical Informatics Physician Director - Sutter Health

Thank you. I just wanted a simple ask. If one of the asks of our committee is to help guide ONC, and we've heard about all the amazing work that's going on, I think it would be helpful for all of us to see an org chart to know how many resources you have and how they're organized, so that we can use that in crafting our input. So, just a comment there. A brief note. We've made a number of references to international exchange. The test, as far as we can see, is really all about national. But I mean, I work out on the left coast. My patients slide back and forth across the Pacific all the time. So, there's a lot of work going on around the rest of the globe. What, if any, effort is going to be made over this next period of time to align or at least acknowledge where our evolving standards may touch on international standards?

Donald Rucker - National Coordinator for Health Information Technology - Office of the National Coordinator for Health IT (ONC)

I can answer that very briefly. We are doing some international stuff with the United Kingdom and Australia in particular, and we look forward, if there are other things that folks want to bring in. The underlying standards work, I think, has historically been fairly international, right, so, when you look at some of the standards. But we're absolutely open to learning from whoever, wherever.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Okay. And Robert, you will have the last comment or question of the day before we wrap up.

Robert Wah - Global Chief Medical Officer - DXC Technology

Thanks. We're doing high finance here. So, let me get my head straight around this. So, just to kind of connect a couple things that we said at the end here, I think this business of international is important to think about. What can we learn from what's going on in other places around the world was one of my points. But the other thing is, what can we learn from other industries? And a couple of us have noticed that around the table, we're obviously well experienced from a healthcare perspective. But there's a lot of activity in retail, and banking, and finance, and places like that, that are moving lots of information around very much more fluidly than we are in healthcare. And is there something we can learn from that process? I've always been hesitant to get involved in the business about financial transactions as related to healthcare transactions because I think the data dictionary is infinitely more complex in healthcare than it is finance.

But just the mechanics of how they're moving data is something that might be worth looking at, because there's a high level of expectation from a citizen patient side that their world that they see in retail, and finance, and banking is not seen when they're on the healthcare side. And so, that level of expectation, we've got to figure out how to meet. So, I know we're probably not gonna add new people to the HITAC, but there may be an opportunity for either testimony to the HITAC or to the taskforces to get that input from other industries that we ought to think about how do we include that. Because I think that's something that – and the other part of that is maybe a more youthful perspective and experience base on how this all works as well. Not that any of us here are old, but anyway, I'll leave it there. So, that'd be my comment, is that maybe in the taskforce process, we find ways to get these other perspectives, because I think that they would be very helpful, certainly in meeting the expectation of our large clientele.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

And that's certainly allowable, to have outside expertise come and brief the committee. So, with that, I would like to introduce to my right here, our Principal Deputy National Coordinator, John White, Dr. John White. Pardon me. Deputy.

John White

Yes, so John and I were talking, and we collectively as the ONC team would like to thank all of you. This is a lot of time. We're asking even more of your time. Presumably volunteered. I'm not sure in every case that sometimes you were volunteered for these positions. There's lots of work to be done. I think this was a very solid first meeting. I want to thank all our folks in the back from ONC who have been involved in this. Having been on the other side of the table on these kinds of things, there is a tradeoff between how much ONC talks to you in these things to get you up to date on what we're doing, and how much we hear and collectively have you talk. We're gonna try to shift that, I think, the next time around, so it's more your talking to us rather than us talking to you. Again, just speaking from personal experience, we will make sure we have discipline on what we send you as pre-work to read. The more that you actually do the reading on the pre-work, the more effective you're going to be. And I know that varies and peoples' time is great. But we're actually open to changing a little bit of the dynamics of information flows

here, and look forward to setting that ongoing balance on things.

And with that, I just want to thank our public for dialing in and participating today. I would like to thank all of you. And we will have co-chairs, and to Robert's comment, we'll also, I think, think about how to broaden this in as many ways as we can get national information. Certainly the taskforces, which Lauren will be working on, we'll make sure those are maximally valuable to all of us collectively. So, with that, safe travels. Thank you very much.

Lauren Richie - Designated Federal Officer – Office of the National Coordinator for Health Information Technology

Thank you. So, just a couple of quick reminders. So, if you are interested in either taskforce, to please send me an email as quickly as possible. And as a reminder to those on the phone, our next meeting will be February 21st, and that will be a virtual meeting. And I will call the meeting adjourned. Thank you.

[End of Audio]

Duration: 274 minutes