Health IT Advisory Committee

Summary for January 18, 2018
In-person Meeting

The January 18, 2018, Health IT Advisory Committee (HITAC) was called to order at 9:00 am by **Lauren Richie**, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), and **Donald Rucker**, National Coordinator, ONC.

Richie: Thank you for being here today. I am going to officially call the meeting to order. I will start with a brief roll call, and then I will turn it over to our national coordinator, Donald Rucker.

Present Members, Representing
Michael Adcock, University of Mississippi Medical Center
Christina Caraballo, Get Real Health
Tina Esposito, Advocate Health Care
Cynthia A. Fisher, WaterRev, LLC
Brad Gescheider, PatientsLikeMe
Valerie Grey, New York eHealth Collaborative
Anil Jain, IBM Watson Health
John Kansky, Indiana Health Information Exchange
Kensaku Kawamoto, University of Utah Health
Steven Lane, Sutter Health
Leslie Lenert, Medical University of South Carolina
Arien Malec, RelayHealth
Denni McColm, Citizens Memorial Healthcare
Clem McDonald, National Library of Medicine
Aaron Miri, Imprivata
Brett Oliver, Baptist Health
Terrence O'Malley, Massachusetts General Hospital
Carolyn Petersen, Mayo Clinic
Raj Ratwani, MedStar Health
Steve L. Ready, Norton Healthcare
Patrick Soon-Shiong, NantHealth
Sasha TerMatt, Epic
Andrew Truscott, Accenture
Sheryl Turney, Anthem BCBS
Robert Wah, DXC Technology
Denise Webb, Marshfield Clinic Health System

Federal Representatives
Kate Goodrich, CMS
Chesley Richards, Public Health Scientific Services, CDC
Ram Sriram, National Institute of Standards and Technology
Lauren Thompson, DoD/VA Interagency Program Office

ONC Executives Present
Donald Rucker, National Coordinator, ONC
Genevieve Morris, Principal Deputy National Coordinator, ONC
Elise Sweeney Anthony, Director of Policy, ONC
Steve Posnack, Director, Office of Technology, ONC
Lauren Richie, Designated Federal Officer, ONC

Welcome Remarks –
Donald Rucker, National Coordinator for Health IT (ONC)
Eric Hargan, Acting Secretary (HHS)

Donald Rucker: This is our first public meeting for the re-assembled HITAC group. We are the advisory committee to advise the country on some key modern questions as we move to electronic health records. 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?

Rucker introduced Acting Secretary of the Department of Health and Human Services, Eric Hargan, who has experience in this space.

Eric Hargan: Thank you, Dr. Rucker, for that introduction and for all you have been doing. That's right. We want to make sure that everyone here understands what a focus this is. I am here to make sure that is well understood. Thank you for joining us on this important occasion. In particular to all of you who have agreed to serve on HITAC, we are grateful for commitment that you have made and look forward to working with you to make these recommendations a reality. The establishment of the 21st century Cures Act was a major step forward. 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, is I believe both telling and important, your immense collective experience on health care and technology will be an important asset and helping us to set a strategic direction for company's health IT system. This body, we expect will have a key role in achieving ONC goal, the goals that we have set for the national coordinator relating to the implementation of national and local health IT on the following target areas.

Number one, achieving health IT infrastructure that allows for the facilitating individual, secure access to their protected health information because we know Americans want control of their own 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.

Of course, considering any other target area that the HITAC identifies as appropriate. The work will be difficult. In my time as acting deputy secretary during the Bush administration, then-HHS Secretary Mike Leavitt made health a top priority. The amount of time he spent on that was an immense. 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 know, as in any ambitious enterprise, some of those efforts came up short.

It was an ambitious undertaking but we couldn't get everything done, but we have many reasons to be more optimistic today. We have made huge progress and more useful, the 21st Century offers us new abilities, new tools and advances for interoperability, allowing new design software applications and tools that will help solve complex challenges. Meanwhile, technology, as we know, has advanced by leaps and pounds in terms of the ability to harness big data through machine learning and store and share data through the cloud. Most important, it has allowed ordinary Americans ability to access and use their own health data.

One of the main goals we have today is to make health data even more accessible through smart phones. This is something that just was not possible for most Americans in 2008, when just 11% had smart phones. But as of 2016, that number is up over 81%. We now have new possibilities for advancement and the expectation of performance. That 81+% of Americans probably, at some point are going to wonder why they can't use their phone to access their own health data and records. It is not just HHS, it is not just stakeholders and regulators gathered here today who are eager to see progress on this front. The high priority placed on interoperability and the promise of health IT went to the very top of this administration. I can personally tell you that the White House is deeply committed to this effort. I have been in multiple meetings at the White House on this very topic already.

But just as important, the demand for advancing health IT also is coming from the ground up. You are working toward 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 has dealt with a complicated medical issue knows the feeling of powerlessness that can beset you, and nearly all of us have been frustrated at some point by the health systems' 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 the source of the problem.

Rucker: One of the charges for the HITAC committee is on privacy. ONC has just announced that Katherine Marchesini will be its Chief Privacy Officer. Her credentials are quite impressive. Also, we are asking members of HITAC who might be interested to volunteer for one of the co-chair positions for the advisory committee and/or a chair position on one of the two task forces already set up. We will have those names for you before the next meeting February 21.

Presentation 1: Overview of 21st Century Cures Act and Office of Policy Update - *Elise Sweeney Anthony, Director of Policy (ONC)*

Sweeney-Anthony: Today Steven Posnack, Director of the Office of Standards and Technology at ONC, will provide some updates on work underway at ONC.

I will begin by discussing key portions of that work, then offer an overview of Title IV of the Cures Act.

Interactive PDF (Portable Document Format) Files
As a learning tool, ONC has built several interactive, navigable graphics in PDF files. They are located on the ONC Home page (beta site).

Certified Health IT. This one highlights the 2015 Edition Certification Criteria. We call it the "wheelie." we wanted to develop a resource that could be used by the community to quickly see the eight certification criteria categories. We hope this is a good resource and we are open to feedback an how it is used and how it works for you.

ONC also created supplemental interactive PDFs highlighting certification criteria that support the access and exchange of health information across the care continuum and to patients.

2018 Model Privacy Notice (MPN). ONC updated the model privacy notice from the original 2011 version, which focused on personal health records, as they were called at the time.
This is a voluntary, openly available resource to help developers provide transparent notice to consumers about what happens to their data.
reference. Stakeholders told us this was needed in the industry, and we hoped to provide that.

Communicable Diseases. We are doing work to think about how health IT can help support the needs of emergencies such as Ebola or the ZIKA virus. This might be through surveillance, case reporting, for example, or turning clinical guidelines from CDC into clinical decision support and EHR systems. Those are some resources that we aim to provide.
In response to multiple cases of the ZIKA virus, ONC updated the interoperability standard to include additional pregnancy information and that was one of the recommendations of the task force under the previous committees.

Disaster preparedness and response. The patient unified look-up system for emergencies (PULSE) provides interconnectivity so provider organizations and healthcare professionals to query for and view patient documents during disasters. Once that was set up we worked with California to identify how it could be integrated into their health IT systems across the state. We're looking forward to the best practices that we have learned from California to inform the work across other states and we're seeing some interest in that as well.

Playbook.
This is the Patient Demographic Data Quality Framework and Ambulatory Guide, a resource to show how IT can help providers in their daily practice, provide information on everything from patient engagement to more specific information about how the certification program operates. It's for those front line practice professionals who are taking in information from patients and inputting it into the system, we know that's an important part of making sure that information lives in an accurate way once it is actually in the system.

ONC has two Playbook modules, one for behavioral health and one for long-term and post-acute care providers.

ONC developed a report called "Improving the Health Records Request Process for Patients," based around some research on patients' ability to access health records and the process to do so. 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 the Cures Act and various operations of the program.

21st Century Cures Act.

Sweeney-Anthony discussed the function of the Policy office at the ONC. She presented key components in Title IV of the 21st Century Cures Act, the provisions most concerning the HITAC. The Cures Act, passed by Congress in 2016, established the re-formed advisory committee with a focus on interoperability.

Sections 4001 through 4008 are most concerned with the HITAC, its work and its goals. Four Priority Target Areas HITAC is expected to address are highlighted in the Cures Act. They are:

1. The Trusted Exchange Framework and Common Agreement;
2. U.S. Core Data for Interoperability (USCDI Glide Path);
3. Standards Use Cases; and
4. ONC's upcoming rule to implement provisions of the Cures Act.

Key points in the Cures Act include:

Reduction of burden. An overarching goal of the HITAC's work is to recommend ways to reduce the regulatory and administrative burden to the federal government regarding the use of electronic health records (EHRs). Additionally, the Act requests recommendations on a voluntary certification of Health IT for use by pediatric health providers.

Transparent reporting on usability, security and functionality. This is one condition of certification for health IT developers or entities, such as providers, which are covered under the Cures Act. Those participating entities must endeavor to conduct EHR activities with transparency and not to engage in information blocking.

Trusted Exchange Framework and Common Agreement (TEF, or TEFCA). The Cures Act requires a Trusted Exchange Format and Common Agreement to provide policies, procedures and technical standards necessary to advance Health IT (HIT) interoperability. HITAC is charged with reviewing the TEF, a draft of which ONC released January 5, 2018. Public comments on the draft are due February 20. (See timeline at the end of this presentation.)

Although the draft seeks public comments, it is a non-regulatory document.

Recognized Coordinating Entity (RCE). The TEF proposes a single Recognized Coordinating Entity (RCE) that ONC will select through a competitive bidding process. ONC plans to select an RCE by mid-2018. This entity will develop a single Common Agreement that Qualified Health Information Networks (QHINs) and those who participate in the QHINs will voluntarily agree to adopt.

The TEF would not prevent existing or new organizations from creating point-to-point or individual agreements (that differ from the single common agreement) between or among entities that have a particular business need to exchange information.

Important goals of the TEF include:

- Increase patients' access to their health information;
- Allow population-level data exchange;
- Provide open and accessible application programming interfaces (APIs); and
- Eliminate the practice of information blocking.

Information Blocking. This is "a practice that is likely to interfere with, prevent or materially discourage access, exchange or use of electronic health information." Historically, information blocking has been a hindrance to developing interoperability.

Rule on HIT Interoperability and Certification Enhancements. The Cures Act requires a rule, also called a regulation, to be published in the Federal Register, that describes the process to sign on to the TEF. HITAC will be charged to review and comment on the rule. The proposed rule is expected to be published in the Federal Register by the end of April, and a final rule by mid-2018. The rule will update certain provisions of the Cures Act.

In addition, the Cures Act requires users to leverage electronic health systems to improve patient care and safety, empower patient use of and access to their electronic health information. Two Government Accountability Office studies, one on patient matching and another on patient access to health information, are required by the law.

Annual Report. HITAC is required to produce an annual report to Congress on its activities, progress in achieving its goals and future expectations. This is due by the end of the fiscal year, September 30.

These slides are on the HealthIT.gov site.

Rucker asked Jon Fleming, deputy assistant coordinator for Health IT, to comment on the Cures Act. He's a family practice doctor who unlike most family practice doctors was also a four-term member of the U.S. Congress and EMR pioneer going back a long way. Maybe, John I think you voted for the cares act. Can you say a couple of words here?

Jon Fleming: Yes, I voted for the 21st Century Cures act. The Act comes as close as I have ever seen to being on target to addressing the real problems and the forward-moving issues.

Question and Answer Period 1

Raj Ratwani: The language in the Cures Act on information blocking also hints toward things like the blocking of information around the assessment of usability of the EHRs and security of HR. Can you elaborate on that and whether that falls under information blocking?

Sweeney-Anthony: Unfortunately, I cannot because it falls within the proposed rule that ONC is drafting. I can't comment right now on the interpretation. However, HITAC members should comment on the proposed rule when it is published and that's expected to be April.

Arien Malec: What we can do to better promote some of this information?

Sweeney-Anthony: There are many opportunities for us at ONC to present on these issues or to make the resources available. We are absolutely open to it. Any resource or suggestion you have in terms of how to reach out, we are happy to bring those back to the public affairs team.

Clem McDonald: The Cures Act says all clinical data should be interoperable. Are there any thoughts about what we start to bite off—because **all** is a big number.

Sweeney-Anthony: This is one thing that we are looking at. Part of the presentation this afternoon will touch on the ways we 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 the U.S. Core data Interoperability. but Steve or -- will jump in with what to add now. If not I am sure it will be covered this afternoon.

Terri O'Malley: What is the process for adding other target areas?

Sweeney-Anthony: As the task force one thing we want feedback on whether we have hit the right targets. Right now it is around the current and then candidate, data class and emerging data classes but we look forward to feedback on whether that is the right way to think about it and of course the right time lines for what we need for interoperability.

Rucker: We are talking about structured data here for the most part, and you also have to think of it in the context of what are the payload standards. It is not just the choice of data but the status the of the standards, and the fitness of those standards over time and getting them at least somewhat right

Patrick Soon-Shiong: Is the ONC, as it moves forward, going to adopt some of the technology that's available today and look forward in fact to things like cloud computing block chain, artificial intelligence? It is not just data information but looking at real-time data?

Rucker: The answer is yes. Steve Posnack has done some work on exploring block chain which you maybe talk about a little bit, but absolutely, we are interested in new technologies. An important technical part of what we are working on is making sure that the transmission of data is not just one patient at a time, the classic provider to provider, but that we actually leverage these technologies to be able to look at populations—collective data. We have gotten a lot of feedback that we need to facilitate exactly what you are asking for.

Ken Katsumoto: I totally support Patrick's comments. The interoperability of executable knowledge is really important, whether it is the establishment of standards, measurement and then support of it, that's first steps but also how is it implemented? There's this important life cycle of standards and data. There's an interface mapping the standard code if we're using local codes. What's the processes so that we make sure that not 80%, not 90% but 100% of data gets encoded and translated. So that's something we should focus on as well.

Presentation 2: ONC's Office of Standards and Technology - *Steve Posnack, Director, Office of Standards and Technology (ONC)*

Posnack: Today I'd like to discuss the certification program. We require that the authorized testing laboratories and authorized certification bodies be accredited so there are ISO standards for the various competencies associate with testing and certification. The accreditation organizations for our program, one is run by NIST, the national voluntary laboratory accreditation program and the other is run by ANSI, which handles the certification side. Both of those, need to be first accredited for their competency.

Addressing surveillance. The other thing that is perhaps misunderstood at times is that the authorized testing and certification bodies that we use are not paid for by ONC. They are separate third-party organizations. They have certain obligations to perform on our behalf at a first level and some of those include the oversight responsibilities: Answering questions such as, Did the product perform in the field appropriately?

We also have post-certification surveillance, a robust approach for health care providers and other stakeholders to submit complaints or reports to both ONC as well as certification bodies and we follow up if there are any issues associated with those products. Our interest primarily is to get the product fixed.

That's kind of a rough overview of the certification program, and its constituent parts. There are a number of different rules that really inform this regulatory architecture. We have the overall program rules that establish the processes, how we engage with certification bodies. We have a 2015 edition and that is commensurate to the EHR incentive program policies and now the quality payment program policies if you are in the ambulatory space. It is kind of a rough subset of a dozen or so criteria. And those are basic functions that Congress required, such as demographics, medication information, problem with information, the ability to exchange certain health information data, and deal with relevant quality information as well.

One thing we administer on behalf of the certification program is what we call the certified Health IT product list. As products get certified we add them to a single listing. This is another acronym, we refer to it as CHPL, or the Certified Health IT Product List. All product information associated with the certification program including all of the data that comes about as a result of the program, are made available.

Most providers need to get a CMS ID number, and in connection with our colleagues at CMS, we realized that health care providers often have multiple technology solutions that they're implementing in their environment. This is especially true in the hospital setting so we wanted to enable a way for providers to pick from a health IT certification product list and put them into a single ID that they could report to CMS. That functionality is also build into the product list.

For anyone interested in the data, we make this available in an open data format. We have APIs that are part of CHPL, access to all of that data, it is all there built in and you are certainly welcome to contact my team if you would like more information about it.

We provide support for a number of electronic testing tools for standards performance. We have done this for the past eight years in collaboration with our colleagues at NIST. They have developed and supported several of the testing tools that we operate for the program.

We also have been ramping up the awareness that we are open to approving alternatives to the government-produced testing methods. Last year we had two organizations step forward to get their alternative testing methods approved. The benefit is that a product could get tested once and use those test results across testing organizations..

When it comes to the other agencies, we do a lot of work in support of and with our colleagues at CMS, VA, and agency for health care research equality, and OIG.

We have developed a web infrastructure now available on HealthITgov. It represents the collective wisdom of our entire community. One thing that we realized as we were working on the road map several years ago was that every time we wanted to talk about a particular interoperability need or a particular set of cases we wanted to address we had to recreate the resources, by the specifications available, what are the IEP available, what are the terminologies that we needed and it became inefficient.

So we wanted to engage with industry to make available a resource for all stakeholders that include a need that we are aware of, presenting the standards and specification, some information you may want to know about where that standard is. Has it been pilot tested? Is it in production? How many people are using it? Are there testing tools available for it? So we provide all of that information through the interoperability standards advisory which is constantly updated.

At the end of December of last year, we published a 2018 reference edition, a snapshot of everything that is in the standards advisory. One evolution that we made was moving from a PDF to online. It is updated real time. We are always looking for ways to improve it.

We have put out a score card, and you can use it to give yourself a check up on how your Consolidated Clinical Documentation Architecture, or CCDA, is constructed. It can be used by health IT developers or by various health information exchanges, registry organizations, anyone that is using CCDA. You can run one through it and it will give you the score. It can be downloaded.

Within the topic of innovation, we look across various different areas for innovative work that is going on. For example block chain was one technology a couple of years ago that had reached a certain level of interest. We ran an idea challenge for white papers, we had over 70 submitted and then we collaborated with our colleagues to run a work shop about block chain in health care. If you go to our innovation section on the tech lab part of the website you can find those white papers which I am sure are still pretty fresh relative to the idea.

We also manage interoperability and action webinars so as we produce particular activities such as patient matching resources, we make available in a half day web session a way to expose everyone to various information that would be available to different stakeholders in that particular interest. Other things that we do, relative to innovation, so far as we have the resources available, we run prize competitions. The America Competes Act allows federal agencies to do various different prize competitions. When we see a particular acute need for focus, we work with industry to develop a prize competition. Right now we have one on API security, and specifically, FHIR, which we call the secure API showdown challenge. We have another on data provenance which is Dr. Seuss inspired called the "Oh the places data goes" challenge.

Rucker: That's a bit of a laundry list but it's important to know what's working, what's not working, what should be done differently. An important part of the committee's work is to give us feedback on those programs.

Question and Answer Period 2

Arien Malec: What is the future of the certification program?

Sweeney-Anthony: The certification program is a really important piece of the standardization and that floor of the interoperability pieces. All of these programs work together.

Rucker: Certainly the intent of meaningful use is really going to be interoperability and the broader work of making sure that the entire stack of federal activities is efficient from a provider point of view.

Malec: Since the 2015 edition, there has been a lot of work on refining the API requirements that were functional certification only. Should I anticipate that there's another certification, a 2018 or 2019 rule coming down that will get incorporated into the MIPS or the APM program that will drive development and activity? If you are an EHR developer, they're important to plan your road map cycle.

Rucker: Let me ask Kate Goodrich, the federal representative from CMS, to comment on that.

Kate Goodrich: We understand the need in the provider and vendor communities in particular to understand the road map ahead of time for the reasons that you just stated. It is definitely very much on your minds.

John Kansky: Does ONC have a role in regulating the prices or is it completely determined by the market?

Posnack: It is completely determined by the market.

Ken Kawamoto: These projects always take longer than one thinks they will. That's a theme here, and so I think it is really important for us to balance both letting the perfect get in way of good but being realistic. Sometimes we will get further if we really consider being thoughtful about not rushing forward with things we're not get quite ready for. So, I think all of us are aware of it, but I want to emphasize that we will go further if we go a little bit slower and more methodically through it.

Public Comment Period 1

Larry Wolf: I am the Chief Information Officer with MatrixCare, our message is about integrated care and better outcomes. Our mission is to leverage technology to improve the quality of lives for seniors. Our customers are primarily providers that support seniors, like planned communities, assisted and independent facilities and home health. The IT community has accomplished a lot and there's a lot more to do. I would like to point out that it is not just about technology. It is also about culture and organizational capabilities because health and health care is a very human activity. I think there's a good guideline there—You want to make the right thing to do the easy thing to do. We have talked a lot about access to information, and I would suggest you also need to equally focus on how we present that information.

Grace Collins: I founded Telecare Givers. It is a curriculum and a compendium app that helps train home health care workers about the latest in telemetric services in a home health care setting. It is basically a work force development project. I have realized over the years that telemedicine has changed and evolved so much and been acceptable, as a word, that people are starting to

understand it. Ninety percent of people want to stay at home as long as possible. A lot of regulations have prohibited me from advancing, but with all of this Health IT work, self tracking, that has been freed up. So in my business plan, I have already put in, on the grander scale, ONC, and I commend you for all of the work that you have done because part of my goal is interoperability and usability from someone who is at a lower level but actually the person who is spending most of their time with the patient. It is not the doctor. It is not the nurse. I appreciate a chance to be here and to tell you more about my project. I hope that CMS and others will adopt this on a federal level. Thank you.

Presentation 3: Trusted Exchange Framework and Common Agreement (TEF, or TEFCA) and U.S. Core Data for Interoperability (USCDI, also called Glide Path) - *Genevieve Morris, Principal Deputy National Coordinator for Health IT, ONC*

Morris: We will put together a TEF task force to actually develop the comments and feedback and recommendations that will come up to the committee for review and come to ONC. we released the framework on January 5 which is two weeks ago. Today is the first official meeting. Public comments are due February 20. By March 19 we expect to have recommendations from the HITAC. As a point of order, the full committee meeting following that date is March 21. The comments will come to us on a Friday. On the 21st, those would be publicly presented during the full committee meeting. April 18 is the date for the U.S. Core Data for Interoperability Task Force comments. Toward the end of this year in December, we would have the HITAC final report that you are working on for Congress. Hopefully around the same time, we will release the final TEFCA.

2018 Timeline
Jan 5—Release Draft TEF
Jan 18—First official meeting, HITAC
Feb 20—Public comments due on TEF
Mar 19—Present TEF Taskforce comments
Apr 18—Present USCDI Taskforce comments
Dec 2018—HITAC Final Report
Dec 2018—Release final TEFCA

For the task force, we have drafted an overarching charge: Develop an advanced recommendation on parts A and B of the draft TEF which would inform the development of both the final TEF and common agreement, which we collectively call TEFCA. We are looking for recommendations around the recognized coordinating entity (RCE), the definition and requirements of qualified health information networks, permitted uses and disclosures, and a number privacy and security items that are included in part B.
These slides will be on the task force website.

What is the draft trusted exchange framework? It's broken into two parts. Part A is general principles for trusted exchange. These are the guardrails that should be placed to ensure trust for folks exchanging data. We have broken it into six principles. These are the same principles we asked for during the first public comment period. There weren't a lot of changes aside from adding in the security and privacy to the principle number four.

Part B is the minimum required terms and conditions. These are legal terms and conditions that are set out across the six principles. We try to keep the same organizational structure in both parts. It

also includes a long list of definitions. One key for reading the framework when you are reading through part A, if something is capitalized, that means it is an actual, formal definition in Part B. Pay attention to the Part B definition because that impacts who that might apply to.

We will work with an industry organization, called a Recognized Coordinating Entity, or RCE, which would develop the full common agreement.

Part B does not in any way contain all of the terms and conditions you would need as part of the 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.

Certainly there are many other legal terms that you need in order to exchange data. That would become the full common agreement. The other legal terms plus the minimum required terms and conditions are included. What ONC would keep up-to-date is the TEF because we anticipate the minimum bar might need to be raised, when you think about security requirements in particular. The common agreement would have to mirror any updates that are made to Part B and the minimum required terms and conditions.

After incorporating comments, the full TEFCA would be posted in the Federal Register at the end of the year.

As we develop the framework, there were five goals that led our thinking around actions concerning the TEFCA:

1. Build on existing work done in the industry. Kudos to the progress the industry has made. We would be disingenuous if we didn't say that we have certainly made progress in the last five or six years. We have made significant progress in many ways technologically from policy perspective and connectivity wise. It included using existing standards that are used now and building off of some of the ways that folks are sharing data now into what is in Part B.

2. Provide a single on-ramp to interoperability. So this is just a concept that now, people have to join multiple networks and they really do not like that nor can they afford it. It's just not really great. We think health information exchanges should work more like cell phone networks where it does not matter which one you are on or which one I am on. We can still exchange text messages and phone calls. I can to my phone number with me if I choose to move off of Verizon to another carrier. That's how we think this should work. Providers can pick the network they want to pick entering it and get access to the data they need and exchange data with the folks they need to exchange with including third-party vendors or folks like qualified clinical data registries.

3. Be scalable to support nationwide exchange. This is where I think we need to be realistic about where we are right now. We have a lot of health systems in the country connected and sharing data. When you move into the ambulatory space including primary care, specialists, long-term care, behavioral health, we just don't have significant levels of connectivity from a query perspective. A lot of those folks are using direct messaging to send messages. Being able to discover patient data in the laboratory setting is still not there.

The way we think about this, if we actually get to nationwide exchange, the number of messages being exchanged every day is billions upon trillions of messages. As we build out the framework, we have to think about being scalable to handle that number of broadcast queries every single day by providers who need to discover patient data in real-time. So that was a very large consideration for us and how we scoped out the requirements.

4. Build a competitive market. Right now, there are a lot of providers that might want to work with third party vendors. There are a lot of third-party vendors that have cool, innovative products that they cannot get the data to make this product work. So we want a marketplace that is not based on hoarding the data and selling the data but is based on data services you can provide. We think that starts to affect some usability pieces. If we had more innovative technology, more sharing with third parties that providers want to do -- use, like clinical quality measures, that gets better usability. We think it is important to even out the market that is now not very competitive in the spaces.

5. Long-term sustainability. This has been a struggle for years. The word sustainability is a bit of a dirty word that we don't like to use. We need that for nationwide exchange. At the end of the day, we need to be able to exchange data not just today but for many years to come. So who can use the framework? From a stakeholder perspective, we try to be parsimonious and who we thought might want to use the framework for exchanging data. The framework is at the top. We try to think about the different folks. If you are trying to build a single on-ramp where providers and patients and other folks only have to join one network, that means these other stakeholders have to be available to them via that network. As we build out part B, we tried to keep in mind we need to use it.

A couple of terms, there's the term Health Information Network (HIN). There's a Qualified health Information Network (QHIN). If you read through the Cures legislation and statutes, it says that we are to develop or support a TEF and common agreement to connect together HINs. We have defined health information networks in Part B in the definition section. We also define the QHIN.

The HIN has broad definition and somewhat purposely so because there are a lot of them We have to follow what the statute says. So certainly, health information exchanges fit into the definition of a HIN. Some of the EHR vendor networks also fit into that definition.

Then we have the definition of QHIN. You have to be a HIN first to be a Qualified HIN. And there is an additional set of requirements around being able to locate what we are calling electronic health information, which is a new definition. Check that out and give us a comment. They must have mechanisms in place to be able to enforce the minimum core obligations and some of the flow-down clauses that are in part B.
You must have participants who are actively exchanging data. In other words, if you are a network who has no users or anybody live in production you would not be a QHIN which is important to make sure we have folks signing on who can support what we need to be supported.

How will this all work, I mentioned earlier something called the RCE. We are looking for an industry based organization to partner with us to be recognized. We want to work with industry to find someone who has experience doing this who has creative agreements and knows what needs to be in those agreements. Also, the QHIN should know how to bring stakeholders to the table to deal with areas of a disconnect between what stakeholders might want and what others might not want. If you are familiar with the work of ONC you know the type of vehicle which allows us to work very

closely in partnership with organizations versus doing a straight-out contract. We will be releasing a funding opportunity announcement for an open, competitive and transparent bid.

This would be around April or May timeframe, with the goal of having the RCE in place no later than August . We will have an objective panel, not ONC staff, to make the selection. We are anticipating a couple of organizations will have interest.

The QHIN would have general governance responsibility. Some of the services that the QHIN would provide include being able to do broadcast queries without having to have a centralized infrastructure. Broadcast query is where you don't actually have to know who you're asking for the data from. That's a pretty important component. We are trying our best not to specify the type of participants that any QHIN would have. It's going to be based on the cases that they support and the services they want to provide.

We don't want to dictate that. However, we have been asked a lot of questions about who isn't and is a qualified HIN, we want to give detail and I would say that these are just examples. One example, and this is not something that actually exists today, would be a QHIN that has a bunch of payers who agree to follow the terms and conditions of the framework.
A regional health information exchange (HIE) on his own would not likely be a qualified network. There could be chances that what happened but likely they were not. A regional HIE could be a QHIN if everybody agrees to the terms and conditions. Likewise, a single EHR vendor network would not be a QHIN based on the requirements. I think the whole system would not be a QHIN based on the neutral requirements.

Question and Answer Period 3

Leslie Lenert: Based on what the policies implement, what's your evaluation strategy for the things that you're doing and how is that build into the standards?
What's' the feedback loop for that.

Sweeney-Anthony: I can answer that quickly and give a overview. Within ONC there are a number of other teams that work on the operations of ONC. One of them is a team that focuses on evaluation and analytics. They focus on that exact question, what we are doing is being measured across different spaces. Looking at things like uptake and certain criteria and products and so forth and where things stand in terms of interoperability. Those types of activities will continue going forward and help us to inform our policy going forward. There's also a feedback loop that we try to build in. With a lot of stakeholder engagements that we use that provide feedback into what we are doing and make sure we are hitting the right mark. The last thing I would add is that we always try to build in these new opportunities and effort for public comment and public engagement and feedback so we are doing it in iterative fashion. Once the final is released, we go back and take the feedback that we have learned from the development of that product.

Unidentified Questioner: Give me an example of a unintended consequence you identified and what you are doing in the future to prevent them from happening again through the policy you've created.

Sweeney-Anthony: Unintended consequences that we have identified, I think one of the things that we have identified at least for me is making sure that the policy where putting together doesn't just touch one particular stakeholder community. Identifying ways to make the policy that we are putting in place in the administration has identified and are understandable to different populations. We have identified that I would say earlier in the process and is something we do different after feedback saying we don't understand what's in the rule or how it affects this population or another. We did quick one-pagers. We are building upon that knowledge and we are doing more so now in terms of making the resources applicable and available to different groups. Likewise with the playbook that also happened where we learned that people are saying we don't quite understand what ONC is doing or how this is applicable to my practice. The Playbook was helpful there.

Christina Caraballo: My question has to do with some of the standards that we have. ONC has done a tremendous amount of work over the past year and it's really becoming interactive and an extremely valuable resource to the community. I was wondering what ONC's plans are to ensure to continue to educate folks outside of our normal dialogue?

Posnack: How we effectively communicate is sometimes 80% of the job. If there are areas where different stakeholder groups we work with are reflected it's often because they have requested it. We encourage that continued collaboration.

Steven Lane: Thank you. 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 and I was trying to fully understand what you were saying wasn't a population query.

Morris: We weren't intending for the population level query to be—I would like to know all the patients that have diabetes in the United States, let me send out a query for all diabetics. A query like that moves toward a gathering and use of data which folks may not be comfortable with.

Rucker: Let me clarify. Very importantly, this does not expand the permitted use of beyond HIPAA. All these queries are things that are already happening today and we are trying to make the same permitted queries efficient. We're really trying to get that pathway to modern computing, at scale.

Lane: Just to comment back, you mentioned the challenges of the payers and requesting data from organizations. It would be helpful if there were clear guidance about what HIPAA says about payer access for these different use cases. Payers are doing so much more in our ecosystem and that would be helpful.

Morris: That's great feedback. Obviously as we all know there's a lot of confusion about the nuances of what HIPAA actually says.

Unidentified: I applaud ONC establishing a baseline for the ability for all participants in the healthcare system, patients, small practices and large institutions to have an equal playing field on access to information. One editorial comment, in some cases the language that is used, it doesn't match and I think it creates problematic interpretations. I think you noted there's a lot of HINs, many of which use this approach because they're working well. We have prescribing networks, lab

and result networks and direct trust and exchange networks. I think there could be a different choice of language and words which make it more clear what the QHIN is attempting to do.

From a policy perspective, in my experience ONC has 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 that exist but not all participants are using them and it's helpful to say that everybody needs to get up to the given floor. In the case of the API-based access, we knew that Smart on FHIR was the ultimate result but we also knew that we couldn't pull something off the shelf that was well tested, well shopped and maintained. In that case, ONC hopefully went to a functional limitation approach, kicked it to the private sector, took up that work and worked with HL7 and established more actionable standards that most of the participants have adopted. In other cases, there has been a lot of work, enough signals and opportunity and people haven't moved and there is a market failure. Naming a standard—even though it's not well tested or defined—is sometimes a way of cutting through market failure.

There's a lot of places where the TEFCA is very specific in terms of which purpose and use fall under common requirements. I think there is a floor right now with patient access and other cases. There is a set of 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 3, which is cut through market failure as opposed to sticking with option 2 which says, some of this stuff has not worked out. But you're selecting the RCE and QHINs, giving them policy goals and asking them to make it happen.

Rucker: We have asked for and received a lot of stakeholder feedback and some of this was a sense that the current build-out (which I'm interpreting as your option 2), has narrow purposes that are very provider facing and in many cases are tamping down economic competition. And they're 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 the congressional recognition that in fact these things have not worked for patients.

Obviously congressional rulemaking, aka laws is a little bit of a coarse instrument and we are left with the operational issues of how we reflect that. The transition, if you will, from option 2 to option 3, reflects the broader public recognition that patients are not in control of their data. They're simply just not part of it. The question then comes, we are using as much of what's out there and getting these broader purposes, how do we do that? There will be a task force on this and we absolutely look forward to getting your and everybody else's thoughts. If this were easy it would have been done already.

Morris: I would counter that and say if we had done option 3, that would be the entire common agreement. We think we actually ended up closer to option two, which is to focus on cutting to those areas where we see problems based on the analysis on the agreements. I sincerely mean this, we had hours upon hours of conversation to take things off the table that are important but are not causing problems. We may not have hit totally on option two but that was what we were aiming for. We look forward to comment on areas where we may have been less specific or more specific.

Clem McDonald: I don't understand why you would totally forbid a centralized system. Are you considering the general logon systems?

Morris: Stakeholders say they don't really want centralized structures. We would be open to comment on whether that approach would work better. The main reason we did not include PUSH is because in talking to stakeholders particularly with use of direct that functioning very well. Early days of direct and I did some analysis on this. EHR vendors were not sharing with each other and that is functioning very well. We felt like the industry figured it out, great job we don't need to touch that. On your last question, we actually have been working on a pilot project with NIST to identify proof a patient end-user Google or Facebook credentials. I would say Google and Facebook don't identity proof so you need to have some mechanism prior to them using those credentials. We are actually doing that project against the new NIST publication and we are monitoring it to see if there are outcomes that we can incorporate.

McDonald: You are saying that PUSH is working so well that we don't need to do it ?

Morris: I would say push from a direct perspective is functioning very well. There are some workflow issues related to the use of it. The other point that I will continue to make is that this is a floor. Just because it's not a part of our core floor does not mean you cannot still use the terms and conditions of the framework to use push cases. That is certainly a possibility where you can do that and still use most of the terms and conditions in the framework.

Carolyn Petersen: I am recommending the ability to accept data on patients is given as a requirement for these qualified HINs.

Morris: Fair point. Most of the time we have been thinking of the end user and in my mind of the participant would be the developer where personal health vendors are helping to facilitate those inflammations. It may not work out that way and they could potentially [Indiscernible] but we don't feel that right now. We were trying somewhat to be a mirror of some of the things that we see.

Carolyn: I recommend that the RCEs have experience with patient collaboration, transmission of patient-generated data or some success in implementing patient portals.

Morris: We will keep that in mind. We are looking for a single RCE, not multiple.

Ken Kawamoto: One thing that would be helpful would be for these cases to have end to end examples that you can provide. For example, I Google search to -- you. And an Australian actress popped up. Let's say what information is being sent and in these queries are you checking based on first and last name and what is it. Who was doing the reconciliation of the data that you're not sure of what data is coming in and what parts are standard. I think the app developer wants to do this have that. I think of a more examples we could have examples of what the issues are.

Morris: That would be great. On the matching piece we did include in Part B a requirement that would be able to use the same demographic information.

Leslie Lenert: I wanted to congratulate you all on the exciting framework that completes the work that was begun so long ago. We have moved from having push operations and now we are trying to implement pull operations and pulling the data into healthcare providers and our networks. I do want to make the comment 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 are looking to achieve. I think it's important that you can document the tools and the system that you put into place are no more

than what's necessary. For example, one question I have is why would a QHIN have to be a vendor neutral organization. I'm not sure that that requirement is necessary. 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 do queries by condition to improve public health. last question, are there allowable research uses of this network to follow on the 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.

Morris: The population level query we just add the way that we stated it and it has to be one of the permanent purposes. We defined what the purpose was which I think was largely the HIPAA definition. We do think that the public health folks could use this were trying to figure out whether could be around a case. We would love feedback around that piece. For the research question, it's not a specific permitted purpose at the moment. I think with anything like this we certainly are making some leap and bounds. We'd like comment on that.

Andrew Truscott: It's excellent to see the level of investment and frankly market awareness in the framework. It's also reassuring to see the level of inquisition around the table. I just want to follow on some of the comments that were made. In one particular area, the framework seems to suggest that a QHIN is required to implement and users. Have you given thought to the potential administrative overhead for a QHIN in this regard?

Morris: We tried to somewhat hedge on who does the authentication. What we tried to allow for was that the QHIN might not be the one doing the identity proofing and authentication. We did try to write it that way and it's possible that it didn't come through and that might be an area where we need to clarify.

Truscott: My suggestion would be if that is our intent, that we are explicit that that is our intent.

Sasha TerMaat: I'm wondering if I'm correctly understanding the role of the broker. Tell me if this is a reasonable analogy. It sounds to me like an old-school phone tree. If I wanted to contact the members instead of calling them each myself I call one person and that person calls a few more. Is that a reasonable analogy?

Morris: At the end of the day it ends up looking like a pyramid or a tree I guess.

Rucker: We are trying to get at the flavor of the modern Internet. There is a technical question that you raise and I think it's worth commenting on the broader issue that we are trying to address and get people's thoughts on the broader issue. The broader issue is that people don't really know who their provider actually is. Maybe I forgot my doctors name which is certainly I would cop to as well and having moved around. Often, who the provider is totally opaque. But we are trying to do is have it so all these new business models that empower patients there is some automation for that search. As with search and computer science in general, there are a whole bunch of ways to do it.

We are very interested in exploring whatever the technical options are that would allow that broader identification and from all kinds of points of view. I think the top level is how do we identify people and get their information in a network way that does not rely on their memory or their ability to identify specific providers. As we think broadly about that, I think that is the problem to be solved. You have to put this into consumer convenience. What we are trying to do is

figure out how would consumer convenience look technically. We're absolutely open to different options. I just want to make sure that for everybody, I think what I understood is the top level question in your comment.

Terri O'Malley: First of all I would like to re-echo the kudos. I have one concern and I hate to kick this one more time. It has to do with the difference between authentication and identification of the source of the data.

Morris: There are two pieces that we currently have in part be that are meant to start to address that but we would very much like recommendations on what more we can do. One is I mentioned we have to use the demographic data in a standardized way. The second is the patient demographic framework that we mentioned this morning. There is a requirement that the qualified HINs annually do that review of their own internal governance processes on demographic data. To make sure that they are handling it to a high levels we can deal with the data quality issues. We would very much like to get recommendations from other folks on what more we can build and to part B with that issue.

Posnack: Let's talk about data. The Cures statue includes a definition for interoperability. That is going to guide the rest of our work. The definition includes three parts which are important in the context of what we are trying to accomplish and regulatory actions and policy that we need to consider etc. Part number one, and this is also a technology perspective, says that the technology can enable secure exchange of health information without special effort on part of the user. It's where it identifies special efforts. The second part of the definition is that the technology allows for complete access card exchange and the use of all electronic information. That is part of what we need to consider and similar language is used. In this context where we have congressional expectation, I think you heard in remarks earlier access exchange reuse. One of the challenges that we have had is putting together all those areas of references in a coherent matter so they are consistently applied in the sections in which they exist. But that's what we have. When we look at the TEF and common agreement and we juxtapose that with the interoperability that we have, 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.

I will take you back on a quick historical journey. When we started to implement the EHR incentive program there were needs on both sides of relaying a certain baseline set of data that needed to be exchangeable by healthcare providers, for transitions of care and patient access. There is a certain amount of data that needs to be accessible to patients. We start to create a common data set that was a baseline, a minimum floor. And that reflected the policy interest at the time. In some cases we saw the market respond by just providing that data. One can argue it was not necessarily the intended outcome that we had wanted or expected. It met the letter of the law but it was not optimal. For the 2014 edition certification criteria, we came out with a term of art to reference this collection of data. We called it the MU common data set. That was our shorthand to say there's a bunch of data elements and the technology has to be able to supply it, it must be acceptable to patients, here are some standards, technology and vocabulary associated with it.

As we went to work on the 2015 edition, that was at a point in time where we started to see an interest in making sure that the broader technological infrastructure that was put in place vis-a-vis certification was available to support many programs beyond just meaningful use. We decided to

re-name that bundle the Common Clinical Data Set. That's the CCDS you still see referenced. That included a various range from patients name and their date of birth to their vital signs and a few other things in between. As part of the new CCDS that we released in the 2015 additional we included the unique device identifier. As we reconcile where we are today and the policies that we have recently set, with what yours have given us. That is where we have this opportunity think about how we would advance our policy interest that we set forward into the future and looking forward, most of the conversations that we have are what are the next steps? What does it look like three to five years on into the future? If we just said we wanted this data element today, that's not exactly how it works. It needs to be built into the workflow and products and everybody needs to agree that this is data we want to be able to exchange. We are at the point now where we are looking to make that next evolution. Now we need to establish the framework and to reflect the work that we need to do moving forward, meet the definition of interoperability. Factoring in how to we get to all data. As we look at the US operability, the initial context in which we are approaching this is framework in common agreements. When you think about Don's point earlier, it's about search. When we look at the data that we are talking about, the data that we have built in to the draft USCDI document is reflective of today's current state. It's a common clinical data set with two other pieces tacked on to them.

This is what we have. The last row are the two elements that are new relative to the current state. Everything else is bait. It's part of what needs to be exchangeable today. There hasn't been a lot of change relative to the data set that we are saying this needs to be accessible. The trust exchange work has a unique opportunity to advance this. The two elements are provenance and clinical notes. 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 the 2015 edition was not getting notes. That was the quintessential missing piece that we had a lot of meetings with. All this other stuff is great, and I appreciate getting into it into the C-CDA but I want the note. So we added that in. It's one of these things that if we wait until later to build in requirements for supporting that it could impose more cost on the industry as opposed to incrementally expanding that capacity from something that gets the job done today to something that can be more robust and comprehensive for additional uses in the future.

What we would like from the charge is to view and provide feedback on the structure and process. Associated with the USCDI. I'm going to frame this out for you and give you a little more detail on how it's structured. What we are looking for are specific recommendation. The mechanisms and approaches for received stakeholder feedback and how the proposed categories would exist and be promoted. How they can be reviewed and a objective way or promotion between the categories that we have stated. We will provide you with prior art from a colleague and several others. A document cited has a lot of different attributes that may be useful to apply in this content. The other aspect of the charge would be, how do we expand the USCDI and by how much. What is the right expansion process. It may depend. One extra data element could be crippling enough in the amount of work required. Additionally, any other factors that we should consider with the frequency that is published.

The cycle that we envision to have here. It's much like many other activities, we have found from a fruitful perspective to start things in a nonregulatory space as much as possible and have them evolve and mature so that what we need to pull them into a regulatory paradigm they are ready with pilot testing done. We are following a mantra of good process makes good policy and what we would like from this task force is to help with the policy. The data right now in terms of the draft is

pretty much what exists today. We would really like your feedback on how we can best shape the process looking to 2019, when it would be the first cycle where we can be looking to expand the USCDI 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? As we noted in the USCDI document we have these three categories that we clumped these data classes into. Using a baseball metaphor, the emerging data classes are AA, the candid are AAA and the USCDI is the major league.

I think the most interesting area for many of us will be the candidate area where as we noted in the document the data policy that we are trying to identify here is, is this data is important enough that networks need to be able to support its exchange and it needs to be made accessible for patient access and capable of being handled in FHIR based or C-CDA based exchange. In order to trigger that response from industry perspective that is what the class is supposed to signify. The indicator that work needs to be done and if that work is completed it will get moved into the next version of the USCDI. That will then subsequently trigger subsequent support. That is pretty much what I wanted to cover in terms of the charge and the look and feel of what were trying to get after right now. Your work would be the formative aspects of how the USCDI moves forward.

Question and Answer Period 4

Sheryl Turney: I had a question that went back to the RCE. I think that the establishment of the current proposal is excellent and is in the direction of where we truly need to go. I was wondering if the governance that you are looking for and the cooperative agreements would include a couple of things. From a national perspective it's problematic to have all of these regional health information networks because they all operate differently and have different data requirements, With also some problematic secondary use of the data that don't necessarily appear to align with HIPAA allowed uses. Would this governance component include potentially a uniform participation agreement and minimum standards for data used for participation and also a participation playbook? Many people have indicated that not all of the constituents participate in the challenge is workflow and communication. Having a playbook that explains what's in it for them often times would be helpful especially as this reaches out to patients and members where they can see where they can benefit from the data.

Morris: The common agreement that we would work with the RCE would be a participation agreement. The goal of the trust exchange at the end of day is to enable not just providers but also payers a single on ramp instead of having to connect to 100 different points. You can pick your one point and be able to get to the data that you need to get to. If your national payer you cross over many states and we know that has been quite difficult. That is really what we want to cut down on. Excellent idea on the playbook.

Sheryl Turney: Based on the initial list of required data elements in the USCDI and to my limited knowledge about patient matching, there appears to be some data that would be missing to verify that the patient is the patient that you are looking for. How are you envisioning that patient identification and matching to work?

Posnack: That is some of the feedback that we expect to get. That is the opportunity that we have in front of us. The curation of the earlier named data sets reflected the dependency on the standards

in which they would be implemented in. As he looked to see what data we needed to specify in the CCDI clinical data set and how it would be plugged in to the consolidated standards, standard itself picked up data elements that would be useful in the situation. When we look at what we have and abstract that to say here is data let's get agreement on the data and then see how that needs to go down in the technical specifications we need to then take another look and that is the reconciliation between what Cures wants and what we have.

John Kansky: During your presentation the examples were extremely helpful and I'm trying to develop my questions. You said that QHINS would 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 dropout or what?

Morris: It would be somewhat dependent. The way I will look at it is that there are flow down clauses that require users to submit the purposes. For example, health systems should be able to support all six. If you're a public health agency you can probably only support one. The expectation would be that the permitted purposes would slow down to the end users who legally can support those permitted purposes.

Kansky: If an HIE has governance rules that prohibit acts are you expecting them to change the rules?

Morris: We understand that the purposes and the clauses accompanied with it may require folks to update their agreements.

Kansky: is an example of an access permitted purpose. You said you would understand why a QHIN – wouldn't want to

Morris: The way we try to set it up as not requiring a outside QHIN to have a particular set of stakeholders. If you want to be a network of just payers you are welcome to do that. The clarification I made is that if you get a request that is one of the six, even if you're not giving direct access to the individual need to respond to that query. You don't have to allow the individual to be end user or participant in your qualified HIN.

Raj Ratwani: Think you guys for the great overviews. My question is more of a comment. In reviewing the five goals they are all clinically important but what I am deeply passionate about is goal 4. One thing that I think we need to be cognizant of and I don't have a deep understanding of the current business models for the qualified health information network. I think we need to be careful to not introduce new barriers and entrepreneurship as we walk through them. You also described a limited number of QHINs.

Morris: I totally agree that data liquidity is key to opening up a market. That's part of why we don't have great products. When you're actually putting those products into practice in the health system they don't work because they can't get the data. With the small number of QHIN we are aware it could cause market tension. One of the requirements of a QHIN is that they would have to report their fee structures to ONC. As part of our job to make sure that there is not unfair practices taking place. We could monitor some of that. I think having a small number of QHINs is actually okay in a sense that it still gives you options on where you go to for your services. At the end of the day we talk about a single on ramp but if you want to be part of multiple networks you can do that. It is

certainly an area where would like to get more comment on. Whether there are another market considerations or protections that we can build in.

Tina Esposito: How are we assessing the differences that those queries may have traditional HIE use, which is point to point clinical care. I just want to get an understanding so I am clear on how we have incorporated the difference in the use of these different queries into the data that we have been collecting and the usability.

Morris: I think what we want to do is recognize that out of the gate you're likely not having all of the data that you need unless a QHIN is amazing. We are hoping that the combination of what we are doing will over time allow for some of those cases and that a provider work with a third party vendor or HUI to do some of those services for them. I think we all have to accept that reality and I am hopeful that we are somewhat speeding up.

Public Comment Period 2

My name is **Grace**, I'm a patient advocate for myself and also for my mother who is 91 who has Alzheimer's. I have a HIPAA security in healthcare certificate. I noticed that basically our HIPAA is being violated all the time. Every time I go to an emergency department I can hear what's going on in the room next door. Another time when I went to the hospital the lady gave me a whole package of other people's information and they came home with everybody's personal information. 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 degree of seriousness of this private information. Machines can only go so far but we need to look at the human element. Yesterday my mother fell and the nursing home told me that the hospital had all information. I went to the hospital. My mother had not had her ID on her and I didn't have my ID, I just rushed over there. My name was not in the system even though it is part of a larger hospital system. I was able to talk them into giving me the information luckily but at the same time I thought this is a breach of HIPAA. I just wanted to address the fact that we always need to think about the human element. Thank you.

Hello. This is **Brian Ahear** I work for Aetna and I was just want to say, within the trusted exchange framework it talks about recognizing that this would require some updates to participation agreements and help capabilities. I would like for the committee and ONC in general to consider the costs of updating all these agreements and HIT underlining infrastructure.

Question and Answer Period 5

Valerie Grey: I just wanted to echo the compliments, fantastic work. I would like to maybe just put two issues on the radar. That is that there are many states that use of HIPAA as their standard but there are also other states that have different rules and laws related to consent. I know it was mentioned in the framework but there is an issue that I found to get very tricky. In order to effectuate some national sharing. I just put that on the radar and I would also mention that the sustainability issue for HIEs is a big one. It has been broadly mentioned but the federal and state government have invested significant funds in standing up not for profit regional and state HIEs. Some of that funding is set to expire. I will like us to think about that impact as we start to talk

about the fees that might get charged to support the infrastructure and the pipes that have been built to try to move the information around.

Morris: We are quite aware of state variation, we are working on a internal analysis. And we're hoping to meet with states around that. There are limitations ONC has. We'd welcome suggestions on that. We are hoping the framework does is make it easier for providers to get access.

Andrew Truscott: Over the course of the presentation we have moved from three letters to Q4 letters and L5 letter acronyms. We do need to demystify this for the patients and providers. I can only applaud that we try to slim down the use of acronyms and come up with nouns that are meaningful and useful to our constituents. I recognize other jurisdictions both home and away have been to a similar process. I would like to see some kind of distinction between that which is considered core and that which is considered a summary or essential.
Morris: I think some systems are set up that way. I can be wrong but I believe that is the case. I personally don't necessarily have an issue with persistence of data but I think it would be helpful to understand from the committee's perspective. I think at the root of we have to be very conscious of the scale at which we have exchanged data is one-fourth of the data we would have to exchange once ambulatory care providers come into the system.

Clem McDonald. Thank you. I like what everybody's saying. My comment is item
s on the list. Doctors notes, I am a physician and a practiced for 40 years, I read notes and I only read the discharge summary. Don't send all the notes. Be a little careful about the notes. There has been a suggestion about a quarter note. Secondly, I'm not a radiologist but you have to get radiology reports higher up. It's probably more than laboratory and I love lab. It's something that injures patients if you do too many CAT scans so it's important not to repeat them.

Terri O'Malley: From the patient perspective that list of priorities is very different. One of the challenges we will have is whose priorities are we following and what is the process we're going to put in place going through that area list.

Morris: I think we need to figure out a way to make sure on how we prioritize in a way that can meet the needs of stakeholders while understanding that were not going to meet the needs of stakeholders all the time and every year. We would like help from the task force to figure out the right way to prioritize so that taking into account the different viewpoints.

Rucker: There's a difference between data that's sitting there and data you have to get people to collect.

Arien Malec: The task force charge I would recommend including some of the comments around prioritizing data that wants to be in the USCDI relative to priority areas. Quality measures being one. Otherwise, you get a wish list of private hobby horses as opposed to a prioritized list that's second to national priorities. Full risk assessment you can't get it currently out of the CCDI the charge of the task force could include that I think that would be useful in sharpening your recommendations.

Ken Katsumoto: One way to look at this is what our vendors and healthcare providers already building in to their interfaces. We have a number of folks were certified. I think as we build these ONC can provide a coordinating role and it will be a natural progression. The second comment is, if

you try to build a database it depends on it might be mapped. So you might want glucose. I think it's beyond just saying labs I think of the labs here are the 50 that are most useful to make sure that we communicate properly. And then to have processes to encourage local institutions to map them properly. Blood glucose vs spinal fluid glucose, for example.

Anil Jain: The QHINs might be in a unique spot to see what data is actually beginning to emerge and we may want to think about how we use the QHINs to get real-time data so we don't make the mistake of putting mandates in place and then have our colleagues catching up. I'm not sure exactly what "without special effort" means. We need to know what it really means to exchange data with a core data set "without special effort."

Denni McColm: Is there a way to submit a question to a task force that you're not on? Or do you just wait until it comes back to the full committee.

Lauren: We'll can work out a way to put a bilateral process in place so you can do that.

Posnack: For those of you that are not on a particular task force you are welcome to listen in to any task force meeting.

Steven Lane: There's a lot of work going on around the rest of the globe and what effort is going to be made to align or acknowledge where our evolving standards may touch on international standards.

Rucker: We are doing some international stuff Australia and the UK in particular. The underlying standards standing work starts with a fairly international. When you look at the standards we are open to learning from whoever and wherever.

Robert Wah: is there something we can learn from that process. international is important to think about. Just the mechanics of how the moving data might be something worth looking at there may be an opportunity for either a testimony or to the task forces to get that input from other industries.

Richie: That is certainly allowable to have outside experts come in and brief the committee.

Rucker: There is a lot of work to be done and I think this was a solid meeting. We will try to shift from having ONC talking to you I think the next time around so it's more you're talking to us rather than us talking to you. Again just speaking from personal experience, we will make sure we have a discipline on what we send you to read. The more that you do the reading of the pre-work the more effective you will be. Thank you very much.

Richie: Just a couple of reminders. If you're interested in either task force to please send me an email as quickly as possible. As a reminder to those on the phone, our next meeting will be a virtual meeting, February 21. I will call the meeting adjourned.

Lauren Richie adjourned the meeting at 3 pm.

Next Meeting
The committee will meet virtually on February 21, 2018.

Meeting Materials
Presentation slides