National Committee on Vital and Health Statistics

Transcript

March 24, 2020, 10:00 a.m. – 5:30 p.m. ET

VIRTUAL

SPEAKERS

NCVHS Members		
Name	**Organization**	**Role**
William W. Stead	Vanderbilt University	Chair
Sharon Arnold	DHHS	Executive Staff Director
Rebecca Hines	NCHS	Executive Secretary
Alexandra Goss	Imprado/ DynaVet Solutions	Member
Debra Strickland	Conduent	Member
Denise Chrysler	University of Michigan School of Public Health	Member
Denise E. Love	Individual	Member
Frank Pasquale	University of Maryland Carey School of Law	Member
Jacki Monson	Sutter Health	Member
James J. Cimino	University of Alabama at Birmingham	Member
Lewellyn J. Cornelius	University of Georgia, Athens	Member
Margaret A. Skurka	Indiana University Northwest and Principal, MAS, Inc	Member
Melissa M. Goldstein	The George Washington University	Member
Nicholas L. Coussoule	BlueCross BlueShield of Tennessee	Member
Richard W. Landen	Individual	Member
Vickie M. Mays	UCLA	Member
NCVHS Staff		
Name	**Organization**	**Role**
Susan Queen	NCHS	Staff
Maya Bernstein	ASPE/OSDP	Staff
Lorraine Doo	CMS	Staff
Rachel Seeger	HHS Office for Civil Rights	Staff
Amy Chapper	CMS	Staff
Natalie Gonzales	OADS	Staff

Geanelle Herring	CMS	Staff
Kate Brett	NCHS	Staff
Marietta Squire	NCHS	Staff
Donna Pickett	NCHS	Staff
Others		
Name	**Organization**	**Role**
Vivian Auld	NIH	
Tom Mason	HHS	ONC
Lauren Richie	HHS	ONC
Presenters		
Name	**Organization**	**Role**
Sharon Arnold	ASPE	Associate Deputy Assistant Secretary for Science and Data Policy
Margaret Weiker	National Council for Prescription Drugs Programs	Vice President Standards Development
Alexandra Mugge	CMS	Deputy Chief Informatics Officer
Mark Knee	Individual	Senior Policy Advisor
Kate Tipping	ONC	Branch Chief, Regulatory Development and Coordination

Call to Order/Roll Call

Rebecca Hines: Welcome to the spring meeting of the National Committee on Vital and Health Statistics. We want to welcome members of the public and a special welcome to our – who can mute yourselves until we do roll call – in this unprecedented time and we are grateful for your service, the generosity of lending your time and your expertise – this committee provides advice and recommendations to the HHS secretary on health, data, statistics, data standards, and privacy all in service of insuring that the best possible information available to inform our national health policy. I really want to thank you. We appreciate that many of you already have more than full-time roles, sometimes double in some cases in these current circumstances. Just big appreciation from all of us for your service.

So – roll call now. My name is Rebecca Hines, executive secretary and designated federal officer for the committee and let us begin with our chair, Bill Stead.

Bill Stead: Hi. I am Bill Stead, chair of the Full Committee from Vanderbilt University, no conflicts.

Rebecca Hines: Denise Chrysler.

Denise Chrysler: Good morning, everybody. I am here. I am with the University of Michigan School of Public Health and the Network for Public Health Law. I am a member of the Full Committee and a member of the Privacy, Confidentiality, and Security Subcommittee. I have no conflicts.

Rebecca Hines: Lee Cornelius.

Lee Cornelius: I am with the University of Georgia, a member of the Full Committee, member of the Population and Health Subcommittee. I have no conflicts.

Rebecca Hines: Nick Coussoule.

Nick Coussoule: This is Nick Coussoule from Blue Cross Blue Shield of Tennessee, member of the Full Committee, the Standards Subcommittee, Privacy, Confidentiality, and Security Subcommittee, and the Executive Subcommittee and I have no conflicts.

Rebecca Hines: Melissa Goldstein.

Melissa Goldstein: Good morning. This is Melissa Goldstein. I am from George Washington University. I am a member of the Full Committee and a member of the Privacy, Confidentiality, and Security Committee. I have no conflicts.

Rebecca Hines: Alix Goss.

Alix Goss: Good morning. Alix Goss is present. I am with Imprado, the consulting division of DynaVet Solutions. I am a member of the Full Committee, a member of the Executive Committee, co-chair of the Standards Subcommittee and Review Committee and I have no conflicts.

Rebecca Hines: Rich Landen.

Rich Landen: Good morning. Rich Landen, Florida, member of the Full Committee, co-chair of the Standards Subcommittee and member of the Executive Subcommittee, no conflicts.

Rebecca Hines: Denise Love. Denise, you are on mute. We will skip Denise.

(No response)

Rebecca Hines: Vickie Mays.

Vickie Mays: Good morning. This is Vickie Mays with the University of California Los Angeles. I am a member of the Full Committee, Population Health, Privacy, Confidentiality, and Security and the Review Committee on Standards and I have no conflicts.

Rebecca Hines: Love your scenery, Vickie. That is awesome.

Vickie Mays: It is San Francisco. I am rooting for California.

Denise Love: Rebecca, I am off mute. This is Denise.

Rebecca Hines: Go ahead and enter yourself into the record, Denise.

Denise Love: This is Denise Love, calling in from Idaho. I am consultant to the National Association of Health Data Organizations. I am member of the Full Committee and member of the Standards Subcommittee. No conflicts.

Rebecca Hines: Jacki Monson.

Jacki Monson: Good morning. I am Jacki Monson, member of the Full Committee, member of the Privacy, Security, and Confidentiality Subcommittee. I have no conflicts.

Rebecca Hines: Frank Pasquale.

Frank Pasquale: Frank Pasquale from the University of Maryland, the School of Law. I am a member of the Full Committee and chair of the Subcommittee on Privacy, Confidentiality, and Security and no conflicts.

Rebecca Hines: Margaret Skurka.

Margaret Skurka: I am a former professor at Indiana University, now with MAS Consultants. I am a member of the Full Committee and a member of the Standards Subcommittee and I have no conflicts.

Rebecca Hines: Debra Strickland.

Debra Strickland: Hi. I am Debra Strickland from Conduent. I am a member of the Full Committee and a member of the Standards of the Subcommittee and I have no conflicts.

Rebecca Hines: And for the record, Jim Cimino is unable to join us today. For staff – logged in yet, but Sharon Arnold is our executive staff director. She is the associate deputy assistant secretary for planning and evaluation and Maya Bernstein also from ASPE is on this morning. Welcome Maya.

Maya Bernstein: Thank you. Do you want me to introduce myself?

Rebecca Hines: Please.

Maya Bernstein: Hi. I am Maya Bernstein. I work in the Office of the Assistant Secretary for Planning and Evaluation where I am the senior advisor for privacy policy. I am the lead staff to Sharon Arnold, who is your executive director. She will address you later this morning, but she had several meetings, as you might imagine, this morning so she cannot join us just yet. I also staff the Privacy, Confidentiality and Security Subcommittee. Good morning.

Rebecca Hines: Good morning. Thank you, Maya. And not on right now for obvious reasons is Rachel Seeger, who is lead staff and works closely with Maya Bernstein on the Privacy, Confidentiality, and Security Subcommittee. She is busy handling the situation and getting out new guidance. She will be on with us tomorrow.

From standards support, we have Lorraine Doo, lead staff to the Subcommittee on Standards, and Geanelle Herring, both with CMS. Good morning, you two. Good morning. Very good.

We have other staff with us. Marietta Squire is our committee management specialist. We have Geneva Cashaw. I just want to also thank our contractor Rose Li Associates for handling the logistics.

With that, I think roll call is complete. I will turn it over to our chair.

Welcome Remarks/Agenda Review

Bill Stead: Good morning and I want to add a very warm welcome to Denise, Melissa, and Margaret to the NCVHS family. We are very grateful for your willingness to join us and we look forward to the expertise that you will bring into our deliberations. I want to thank everyone for making the time for this meeting as we deal with the unprecedented global public health emergency.

The timing of this meeting is important because we are trying to respond expeditiously to the DSMO's request that we recommend HHS adopt the update retail pharmacy claim standards. We are trying to advance our collaboration with ONC and HITECH to enable convergence of administrative and clinical data. The crisis that we are in underscores the necessity to achieve that goal. And we also hope to agree on a path forward for privacy, security, and confidentiality, which may also be influenced by the emergency that we are in at the moment.

With that sort of highlight, let me walk you through the agenda briefly. We are going to take a little longer than usual in our introductions to allow the new members to say a little more about themselves and to allow the Full Committee to also give a little bit more expanded introduction.

Sharon is then going to join us for the ASPE update so that we can ask her for guidance from the department regarding the committee.

Then after a short break and I am going to have to step out briefly after the break to deal with some COVID-19 things at Vanderbilt. I will rejoin as quickly as possible. But after we come back from the back, Alix and Rebecca will carry the time as we do the NCPDP change request first sort of walking through the framing and considerations before lunch and then having both the Full Committee discussion and public comment on our response to the change request. We hope at the end of that block, we are actually going to be able to approve a letter of recommendation to the secretary. We will see if we are all comfortable with that at that time.

Then we will shift into updates related to the convergence of standards with first the new interoperability rules that were released a little bit ago. And then a discussion of the scope of our Standard Subcommittee and Full Committee work on convergence of administrative and clinical data standards and the work that we are doing in collaboration with ONC and HITECH. Then we will have a time for committee discussion at the end of the day. Then adjourn.

And come back in the morning at 8:30 Eastern and the whole morning is really going to be focused on the privacy, confidentiality, and security, starting with an update on the NIST Privacy Framework and then an update on safeguarding the bioeconomy and then the discussion with the Privacy, Security, and Confidentiality Subcommittee about their workplan and going forward.

After lunch, we will have an update on the FHIR at Scale Task Force, which relates to the work that we are going to be doing this afternoon and then we will walk through our own workplan to update it to reflect what we have learned over the course of the meeting and then close with public comment. That is our plan of attack unless anybody has suggestions for any modifications.

Alix Goss: Bill, this is Alix. I just want to let you know that I will need to depart at 4 o'clock to go to an ONC taskforce meeting.

Bill Stead: Yes, I am aware of that and thank you for mentioning it so everybody understands the needles we are trying to threat as we go through the course of the day.

Rebecca Hines: I believe that is 3 o'clock. Correct?

Alix Goss: Oh my goodness, yes. Thanks for keeping us orchestrated, Rebecca.

Bill Stead: That is 3 Eastern. Then I think we are ready to roll into the new member self-introductions. Rebecca, will you take the baton to manage that?

New Member Orientation

Rebecca Hines: Sure thing. We have three, actually four new members, three of whom are able to join us today. What we would like you to do, Denise Chrysler, Melissa Goldstein, and then Margaret Skurka. I can see you all so thank you for that – to say a little bit about your expertise and what drew you to serving on this committee and then the members who have been on a while will then also introduce themselves and share a little bit about their background so that we can start to get to know each other.

Let us start with Denise Chrysler.

Denise Chrysler: Hi everybody. I have been a public health attorney for over 35 years. It is a great honor to me after all these years to be appointed to the NCVHS and I hope I can contribute all of these years of experience to the Full Committee and to the Privacy, Confidentiality, and Security Subcommittee and also someday the Population Health Subcommittee.

For 27 of my years, I was an attorney to Michigan State Health Department. This included as an assistant attorney and then the state health department's director of legal affairs. In 2010, I became the director of the Midstate's Region of the Network for Public Health Law. This is located at the University of Michigan's School of Public Law.

We are partially funded by the Robert Wood Johnson Foundation to support and promote the use of law to solve public health problems and we provide direct technical assistance, training, and education, practical tools, connect people with one another to build a public health law community.

Since 2012, I have served on my local board of health. I have spent my career assisting state and local health departments to implement their powers and responsibilities, which is especially important right now to prevent and control disease, to address environmental hazards, and to promote wellness. My work is especially focused on data for public health purposes. This includes legal issues related to public health surveillance and public health registers. While I was at the state health department, I was its privacy officer. I served on the IRB and I was part of our Public Health Emergency Preparedness and Response Team.

Since joining the network, I have continued to work on legal issues related to public health and surveillance and intervention. I have added to my work many issues related to multi-sector data sharing to go upstream and address the social, economic, and environmental factors that affect health. Glad to be here.

Rebecca Hines: Thank you, Denise. That was very helpful.

Melissa Goldstein.

Melissa Goldstein: Good morning, everyone. I am very excited to be joining the committee. This is my first Full Committee meeting. I am professor of law, bioethics, and health policy at George Washington University and the Milken Institute School of Public Health.

I have been working in the area of health IT, particularly in the area of privacy and security since 2005 when I was at the Markle Foundation. I have also served for periods of time in the Federal Government. Once I was senior advisor to the chief privacy officer in the Office of the National Coordinator for health IT. And more recently, I was the assistant director for bioethics and privacy in the White House Office of Science and Technology Policy.

My writing and my publications and my speaking is mostly focused on privacy and security issues, also data ethics, research ethics, and the physician-patient relationship. Like I said, I am very excited to be joining the committee. Thank you.

Rebecca Hines: Excellent. And Margaret Skurka.

Margaret Skurka: Thank you. I am Margaret Skurka. I am happy to be a part of this committee. I come to you from suburban Chicago where I have spent a lifetime living. And I have worked 42 years for the Indiana University Campus, which is just across the state line in Northwest Indiana and now professor emerita from there.

Along the way, I was very active in the National Association and International Association. I was president of HIMA let me say fortunately when Linda Kloss was our CEO. She actually invited me the last two summers to come to the special meetings that you have had and I certainly have gotten interested in the work of this group at that point.

I was also president of the International HIM Association and I have done quite a bit of work since 2005 with WHO Family of International Classifications. That is then a lot around ICD-11 work.

My goal certainly I hope in my tenure on the committee is that we not repeat the painful process we did when we moved from I-9 to 10 in 2015. I was on the road for AHIMA with those seminars and the education nationwide of that and the delay after delay. I think it took us 23 years or something from release and we were one of the last countries if not the last country to adopt. I hope we have a much more expeditious and a good process this year and the next coming years. As we move towards 11, we will have to for mortality and as we evaluate whether we do that for morbidity. Thank you.

Rebecca Hines: Thanks, Margaret.

Bill, I am thinking maybe you could begin and just share maybe one minute of relevant background that – your expertise with the committee's work and then the other members can do that for our three new members and the members of the public as well.

Bill Stead: Thank you, Rebecca. I am – and a biomedical informatician. I am an academic medical center – having grown up on the Duke campus where I did all of my education and training plus my early faculty years. I came to Vanderbilt in 1991 to build up what is now the Department of Biomedical Informatics and the related informatics infrastructure both at Vanderbilt and the national scene.

I tend to move back and forth between envisioning the long-term potential for informatics and computation to transform health and biomedicine and then the research and development to test the ideas and to transfer them into practice and policy.

I currently serve as the chief strategy officer of Vanderbilt University Medical Center, a large tertiary academic center that is a hub for a five-state clinically integrated network. My writing and research are focused on system-based care, learning and research, leading to personalized medicine and population health management. Thank you.

Rebecca Hines: Thanks, Bill. Denise Love.

Denise Love: Thank you. Just in a nutshell, I left clinical and public health nursing in the early '90s to work at the Utah Department of Health to establish hospital reporting statewide, which in those days was quite controversial, but it became a passion of mine. Health data policy and governance for public reporting.

After establishing reporting systems in Utah, a range of them, including emergency department and hospital and claims, through – I took these on the road nationally through NAHDO, National Association of Health Data Organizations, and worked with states all over the country to establish their own statewide reporting systems, hospital claims and emergency department.

We co-founded the All-Payer Claims Database Council. I worked with Denise Chrysler and some of you all as we navigate the very complex issues related to public databases and access and reporting.

I was a frequent NCVHS presenter around ICD-10, privacy and governance related to these public databases. I am pleased to be part of the national committee and work with experts from all over the country.

Rebecca Hines: Thanks, Denise. Lee Cornelius.

Lee Cornelius: Thank you. In short, I am currently the director for the University Center for Social Justice, Human and Civil Rights. I am a trained survey methodologist and was actually a former – what is now the Agency of Healthcare Research and Quality on national medical expenditures.

My areas of work – equity of access to health care, which is then a large part of my career in HIV prevention treatment and adherence. Thank you.

Rebecca Hines: Thank you, Lee. Nick Coussoule.

Nick Coussoule: Good morning, everybody. Again, this is Nick Coussoule. I am currently the senior vice president and chief information officer or chief information and strategic technology officer at Blue Cross Blue Shield of Tennessee where I have been in this role for 12 years.

My career started in consulting both operations and technology in the US and abroad. I spent several years in Europe – industrial and manufacturing businesses. I have a little bit of a different background from that perspective.

I spent six years for a global insurance company and then the last 12 years specifically with Blue Cross Blue Shield of Tennessee where, again, I head up the technology organizations, a few other functions. That also includes responsibility for our information security program.

I have been on the committee for four years – for a next term and I am very excited to be here to continue the good work that the committee has done for a long time. Thank you.

Rebecca Hines: Thanks. Alix.

Alix Goss: Good morning. I cut my teeth in Medicare Part Environment. I come to my role at NCVHS with a practical lens of how are we going to make this work, having really grown up inside of operations management and updating all aspects of Medicare program with a focus on integrating – policy, technology, and workflows to achieve business objectives and compliance.

That led me into representing CMS – X12 standards community table, which led me into a decade of work within X12 and various leadership positions, which also provided me with a tremendous opportunity to collaborate in the standards community – small, but mighty group of people that come together to shape our health care standards.

That work has served me well over the years in understanding how we need to come together to – more effectively. That experience helped me also when I was the state health IT coordinator in the Commonwealth of Pennsylvania, responsible for health information exchange, independent state agency.

I am currently a consultant and try to bring all of those experiences to bear and very much – my work with the standards focus within NCVHS, but also participated in some other population health activities along the way with – social determinants of health – framework that we did.

Currently, the standards work is particularly important as our nation advances toward interoperable health care and the convergence of clinical and administrative data. You will be hearing a lot more about that this afternoon from Rich – project. But part of the work that we are doing also includes our coordination with the Office of the National Coordinator because it is time for us to unify our framework

of policy, technical standards, and overall collaboration to ensure that we can get – more effectively to achieve better outcomes, more transparency and underscore patient safety.

I am very proud to be a part of NCVHS and in my second term and looking forward to wrapping up in some high notes related to convergence of clinical administrative data.

Rebecca Hines: Thank you. Rich.

Rich Landen: Good morning. I am Rich Landen. I have been happily retired for about three years, living in Florida. My education includes a master's in public health and business administration from Columbia University. And the first ten years of my career was in the hospital operations. After that, I moved over to the payer trade association side of the industry where I was assigned responsibility for at times standard paper claim forms, but that morphed into electronic standards and got me involved with X12 where I spent more than a few years and was instrumental, I think, in the initial development of the standards we have come to know and love like the 837.

Later on, I made a switch over to the electronic health record. I worked for a small developer and did federal regulatory compliance for the meaningful use program. As part of that, I got involved with the MCHR association and particularly the patient safety – which eventually I chaired.

I think over and above all my initial orientation to health care was two years I spent right after college as an orderly in a hospital – Denver. I really burned the industry from the ground up there. Lots of good exposure to the patient and staff. And a lot of what people from that part of my life taught me still rings true today when we look at the health care delivery system. That is it.

Rebecca Hines: That is a great story, Rich. Thank you for sharing that. I hadn't heard that before. You have been on the committee for how many years?

Rich Landen: Started my fifth.

Rebecca Hines: Deb Strickland while we are on standards.

Debra Strickland: Deb Strickland. I have 20 plus years in the standards development, having been a co-chair of the 35 HIPAA transaction that goes back to the provider. I worked for a health care payor for 17 years and then bounced around to – aspects of the industry from Blues to Medicaid as well as providers with a concentration on obviously being that I was involved in the electronic – understanding the complexities of the provider environment and the things that they need in order to post to their patient records correctly. I am part of –- team as well as the intersection of clinical and administrative data taskforce as well as my reappointment here on NCVHS.

Rebecca Hines: Thank you, Deb. Let us go to Vickie Mays.

Vickie Mays: Thank you. Good morning everybody. I am a professor in clinical psychology at University of California Los Angeles as well as the School of Public Health and Heath Policy and Management. As a clinical psychologist, I, of course, have patient experience. One of the areas that I tend to work in is integrated care. Very interested in making sure that behavioral and mental health services are occurring within the health care environment and in a very seamless way.

I spent about five years funded by the Kellogg Center in recovery and disaster response. I hope to rebuild the mental health system in New Orleans and some of the surrounding area. We retrain people. We, again, put things into the integrate care system to take some of the load off. I kind of come to this issue of emergency preparedness response and recovery with several years of experience. I am also a callout person for mental health services and disasters here in Los Angeles.

I also have a very strong identity as a researcher in population health. I run a center funded by NIH on minority health disparities. We are in our 14th year and we are waiting to see about our renewal. Fingers crossed on that. But there I do population health issues particularly in terms of looking at areas of equity and access in both physical as well as mental health.

And, finally, I guess the other thing that is probably relevant is I am in my second year on PRIM&R, which is the Board on Public Medicine and Research, which is really designed to look at all the ethics and IRB issues. I have served as vice chair of our IRB over time. On PRIM&R, we are often looking at some of the response issues and research as well as how to protect patients and have the ability to participate in research as equitably as possibly.

Rebecca Hines: Thank you, Vickie. Frank Pasquale.

Frank Pasquale: Thank you. This is Frank Pasquale. I teach at the University of Maryland School of Law. In other advisory roles, I have been a member of the Council for Big Data, Ethics, and Society. That was a project of the National Science Foundation, the advisory board of AI Now. I have also done that for electronic privacy information center and open markets.

In terms of my contributions in the area, it is mainly in legal and policy research on data and privacy policy. I wrote a piece called the Grant Bargains for Big Data about seven years ago. I was trying to give a sense of the types of new issues that would be arising as more and more big data enter the health care system. Other pieces included rethinking health privacy, chapters on health information law. And more recently, I have been moving into the AI area in a piece called Data-Informed Duties for Artificial Intelligence Development.

My main interest is in terms of the broad theme of the research that I have been doing has been in brokering interprofessional conversations on optimal data use. I think it is really important to bring together scientists, medical professionals, legal professionals, social scientists to talk about the full implications of data, data use, transfer, collection analysis. Those are my – a little introduction to my work. Thanks so much --

Rebecca Hines: Thank you, Frank. Frank joined the committee. He is the most recent addition and he is our new co-chair of the Subcommittee on Privacy, Confidentiality, and Security. We thank you for stepping up. Normally, you get a pass on being asked to serve as a chair or co-chair your first year. We are especially appreciative of you taking that on.

I think our last member to share your background is Jacki Monson.

Jacki Monson: Good morning. Jacki Monson. I currently serve at Sutter Health as the chief privacy officer and the chief information security officer. My passion, my focus, my entire career has been on privacy and security. I am trained in a legal background and use that skill set every day, but really like the boots-on-the-ground practitioner perspective.

The expertise that I bring to the committee and just in general is all things privacy and security and I like to think that I am very practical and can also share the experience as a practitioner, which is sometimes very different than the legal or the regulatory perspective and the application of that.

That is what I have done my entire career, mostly in large, integrated health care systems like Sutter Health. I was at Mayo Clinic before that and have a couple of experiences on the plan and PDM side. That is about it.

Rebecca Hines: Very good. As you can see, we are all in good company here. It is a real privilege to work with you all. I do not think we have got anyone else to chime in here. Bill, I will turn it back over to you and Greg, if you could bring up the slide deck.

Overview of Strategic Plan and Selection Criteria for Committee Projects

Bill Stead: Thank you. Every time I hear the kind of summary of our backgrounds and interests, I am simply in awe of the family that we have to work with. The diversity is really important because the National Committee has a practice of trying to achieve unanimous agreement with our recommendations regardless of which subcommittees they come out of and that forces us to take the time to learn how to talk in ways each other can understand. Although that can from time to time feel a bit like a slog. It is the key to our success. I just cannot tell you all how grateful I am for the effort you put into this committee.

With that, I will switch over to walk through at high level, our strategic plan and how we make decisions about which projects we take on. In 2015, the National Committee developed a strategic plan. We kept it at high level. We revisit it annually and it was last updated in 2017.

The vision communicates our why. Improved health and well-being of the population of the US and its territories through advanced national health information and data policies.

The mission describes our how, which is to assist and advise the Secretary of HHS and Congress by convening stakeholders to identify and frame the essential health information/data policy concerns and needs.

Our scope is national health information policy and health data and vital and health statistics, standards, privacy, security, and administrative simplification. It is broad and that plays into the reason we need the diverse committee.

We identified four strategic goals. To improve the data usability and analytic capabilities to sustain continuous improvement in health and well-being for all. Second, to accelerate adoption and implementation of standards to achieve the purposes of safety, effectiveness and efficiency, privacy, security in interoperability of health data and systems. Third, to expand appropriate access and use to date while ensuring relevant safeguards and finally, to improve health information and data policy by taking the long view. The fourth goal is one of the things that makes NCVHS a little different from many other FACAs, which are totally focused on the next several months. We really are supposed to take the long lens and then to develop near-term recommendations, but reflecting what we learn from that long lens and communicating it because most of the changes we are trying to achieve take a decade or more to play out.

Our approach to achieving the strategic goals is laid out in the objectives under each one. You will see in the plan which was emailed to the members by Rebecca and it is accessible to the public on the website that each goal has objectives that go from assessing the current state to identifying opportunities and threats to recommending access because each of our projects essentially flow through such a time course.

Just to give you an example, this is the timeline that our recent work around health terminologies and vocabularies took from when we made the decision in the Standard Subcommittee to develop the scoping document and to advance that to the Full Committee to begin to use our regular meetings to brief the committee as background as we revise the scoping document and obtain collaborative support from the National Library of Medicine for project support.

We then moved into drafting a formal Environmental Scan with the help of the NLM. That led us then to provide the background for a organized expert roundtable in the first of two that was in July of 2018 and that developed the new draft criteria that we recommended to the secretary of new ones for adoption of terminology and vocabulary standards and for the practices around maintenance and implementation of those standards.

We then began to scope out the project based on those criteria for how to evaluate ICD-11 for fitness in the US and what it would take to implement it over time and communicate to people about it. An August 2019 roundtable around those resulting in, I believe, November of 2019 letter to the secretary.

When we decide to take on a project, it is a big decision because we are basically setting in motion this kind of – in almost all cases, 18-month to 36-month journey. Across that journey, we have incremental deliverables that help get early occupancy of what we learned. But in essence, we lock ourselves – we can obviously change course, but in essence, we are committing to that kind of journey. It is very important that we make those decisions carefully.

The last little block of the strategic plan are the selection criteria that we use to make decisions about which work we are going to take on. The first criterion is that the project has to be consistent with our mission, which is directly derived from our charter, and it needs to be appropriately scaled to the kind of resources we can bring to the table. NCVHS is not an operating arm. We are an advisory body. We can inform and recommend. We cannot actually do the heavy lifting. To do the heavy lifting, we have to use our convening authority to engage the public and private sector in actually doing the work that needs to be done.

Since we have limited bandwidth, we try to select projects that are complementary and aligned with one another so that progress on one moves the others. We are attempting to get more bang from the buck from each project than we would get on its own because of that collective impact, if you will.

And then we want the work to result in information or recommendations that are actionable by the Secretary in partnership with state and local organizations and agencies where appropriate or actionable by the private sector. Those recommendations we try to make actionable within a 6 to 18-month period whereas our reports and vision pieces – we expect to have a ten-year or more shelf life and to guide what will happen.

And then we have to fulfil our mandated requirements and we are a committee that is authorized in law and that has certain things that we are required to do such as our periodic report to Congress on the

status of the implementation of the administrative simplification standards and privacy components of HIPAA.

And then we have to take into account urgency and resources available to ensure project completion.

This is how we think about what we can do. You will want to have that in mind as we go through the scoping document this afternoon for the standards work on convergence of clinical administrative data and again tomorrow as we work with privacy, security, and confidentiality around their workplan.

Just a reminder of how we work. In essence, projects originate in the subcommittees. In the discussions at that level, the subcommittees decide when they think a project is ready to surface to the executive committee as something that actually has a draft scoping statement. But when we bring something to that level, we ask that it come with a scoping document that lays out a little bit of the background and what we would do when. Those documents constantly change. They live in word processors, but they always help us know where we are and what the next steps are.

We then have a workplan, which is on pages 11 to 13, I think, Rebecca will correct me if I am wrong, of the eAgenda book. You will see that workplan is laid out with four quarters and then a beyond period. Those are the columns. And then each of the projects we are working has a lane or a row in the workplan. As the Executive Committee works monthly, we update that. We also updated – we have a block on the Full Committee agenda for tomorrow afternoon where we will pull up the workplan and we will edit it in real time on the screen, reflecting what we think we have learned over the course of the next two days so that we see what our path forward looks like. Each quarter we roll it forward. We always have a rolling four-quarter view with one column for things that we are thinking that we know are outside of those four quarters.

The Full Committee, as I said, is at the transition between the introductions and this block. The Full Committee deliberates and votes on all proposed recommendations and reports. As we go through the workstream, we take time in each of our Full Committee meetings to bring the whole committee along with what we have learned since the last meeting so that people are not surprised when things get to where we are ready to take action. At that point, I will stop the download and raise your hands if you have questions or comments you would like to make.

Rebecca Hines: As a reminder, the raised hand feature for members is at the bottom of the participant box.

Bill Stead: Even though most people have lived it and the new committee members have heard it briefly once at orientation, I cannot believe that is all that clear, but maybe it is.

Rebecca, anything else we should do while we wait for Sharon to join us?

Rebecca Hines: Sharon is not online. Greg, do you happen to have the workplan that you could bring up on screen so we can take a look at that while we are waiting for Sharon?

Bill Stead: Absolutely perfect. Do you want to walk through that briefly, Rebecca, or would you like me to?

Rebecca Hines: I am happy to. If you can scroll down, Greg, to the first line. This is really for all of us, but the new members – this will be new for you. As Bill mentioned, we have a row to track what is

happening and the blue is the milestone of coming to a Full Committee meeting. We try to make sure the Full Committee is up to date. The first project that we have active is the convergence of administrative and clinical data. We will be spending a fair amount of time on that later this morning actually or actually this afternoon and there is a draft scoping document that we hope will provide enough detail that we can all agree that we should move forward on this. You will have an opportunity to ask questions of the Subcommittee on Standards and make any refinements. That is one of the beautiful aspects of bringing projects to the Full Committee is we discover we can get little myopic in the subcommittee view. The Full Committee says hey. What about this? Did you think about that? Bringing projects to the Full Committee several times a year is very helpful.

Rich Landen: -- a comment, if I may. My hand is raised. I just want to point out the far-right block that the Standards Subcommittee maybe primary there, but there is a very important tie in at the Privacy Committee as we get into the convergence of administrative and clinical standards. It is going to open up all sorts of new possibilities for good and --

Rebecca Hines: That is great. That just makes Bill's point for us that here is an example of a project that really needs to be looked at from a wider lens than just one subcommittee.

Alix, if you are available, it would be great if you could speak to the collaboration that is underway that you are heading up with ONC and their federal advisory committee.

Alix Goss: Very happy to. Actually, I would like to weave in the aspects related to Predictability Roadmap and set some context between the Standards Subcommittee and the Review Committee. The Standards Subcommittee looks – as to the terminologies, vocabularies, identifiers, and transaction standards – predominantly an administrative focus, but it is not limited exclusively to administrative focuses. I should also in addition to transaction should include operating rules.

When we think about the Review Committee that committee's scope is really to look retrospectively at where we have come from. In 2015-2016 timeframe, we did an extensive analysis of what we had adopted under the HIPAA framework. And it was very clear to us during that Review Committee report that we needed to learn from the past, improve the predictability for how we move forward with adopting administrative transactions and operating rules and terminology and vocabulary and that need for creating predictability also included the opportunity to converge the electronic health record standards that were adopted under the HITECH, Health Information Technology for Economic and Clinical Health Act with the framework that we had adopted under HIPAA. If we are really going to address – eliminating friction in the system and unwanted costs – really trying to achieve better outcomes in patient care.

One of the things that happened was that the 21st Century Cures Act created a linkage between ONC's work, the Office of National Coordinator's work and the National Committee on Vital and Health Statistics. It is a very natural progression of the landscape – with the stakeholders of really coming forward in that landmark legislation.

As part of that 21st Century obligation, we created a very collaborative relationship with the Office of National Coordinator over the last year and a half or so – each organization has its own set of responsibilities and obligations; however, we are linking arms to – efficiency in addressing a number of issues related to convergence, using what is called prior authorization as the exemplar – object in the middle of our conversation to help us improve the overall workflows and outcomes related to the prior authorization function.

The Office of National Coordinator has its own federal advisory committee called HITAC, Health Information Technology Advisory Committee. It has some taskforces. One is called the Intersection of Clinical and Administrative Data, ICAD. I am grateful that my NCVHS members – health care folks because they know the acronym talk and will hopefully be mindful as we move forward for the public – explain our acronym usage.

Intersection of Clinical and Administrative Data or ICAD has a project underway and with regular meetings. We have representatives for NCVHS sitting on that taskforce. Rich Landen is going to talk more about that, but it is great to have Rich and Deb and Jacki Monson all participating in that group, which I currently co-chair with – member.

I am going to move back to our convergence project. Rich is also going to talk about this this afternoon. We look forward to having a robust discussion around – document that we are proposing to address opportunities to improve the administrative data standards and to do that with a much more global view, which will incorporate clinical data. We will be kicking off that project later that year as you can tell by the workplan.

Rebecca, back to you.

Rebecca Hines: Thanks, Alix. In the interest of time, I will just point out one more row, which is the fiscal year 21, which begins October 1, our 14th report to Congress. This is a project we through every two years, developing a report to Congress primarily to report on administrative simplification implementation and how that is going from the committee's vantage. But we generally include all of the committee's work and how it supports policy development. We will be undertaking that in the year ahead. I think we are going to try to speak to it at some point today just to think about – or I guess the June meeting – but to think about what we need to focus on for this next report to Congress.

With that, I think we can turn it over to the next part of the agenda. Sharon Arnold has joined us. Sharon, thank you for briefing the committee an update from your advantage in the Office of the Assistant Secretary for Planning and Evaluation.

ASPE Update

Sharon Arnold: Thanks very much, Rebecca. Can everybody hear me okay? I want to give you an update mostly on what the department and ASPE is doing around COVID-19 because, as you can imagine, it is all COVID all the time right now. Let me just give an overview of what is going on in the department.

First, we have new guidance for employees. Most employees are on telework. Most of the buildings are closed with just a skeletal staff focused completely on COVID-19, the Preparedness Taskforce, et cetera. That is our day-to-day operation, but there is still a lot of work going on, as you can imagine.

We have been very busy pumping out guidance to the community. You will see a tremendous amount of guidance coming out from CDC both to patients, the general community and all different kinds of provider groups on a range of topics. We have HIPAA compliance and waivers to covered entities, guidance on that. SAMHSA has guidance on continued services for persons with substance abuse disorder. CMS has pumped out a tremendous amount of guidance as well. There are waivers for entities, support for telehealth, et cetera. We have guidance on civil rights protections for individuals during this COVID emergency. In particular, we have guidance on the release of disclosures of PHI about individuals who had been infected or exposed to both law enforcement and first responders.

We have a number of guidances to professional organizations, hospitals, emergency departments, physicians, nursing facilities about operating in this environment and the relaxation in some cases of standards during this emergency. There is guidance to commercial entities, businesses on how to operate.

In addition to pumping out guidance, we are doing a lot of gathering of data and production of data both from states and localities and also collating data from other countries to understand trends and model the impact of coronavirus.

We are providing TA to Congress on legislative proposals that are moving through Congress. We are also providing a lot of analysis and support to the taskforce leadership both at the White House and FEMA. We are also on a day-to-day basis guarding against the increase in cyberattacks that we are seeing. I understand that not only HHS, but other government entities are seeing an increase in the number of cyberattacks. That is just a brief roundup of the kind of activities that are going on around the department. I am happy to take questions, comments, whatever. Thank you very much.

Bill Stead: Folks, this is where we learned how to use our raise the hand to ask questions. I see one up from Vickie. Go ahead, Vickie.

Vickie Mays: Thanks, Bill. Thanks, Sharon, for the update. I guess one of my questions is is there anything that we, as a committee, should be doing to help with the data collection and access issues. I have been following somewhat closely some of them. Issues of coordination, thinking about how to get the data faster for CDC. There are lots of different issues. I am just wondering if there is any way that the committee can or should be helpful to you during this time.

Sharon Arnold: I think one of the things we are spending a lot of time thinking about although I am not sure it is completely well organized is what are some unusual data sources that we do not use on a regular basis that we could think about using to monitor trends and to understand the impacts of coronavirus and use of resources around the country. I would say that to the extent that you are aware of data resources that we do not often use and think about, we would welcome any ideas that you have for new sources.

Vickie Mays: Great. Thank you.

Sharon Arnold: It looks like there are no other questions.

Frank Pasquale: This is Frank Pasquale. I just was wondering. In terms of the timing, there is a little disconnect because I realize that like right now during the midst of an emergency, but our committee, as Bill explained earlier, is on a longer timeframe. And I am just wondering. To what extent do you think – I know it is hard to forecast the future, but there will be emphasis on or a need for the development. You mentioned new sources of data – the development of new standards for new sources of data and also the development of standards for the disposition of data after an emergency. Because I think what is kind of interesting is we certainly want to accelerate as much as possible the data collection analysis and use that is necessary for combating something as great as COVID.

I am also wondering about whether those practices continue afterward and also to what extent might expert advice be helpful in terms of looking internationally at what happens with this data once it has been collected after the emergency has abated.

Sharon Arnold: Can you give me an example of what you are talking about? I am not completely following.

Frank Pasquale: For example, in Singapore, there is an app called TraceTogether. The government mandates that individuals have TraceTogether app on their phone. The phone will give a sense – will report back with respect to Bluetooth contacts of individuals. This has been pointed out by some observers of COVID-19 as a very important aspect of emergency urgent contact tracing that does not necessarily collect contact data or collect location data the way that the Chinese Alipay and Ant Financial approach does.

We could also compare the approach of the Israeli government, which has been in a bit of a conflict with its own supreme court over the exact scope of data gathering that could be used in this context. And also, I think, the broader context is just looking at, for example, how South Korea and Taiwan also have harnessed the use of big data.

I guess the question would be – we do see that there are countries that are getting this under control. Some of the ways in which they are getting it under control are by using big data, but that is only one small facet of a much larger aspect of public health measures that those countries are doing.

The question I guess would be first would be given something and just to give a concrete example – a very concrete example of the Bluetooth context with the TraceTogether app in Singapore. Let us say if that was something that was implemented or was proposed, would it be helpful to have the advice of experts on data policy, privacy, confidentiality, and security with respect to the disposition of that type of data after the emergency abated, after the curve has been flattened or after the emergency declarations are over?

Sharon Arnold: I certainly think an analysis after the fact looking at the experience internationally of some of those apps and resources would be very helpful. I think they would not necessarily be helpful operating in the current environment. Although I suppose that if the current emergency lasts for a lot longer, we may want to experiment with the use of some of those apps in a limited circumstance. It could be that in the shorter term maybe some information would be helpful, certainly as an evaluation and recommendations about what to do the next time and how things worked. I think it would be extraordinarily helpful. Thank you.

Denise Love: Thank you, Sharon, so much for the update and my heart goes with you all at HHS for this crazy time, I am sure.

But before this COVID hit, so much of my work and my colleagues' work were really deep into some of the surprise medical bill transparency initiatives, which seem so trivial right now. But I also know that I was pretty excited about the Public Health Modernization Act and some of the funding that will, I suppose, continue to go to CDC for integrated public health reporting systems. I am assuming those things are on the back burner, but especially the Public Health Modernization Act. It seems that this COVID has brought it to the fore how important retooling some of these siloed systems that CDC have become. I am just wondering if those things are just completely off the radar screen or still going forward.

Sharon Arnold: I do not think I can speak to whether it is off the radar or going forward. I really do not know the specifics of those activities. I do know that there is a lot of work that is going forward, a lot of everyday work, but to the extent that specific individuals are required for more urgent activities, they

are getting pulled for more urgent activities. But there is a lot of the department's day-to-day work that is continuing to go on. I cannot speak to those activities specifically.

Bill Stead: I suspect it is not active in the midst of the current emergency, but it has been a while since you were able to update us on the Evidence-Based Policymaking Act and the work to advance it. Is there something to report on where that stood before we got into the emergency?

Sharon Arnold: We are continuing to make progress in that arena, trying to work through. I think the complicated process of what our policy is going to be in identifying data resources, how we look at them, how we identify priorities in moving forward and making data resources available. There has been a lot of work that has gone on in that area. Unfortunately, that particular work has been on pause for the last couple of weeks. But I think we have made some really good progress there.

We are also continuing to move forward on developing evidence plans both at the department level and at the agency level, the operating division and staff division within HHS. That is mandated by the Act and we are moving forward on that front as well so anticipate being able to report out the important key questions that each of the agencies has and the data sources and methods that we will use to address them towards the end of the year as mandated by the Act.

Did you have something specific in mind that you wanted reporting out? We have a lot of work that is going on at a low level, but nothing that we are ready to roll out at this point.

Bill Stead: That is very helpful. Thank you.

Sharon Arnold: Maya, you might have something to add here.

Maya Bernstein: I just wanted to mention that OMB in the last couple of weeks actually put out the fourth round of its guidance to agencies. We can get you a link and a copy to that.

I think, Sharon, mostly we were expecting more on Title II, but I think it mostly had to do with evaluation. We are working on Title II rather than Title I. But that also came out and if folks are interested in the Evidence Act, they might want to take a look at what OMB has to say in their latest guidance.

I think now we can expect that they will move even slower on getting out the guidance. It is a complicated Act and they also have like HHS are weighed down with what is happening with the coronavirus work.

Sharon Arnold: Thanks, Maya. Denise, did you have another question or is your hand still raised from before?

Bill Stead: Denise, you may be on mute. Assume her hand is down.

Sharon Arnold: Sorry that this was not quite as informative maybe as you would have hoped as I am sure you understand. We are in the middle of an emergency. There are a lot of activities going on. Continue to check our various websites for information and do not hesitate to reach out to me if you have specific questions. Thank you very much.

Bill Stead: Thank you, Sharon. I really appreciate you making the time to visit with us this morning.

Sharon Arnold: My pleasure. The work of the committee is extraordinarily important in the long run and has been very helpful in the past. I really do appreciate it.

Bill Stead: Rebecca, do we have something else we should do or should we transition to break?

Rebecca Hines: I am sure people would appreciate a slightly longer break and then we can resume at 11:45.

Bill Stead: Thanks, everybody. We will start back up at 11:45.

Break

NCPDP Change Request Submitted to NCVHS

Alix Goss: I believe we have a presentation up. If we could go ahead and advance the next slide. What I would like to do is level set on what we are going to be doing between now and lunch and then when we return from lunch, I am going to be giving you an initial overview of the NCPDPD, the National Council for Prescription Drug Program, a change request.

I am going to be tag teaming today first with Margaret Weiker, who is going to give us a deep dive into – overview, I should say, into – the changes that have occurred since the last time NCVHS took up a consideration of a pharmacy-related standards upgrade under HIPAA.

When we get through the first 45 minutes, we are going to take a break for lunch and then when we come back, Rich Landen is going to walk us through the processes that we have undertaken to evaluate and consider stakeholder feedback on the change request that we have received, leading us into some discussion and also ensuring another opportunity for stakeholder input through a public comment period, bringing us home next steps and hopefully being able to bring forward for discussion and vote by the Full Committee on recommended next steps.

With that overview, I would like to go ahead and get started and advance to the next slide. Rebecca, I am not monitoring the chat box. If you get any hands raised if you would be so kind as to interrupt me, I would greatly appreciate it. Folks, if you do have questions as we go, please let me know. The first 45 minutes of this presentation will be level setting. It is important to have good context to help us with the afternoon discussion that Rich will be walking us through.

The National Council for Prescription Drug Programs or NCPDP is the pharmacy standard, ANSI-accredited standard within the United States.

In January of this year, we received a request, a formal change request letter asking us to consider another upgrade to the named standard. Currently in the United States, we are operating under version D.0. That has been in place for a while. We will give you a little bit of a timeline on that in a moment.

The Designated Standards Maintenance Organization or DSMO is the formally named organization that would send NCVHS upgrades to HIPAA standards, transaction standards. The NCPDP had done their variety of work, producing a new version and had gone to the change request process ultimately sending us a letter to request consideration to adopt a new version, which we are calling F6. This may sound very familiar to a lot of folks because about two years ago, we undertook an effort to look at version F2.

Since we have looked at F2, evaluated it with stakeholder input and recommended it to the Secretary of HHS for adoption, some things have changed in the landscape. We are going to spend some time going over what has changed. But the key factor that we want to call out at this point is that there are new drugs coming into the marketplace that have price points of over $1 million.

The current D.0 standard does not, more F2 -- do not accommodate the appropriate field length for prescriptions that are greater than $999,999.99. As such, to accommodate the new expansion in new drug costs and other enhancements, the industry has collaborated, gone through the appropriate processes and asked us to consider making an update to our prior recommendation. It is important to understand that version F6 that we will be talking about today includes all the modifications since version D.0.

To give a little more context, in 2009, HHS adopted the NCPDP standards along with some other ones, but we will stay focused on pharmacy for today. The pharmacy transactions were expected to be used across the United States with a mandatory compliance date in 2012. That included version D.0 and Medicaid subrogation standards.

Those standards were in place for a while and they really include the telecommunication standard, implementation guide that we referred to as D.0, the batch standard implementation guide version 1.2 and batch standard Medicaid subrogation implementation guide version 3.0.

What is important to understand is that we are really only today talking about the telecommunication standard implementation guide version D.0. This includes transaction capabilities for claims, eligibility referrals, certification authorization, coordination of evidence.

The industry has been consolidating needed changes for a while since D.0 was put into obligated use in 2012. They brought forward version F2 for our consideration and we had a hearing in March of 2018, resulting in a letter that we put forth recommending adoption in 2018, May of that year. Since that time, not only have the prescription cost dollar values increased, but other changes have been identified through the industry.

In 2019, NCPDP developed and finalized through their processes version F6, advancing it into the DSMO, the Designated Standards Maintenance Organization process, resulting in us receiving a letter in January of 2020. We have undertaken a stakeholder engagement process leading us to today.

The NCPDP recommendations for F2 to replace D.0 really reflected more than a decade worth of changes that were needed in the industry. We evaluated version F2 and its Medicaid subrogation counterpart in the 2018 timeframe, including revisions related to data elements. There were 218 data elements added, 46 were sunset. There were hundreds of requests that were put in for not only data elements, but also for the external code lists. For instance, there were 152 existing data elements that had values added, redefined or renamed, 211 reject codes were added, and 125 reject codes were sunset. This is just to give you a little bit of the flavor of the kinds of volumes of changes that were undertaken by the industry.

There were also beyond regular data maintenance types of changes. There were some notable changes related to the opioid epidemic. For instance, the total prescribed quantity of remaining was added for controlled substance use and the field allows the processor to identify the accumulated prescribed quantity remaining.

In 2018, we undertook review of the improvements in F2 to meet the industry's needs and were not able to be met in version D.0. As noted, this included reimbursement methodologies, workflow automation, and information allowing the pharmacy to better communicate alternative therapy availability with the patient.

All of this does support patient safety mechanisms and improved communications. When you are looking at increased potential for exchanging information, it is going to aid interoperability.

Through our hearing in March of 2018, which we also did virtually, we produced a letter with recommendations to adopt upgraded versions of the standards. We wanted to replace version D.0 with version F2. We did want to update the Batch Standard Implementation Guide Version 15 and adopt the updated Medicaid Subrogation Implementation Guide Version 10 to replace Version 3. For those of you who may not be familiar with the subrogation processes, this has to do with the pay and chase of who is the payer and that is responsibility for coverage of services for a given patient and this supports federal and state processes for the payer of last resort.

So – letter in 2018 or as a part of it, we addressed implementation timing. There were synergistic recommendations on the lines of some of our Predictability Roadmap efforts to expedite rulemaking to the extent feasible and to publish a final rule by the end of 2019. You will note that this has not happened to date. There has been no proposed adoption of an upgraded NCPDP set of standards.

But during our May 2018 recommendation letter, we wanted to make sure we were providing ample time for implementation following the publication of the final rule.

Timing of compliance dates is important when you think about the industry's management of eligibility changes, managing flu and influenza and a variety of other dynamics that happen from late fall to early winter.

The industry during its testimony to NCVHS Standard Subcommittee was very clearly that they would like to have June as a compliance month and that they wanted to require the update version of the standard be used by the compliance date, but allow both the versions of the standards to be used for an overlap period. This really supports robust testing and integration and mitigation of operational dynamics, their experience once you go into a real-world set – of the transaction.

A recommendation letter of May 2018 recommended full compliance by the end of the third year and only allow the use of the new versions as of the compliance date.

At this point what I would like to do is – so she can walk us through a more detailed update of the changes since F2. Keep in mind when we receive the change request from the DSMOs, we were being asked to evaluate F2 to F6 because we have already completed a detailed evaluation in stakeholder engagement related to upgrading from D.0 to F2. I look forward to the review of the changes in F6.

Margaret Weiker: Thanks, Alix. Next slide.

Alix Goss: They may be converting, Margaret, to go to your slide decks – your slides --

Margaret Weiker: I am Margaret Weiker, the NCPDP vice president of Standards Development. NCPDP is a not for profit, multi-stakeholder forum for developing and promoting industry standards and business solutions that improve patient safety and health outcomes while also decreasing cost.

The work of the organization is accomplished through its members who bring expertise and diverse perspective to the forum. As an ANSI-accredited standard developer, NSPDP uses a consensus-building process to create national standards for real-time electronic exchange of health care information. To our collaborative problem-solving forum, we also developed standardized best practices for product labeling, dosing instructions, patient communication and education and other practices important in safeguarding patients. Our data products developed by industry for industry help support the important work of our members.

Alix touched upon this. On August 17 of 2017 Change Request 1201 was entered and that requested the telecommunication standard version F2 and the batch standard version 15 be adopted under HIPAA. Change Request 1202 was a request to adopt the subrogation implementation guide for batch standard version 10 for Medicaid use only. That was to replace the previously adopted subrogation standard.

The DSMO, the Designated Standards Maintenance Organization, sent a letter to NCVHS on January 9 of 2018. NCVHS held a hearing on March 2018 or in March 2018. And NCVHS sent a letter to HHS on May 17, 2018 requesting the Secretary to adopt the standards that were mentioned in the Change Request 1201 and 1202.

On November 10 of 2019, Change Request 1208 was entered into the DSMO Change Request System. That was to request the Telecommunication Standard Implementation Guide version F6 be adopted as a replacement to our previously requested version F2. Even though the DSMO did not have a fast track process per se, my fellow DSMO'ers, which I would thank greatly for doing this, expedited the review of the change request. On January 21 of 2020, the DSMO sent a letter to NCVHS requesting that they move forward expeditiously in regard to holding a hearing and going through the process that is outlined in regard to adopting of standards under HIPAA.

Here we are March 24 of this year, having that NCVHS meeting. Once again, I would like to thank all of the DSMO organizations for getting this done very expeditiously.

DSMO Request 1208. I have cut and pasted into this slide and into the next slide, the actual change request that was entered. The first paragraph already talked about the dates that both Alix and I have mentioned.

Also, one of the driving forces or the primary driving force to move to another version was the prices of drugs that are coming into market and the dollar amounts associated with those. (indiscernible) F2 can support a drug that cost a million dollars. We are seeing these come on the market today. In reading some articles, et cetera, we expect there will be hundreds more new therapies that are developed. These are groundbreaking type of therapies, gene therapies. They target certain cancers, rare diseases. There are drugs that can cure a certain type of blindness. Very valuable type of drugs.

We requested that version F6 be adopted for the standards that you see listed: eligibility verification, claims, service billing, information reporting, prior authorization and predetermination of benefits. Eligibility claim service and prior authorization have all been adopted under HIPAA. Information reporting and predetermination of benefits have not nor do we want them to be.

I want to emphasize that there is no change to the Batch Standard Implementation Guide Version 15 that was in Change Request 1201 as it supports Version F6, which supports the telecom standards. And there is also no change to Change Request 1202, which requested the Subrogation Implementation

Guide for Batch Standard Version 10 being named in HIPAA to replace the Medicaid Subrogation Standard Implementation Guide Version 3.0 for Medicaid use only.

Between Version F2 and its finalization and then the finalization of F6, 25 Data Element Request Forms or DERFs is what NCPDP calls these. These are what others would call a change request. Twenty-four data elements have been added, 29 data elements had been sunset, and 54 data elements have been modified.

Some of the notable changes between F2 and F6. Obviously, the first one is the increase in dollar fields. We increased all of the dollar fields by three digits except the other payer patient responsibility amount, which increased by one digit.

We also modified the patient ID and associated fields with the patient ID to make them repeating data elements to support communication and sharing of multiple universal patient identifiers from different enumerating entities on a single transaction. We also modified the situational use of the patient ID.

We modified the Prescriber DEA Number situation. And we did that as there are many state laws as well as some federal laws that prohibit the use of the DEA number on a claim.

We also added a data element called Species. This was to support the billing for non-human species, primarily veterinarians billing for drugs.

The Scheduled Prescription ID Number. We increased the link to accommodate state requirements for a unique serialized number on a prescription form. We also sunset the CMS Part D Defined Qualified Facility as the patient resident field contains enough detail to support any previously intended use of this field.

We also created an Invalid Provider segment. And the purpose of this new segment is to expedite the resolution and provide appropriate access to care by providing the specific federal and state file source and the associated state code if it is applicable used to determine the point of service rejects. The name of the specific data source will allow the pharmacy provider to clearly communicate to the prescriber or provider business unit the conflict details to determine next steps. This may include operational and workflow actions to ensure the patients and/or a corrective action plan is implemented.

The formulary alternative effective date was added to proactively communicate an upcoming formulary change information with both the patient and prescriber, which could potentially mitigate access to care and adherence risk.

The ID field listed, prescriber, primary care, associated service provider, ID prescriber, alternative ID and provider ID were all linked in from 15 to 30 bytes to support state license number formats that are standing beyond 15 characters as well as to promote harmonization of billings across the NCPDP standards that use these data elements.

We also increase the field length of the Original Manufacturer Product ID and this was done to align with the other product ID fields. In addition, we added clarity to – the other segment in regard to the groupings of other payer percentage tax exempt indicator and other payer regulatory fee grouping.

We made some extensive modifications to the DUR/PPS response segment to capture within codified fields critical data elements regarding the DUR conflicts that is currently being returned in text fields.

This will allow or increase patient safety, workflow efficiencies, and better support the harmonization and the DUR information communicated between the payer, pharmacy, prescriber and patient. We added 16 new data elements. We modified some bill names. We expanded the use of a couple of fields to be included in the response transaction, which were only in the request transactions. We modified names of the DUR free text. We increased the length of that field and therefore sunset the DUR additional text field.

The Response Other Related Benefit Detail Segment was added to other transactions specifically the claims service response to identify other benefits associated to the patient. When this segment was first developed and added to the standards, the business case was limited only to Medicare Part D E1 transactions, which is the eligibility transactions. And since that time, there has been business needs added to the other.

We have also done some cleanup to improve readability, provide clarity and we also removed some irrelevant information.

That is more of the technical, what we changed to the standards. What are some of the benefits? One, it improves the functionality. Obviously, again, with the cost of the drugs, it would allow these drugs to be billed electronically and go into the current processes that we use today for all of the other drugs that are submitted electronically.

Patient safety processes are enhanced through enabling pharmacy and prescriber system automation and intra-operability of clinical information as a result of replacing free text clinical and non-clinical information with codified fields.

IT development, testing, and implementation burdens are reduced. This is a result of eliminating intermediary qualified message solutions and prior versions and enhancing the use of the other related benefit information segment.

Patient access to care is expedited through workflow, interoperability between the payers, the pharmacy and prescriber as a result of new response data elements to better communicate current and future effective date plan formulary, alternative information, and patient cost share amounts.

Why adopt the Telecommunication Version F6? It offers enhancements that better support current and future business needs. It improves the structure to support the clinical evaluation of prescription products and planned benefit transparency, which are key components and achieving expected health care outcomes related to value-based care, digital therapeutics, social determinants of health and other areas of health – innovation. It enhances drug utilization/patient safety mechanisms by providing better tools to address health issues such as the opioid epidemic.

It expedites plain resolution through improved data analytics. By any time, you remove free text and put it in a codified field, you can now do data analytics with that information. And it also, as I mentioned, approves the adjudication of claims as it would allow the industry to use the standard processes that we use today for those drugs that cost over a million dollars or a million dollars or over.

The NCPDP SNIP Committee met and submitted a letter in regard to the questions. We also developed a timeline recommendation. NCPDP recommends HHS named Version F6 in a proposed rule as soon as possible and no later than December 2020. And the Final Rule be published no later than August 2021.

This timeframe allows stakeholders to begin planning and allocating the applicable IT budget and development phases. NCPDP recommends HHS adopt a compliance date no sooner than May of 2025, which is based on stakeholder analysis indicating the development and testing effort for version F6 to be far greater than previous HIPAA-named versions. Most of that has to do with the expansion of dollar fields.

However, the health care industry is rapidly changing, as we all know, for business needs and regulatory requirements could quickly necessitate the implementation of enhancements in version F6.

NCPDP recommends the timeline outlined above be supported and adhered to by HHS and communicated as soon as possible to allow stakeholders to begin budgeting, planning, development work and coordinating the necessary trading partner agreement.

What happens if the timeline is not met? If the Final Rule is not published in the recommended timeframe, industry will need to continue to use the HIPAA-mandated NCPDP Telecom Standard Version D.0 and the associated workarounds including manual claims processing, splitting of claims for million-dollar drugs and manual workflow steps to identify and act upon patient safety alerts.

Furthermore, the future use of the 8-byte IIN, which is previously known as the BIN or the B-I-N is not supported by Version D.0 and this will prevent processing and routing of claims. In my discussion with ANSI, who is the numerator for the United States as the IIN as the ISO standard used all over the world in assigning numbers that they will have to start assigning eight-digit numbers that do not end in 00 in five to ten years so something to keep in mind.

Other features such as medical and other related benefit information will simply not be available to trading partners for enhanced patient care coordination if Version F6 timeline is not met.

NCPDP requested NCVHS include a reminder in their letter to HHS in regard to the DSMO Change Request 1201, for the Batch Standard Version 15 and then for the Subrogation Implementation Guide for Batch Standard Version 1.0 to be named in HIPAA for the Medicaid use to replace the Medicaid Subrogation Implementation Guide. We also request that NCVHS include the adoption of the telecommunications standard version F6.

I want to provide a bit of a clarification. On the one slide where I listed the transactions that are supported by the telecommunication, I listed prior authorizations, which have been adopted under HIPAA for prior authorizations that are initiated from the pharmacy. For prior authorizations initiated through a prescriber, you use the NCPDP strict standards. I just want to make that distinction.

And lastly, but more importantly, I want to thank NCVHS for acting expeditiously on the DSMO request, scheduling the hearings, and thank Alix Goss and Lorraine and Rebecca and Bill for working us into today's meeting. Thank you very much. As I have been known to say in the past, happy trails.

Alix Goss: Thank you, Margaret, but you are not quite off the hook because I want to make sure – see if there are any questions. Although the Standards Subcommittee has been taking a deeper dive into the topic. We do have some Full Committee members that may not have the background that we do and may have some questions for you or me regarding the concept we just delivered over the 40 minutes.

I think this is the appropriate time for folks on the NCVHS Committee if you have a question, please raise your hand. And of course, Rich, please kick us off.

Rich Landen: Thanks. Margaret, thanks for an excellent overview presentation. I first want to just set some background, particularly for our newer NCVHS members that although we talk – or Margaret talked a lot in her slides about the benefit of the patient, this is really all business-to-business processing and workflow. It is designed to move data real time and have all that data then machine processable. There is no real patient involvement in this dataflow. I just wanted to make sure that is clear that we are talking business-to-business and not patient involvement.

Margaret, a question for you. You had two slides on DSMO Request 1208 on the second – you mentioned information recording and predetermination of benefits were in that – but are not for HIPAA mandates. Can we assume that those are structured within the Implementation Guide such as NCVHS does not have to worry about that being confused as a HIPAA mandate or do we need to pay special attention to that and call it out in our communication to the Secretary.

Margaret Weiker: The Implementation Guide, Rich, is structured to where there is a separate section for the information reporting and predetermination of benefits. It is clearly marked of what transactions and what segments and data elements are applicable to each transaction. And the reason why those were included is I went way back into the beginning of adoption and we had lifted those when we moved from F1 to D.0. I brought those over as well so we would have consistency from the beginning to the end. But they are clearly marked --

Rich Landen: Again, just to be sure, assuming we recommend adoption and assuming that the rule promulgation process adopts their mark in such a way so that both the regulator and the industry will understand that those are not mandated under HIPAA.

Margaret Weiker: Correct.

Alix Goss: Thank you, Rich. At this point, Nick has his hand up. I do not believe he is on video, just on audio today.

Nick Coussoule: Correct. Thanks, Alix. Margaret, just one question. Clearly, there are a lot of benefits which you have articulated and even a lot more details behind the scenes. Have you taken an effort to try to quantify any of either the productivity benefits or things that are a little more directly visible as far as being able to support the change?

Margaret Weiker: NCPDP does not normally have that kind of data. Our members typically have that data. I am hoping in their letters to you all in regard to the questions that they have provided a high level or detailed information around that. But NCPDP typically does not gather that information.

Alix Goss: Denise, is your hand up?

Denise Love: Yes, I am getting the hang of this. Thank you, Margaret. I really always have appreciated the leadership that you and NCPDP have demonstrated over the years. I have learned a lot from you.

I should have caught this before, but can you just give a couple examples of the irrelevant information that was removed from the previous transactions just to give me a feeling what was dropped and what was perhaps lost.

Margaret Weiker: We had two segments in the standard which supported prescription drug monitoring and they were only used for PDMP programs. We moved the PDMP out of the telecommunication

standard and created a separate standard for it. One of the reasons was the need to make changes to it and we all know about the HIPAA process and how long that takes. We moved it out into its own standard. When we did that, we did not quite remove everything that we should have removed when we did that – like an example of the irrelevant information because the fields do not exist in the standard anymore, processing, anything like that associated with that was removed.

Denise Love: But the capacity for integrating with the Prescription Drug Monitoring Programs still survives. It is just not in the same form and embedded in the HIPAA segments. Correct?

Margaret Weiker: Correct. It is still in the same format. It uses the telecom EDI syntax field, et cetera. But we moved the data out or the formats out of the telecom and created its own standard.

Denise Love: Okay. Thank you.

Alix Goss: Are there any other questions from the committee for Margaret or me? I think, Denise, you just need to lower your hand because I do not think you have another question at this point.

At this point, Rebecca, I am not hearing any further questions. I believe we are just shy of our scheduled break for lunch. What I think we want to do is possibly just queue people up for what the process will be for later today on the public comment period, which would take us back to the other slide deck. We want to go over that public comment period just so people know how we are going to be handling that later today.

Rebecca Hines: Alix, are we on track to stay at the 2 p.m.? Great. While Greg is bringing --

Alix Goss: It depends upon how many questions we get on the other thing. But I think, Rich, you are going to be covering that point. I still think 2 o'clock is on schedule for public comment.

Rich Landen: Right. That is approximate, but before we get to the public comment, we want to review the written comments that were submitted already. That is probably going to take about a half an hour so 2 o'clock is a good target. But we did want to make sure that our webcast participants understood what our process is going to be and they can think ahead then to how and when they will be able to submit their public comments.

Rebecca Hines: Yes. The slide that is up now gives the instructions for when we get to that time. Hopefully, exactly 2 o'clock so people see that we are with the agenda that at 2 o'clock, we will open things up for public comment.

With that, enjoy your hour and one-minute lunch break. We will reconvene on time at 1:30 and that will give you half an hour to share with everyone the substance of the comments we got earlier this month and then we will open it up for public comment at 2 and then see if there is enough to go on to move forward.

Alix Goss: Thank you, Margaret, for your support in today's presentation. Have a good lunch everybody.

Margaret Weiker: Thank you, Alix.

(Break for Lunch)

NCPDP Change Request Submitted to NCVHS

Rebecca Hines: It is 1:30. So as promised, we should get started on time.

Bill Stead: I will beat the gavel to say we are back in order.

Rebecca Hines: Take it away.

Rich Landen: This is Rich Landen and co-chair with Alix of the Standards Subcommittee. This morning we got a lot of the background information from what Alix presented to us. We heard a lot of the detail about what is in the F6 standard and going back as far as D.0 from Margaret Weiker at NCPDP.

My role in the next few minutes is just to let you know what we got in response to our Federal Register Notice from end of February and summarize the written input that we got from stakeholders.

Besides the Federal Registry Notice, we did an industry outreach, additional industry outreach to subject-matter experts from NCVHS and NCPDP to supplement the request, not just relying on the Federal Register Notice.

What we ask is a series of seven questions. Commenters, of course, were not restricted of those seven questions. Over the next few slides, we will talk about what we got in. But here are the seven questions we asked the industry stakeholders. That is what their views are, what – enhancements between F6 that NCVHS recommended a couple of years ago for adoption. And as you recall, it has not yet been acted upon by F2 and then now F6 proposed to replace up. It is the difference in that gap and again, going back. The standard in effect right now is D.0. There are a lot of things that are within F2 that are not in D.0. All of those things that were in F2 are pretty much contained in F6.

When you hear the industry responses to the question about F6, remember that we are focusing on the gap between F2 and F6. But from the industry perspective, the adoption process will actually be moving from D.0 to F6 assuming HHS accepts – recommendation.

The second question was about the timeframe. The third question is when must the standard be available for use? Deadline for adoption. The fourth question is until the standard is adopted and remember the adoption promulgation development implementation test is a multi-year process. Until that is completed, what are the workarounds for the million-dollar drugs, which is kind of the centerpiece of the F6 enhancement?

What are the barriers to implementing F6? Any time NCVHS and the Standards Subcommittee considers recommending a new standard for adoption, we always have to be very careful about understanding what some of the barriers to the implementation are because we need to take into account our consideration of the challenges this poses to the industry, not just focusing exclusively on the advantages of – version.

And as we have learned in the past, some segments of the industry typically are more impacted by changes than others. That is a little bit less pertinent in the pharmacy world although it is still pertinent than it is in the medical world. But we are talking about doctors, pharmacies and in addition, we saw some of the references that have –

We always ask the industry about qualitative and quantitative costs and benefits of a proposed new standard and then the key question is has the standard been tested – to what extent is the standard proven and to what extent is it still theoretical.

This slide lists ten points that have since the get-go of HIPAA, laid the fundamental concerns or objectives, principles by which we must consider adoption of updated standards. That has to be something that leads to cost reduction through efficiency and effectiveness. It has to meet the needs of the community, the users. It has to be consistent with other standards. We cannot have standards that do not work together well unless there is no alternative.

It has to have a relatively – development cost relative to the benefits. It must be developed by and supported by an ANSI-accredited standards development organization. It has to have timely development testing implementation and updating procedures so that it can be maintained over time and implemented relatively quickly.

Seven. It must be technically independent of the technology platforms and the communication transmissions protocols used in business-to-business.

Eight. It must be precise and unambiguous and hopefully as simple as possible to meet the workload requirements.

Nine. It must resolve in minimum data collection and paperwork burdens.

And ten. It must incorporate flexibility to adapt easily to changes in health care and in infrastructure.

We have received written input from ten stakeholder organizations, all of them national in scope, representing pharmacies, pharmacy benefit managers, PBMs, community pharmacies, chain pharmacies, technology providers, and vendors and health plans specifically, vendors representing the health plans and their pharmacy business. Also, included in there was one comment from a federal agency, which I will get to more in a little bit later.

There was general support for the adoption of NCPDP Version F6 based on its accommodation of the changing landscape of health care operations and technology. Of all ten comments we received, zero opposed the proposal. In short, we had nine in favor in one, the federal agency that I referenced, simply thanked us for making them aware of this issue and they will study it but they did not include in their written response an opinion one way or the other about support of opposition. That tenth response – we kind of put that in the neutral bucket. We have nine in favor, one neutral, zero opposed.

The other themes that came out were the timely adoption of the standards by HHS as critical, as you may recollect from this morning. Alix talked about how much this relates to our Predictability Roadmap. And then an axiom of IT for health care is industry will not start development work for significant testing prior to the promulgation of a federal rule. Developers simply do not budget those extensive resources until they have something concrete to work with and that means a federal rule.

In the past when an entity has attempted to do that, we have seen all too often that the federal rule either did not happen timely or it included something that was unexpected and those development hours then were pretty much wasted. Whether we like it or do not like it, it is pretty much de facto that development work on F6 will not start until the industry actually sees a rule in the Federal Registry.

And the fourth theme of the commenters is that the implementation date should not interfere with pharmacy change periods for peak influenza spikes. What that means is most of the time in the HIPAA era, we, the industry, have scheduled implementation days to essentially start January 1. And what we find around January 1 is there is too much other stuff going on: year-end reporting for corporations and organizations, holiday periods. January 1 is the cut over date when most insurance plans – insured individuals will change from one benefit plan to the next. There is just too much going on that is competing for the same resources that would be required to implement the change in the NCPDP F2 or F6 standards. That is why we will see going away from the January 1 implementation date. As you will see later on, NCPDP is proposing a May implementation date.

Continuing on, F6 brings incremental improvements over F2, as we heard from Margaret. Greater automation and interoperability between systems, less manual effort and all this results in better information flow, better decision and clearer decision making and hence particularly when you look at either the provider or particularly the pharmacist's interaction with the patient, it improves patient care.

F6 is a real-time transaction, as mentioned before. There is another standard from NCPDP that is the batch transaction standard that is not included in the update.

And seven. The level of lift and the cost is – the commenters – pretty strong consensus. It is going to be at least double that of what it cost them to implement D.0. A lot of that is the cumulative effect of everything that is not in D.0. but was in F2, and now is being moved into F6. But that also represents over ten years of updates being put in one fell swoop, again reference back to our Predictability Roadmap.

The next section we have tried to summarize the written responses – the questions. Again, kudos to the staff for doing this, Lorraine Doo of CMS.

Question 1. What were the main enhancements? Elimination of some of the free text fields and replacing with codified fields. Always better for machine processing that we use codified fields rather than then free text.

Improves interoperability. Again, codified fields. Mitigates the need to split claims for high-dollar claims. Provides more data that can be used between long-term care providers and PBMs, including information needed to prior auth. Enhancements of drug utilization review fields.

Question 2. What is the timeline for adoption? Here and I think Margaret went over this in her segment of the presentation, but I will repeat it again. The recommendation coming from NCPDP and was supported by the consensus of the written commenters. NPRM released by the end of this year. The usual two-month comment period. Final Rule by the end of August of next year. Three years for business development, planning, testing, trading partner certification, pilot use, and although it is not in this slide, very importantly, the budgeting with particular emphasis on state Medicaid and federal agencies. It is a long cycle to get the budget approval necessary to get everything in place by the implementation date.

Back to line six then, NCPDP recommends full use of version F6 at the end of August 2024, but an additional nine months for testing and fixing, getting the bugs out of the system so that after May 1 of 2025, the HIPAA standard would then be the exclusive use of NCPDP version F6.

Just to clarify, during the period from essentially end of August 2024 to May 1, 2025, both the D.0 and F6 would be acceptable.

And as we talked about – I think we referenced a little earlier. We are specifically and intentionally recommending the May 1 or the August 28 and then the May 1 for the compliance date to avoid the conflicting resources that typically go along with a January 1 implementation date.

Third question. What is the latest date the standards should be available for us? And census again is adopting the standard in an NPRM by the end of this year. If there are delays in the timeline that will necessitate continuing industry workarounds such as more of the claims would have to be processed manually. Big dollar claims. Those are the million-dollar drugs of which there are several now, but many more on the horizon. They would have to be split for some other process.

One submitter commented that moving to the next version if F6 is delayed would make it obsolescent and would require either to replace it with a new version or continue workarounds and not a good idea.

Ongoing delays of adoption of standards hamper the ability to meet daily business processing needs and challenges.

Fourth question. How will the industry accommodate high-cost medications over a million dollars? As you recall, a million dollars was more characters than the current field can support. Submitters identified workarounds.

The solution will require major investment – the IT development work. Interim standards will present barriers that require either unique solutions for each organization or each set of trading partners. Some options will not be scalable and may not allow claim splitting. Claim splitting is essentially breaking the claim into two components, but that would allow the claim or both halves of the claim to be processed electronically rather than dropping to manual processing.

Some high-dollar medication therapies have limited or exclusive distribution dispensing networks. That will create complexity to the variability of manufacturers or unique payer needs.

Submitters made several suggestions that if F6 is not adopted, pharmacies may submit multiple claims for the same service or pay them as a split claim we were talking about. They revert to Universal Claim Forms. Pharmacy could submit special handling invoices. Again, it is not efficient. For coverage coordinated under the medical benefits, pharmacy submits drug claims, provider submits claim for drug administration. Again, it is less simple than it might be if the standard is adopted.

Question 5. Implementation barriers for version 6. Who could be impacted? Responses included. The compliance dates could conflict with other prescription benefit implementation. We have talked about that before.

Field expansion will have significant workload and financial impact on systems. It is not trivial to change the length (inaudible)

Technical and operational learning curves from employees. It is not just the IT and the development, but it is also the business operation folks that need to know how to work with those systems.

Possible lost or delayed opportunities to limited resources, time constraints, coordination of quality assurance, and user acceptance testing. All organizations have to do significant planning and significant development. Some organizations may have more challenges than others such as State Medicaid programs and some smaller entities.

As we have seen in the past, sometimes Medicaid changes requires an act of the state legislature. Some states that is true. Other states it is not. But in all cases, Medicaid is a creature of state government. But the decisions tend to take a lot longer than private sector decisions.

Qualitative and quantitative cost benefit information. Again, no hard dollars and cents came from the written comments. But we did get a good sense of the consensus that estimates were between double and four times that of cost they incurred implementing D.0. Again, depending on the size and the complexity and the role of the market segment of the implementing entity, that cost could be $100,000 or for a large organization were in the multiple millions of dollars.

Thousands of labor hours needed for business teams and planning, development, testing, and training on the new systems. Costs will vary among different pharmacy chains based on size, scope of services and business models. Hardware and software maintenance costs allocated specifically to F6 implementation are estimated to be in the tens of millions of dollars. It is a big-ticket item for the industry.

Benefits include improved patient care, greater ability to changing health care delivery and payment systems. As we all know since D.0 came, we have ACOs. We have a lot of both governmental and insured products that look, feel, and work very differently from traditional indemnity insurance products that were shall we say, a much more dominant back in the day.

Has the updated standard been tested? What about testing strategies? Responses from the written comments included testing of the updated standards will be first conducted internally by the covered entities followed by trading partner testing. Again, as we have stated several times, the development testing is typically not done until after a standard is named in regulation.

Some additional comments that we pulled from the written submissions. Barriers. Current HIPAA process may need to evolve to allow more timely and cost-effective implementations – is a common theme that we heard in our Predictability Roadmap hearings and – again, it goes back to the need for smaller and more frequent changes to standard. But changes – suggestion came to reduce the size of the payload, update the legacy systems behind it and somehow optimize what is now a rigid process for HIPAA standard updates.

The barriers prevent the industry from being innovative, from building and piloting solutions prior to the changes being mandated and that means they are behind the eight ball and reacting to changes in the business of health care and pharmacy development.

What is the value? Commenters suggested that NCPDP is a real-time transaction standard that allows pharmacies to verify eligibility, determine coverage, learn if alternative medications are on the patient's formulary and importantly inform the patients of their required copay, and then submit the claim all in under three seconds.

At this point then, I think it is close enough to 2 o'clock. What we would like to do is invite all the attendees on the webcast to give us oral comments. If, Rebecca, we could go to the instruction slide for how they make those comments.

Public Comment on NCPDP Change Request

Rebecca Hines: Thanks, Rich. On the screen are the instructions for submitting public comments. You can send them by email. I have not received any. That is NCVHSmail@CDC.gov. If you would like to make a live public comment, you have up to three minutes. If you are audio is through Zoom, click raise your hand to have your audio unmuted. And if you are calling by phone, press Star 9 to request that your phone be unmuted. We will wait a moment to see if anyone raises their hand on the attendee list. Again, if your audio is through Zoom and you would like to make a public comment, click raise your hand. If you are connected by phone for audio, press Star 9.

Rich Landen: While we are waiting for that, let me just explain to the Full Committee that after we hear through the public comments and then the assumption is that we have the written comments in hand, what were the oral comments, then we will go to the committee members and ask for questions and then we will go into a discussion about F6. Assuming we come out with a census of the group then we will determine next steps. After we hear the public comment, we will go back into it and I will give you a little bit more detail about the draft recommendation coming out of the Standards Subcommittee.

Rebecca, back to you.

Rebecca Hines: At this time, we have received no request to submit public comment either by email or on the platform. I think if we can continue. If somebody raises their hand, I will let you know and we can open up the line for them.

NCPDP Change Request Submitted NCVHS (Deliberation)

Rich Landen: We can go back to the next slide in the deck. We have heard what was submitted to us pursuant to the Federal Register Notice and the industry outreach that we did. We have no additional comments today from the webcast attendees.

I think at this point, let us open it up to questions from the NCVHS committee members. Again, using our nifty electronic "raise your hand" button, see if there are any questions.

Rebecca Hines: Alix Goss has her hand up.

Alix Goss: Great job, Rich, on running through this summary of information we received from the written comments from the nine submitters. I just want to acknowledge the level of coordination that we have seen within the NCPDP community. Margaret mentioned a phrase in her presentation of SNIP, Strategic National Implementation Process, which was a best practice that was implemented or discovered in the initial round of HIPAA and where we have seen through the F2 hearing and now this latest round of stakeholder comment solicitation – the pharmacy industry is working very closely together to understand the opportunities and technological barriers that could be overcome through their transaction standards and to figure out not what it only means to fix the technical issues, but it means to implement and advance use of those transaction standards as a community. I really want to do acknowledge the level of coordination within the pharmacy community.

Rich Landen: Thank you, Alix. I do not see any other hands up.

Let me take a step almost seems back. It is not. Let me describe to you the recommendation that is coming out of the Standards Subcommittee. We chose not to show these recommendations until we completed the public input section of this and the summary and the comments. But the Standard Subcommittee after reviewing and discussing the written comments had a very strong consensus that

NCVHS should move forward with recommending to the Secretary the adoption of the NCPDP Telecommunications Standard Implementation Guide version F6. This would be in lieu of our previous – would supersede our previous recommendation recommending F2. It would not impact our previous recommendation on the batch transaction recommendation from a couple of years ago nor the Medicaid subrogation recommendation in that same letter. It would just be instead of adopting F2, we would recommend F6. That is the first point from the subcommittee.

The second point was to include in our advice to the Secretary a recommendation to promulgate rules and implement according to the timeline that NCPDP and the public commenters put forth. Let us recap here. NPRM by the end of this year, assuming favorable public comment, Final Rule by end of August, September 1 of next year, three-year implementation window combined to allow time for planning and completion of necessary budget cycles. And then beginning in September 2024, allow the use of F6, but do not mandate the discontinuance of D.0 and that period, that dual use period, that window would go on for nine months. And then after the nine months, beginning May 1, 2025, only version F6 would be in use. Again, the reason for May, we have talked about – that the recommendation from your subcommittee.

Let us open it for discussion. Kick the tires, poke holes, ask questions, challenge it. Because what we need to do is get the consensus of the Full Committee. Our go-forward plan is, one, assuming we do achieve a consensus today whether it is as drafted or as modified. Then we would have our bullet points sufficiently clear that it would be appropriate at that time then for someone to make a motion to authorize the Executive Subcommittee to actually flesh out the letter that would contain the recommendations and go to the secretary. In that way, we would be able to actually get a letter off to the Secretary before our next Full Committee meeting.

Are there hands that would like to kick off the discussion?

Alix Goss: Rich, I will chime in here since no one else is raising their hand at this point. There was a lot of subcommittee discussion around the duration of the implementation period with kicking off – that we would release a recommendation letter imminently on the heels of this hearing so to speak and that we would have timely response form the industry, but that it was from the feds in advancing a rule. And that it was still going to take several years to be able to – full compliance date using the full capacity of F6 and take us until 2025. As I thought about the – impacts and the number of changes that we all experience like when we did the Y2K changes and the number of operational workflow implications from over a decade changes now that – gathered up since D.0 was mandated more than decade since its mandated use. It really seems to me that it is giving us a runway that is viable for the industry with a lot of other things occurring.

I just thought I might comment on it may seem like a long way out between now and May of 2025. But when you think about the level of lift that the industry is going to have to go through, it is probably spot on.

With that said, I see that Vickie has raised her hand.

Vickie Mays: Thanks, Alix. I think you may have answered my question because it was about the time. And one of the things I am looking at is that the Final Rule gets published September 1, 2021. And I was trying to get a sense of this – this really hits what Bill was saying this morning about sometimes our work really is to deal with kind of – a long view. But I think I get it.

I get why it is not starting until when it starts. But can you just walk me through the process of why the Final Rule would not get published until 2021?

Alix Goss: When we think about the timeframe that we have right now, we would – kind of sketch this out. Rich, is that okay or do you want to take this?

Rich Landen: Go ahead.

Alix Goss: We write a letter – today we get approval from the Full Committee to advance. We write a beautiful letter and we get – approval for the Executive Committee to do the fine tuning and blessing of that letter so it can be issued. Then it goes to HHS who then will likely refer to the Division of National Standards for Processing – it goes to DNS – write up a proposed rule. They will have to do all kinds of content details related to regulatory burden, policy framework, explanation of all the changes. Some people can appropriately comment during the Notice of Proposed Rulemaking or NPRM public comments. They then get all the comments that come back in. They have to process that and then write a new rule that addresses all their obligations and again goes through the whole clearance process, which – cross-agency coordination, OMB, gets out – I am sure Lorraine is going to keep me on this if I mess anything up here.

And then what will happen then is the Final Rule will then get published. There are certain periods of time that are needed for writing for industry to review and comment, for the feds to review the input they received and then – response and get back through the clearance. That is a need for due process.

But on the heels of that then the industry knows they are safe to get their leadership support to start allocating resources on the technical, operational business – changes that the implementation guide will impact.

Vickie Mays: That is helpful. I was trying to think but it sounds like from what you are saying, there is no pressure on our part to drive this faster. There is nothing that the industry is asking for to want this to be faster. That this is really a due process that really needs to take the time that it takes despite the fact that these are things that are really needed.

Alix Goss: I think that the NCPDP pharmacy community realize that they have asked for the utmost efficiency of the federal partners in all of this providing them with what they think is realistic for the implementation timeframe. This is already asking the feds to be rather expeditious to our letter and to move very quickly and, one, to act on it, and then move it through the process with skill.

Vickie Mays: Okay. That is very helpful, thank you.

Rich Landen: Vickie, just to add to what Alix said, she described the process for promulgation and publication very well. But certain components of that are regulated by the Federal Administrative Procedure Act. There are different sub-pieces in there that have their own timeframes. Public comments must be at least two months. And for us to be recommending a Final Rule essentially, a proposed rule essentially within nine months and then a Final Rule nine months after that that is really pushing the bureaucracy along quickly.

Generally, my experience is – anything less than a full year to come out of an NPRM, the full year after the NPRM to come out with a Final Rule. The feds really have to be motivated to address some sort of

crisis like the opioid crisis, as an example, in order to get a rule out that fast. Nine months is pretty aggressive.

Vickie Mays: Learning all the time from the two of you. I was hoping that maybe we needed to go faster and now I appreciate that this is fast.

Rich Landen: Right conclusion. Thank you.

Nick Coussoule: Thank you. This is Nick. Vickie, at the risk of piling on just a little bit, those of us who are operators tend to think more in the frame of days and weeks, maybe months and not in years. But unfortunately, there are a lot of things that get in the way of trying to do something like this at the scale that it is at, not the least of which is assuming that the federal process works as we understand and have laid out.

Software vendors need to change their products to support all this, which they will not do absent the finality of rules in place because otherwise they are trying to hit a moving target. Then that gets in place and people need to plan those kinds of upgrades, which are generally not trivial either. It is understandable that the timeframe is measured in years and not months.

One of the frustrations that I have a little bit is that the process in place really does not respond quickly to industry changes. But if they are not done and pushed on a regular basis, you perpetually get further behind.

I think what has been done so far and I really will laud Margaret and team putting all the backup and the details together for this. I think they have actually done a great job of laying this out for us and for the industry to understand. I think we are doing our diligence to try to get that done and feedback. Even though it seems like a very long time and it is, the reality of queuing these up and getting them in play is really important to move as fast as we can given the general constraints of the system.

Vickie Mays: I appreciate it. As I said, it just seemed like maybe we could rush this and now I am appreciating all that has been put together and that this is a rush.

Bill Stead: I want to weigh in with real thanks for both the way NCPDP and the DSMO have worked to get this in this form and the way the subcommittee has worked to expeditiously collect the feedback we need from the industry. There has been a lot of work there that is the iceberg under the tip that Rich and Alix have so eloquently presented.

I think it is important that we proceed with this recommendation because I think we have the opportunity to really move forward with all of the advances that are built into the standards since D.0. They are substantive. Rich and Alix will tell you. I have not liked this timeline any more than any of the others of you. But I think that we are doing what we can do to move expeditiously. If HHS will join hands with us and do their part as outlined in this by the end of the calendar year that will get this moving so that we are not revisiting this question as part of some future FX a year or two down the pike. We really need to somehow get a line in the sand and get this thing into this very hard system change process and move on. I am very supportive of the recommendation and very thankful to the unbelievable work by the subcommittee staff and the people in the industry.

Rich Landen: Thanks, Bill. Let me probe a little bit for the other committee members. Lee, Jacki, Frank. You have part of this process before as we come to consensus. Do any of you have any questions or concerns?

Frank Pasquale: No questions.

Rich Landen: Jacki.

Jacki Monson: No questions or concerns for me either. Thank you for asking.

Rich Landen: Lee.

Lee Cornelius: This is Lee. No questions or concerns. Thank you so much for asking.

Rich Landen: And the recently joined folks who have not been through this process with us before. Margaret. Any questions?

Rebecca Hines: Melissa's hand is up, Rich.

Rich Landen: Melissa.

Melissa Goldstein: Hi. I hate to be the bearer of bad regulatory news. But I actually am a little concerned that the timeline put forward is perhaps too ambitious especially in light of what we are going through now. I wonder about HHS' ability to get out a proposed rule by the end of the year because all of the people that would be working on such a rule are busy. I am not sure when they would be able to take it up. It does take a lot of time to actually draft regulatory language. I certainly am in favor of moving forward with the recommendations. I am just not sure that the regulatory timeline is really realistic.

Rich Landen: Excellent observation. Let me just respond by saying we are making recommendations. We do not control this. We completely understand the timeline we are suggesting may or may not be bought into by HHS.

What we have going in our favor to address your comments is that the Division of National Standards has been actively working on its due diligence for the F2. Our assumption – again, this is unilateral. This is us. This is not DNS. Our assumption is a lot of the work they have done for F2 will be very much usable for F6. That is the primary reason that in my own mind I am thinking that this timeframe while aggressive and certainly recognizing the current crisis that is going on and is a total unknown, a total aberration from the usual process, HHS, DNS, may or may not be able to make this timeframe.

One of the things that we would need to be ready to do in the future would be to react if DNS came back to us and said we cannot do this. We need an alternative. While we have experience with that in the negative before because so often, we will make these recommendations and either we will or will not specify a recommended timeline. But DNS takes the time it needs to produce the – the Final Rule. That is not within our control. And as we have seen with F6, there was not and since we recommended it, there has not been rule making.

I think your question is spot on. We do not know if this is feasible. But I think our approach still needs to be this is the timeline that NCVHS believes would be in the industry's best interest; therefore, we should

propose it. And if it is not achievable then either DNS works with industry or DNS and us, NCVHS work with industry in the future to re-specify the timeline.

Others on the subcommittee want to chime in on that?

Alix Goss: You handled that really well, Rich. I think that – this is a very unprecedented time. But even if we were not in this time, this would be an aggressive ask. But we have also spent the last couple of years at least in a detailed conversation around how to move things more expeditiously through the process and to inform – and to have the feds inform us of the details that they need to be able to most effectively work through their own the Administrative Procedure Act obligations.

I would hope that the work of assessing F2 would be leverage-able in advancing an F6 for rulemaking and that maybe in one of these rules, they will be able to provide us with additional preamble and insights into other ways that the industry can be more effective partners in making the pieces of the puzzle come together more efficiently.

Rich Landen: Thanks, Alix. Margaret?

Rebecca Hines: Is that Margaret Skurka you are asking for or Margaret Weiker?

Rich Landen: Margaret Skurka. Committee members only at this point. If you have no comments, that is okay too, Margaret.

Rebecca Hines: What about Denise Chrysler?

Rich Landen: She is next on the list.

Denise Chrysler: This is Denise. Thanks a lot for asking. I am a little overwhelmed by this topic, but I am sure after I am on a few months, it will all make more sense. I have no questions or concerns.

Rich Landen: Thank you. I hope you will hold on to your optimism. Those of us who have been through this a few times are not nearly that optimistic. This is always overwhelming.

Rebecca Hines: Rich, Margaret has her hand up now.

Rich Landen: Margaret Skurka.

(audio problem discussion)

Margaret Skurka: I have been in listening mode all day and I feel as a newbie that that is appropriate. I feel like I am in learning mode and I am impressed by the depth and the extensiveness of the reviews and the recommendations. It seems like things are solid.

I worry too because I think everything, as one of our speakers said this morning, is everything is COVID-19 and nothing else. But it may – change in the next months going forward so that other work can be focused on as we master this nightmare.

Alix Goss: Margaret, I just want to commiserate that although I have been on the committee for a while, I never will forget just how overwhelming it feels to join the committee and run in the pack so to speak.

There is a lot. You too will be at the point where you will master things you never thought you were going to completely understand or wanted to understand. It is a great team.

Margaret Skurka: Thank you. I had a little conversation with Linda Kloss last month. She gave me lots and lots of wisdom. I was taking copious notes.

Rich Landen: Okay. I see no more hands and with one eye on the clock. Let me just recap what I think the recommendation is then. There are two parts. The first part is to adopt as a HIPAA standard the NCPDP Telecommunications Standard Implementation Guide version F6. And the second point is to promulgate and implement according to the recommended timeline. We have been through it before. Essentially, it is requesting and recommending an NPRM by the end of calendar year of 2020 and then full and exclusive compliance with F6 beginning May 1, 2025.

If someone would like to make a motion to that effect, then we will turn it back over to our chair to establish consensus around the motion.

Alix Goss: I would like to make a motion that we would adopt the recommendation as outlined on this slide with appropriate letter to be crafted with recognition of the COVID-19 concern, but that we move forward as proposed by Rich.

Nick Coussoule: This is Nick. I will second that.

Rebecca Hines: If you are in agreement, raise your hand.

Alix Goss: We cannot go there yet. We have comments, questions, and discussion.

Bill Stead: Wait. Wait. We need to know if anybody has any discussion before we go to the vote. Raise your hand if you want to make any additional comment before we vote on the motion. I see Melissa's hand is up.

Melissa Goldstein: Yes. I really am enjoying the process of thinking about the recommendation. While I have not participated in this particular process, I have cleared regulations and I have also been on the White House side of working with OMB on regulations as well.

I do think it is important to phrase the recommendations as Denise noted with the caveat of the COVID-19 time period and our understanding that the timeline may need to be adjusted for that reason. I agree with it as stated, the motion.

Alix Goss: Thank you, Melissa.

Bill Stead: This is Bill. Does that mean you asking that that actually be put into the recommendation? The Subcommittee as it is drafting will need to know really precisely what --

Melissa Goldstein: That was as I heard Denise --

Alix Goss: Just for point of clarification. It was Alix that made the motion and I wove into the motion Melissa's feedback and the COVID-19 so that we could be acknowledging of the dynamics inside the Federal Government at the moment.

Bill Stead: Perfect. Thank you. Any other hands?

Alix Goss: I feel like Frank wants to say something. Thank you.

Frank Pasquale: Thanks.

Bill Stead: I am not seeing other hands. Rebecca, would you like to drive the process to do the vote counting.

Rebecca Hines: Sure. Now we are ready to take a vote. Members only on the panelists' list. If you agree and want to vote to approve that these recommendations be put into a letter that would then be send to the Executive Subcommittee to give final approval and submission to the HHS Secretary. I see we have approved – Bill Stead, Deb Strickland, Lee Cornelius, Alix Goss, Jacki Monson, Denise Chrysler, Rich Landen, Denise Love, Nick Coussoule, Melissa Goldstein, Vickie Mays. We just need --

Alix Goss: Frank raised his hand literally. He did not raise it in the chat box.

Rebecca Hines: Margaret Skurka, we need to see your hand raised or not. There we go. I think we have unanimous approval of these two recommendations that are on the slide with the addition of acknowledging that the COVID situation may impact the ability to implement the recommended timeline.

(Applause)

Rebecca Hines: The motion is approved, and it is time for a break. We shall reconvene in 15 minutes. At 2:45, we will have two guest speakers from the Office of the National Coordinator and one guest speaker from CMS.

Alix Goss: I am sorry I will miss it.

Rebecca Hines: Have fun Alix.

Break

Rebecca Hines: Thank you all for letting us know you are back. We are very excited this afternoon to have three guest presenters, one to start, Alex Mugge who is at the Centers for Medicare and Medicaid Services. She's the Deputy Chief Informatics Officer of CMS.

Followed by Mark Knee, Senior Policy Advisor, and Kate Tipping, the Branch Chief of Regulatory Development and Coordination at the HHS Office of the National Coordinator, both of them. So lots has happened which they will share with us today in terms of these new rules being issued in the recent weeks. And with no further ado, Alex, take it away please.

Update: New Interoperability Rules

Alexandra Mugge: Thanks very much. Thanks everybody for having us here today to talk through the rules, we appreciate it. We appreciate this opportunity to share just a quick overview and hopefully have some time for Q&A from folks at the end.

This is Alex Mugge from CMS, and I just for one want to say that I'm very excited about the rules being out, both the CMS and OMC rules I think marks the beginning of a new data exchange landscape. It's going to open many opportunities for stakeholders, and we're just really excited about all the possibilities that this brings. So excited about the implementation work that's going to be kicking off with these rules, and just everything that we have to look forward to over the next about one year for our rule and about two years for ONC's rule. So I'm going to cover the CMS rule, and then I'll go ahead and hand over to OMC to present their work.

I just want to set a little historical context for the reason that CMS initiated this rule writing process. So many of the policies in this rule are not actually statutorily mandated but were really more homegrown policies that were born out of what we were seeing in the healthcare landscape.

So CMS, we have historically experienced a lack of data exchange and transparency in healthcare that has really led to this fractured system like what you see depicted on your screen, in which patients, providers, and payers each have their own set of data, but that data does not necessarily flow to one another, and there's no comprehensive health record for patient.

Patients don't have control of their own healthcare data, and they have to kind of rely more on their own personal experiences and what limited data they may have access to, or what limited outside knowledge they have to make critical decisions about their care. Overall, this fractured healthcare system approach was simply not working.

If we go to slide three, the next slide, this really demonstrates the goal of what we're trying to get to, the goal of the connected healthcare system, in which patients, providers, payers, but also researchers and all the stakeholders in healthcare, developers and others, all have access to the data that they need to make critical decisions about patient care, to provide the best possible care.

We at CMS believe that electronic data exchange is the future of healthcare, and that interoperability can really be the foundation of value based care if that data is available and if we're really getting that comprehensive patient record. So the goal of this rule and future work that we will be doing around interoperability is really to get to this universe in which patients and providers and payers have everything that they need to make the right decision for patients when they need that information most.

Going to the next slide, kind of getting to the meat of what's actually in the CMS Interoperability and Patient Access Rule. I'm going to go through each of these policies in their implementation timeline order, so going kind of straight across on the slide here. Just before kind of diving in I just wanted to recognize that really the foundation underpinning of all of the policies in this rule and of all the work that we're doing around interoperability and patient access is really based on a foundation of privacy and security.

So there wasn't a meeting that went by or a policy session that went by when we were drafting both the proposed and final rules where we didn't talk about patient privacy and security, and ensuring that patients be at the forefront of making the decision on where their data would be shared outside of HIPAA space.

And so I'll get more into that as I get into the proposals, but I just wanted to highlight that as across the board for each of the proposals that was always our first thought, is how to protect the patient, how to

watch out for their privacy and security and ensure that the patients are educated and know how to make the right decision about where their data should flow.

I also want to highlight also before jumping in, we're of course very excited about this rule and the OMC rule, but we acknowledge that this is by no means a final step for interoperability. Interoperability is a journey that we are all on together, it's not an endpoint. And so we believe that these rules are a good start or a good beginning of some opportunity for many stakeholders in healthcare, but we have a lot of work to do in the future to get to true interoperability.

And so we want to continue working with all of our stakeholders and partners to continue to develop and build out this roadmap that you see here on the screen. We've got a long way to go, and as you can see our roadmap ends at kind of an arrow, to demonstrate that we're going to continue to build on this roadmap, and that there is more work to do.

So just starting with the first policy, the first that will be implemented, starting in the fall of 2020, or starting six months after the final rule is actually formally published in the federal register, hospitals will be required to start sending admission, discharge, and transfer notifications to other providers. And so to providers who are associated or identified by a patient as their primary care provider.

We propose this as part of the conditions of participation for all hospitals participating in Medicare and Medicaid, because we believe that these notifications will greatly enhance the patient care coordination. When a patient is discharged from the hospital their provider should be made aware of that in case there is additional follow up that needs to be done with the patient. So this allows those providers to get a heads-up, hey, your patient has been discharged, you may need to follow up. So that proposal is in place to be effective again six months from when the rule is actually published in the federal register, which has not happened yet but we look forward to that happening very soon.

Then later this year we will begin publicly reporting the names of clinicians and hospitals who have attested through our promoting interoperability's program that certain information blocking provisions in a manner that indicates that they may be engaging in information blocking.

So as part of our promoting interoperability's program we have several application statements that folks have to indicate if they have knowingly or willingly blocked information. If they answer those in a way that makes it appear that they have been information blocking, we will publicly report their names on a CMS website to provide more transparency into those providers who may be information blocking

We got a lot of feedback when this was in the proposed stage, and I just want to highlight CMS acknowledges there is much more work to be done here around information blocking, and there are many other disincentives to consider for information blocking, but this is one first step in just giving a nod to the severity of information blocking and the challenges that it poses to interoperability, and just one thing that we can do to help prevent the practice of information blocking.

Also, around the same time we will also be publicly reporting the names of providers who have not posted their digital contact information in our NPPES provider director. We are looking at this provider directory, at the NPPES directory and the ability to collect digital endpoints as a real opportunity to enhance that directory to provide interoperability information.

It does no good if you have really great information if you have nowhere to share it. So by providing digital contact information in NPPES we hope that providers can use this as a resource to find other

providers, share information, and look one another up for purposes of referral, care coordination, et cetera. So starting in late 2020 we will publicly report those providers that haven't entered their information there.

Rebecca Hines: Alex, can you take two sentences for our new members and just define information blocking?

Alexandra Mugge: Maybe I should leave that a bit more to ONC. But in general, the process of information blocking is when you have access to certain information, let's say patient information, and you willingly or willfully withhold that from another provider.

So if a patient is going to another doctor, if you withhold that information from the other doctor if it's requested, that would be information blocking. I know ONC is going to go into that in great detail when they go over their rule, so I'll probably avoid going into any more detail on my presentation. Any other questions just before I dive into the API proposals that are in our set?

Rebecca Hines: That just came across the chat, so I figured I'd toss it in while you are in process. Sorry to interrupt.

Alexandra Mugge: Thanks for calling that out. Happy to answer, but ONC will be much better at that. I'll leave it to them. So the next set of policies, I keep calling them proposals but they're now finalized, the next set of policies is really geared more towards the payer side and API access to data.

So starting on January 1 2021, that's really where the rubber hits the road for patient access. And this is when we are going to require that all payers that are regulated by CMS, so that includes Medicare Advantage, Medicaid Managed Care, Medicaid Fee for Service, CHIP Fee for Service, and the qualified health plans and the federally facilitated exchanges. All of those payers will be required to provide patient access to their claims and encounter and some limited clinical data through a FHIR based API.

And what this really means is that patients will be able to directly from their smart phone download an app of their choosing, connect it to their payer's API, and be able to access their claims information and their encounters and some of their clinical information in a format that makes it really easy for them to access and understand. So again, that starts on January 1, 2021.

Also, on January 1, 2021, we will be requiring the payers to make their provider directories available through a FHIR based API. By making provider directories available in this format we are allowing some new innovation in developers to enter into this space that will be useful for both existing patients to find a provider in their network, but also when a patient is comparing health plans, there's an opportunity there for developers to come up with apps that would be able to compare networks and help patients find the provider network that best fits their needs.

So I do want to highlight that through our comment process and just through a lot of the work that CMS has done jointly with OMB we're aware there's a lot of work that needs to be done in the provider directory space, there's a lot of inaccurate data out there, data that's not always up to date or timely.

We understand that those are still challenges that still exist, and this proposal does not directly address those challenges, but that is something that we are going to be focusing on in the coming year or so, and hope to help payers and others correct some of those inaccuracies. But again, these API proposals really

make it easier to take the data once it is established and published out there and make it more usable for patients.

Then moving to January 1, 2022, one year later, that is when we are requiring all payers to exchange data at a patient's request when the patient changes from one payer to another.

So if I am going to open enrollment and moving from one payer to another payer, I shouldn't lose access to all of this great data that I've had access to through my patient API. I want to take that data with me and make sure that I have that comprehensive health record and have it follow me through my healthcare journey.

So starting on January 1, 2022, payers will be required to exchange data when a patient requests it and have that data follow them from one payer to another, allowing them to really establish more of a longitudinal health record as they move throughout their healthcare journey.

Then finally, in April of 2022, we are requiring the state Medicaid offices to exchange certain enrollee and eligibility information with CMS daily for our dual eligible population. So for those enrollees that are eligible for both Medicare and Medicaid we are going to be requiring data exchange to happen on a daily basis so that we can better ensure benefit coordination for that vulnerable population. Currently the data is exchanged monthly, by increasing this to a daily exchange we hope to better enhance that benefits coordination and ensure that beneficiaries are not falling through the cracks as they enroll or disenroll in some of the state programs.

So there's a lot in this rule. It affects a little bit of just about everyone that we regulate, from payers to providers to hospitals, clinicians. In the proposed rule we also had an RFI on post-acute care and on our CMMI model.

So this rule really goes across the gamut of the folks that CMS regulates. That is absolutely intentional, we believe that we'll take all stakeholders and the healthcare industry to really engage in interoperability in order for us to achieve true interoperability, and this rule was designed to try to incorporate as many stakeholders as possible, and really highlight that it takes all of us working together to reach that interoperability goal.

If we can go to the next slide, there are a couple slides here that we've included that just touch on a few of the impacts of the rule. I'm not going to walk through each of them, but just to kind of highlight them, the main points. The rule is very wide reaching in the sense that it touches just about everyone that we regulate, but it's also wide reaching in terms of its impacts on healthcare and on the stakeholders directly affected by these policies.

So in particular, we want to highlight that patients will finally have access to, easy access I should highlight, directly from their smart phone, to data in a format that they can understand. Patients will have the option to choose from different apps, as we've seen with our blue button initiative, which is CMS or Medicare fee for services, patient access API, we've seen many apps setup that each serve different types of functions. Patients will be able to choose which app they want to access their data. And that's a critical point because it really allows a patient to customize their healthcare experience.

I'm also going to pause here to highlight some of the privacy and security provisions that we have put in place. As I'm mentioning, patients have the option to choose an app to access their data. As part of our patient access API policy we are allowing the payer to have the apps attached to certain privacy and

security provisions, saying for example that they have a privacy policy that's written in plain language, that patients can understand, that patients have accepted or reviewed and accepted that privacy policy.

So payers will be able to ask for that attestation from the application, and will be able to work with their patients and educate them to help them understand which apps to choose. This is part of the privacy and provisions that we put in place to protect patients, but what we've really tried to put a focus on is that education of patients.

We want to make sure that we're balancing patients' ability to access their data with their privacy, and ensure that patients really know what they're looking for, know what they're asking for their payers to share, but also that we're ensuring that patients are able to still get that access. So it's something that we've really spent a lot of time on in the rule and continue to look at over time, but really ensuring that the patient ease of access stays in place as our privacy is also protected with these policies.

Enough on the patient impact slide, there are some other impact here that we really want to highlight, on the provider directories, and on better care coordination, all around our first priority with its rule was to focus on improving the patient care experience and improving value based care.

On the next slide I just want to highlight quickly some of the impacts to providers. The policies in this rule have really helped to unlock some new data about patients and will enhance the provider experience as well. Patients will be able to share their data with their providers, providers will be receiving event notifications from hospitals to improve care coordination. So this really opens up a lot of opportunities for providers to better engage with their patients and better manage their patient care coordination as well.

So that's a critical point, and we want to highlight that we have more policies that we are looking towards in the future that will even more enhance the provider experience with interoperability and their patient data. But this rule certainly opens a few doors and unlocks some data for providers to help them again with engaging with their patient.

And then finally in the next slide, historically CMS has spent a lot of time and a lot of effort in their interoperability efforts focused on clinicians and hospitals, our promoting interoperability's program, or formerly the meaningful use program, were very focused on the use of EHRs in a clinical setting.

This rule is the first time we have more engaged the payers in the interoperability space, and the first time we've engaged them in more health IT efforts to improve the flow of data in healthcare.

And payers are really critical in this space because they have a unique relationship in that they have their enrollees, the patients as their enrollees and their members, and they also have a unique relationship with providers, in that they contract with their network providers and they have an ongoing data exchange with providers who are seeing their patients.

So payers are really uniquely positioned to get data from both of those entities, and it's critical that we engage them in the interoperability space, which is what we have tried to do with this final rule. So like I said at the beginning and alluded to we're very excited for this rule to be out because it has really engaged payers in a way that they haven't been engaged in this space before, and we think that this will open some great opportunities for payers to engage with interoperability, for them to really have an enhanced relationship with their patients, and to just free up some data that has been historically

untapped in this space. So looking forward to the opportunities that we will see there in the coming year.

On the next slide I think we have just a link for some additional resources. There are some absolutely fantastic resources to support implementation at this link. This is going to be a great place for payers to go to see some of our implementation guidance. And additional support for implementation. So I want to make sure that we've highlighted this link and it's available to folks just to reference and read through.

And then I think with that my next slide was going to be for questions, but I think we might hold that until after ONC's presentation. So I will go ahead and hand it over to ONC. Thank you very much for bearing with me as I walk through all of this, and I look forward to your questions at the end.

Rebecca Hines: Thank you Alex. Really appreciate it. So we'll be bringing up the ONC presentation, and Mark and Kate, the floor is yours.

Kate Tipping: Thank you Alex, thank you Rebecca. Thanks for having us today. As Alex said, we're too, very excited for the rules to be out, but we have much work to do. So we're just going to give a quick overview, very abbreviated version. I just want to note that we do have a number of webinars that we've given over the past couple weeks, the recordings will be up on our website as well as the slides, and then we have upcoming webinars that you can look for more detailed information.

Before we dive into anything I just wanted to note while we do make every effort to make sure that this presentation is accurate, this presentation is not a legal document. The regulation itself is the legal document. So please refer to that. This presentation I also want to note was produced and developed at the taxpayer expense.

So again, this will be a very abbreviated, high level overview of our ONC Cures Act Rule. I'll go over the Cures updates to the 2015 edition certification criteria, the conditions, the maintenance of certification, and the enforcement of those. And then my colleague Mark Knee will lead the discussion of the information blocking provision.

A bit of background. So the 21st Century Cures Act, which was signed into law December 2016, included Title IV, which deals with health information technology, and some of the items included were regulatory requirements, and others were not. So based on that we have put out the notice of proposed rulemaking in March of 2019. We received over 2000 comments, which informed the development of this final rule, which we did post on our website, March 9th.

So we received a broad array of feedback from stakeholders, from patients, doctors, hospitals, developers, and the public in general. We thank everyone for providing the feedback, and like I said it has been extremely helpful in the development of this final rule.

And the final rule, we support the role of all of these players in determining what patients need. The patient needs to be at the center of their care, they need to be a part of their care team so that they can inform their own care. And part of that is having the data available to them. And the provisions of this rule support the patient's ability to also shop for their care.

In terms of the doctors and hospitals, we need to make sure the data is available there, and that the data request can be easily and inexpensively fulfilled, so that information can get where it needs to go to support a care decision, and part of that is choice and allowing choice is very important.

We also think about the developers. The developers are a huge part of the equation here. They need to have the right information, and they need to comply with the laws and regulations. So how they can support the flow of the data, whether in terms of the conditions of certification around the application programming interfaces requirements or the information blocking section as it relates to how the information can be moved to avoid an information blocking complaint, we do want to make sure that the information can be moved and it can be moved easily, and moved in a way that it needs to move so that it can be used in the right way. And how you can fulfill a request, and when a request does not have to be fulfilled, which Mark will discuss in the information blocking portion.

And then to the American public, we're all patients, and at one point of our life, it's important that the information is available and that it can be used by the patient themselves and maximizes the ability of public input for innovation and transparency in healthcare that's necessary.

I want to highlight the specific criteria and give an overview of our approach for updating the 2015 edition certification criteria. First in the proposed rule we did propose that these would be updates to the 2015 edition rather than an entirely new edition.

We did receive a number of comments regarding whether it should have been a new edition, but ultimately our determination was that we only had about four new criteria, and mainly these criteria were updating standards, so we did just provide an update to the 2015 edition and not an entirely new edition.

So I'm just going to highlight here, at the top we have the time-limited and removed criteria. This describes those criteria that are either outdated or no longer necessary.

So on the left-hand side, under the time limited, these are previously associated with stage one or stage two of the EHR incentive program at CMS and the Medicaid version. And some of them we left as time limited as opposed to removing them entirely, because we wanted to wait until the Medicaid program sunsets them so they're still available for those program purposes.

And then for the program list, medication list, and med allergies, I just want to clarify that it doesn't mean that these data elements are going to go away, but the specific certification of how the data elements are captured will no longer be a certification requirement. The data will still be captured, but we won't require a specific way in which it needs to do so.

And then the next revised criteria, most of these focus on the interoperability criteria, and the majority of them are being updated to comply with the United States Core Data for Interoperability Standard, as opposed to the common clinical dataset.

I'll touch on the USCDI next, which is the United States Core Data for Interoperability. But most of these include criteria that reference the C-CDA, the view, download, and transmit, and also includes an update for the C-CDA to include the C-CDA companion guide. But the majority of those are just updating the standard within the criteria.

And then the right side, the security tags send and receive, that was previously the data segmentation for privacy criteria. They are voluntary criteria, and we did rename them to be more in line with what they actually do, which is tagging the data, and we updated those to allow for tagging at a more granular level. We did hear from folks that that was what was important, and what we had previously which was only at the document level wasn't getting to the point where if it was a more granular tagging it would be more meaningful. And that's important for a number of use cases, mainly for behavioral health or opioid use disorder and pediatrics.

And then we also revised the electronic prescribing and the CQM criteria to align with requirements with CMS. So for e-prescribing for part D aligning with the standard that CMS has already began implementing as of January 1st of this year. And then the clinical quality measures aligning with CMS implementation guides for the QRDA so it removes a layer that developers would have to certify to.

And then the last section here is on the new criteria. So this is the EHI export, and we did limit the scope of this. We aligned the definition with electronic health information definition for the information blocking definition of EHI, which Mark will go over. We heard that the alignment was essential through the commoners.

And then the API criterion, we established a new API criterion that requires developers to support standardized API for both single patient and population services. And the certification criterion is limited to API enabled read services using the HL7 FHIR release four standards. We also adopted two new privacy and security attestation criteria, the encrypt authentication credential, and multi factor authentication.

So a quick piece on the USCDI. Basically, as I mentioned we focused just on the interoperability criteria. We adopted new required data classes and data elements. As you can see here the provenance, clinical notes, pediatric vital signs, and address, email, and phone number, which the three will support patient matching use cases.

Some brief information on the USCDI. I just want to note that when we talk about USCDI within the criteria for the interoperability criteria, these updates we put in the rule, they can be made over the next 24 months. So for the first 24 months they can certify, continue to CCDS or update to USCDI for the first 24 months, but at the end of the 24 months is when it switches exclusively to updating the USCDI standard.

And again, I'll provide a quick summary of the conditions and maintenance of certification requirements. We did do a whole webinar on the conditions and maintenance of certification requirements, and then there's another upcoming one that you can look to on our website, but I'll give a quick overview here.

So Congress requires through the Cures Act, that we establish this concept of conditions and maintenance of certifications for the certification program. I'll highlight the finalized approach where we have an initial certification requirement for health IT developers and their health IT modules, and then we have an ongoing maintenance requirement for continued certification for those health IT modules.

And technically there's seven conditions with accompanying maintenance of certification requirements, but the seventh one here will be in the future, the electronic health record reporting criteria. So in the rule we go into detail on the information blocking, assurances, communications, application programming interfaces, real world testing, and attestations. I think I'll hold on going into more detail, I'll just point you to the webinar for those.

And then the way we will enforce, we're leveraging the directory view process that we already used for overall ONC surveillance within the program. So if there is a nonconformity it results in a corrective action plan. And ultimately if a developer follows the corrective action plan, or doesn't follow the corrective action plan, it can lead to a certification ban. But we are leveraging that process, and developers are already familiar with that. I will hand it off to Mark to talk about information blocking.

Mark Knee: Thank you Kate. And thank you all for having us here today. It's my pleasure to be here talking about information blocking. As Alex and Kate both mentioned, both our offices have been working on these rules for quite some time, and it's very exciting to finally get to present our final policies and roll out everything to the public. So before I move on, my name is Mark Knee, I'm a senior policy advisor in Office of Policy at ONC with Kate.

And as Kate said there's a lot in our rule, it's 1200 plus pages, so this is going to be a very abbreviated overview of information blocking to allow for questions. But it's always great to refer people to the regulation itself to take a look, as well as the webinars and the fact sheets and other materials you have on our website.

So just as far as level setting here, before I get into the slide, in our rules there really are essentially two rules. There's the information that Kate just conveyed, that has to do with our certification program, and there is an information blocking condition of certification that's specific for developers. So all the stuff that Kate just talked about applies to developers of certified health IT under our program.

What I'm talking about is information blocking more broadly, as it was stated in section 4004 of the 21st Century Cures Act, and it applies to developers of certified health IT but also to providers and health information networks and exchanges as they're defined in our regulation. So that's an important scoping point, just to level set here.

So the screen you have here goes over some of the main points that were in section 4004 of the 21st Century Cures Act. So the Cures Act defines information blocking, and we've also defined information blocking in our final rule, as essentially the same definition as in Cures, with some slight modification, and I'll get into that, in other words the question earlier for Alex, and I'll talk more about the definition of information blocking on the next slide.

The 21st Century Cures Act also authorizes the secretary to identify through rulemaking, which is what we just did, reasonable and necessary activities that do not constitute information blocking. So there's this broad definition and then the Cures Act says ONC by delegation should come up with these situations when it may look like information blocking but there's a really good reason why someone is not sharing the information and that would be considered an exception. So that's what we've done, and we've laid out eight exceptions in the final rule.

The 21st Century Cures Act also identifies the HHS Office of Inspector General to investigate claims of information blocking, and we've been working very closely with OIG on the rule, and also implementation and enforcement issues moving forward.

There's a penalty structure in the 21st Century Cures Act. So one of the reasons why many people are very interested is that there are pretty harsh penalties for folks who are found to be information blocking, for developers, networks, or exchanges it would be up to a million dollars of civil monetary penalties per violation.

For providers it says in Cures that it would be appropriate disincentives, then we had a request for information in our rule, and we have not identified the appropriate disincentives in our rule, but there will be a rulemaking in the future that will address that issue. And it also charges OMC, my office, with implementing a complaint process, and we're updating our current complaint process to accommodate the new information blocking complaints we're going to be seeing.

So since we don't have too much time, and even if we did, this slide is really important, because it essentially provides if you're a lawyer on the phone it's kind of a prima fascia case, or in layman's terms a checklist of what you would want to look for to determine if you might be information blocking or if an individual or entity you're interacting with might be information blocking.

To answer the question that was posed to Alex, what ONC is talking about with information blocking is except as required by law or covered within one of the exceptions within our rule, a practice that is likely to interfere with the access, exchange, or use of electronic health information. And we've defined these terms in our rule.

So looking at this checklist you have that the actor is regulated by the information blocking provision. So what we're talking about there is Cures identifies four groups of actors, so that's developers of certified health IT, health information networks and health information exchanges, as well as healthcare providers, as the actors that are regulated by the information blocking provision.

In our final rule we've made one definition for health information network and exchange, which is based largely on comments we received from the public that said it's not clear where the dividing line is between those two terms, so they've been combined into one term. So there are now three actors that are really regulated by our regulation.

So the second bullet here is involves electronic health information. So in order for information blocking to take place there has to be EHI in play, and EHI is defined in our regulations, it aligns with the designated record set for EPHI in HIPAA. So that's an important point there.

The third bullet says that a practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI. So here we're talking about there has to be this threshold interference with the access, exchange, or use of EHI. And we talked a lot in our rule and in the proposed rule as well as the final rule about circumstances that would or would not constitute an interference.

Next you see the requisite knowledge by the actor. This one, generally the Cures Act treated and our rule treats the three groups of actors the same, but in this regard Cures was a bit different for developers, networks, and exchanges, the knowledge required is that they know or should know that such practice is likely to interfere with the access, exchange, or use of EHI, whereas a healthcare provider would only have to know that such practice is unreasonable and is likely to interfere with access, exchange, or use of EHI.

So there's a bit of a higher threshold for providers to have the requisite knowledge. And again this is really important, because when you look at the penalty structure, being classified as a provider has a different penalty associated with appropriate disincentives as opposed to a developer, a network, or exchange, which would have the civil monetary penalties.

So next you have not required by law. What this is saying is if there's a law already existing that says you're not allowed to share certain information then that's almost a built-in exception that Congress provides in the Cures Act.

And then last, what I'll talk about in the coming minutes, is the exceptions that we lay out. So these are the reasonable and necessary practices that it might look on its face like you're interfering with the access, exchange, or use of electronic health information, but for reasons such as preventing harm or privacy, security, any of the eight that we lay out, they would not be considered information blocking. So if you check these boxes, all of them, then it might be information blocking, and you might want to look more closely at your practices or the practices of those folks who you're interacting with.

So we have a compliance timeline for information blocking. In the rule actors do not have to comply with the information blocking provision until six months after the publication of the final rule. And as I said we're working very closely with the OIG, and really, it's going to come down to when the Office of the Inspector General comes out with their final civil monetary penalties rule to determine when the enforcement will begin.

So this is what I talked about before, the different groups of actors that we're going to be looking at. So here you have, and I'm just going to highlight a few of the terms and ideas that were key, but again there is a lot here. So we combined the definition of health information network and health information exchange.

We also limited the types of actions from the proposed rule to the final rule that will be necessary for an actor to meet this definition. We heard from commenters that they wanted more clarity and specificity about what the definition means.

In addition, we've revised the definition of health information network or exchange, how to specify that to be a HIN or HIE there need to be more than two unaffiliated individuals or entities besides the HIN or HIE that are enabled to exchange with each other.

And the last change we made from the proposed rule is we focused the scope of the definition to be about or related to treatment, payment, and healthcare operations as they're defined in the HIPAA rules. An overarching comment we heard from folks is that it will be helpful to align as much as possible with HIPAA, and we tried to do so as much as made sense in the final rule.

So this slide has our definition of electronic health information. This is really important obviously because in order to even be in play for information blocking there has to be electronic health information. So we focused the scope of electronic health information in section 171.102 of the final rule to mean EPHI is a term that's defined for HIPAA, give the extent that it would be included in the designated record set, other than psychotherapy notes or information compiled in anticipation of or for use in a civil, criminal, or administrative action proceeding.

We don't expressly include or exclude price information in this definition. So to the extent that EPHI includes price information and it's included in the designated record set it would be considered EHI for purposes of information blocking. We receive lots of comments on price information and price transparency, and we did have a request for comments and a request for information on that, so we just wanted to clarify where we landed there.

We also clarify that until 24 months after the publication date of the final rule, and the rule has not actually published in the federal register yet, EHI for purposes of information blocking is limited to EHI identified by the data elements and the USCDI standard that Kate talked about in section 172.13.

So for the first two years there's this more focused scope, limited to USCDI data, and then after two years the definition you see here with the designated record set. And this aligns with one of the exceptions, the new content and manner exception, where we have the same timing.

I think we're going to skip the next couple slides. Since I'm running short on time I'm going to just quickly run through an overview of the exceptions. So like I said, the exceptions are reasonable and necessary activities that make it so that it's not considered information blocking.

So here you have, we've reorganized the exceptions into two categories. On the left-hand side you see we have exceptions for not fulfilling requests to access exchange or use EHI, and that would be for preventing harm to a patient or another person, for privacy, for security reasons, if the request is infeasible, and also to improve the health IT performance overall.

On the right-hand side of the screen you can see we have exceptions for procedures for fulfilling requests to access, exchange, or use EHI, and those are the new content and manner exceptions, so this is the only exception that we've added on from the proposed rule. And also an exception for fees and licensing.

So really what this slide is saying is if you meet the conditions of the exceptions on the left-hand side you would not need to provide access, exchange, or use of electronic health information in those circumstances. However, if you meet all the conditions of one of the exceptions on the right-hand side you would still need to provide access, exchange, or use of electronic health information, but using the procedures that are laid out in the final exceptions.

Real quickly, this is the new exception I mentioned. So this one says it will not be information blocking for an actor to limit the content of its response to a request to access, exchange, or use the EHI, or the manner in which it fulfills a request, provided certain conditions are met. And a way to look at this one is really it's the what and how exception. So what electronic health information do I have to provide and in what manner do I need to provide it. So as you can see there's a content condition here as well as a manner condition.

So the content as I alluded to says that for the first 24 months all that's required to fulfill the condition is that an actor provide the data elements represented in the USCDI standard, and then after that 24 month period it would expand out to the full EHI definition, which I just talked about.

And then the second part like I said is the manner condition. So what we say here is that an actor must fulfill a request in any manner requested unless the actor is technically unable to fulfill the request in the manner requested, or can't reach agreeable terms with the requestor to fulfill the request.

And so what we've tried to do here is make an exception that's responsive to comments that said we don't understand when we have to provide access, exchange, or use in the manner requested. So if you're technically unable then you can't, and then there's an alternative manner or prioritized list which I'll show on the next slide which shows what the requirements are. But also, if you can't reach agreeable terms with the requestor to fulfill the request.

And as you see on the second bullet here, if an actor fulfills a request in any manner requested, the actor is not required to comply with the fees or licensing exception. So this taken along with one and two on the screen is we believe very responsive to comments that were concerned about how this would affect innovation in the market, because what we're seeing here is that in every situation the actor can negotiate terms and licensing, royalties and fees at a market rate for these services or licenses, and they would have the opportunity to reach agreeable terms with the requestor. However, if they were unable to reach agreeable terms then we provide an opportunity to meet the exception by providing access, exchange, or use via an alternative manner.

This is the alternative manner I was talking about. So if you're bumped down to here then the first order of priority is to provide the access, exchange, or use of EHI via certified technology, if you're unable to provide it via certified technology then you would move to number two, which is using standardized technology, content and transport standards specified by the requestor and published by the Federal Government or a standards development organization accredited by ANSI.

And then last, this is kind of a catch all, but if you're unable to meet one or two and you're technically unable to meet one or two then you still could meet the exception by providing access, exchange, or use of EHI via an alternative machine readable format, including the means to interpret the EHI, agreed upon with the requestor.

So that was like I said a very quick overview of information blocking. As we said previously we have a lot of great resources on our website, www.HealthIT.Gov/CuresRule. You can view the Final Rule there, the reg text as well as the preamble, fact sheets, we have the webinars which have already taken place which are recorded and on our website like Kate said, as well as the upcoming webinar schedule. We have some great fact sheets and other resources that we're developing on an ongoing basis. So with that I think I will say next slide just to have our contact information up there, and we can open up to questions.

Rebecca Hines: Thank you, all three of you, that was an incredible amount of information. So members, staff, if you have any questions please raise your hand.

Nick Coussoule: Thanks very much for the information. One question I have, and it might be directed to Alex, there have been some kind of rumors running around in regards to just given the current challenges with COVID-19 and all the things surrounding that, whether the January 1, 2021 is still going to be the requirement date for the implementation. Can you provide any insight into that possibility?

Alexandra Mugge: Thanks for the question. This is an ever-evolving situation, and things of course are just changing on an hourly basis. So I don't want to say anything one way or another. We're certainly listening to all the feedback that we're receiving, and we will assess that as we go. But right now there is no change to the timeline, it is still January 1, 2021.

Rebecca Hines: Denise. You are still on mute. We'll go to Frank next and we'll come back to you Denise.

Frank Pasquale: Hi. Just wanted to say thanks – reiterate those thanks for such a very comprehensive and helpful set of presentations. One of the questions I was wondering about is I guess my first question would be just to confirm the purpose of the rules would be to enable say patients to request from providers, payers, others the download or transfer of their information to apps of their choosing. Would that be correct? Or one purpose would be that.

Mark Knee: From ONC's perspective, yes. I think that's accurate. That's one of the purposes that we were trying to enable. I mean overall we're trying to let the data flow and enable access, exchange, and use, particularly patient access and provider access, but that would also include third party apps.

And a discussion in the slides which I skipped over that had to do with privacy issues related to third party apps, which was an issue that was commented on quite a bit, and we clarify that educational materials related to privacy would not be considered an interference there. So we thought about many of those issues as we came up with the final rule.

Frank Pasquale: Can I follow up? This is Frank following up. One thing I was wondering about is I guess that the default in the American legal order with respect to privacy policies and in some extent security, except of course for the FTC on fairness authority, would be that the terms and service of the app would govern.

And there are two questions that sort of raised to me. One is there any sort of an effort to police or to give consumers information about apps say that have very loose or not very protective terms of service with respect to privacy or security.

And the second I guess would be that if the app say is owned by a corporation that is organized or that is based outside of the US, does that foreign country's laws govern both the terms of service and other elements of data use and protection, or does the American law run with that data?

Mark Knee: Those are great questions of course. And I'd have to say that the level of specificity, I don't think I can really answer that right now. What I'd say is we do lay out some criteria that would be looked at to determine whether the educational materials would all under the scope of what we're saying would be appropriate and not considered an interference.

And so I'd refer you to the discussion, it's in the interference section of our information blocking section of the final rule, to get a sense of kind of the boundaries that we lay out, or you're welcome to submit the question to us, and we can get back to you on that.

Rebecca Hines: Alex, did you want to add anything?

Alexandra Mugge: I just wanted to say I guess on the first part, I guess I'm a little wary of the term the data is downloaded. What I would say is that's a primary purpose of the rule. Because I think more importantly than saying downloading the data, which implies that it's downloaded, hard downloaded to a particular server or a particular app, more so the purpose of the rule, in ONC, if I'm speaking correctly on your side, but certainly on the CMS side is to ensure that patients have the ability to access and use the data in a format that makes sense to them, and that is convenient and understandable to them.

And then in terms of the privacy aspect, I certainly share what ONC has said, and also again highlight that we have put a heavy emphasis on patient education and also allowing and encouraging payers to take part in that patient education to ensure that folks really understand where they are allowing their data to be accessed, and by whom.

So that's a pretty critical part in the success of these policies, and then certainly we have certain best practices and ideas on how the terms and conditions should be constructed for these purposes, and we have educational materials available for that, and also of course defer to the FTC on the governing of the apps themselves. So I just wanted to make sure that point was clear because I do think there is a certain

implied ownership when you say download of the data or sort of static nature of download versus really accessing and sharing.

Mark Knee: That is a very good point. Just to emphasize what Alex said, information blocking, we talk about access, exchange, or use of EHI specifically as Kira said, and we've defined those terms, and also if you read our rule we do address kind of the IP issue that Alex kind of alluded to as far as needing the necessary rights sometimes to access, exchange, and use EHI. So a very good point Alex.

Rebecca Hines: Denise, it looks like you're unmuted now.

Denise Love: Sorry, I am working two screens and my mouse gets lost between the two screens, so apology if I'm slow on the draw. This is for Alex a little bit. I even hesitate to ask the question, but I have a little PTSD whenever it comes to provider identity management, because of the nature of multiple MPIs, and the difficulty of any attribution or measurement of provider level, whether it's primary care spend, total cost of care, network adequacy.

How, without getting in the weeds, how will that work, or I could put a plug in here to maybe reach out to the many states who are working on all payer claims databases with or in tandem with their HIEs to harmonize and reconcile those provider directories. It seems like there could be some cross lessons learned.

Alexandra Mugge: Yes. Specifically, just to make sure that I'm answering a question, specifically your question is really basically how to clean up our provider directories, and given the number of provider directories that are out there, I believe it's over 1000 provider directories?

Denise Love: Probably more.

Alexandra Mugge: Yes, that's what I understand. We initially starting out since we were in the hundreds and found that there are actually thousands of provider directories out there, we kind of had to reconcile some of that and some lessons learned across the board. So this is part of the challenge that we're I think kind of just gearing up to tackle at this point.

ONC has done some excellent listening sessions over the years with CMS and others, and we've heard from our partners at the payers, in particular folks like AHIP and working with their member organizations and others to talk about, we've been working on this problem for a long time, and spent years trying to research all of the errors that are out there, and what can we learn or what efficiencies can be gained across the different provider directories.

Unfortunately I have to say it is a problem that we're kind of just starting to tackle now, but I think that ultimately CMS can play a significant role in this space, being that we do have interactions with all the payers, with all the providers. Just to get an MPI you have to register a MPD(?) so that's a really good starting point for trying to get some accurate information. But this is unfortunately just not a perfect space right now, and the exact approach isn't clearly defined.

But we're trying to work with our stakeholders across so that we can gain some of those efficiencies, and we can identify what's working in those other thousands of directories and what's not, and try to make sure that we streamline this to give accurate data and also reduce some of the burden, because it's no fun for providers either to be hounded by 30 or more payers and other entities to update their

data, is there a way that we can streamline that, those are just some of the questions we're taking a look at as we try to figure out the best next steps for improving that data.

Denise Love: I would be happy to serve as a connector with the all payer claims database council who works with the over 20 states doing this very thing. I think there's a lot of cross learning that could happen there, and maybe consolidation.

And then I have one other question of our ONC friends, and this is just a real quick one, because I think the answer is yes. I see some loopholes in the information blocking, some big ones, and I'm assuming the privacy loophole has some parameters set in the rule which I have not read, because privacy can be used in a lot of ways to not do what you don't want to do.

Mark Knee: Right. I would say I believe we address those loopholes quite well. In the proposed rule we talked about how HIPAA should not be used to information block, although of course there's tons of legitimate times when HIPAA is appropriate, but we explain that it shouldn't be used inappropriately, and I believe we've even tightened it up as far as loopholes go in the final rule. So I suggest you take a look at that exception and the others, and let us know if you have any questions or anything like that.

Denise Love: Thank you.

Rebecca Hines: Debra.

Debra Strickland: Thanks. My question is I think for Alex about the providers pinging other providers to let them know that the patient has either been admitted or discharged or whatnot. What's the transaction that you're going to use in order to do that, and how are these providers all going to be interconnected and knowing and being prepared to receive that information unrequested?

Obviously if someone gets admitted then Dr. Smith is going to tell Dr. Jones that they've been admitted. If this is all expected to be done electronically, that's going to be some coordination, and every single provider is going to have to pretty much be connected to every other single provider. How is that going to be logistically handled?

Alexandra Mugge: Sure, and I love the way you ask that, and I wish that I could say that every provider was already connected to every other provider, because wouldn't that be a picture of interoperability? But yes.

So this already to a certain extent already exists today with hospitals sending notifications, oftentimes it goes through an HIE for example, but starting on the sending end I suppose with hospitals we actually include some discussion in the rule about how hospitals who have an EHR already have this technology in place, whether it's turned on, operationalized, or however we're using it is really what we were trying to get more at with the policy, but the technology is already in place.

We did not specify a standard for this in particular, there are multiple ways of doing this using different standards. But what we just encouraged was the actual act of sending the notification.

And like I said once the notification is sent it may go through an intermediary such as an HIE, or there may be providers that are already connected through the health system, through their EHRs, as the patient, like I know that my doctor is directly connected to the hospital that we go to. So when I go into

the hospital they would have my information in the doctor's office and vice versa. So that's an easy direct connect there.

But what we have discussed more kind of at length in the rule is the hospital is really making an effort to send it to the providers that the patient has identified as their primary care doctor or as somebody who is responsible for their care, or they have some established relationship with.

And that may go through a variety of different avenues, depending on the technology standards, depending on the data intermediaries. And we were less prescriptive there, and more so we focused on the act of actually making sure that the trigger is there, the notification is going out.

Debra Strickland: And that they are ready to receive it at any given time. So the Dr. Smith that doesn't know he is going to get any notification is prepared, ready with that connection or whatever, and that information is going to be able to come into his system and be usable to him upon the receipt of it. So that's why I was wondering about the standards.

Alexandra Mugge: And it may not. I want to be clear that there may be providers out there who don't have the receiving ability. And that's not who the policy is geared towards. The policy is on the hospitals to send the notification. They cannot, and we would not hold them responsible, for ensuring that the provider on the receiving end can receive it, however it would be our hope or it would be an ideal world to see that the hospitals are working with their community providers to ensure that that does happen.

We understand that there are going to be instances where a provider may not have an EHR or may not have the technology in place to receive the notification, and we do understand that. That's maybe phase two of the plan, to continue looking at making all of this possible.

Debra Strickland: Thank you very much.

Rebecca Hines: We have time for one more question.

Melissa Goldstein: Hi, thank you, yes. This question is for both of you. I'm wondering about that patient education material that you both mentioned. I'm wondering if there are any studies that either CMS or ONC conducted or possibly some other peer reviewed research in the literature that you could point us to that shows the success of patient education, particularly in the area of API usage, and apps?

Mark Knee: I guess from ONCs perspective, Kate, feel free to jump in. I'm not aware, I'm not sure that we put any such studies in the rule. We did cite some other studies. I know for information blocking Julia Adler Millstein did some great research on information blocking, but I can't speak to the specific question about APIs and patient access.

Kate Tipping: I was going to say I think we'll have to get back to you, get some more information if there is any.

Melissa Goldstein: Thank you. I was just wondering what the reasons are for expecting that we'll succeed in a privacy context, I think that's what I'm really wondering about.

Alexandra Mugge: Can I just ask, when you say from a privacy context, can you just flush that out a little bit more? Certainly from an app context or from folks wanting to use apps we have a little evidence from across industries and then on the Medicare fee for service side we've seen a pretty significant

adoption of our blue button API through the apps that are available there. But if you could just make a more finer point on the privacy side, that will help us to dig into it a little bit more when we take this back.

Melissa Goldstein: What I thought I heard both of you say, although I might have misinterpreted, is when you were talking about all of the privacy concerns that were raised in response to the NPRM, that you mentioned that you had emphasized the use of patient education, particularly, from the provider side about needing to pay attention to using the APIs and using the apps and making sure that they I guess balance the benefits of using the apps and the API interfaces with the possible, what I thought I understood was privacy dangers or concerns that they might have. So what I was wondering was what is the purpose for thinking about patient education as an outlet for this type of addressing the problem.

Kate Tipping: Melissa, could you share your email information and we can follow it up?

Rebecca Hines: Kate, just send it to me and I'll share the answer with the full committee. Thank you very much Kate and Alex and --

Mark Knee: Definitely. It's a good question for sure, we'll look into it.

Rebecca Hines: And it is a topic that our subcommittee on privacy, confidentiality, and security has been focused on and discussed. So it would be great to have the baseline of what's actually already been done or is underway. So it doesn't appear we have any more hands, and we're pretty much on time to move to the next agenda item. So thank you again, I'm super grateful to our colleagues at CMS and the Office of the National Coordinator. Thank you.

This was very informative today. There were a few follow-up items, so we look forward to hearing back. So I'm going to turn it back over to Rich Landen, co-chair of the Subcommittee on Standards, to start our 4:00 block. We're in the final stretch of the meeting today, starting off with an update on the Office of the National Coordinator's task force within their federal advisory committee, and actually the reason Alex is not on the line with us right now is because she is over there. So Rich, I'll send it over to you.

Subcommittee on Standards: Convergence of clinical and administrative data

Rich Landen: Thanks, Rebecca. New acronym, ICAD, Intersection of Clinical and Administrative Data Task Force. HITAC is not a new acronym to this group. We've been working with ONC and its Health Information Technology Advisory Committee for a while. But the task force, the ICAD task force, has just gotten off the ground.

The ICAD Task Force technically is a task force of HITAC. It is not a task force of the National Committee on Vital and Health Statistics. Nonetheless, because the primary vision for the task force is in the area of the convergence of clinical and administrative data, ONC and HITAC refer to that as intersection, NCVHS terminology tends to refer to that as convergence. So the vision is shared.

ONC and HITAC, generally speaking, work in the area of clinical data standards, whereas NCVHS charter is in the area of the HIPAA, administrative standards. And back in the time when the HIPAA legislation was passed there really were no clinical standards. If you remember back then, and this goes back to the early part of the 1990s, we as a country were in a good position to start automating some of the basic financial and business transactions, specifically starting with the claim, and the claim payment, 837 and 835 as you all know well.

But on the clinical side there were no standards, and by and large the capability of the provider community, be that institutional or small practice, did not have EHRs as we know them, did not have a lot of IT support.

So at the time that HIPAA was developed there was absolutely no possibility of any sort of convergence or intersection between the administrative standards and the clinical standards that had come over a long period of time in evolution, and it is now, and this is 2020, so this compared to 1992 with the first WEDI reports, this is the time where the technology and the healthcare culture is ripe to start merging the two, and treating healthcare data as healthcare data rather than in separate buckets, in separate processing streams, in separate transmission streams as administrative data or clinical data.

The role of the health plan in that time has also changed, where health plans have not. In the early '90s they were not large consumers of clinical data, other than as claim attachments in a paper world, or at that time as some sort of higher auth or utilization review, also very paper oriented back at that time, but times have changed.

So the vision for the HITAC ICAD Task Force is to support this convergence of clinical administrative data to improve interoperability, to support clinical care, to reduce burden, and to improve efficiency. So you see the term reduce burden, that's kind of an ONC charge under its legislation, but improving efficiency, you might recognize that language from the HIPAA legislation that modified the NCVHS charter many years ago.

The charge of the task force is to produce information and considerations related to the merging of clinical and administrative data, including transport, rules and protections, and we're focusing on as Alix Goss likes to term it an exemplar, using prior authorization as kind of the test vehicle as we get into looking at the opportunities and feasibilities of the different potential approaches to this convergence or intersection of administrative and clinical data.

So the specific charge of the ICAD is to design and conduct research on emerging industry innovations, validating and extending landscape analysis and opportunities. NCVHS members who were around a year ago might remember the HITAC meeting at which prior auth was featured, and we learned from testimony of many different groups that there is an awful lot of activity going on around trying to get improvements to prior auth, but they were all fairly one off and not well focused.

Out of that conversation, I believe that was a year ago, that was last March of 2019, part of the light bulb went off as far as hey there is some real possibilities here for HITAC and NCVHS to jointly develop the landscape for both of us to achieve our goals.

So the research will continue to invite industry to present both established and emerging end-to-end solutions for prior auth, both medical and pharmacy, and to support effective care delivery, reduce burden, and promote efficiencies. So we're looking to identify patient focused and process focused solutions that remove roadblocks to prior auth and promote clinical administrative data and standards congruence. We're trying to kill a lot of birds with just one stone here.

Rebecca Hines: Rich, Denise has a question.

Bill Stead: I think that is a hanging chad.

Rich Landen: So the task force will produce recommendations and related convergence roadmap considerations for submission to HITAC. The task force will file its report with HITAC. HITAC will debate that and then make recommendations to ONC. The task force will share its deliverables with us to inform our work on convergence and prior auth activities. And later on, still this afternoon, we'll get into the actual scoping document for the NCVHS project on convergence and prior auth.

Back to the ICAD, it will also then make public a summary of its findings once the activities are complete, and we're expecting the work to wrap up no later than September of this year.

This impossible to read slide, at least this scale, shows the member list. I would like to specifically call out they HITAC has invited, ONC has invited Alix Goss to be one of the two co-chairs. And her fellow co-chair is Sheryl Turney from Anthem. And you can see the other members are mostly from HITAC. There are several of us, myself, Debra Strickland, Jacki Monson from the Standards Subcommittee, and there are a couple individuals who are neither NCVHS nor HITAC members.

What are the challenges? Separate standards for clinical and administrative data. 21st Century Cures put burden reduction for admissions on the target list for ONC working in partnership with CMS. As we have discovered in our annual reports and our report to Congress, some of the HIPAA transaction standards have very low utilization rates despite the mandate being in place since 2003.

EHR capabilities have been notably advanced over the past decade in parallel to care delivery and payment reimbursement models. You heard much more of that particularly from the ONC presentations on the data blocking, the interoperability in the last hour.

And the lack of harmonized clinical and administrative data standards lead to ecosystem burden, such as inefficiencies, time consuming discovery of payer specific requirements, technical barriers related to vendor support and integrated platforms.

And all that makes it difficult for all parties in the healthcare ecosystem, providers and health plans, pharmacists, and above all the patients, to access information that exists somewhere in the system. So the bottom line is this all impacts patient safety and quality of care.

The policy landscape and the current work. The policy landscape is encouraging, federal policy is encouraging integration of data and reduction of burden to improve patient safety and care quality. We've got as you well know HIPAA, we've got the Medicare Modernization Act, we've got ARRA HITECH, which has been introduced, 21st Century Cures which drove most of the last hour of presentation. The 21st Century Cures as you heard from ONC also specifically asks ONC and NCVHS to engage mutually in this journey.

So in March of last year as I mentioned the HITAC committee met with the NCVHS Subcommittee on Standards, there was a joint ONC-NCVHS discussion during June and November, and there have been ongoing discussions of opportunities to identify and support potential approaches as administrative and clinical data converge.

So standards rulemaking authorities are separate across different programs. This is one of the challenges to living in the US healthcare system. HIPAA standards are adopted by the Secretary of HHS, who has delegated authority to the CMS Division of National Standards. HIPAA rules apply to covered entities and only to covered entities, also defined as health care providers, clearinghouses, health plans, and health plans include Medicare and Medicaid.

HIPAA stipulates that the NCVHS role is to provide input into standards adoption and implementation through recommendations to the HHS Secretary, as we just did today for NCPDPs at six.

Separate from that the EHR standards and EHR certifications are under the authority of ONC. New standards such as HL7 FHIR can be adopted under various authorities, the CMS interoperability rule, which will affect Medicare Part C, D, Medicaid, the exchanges, and Medicare health providers, and ONC can adopt rules to adopt FHIR standards under the Health IT Certification program.

So why we are speaking at a high level of the convergence or the intersection of clinical and administrative standards, we've chosen as our test case if you will to focus on prior authorization. And for those of you not in the standards subcommittee, most of you will know it is either from your personal experience or your professional experience, prior auth is an administrative process which requires healthcare providers to request approval from a health plan to provide a medical service, a prescription medication, or some supply to the patient. That authorization has to be obtained in advance of the service or prescription being delivered to the patient.

Health plans' purpose for authorization is to ensure the evidence based guidelines are adhered to to prevent potential misuse or overuse of services, and to some extent to control costs and to monitor care coordination. I'll add to that it's also to determine whether it's in the patient specific non-listed coverage or not.

Authorizations are contractually required for the most part under a payer's medical policy or coverage rules to support downstream payment processes. And there are separate medical and pharmacy standards adopted for prior authorization.

Under HIPAA prior auth transactions for referral certification and authorization are in 45 CFR section 162, at the request of a healthcare provider to a health plan for the review of health care to obtain an authorization for the care, or B a request from a provider to a health plan to obtain authorization for referring an individual to another care provider, or C a response from a health plan to a health care provider to a request as described above. So this is the flow back and forth between the provider and the health plan as specified in federal rules and regulations.

Current standards for prior auth. Under HIPAA for medical services, including hospitalization and dentistry is the ASC X12N 278 transactions, specifically version 10, X217, the implementation guide. For retail pharmacy drugs it's the NCPDP D.0 Telecommunication Standard that we've talked about so much today.

However, for Medicare Part D, CMS has a final rule in place to adopt prior auth or electronic prior auth between prescribers and pharmacists. NCPDP version 2017071 Script Standard known as ePA and the adoption of the standard is required under the SUPPORT Act of 2010. So you see that's neither yours nor HIPAA.

So what are the methods of Electronic Prior Authorization currently? HIPAA leverages EDI through the X12 standards, but it has a major exception in that HIPAA permits portals, or let's say the evolution of what used to be called direct data entry. Promoting interoperability, again the new name for meaningful use, that program leverages APIs, you heard about earlier today, and FHIR. In practice providers largely use portals, phone, fax and mail, because the electronic standards, specifically the X12 standards, has not proven terribly advantageous for the industry to adopt.

So obviously the use of portals, portal works well between a provider and a single health plan, but how many health plans does that provider's office have to interface with? And each portal then is maybe the same content under HIPAA, but is a different place to go, is a different process, it's a different thing to learn. Of course, fax and mail, you're often limited. Pharmacy industry is using NCPDP SCRIPT standard on a voluntary basis.

Task Force Timeline, getting back to the ICAD. Establishment happened earlier this month. The task force appointments were made, the co-chairs were appointed and the members have had two calls now, today is the third call of the group, and they are in process of figuring out what they will be tackling, how they're going to tackle it, possibly dividing into subgroups. But they will work practically I believe, pretty much every week. There is a 90 minute conference call scheduled for the full task force. Additional calls will be setup for subgroups if needed.

That will continue through May and June, July and August, and then hopefully by September all the work will have come together and we will have done the research, we will have crunched the data and come up with consensus on recommendations to submit from the task force to its parent, HITAC.

Rebecca Hines: Rich, this is Rebecca. Could you restate the CMS final rule details associated with the NCPDP SCRIPT EPA standard? A listener said it's her understanding the rule has not been published as final.

Rich Landen: I am not sure of the status. I thought we had been told that it had been finalized.

Rebecca Hines: That is what I thought. We got an answer, it's true that it's still in proposed phase. It's going through clearance right now, I just got the answer from Lorraine Doo, thank you Lorraine.

Rich Landen: Next slide please. As I mentioned, ICAD Task Force will meet weekly. All task force meetings are open to the public and will include a public comment period, similar to what we do with our NCVHS. The process used to reach agreement is decision making through majority consensus, deliberation among the task force, consideration of all expressed points of view, differences resolved through discussion, and identify areas of agreement and disagreement. So it's a process that's pretty familiar to this NCVHS group.

As I mentioned HITAC task forces do not provide advice or recommendations directly to ONC. The task force reports up to HITAC, which will then deliberate, similar to what we did today with NCPDP version F6 for the subcommittee up to the full NCVHS.

Draft recommendations are submitted to HITAC for final vote and approval. Final recommendations are transmitted from HITAC to ONC for its consideration. Again, HITAC, similar to us, is advisory.

The National Coordinator will consider recommendations to inform ONC policy and/or programs. Recommendations will also advance to our NCVHS Standards Subcommittee. As I said, we've got four of the Standards Subcommittee members on the ICAD, and we will bring back all that information as input into our own project and process here. Final recommendations from HITAC will be posted on HealthIT.gov, which is ONC's public website.

What's the current landscape for prior auth? As I mentioned earlier, there are numerous challenges for payers, providers, and patients when conducting prior auth. Examples of these requirements and opportunities for improvement include the 278 version 5010, rather than the NCPDP SCRIPT transaction

for medication authorization requests. SCRIPT does the job much better than the 278, but the 278 you have a mandate.

Limited adoption or support for the 278 among the medical services community. And the transaction reflects outdated and very complex workflows that are not easy to be resolved, and certainly pose a challenge for the industry over years.

ONC has compiled a list of key artifacts outlining the current landscape of standards and mechanisms for exchanging the data, which was shared with the task force to inform its work.

That's in a nutshell what the ICAD is and where we are now. As I mentioned this is week three of its existence, it's just getting started, it had the initial orientation meeting with the input from the ONC presentations, and we will start seeing where that takes us in terms of discovering everything that's out there, updating the landscape, knowledge, and then pursuing avenues of opportunity.

So I'll open it up for questions from the committee members. I am seeing no hands, and I'm not thinking that this really is a surprise to any of you, we've been talking about it pretty much all along, and we're at the very early stages. But certainly, stay tuned, we'll keep updating the subcommittee, but also the full committee as we go forward, and then again the target for completion is September. Nick, I see your hand up.

Rebecca Hines: Greg, can you unmute Nick?

Greg Richards: Sure.

Nick Coussoule: Obviously as part of the standards subcommittee, I get this information pretty regularly. Do we have a thinking process about how we'll share some of this with the full committee, either kind of between meetings or anything of that nature, or do we just look at it as a meeting by meeting update?

Rich Landen: I am hesitating because no, we don't have a firm plan. We do, we'll look into a little bit of detail later as we talked about and seek approval of the project scoping document. But we envision regular updates as you said of the standard subcommittee.

We have, part of the plan is to reach out regularly, but more on an ad hoc basis to the privacy subcommittee as the ICAD work gets into that area. I don't think we've got terribly specific plan for interim updates to the full committee, but we will certainly do that as events warranted. Certainly, at our next full meeting we will have a formal update, PowerPoint presentation on the status. Is there anything more specific that you'd like to suggest?

Nick Coussoule: I think that is good. I sit on the Privacy Subcommittee as well, so I have some insight into that, and we'll likely share with the executive committee too. I'm just trying to think as this is likely going to span other parts of the committee over time, so I think what you mentioned makes perfect sense.

Lorraine Doo: Rich and Nick, this is Lorraine. The ICAD is just really launching, and Rich of course you know because you're also sitting on that, and they've really just begun those really robust conversations, and had such a great meeting last week. And so maybe, I don't know, would it be helpful to share the presentations or the links to the presentations from those meetings, would that be useful?

Rebecca Hines: They are posted on the ICAD web page if people want to go check them out. And I think the audio is as well. Like today, right now, they just wrapped up their weekly meeting looking at durable medical equipment workflows. So as their first use case.

Lorraine Doo: After Rich gives his presentation on the project plan for the standards subcommittee, part of it as Nick was talking about it sort of reminded me that all that information is part of the discovery that the subcommittee is going to be doing that could be helpful information if we somehow consolidate it or have bullets that would describe that work.

Rebecca Hines: Indeed.

Rich Landen: Thanks, Lorraine. I appreciate that input. And that reminded me that one of the comments I wanted to make is on last week's conference call when I was simply amazed at the energy and the knowledge of the members of that task force. What I think impressed me the most is how many of them came up with interesting challenges and opportunities that were all focused on the patient as opposed to the technology or the business processes.

Any time the task force looked at a specific problem there were always two or three or four of the members that would say well what does this look like to the patient, what does it mean to the patient. So even though they were expert at some aspect or the other, let's call it the system, the approach they were taking was looking at it through the patient's eyes or how it affected the patient.

I was very pleased that so many of them were taking that patient related perspective, and I further have to say that not everybody agreed with everything, but we all manage to talk to each other rather than at each other. So it's off to what I would describe as a very auspicious start, there seem to be some good dedicated people that know how to work. Other questions? I guess we're ready to go into the project scoping document then?

Rebecca Hines: Actually, Rich, I think we are going into the slides for the convergence project. Greg, that's file H.

Greg Richards: Just one second.

Rich Landen: That looks good. We talked specifically about ICAD. This is getting to the larger picture and leading toward our NCVS project scope. The overarching issue as I mentioned is convergence of administrative and clinical data, and we're using prior auth as an exemplar of the opportunities and challenges to that convergence.

In the next few minutes, we'll be going over the setting the stage, looking over our shoulder, and currently what we're doing, what NCVHS is doing with the predictability roadmap regarding standards adoptions. We'll be talking a little bit more about convergence of the administrative and clinical, although I'll try and skim over the parts where we've already discussed. And then we'll re-emphasize our coordination with ONC, and then we'll kind of describe what we see as the prior auth journey.

Looking toward the future then we will look to the whole subcommittee to review the project scoping document that was in the agenda book, and talk a little bit more about the ongoing collaboration with ONC.

So Predictability Roadmap; we began to work on Predictability Roadmap quite a while ago, to address issues with the adoption and implementation of standards. I think it has been about two years. We shared this information and process at several meetings, and we've got documents relevant to it on the website, had made some recommendations on this to the Secretary, have heard some good hearings, lots of information in there about what's working and what's not working with the HIPAA rule promulgation process and what the industry is looking for but it's not getting out of the system that was designed right after the 1996 legislation, and we started to get the rules on how HIPAA standards would be adopted, and then we've had just the two rounds of adoption that have happened so far.

So also looking for improvements in federal processes such as more visibility into existing regulations, more frequent guidance, so not rulemaking, but just kind of substantive talking about challenges that industry is facing relative to the rules and what might be done about those challenges, getting a little more outreach to the industry.

One of the big items in the predictability roadmap, testimony and discovery, was more timely regulatory activity. So the industry was very clear it wanted more frequent updates but with more digestible bites, so not a huge burden to update every 10 years.

Looking for improvements in the SDO processes, greater diversity of actors, the affected participants in the industry. Looking to get those folks involved earlier in the standards development and operating rule development process, because right now standards organizations are open to anybody who wants to participate, but there's a high cost to participating, and there's a lot of the users of the standards who cannot or choose not to afford that cost.

So we're looking to see what, the predictability roadmap is trying to consider what other tools there might be to get that input from the end users earlier into the standard development process, rather than waiting to hear from them either at the SDO's public comment period after the rule has been developed, or even worse, waiting to DNS, the Division of National Standards, puts out an NPRM eliciting public comment.

We also want to make sure that the standards can support innovation and meet evolving business and technology changes. And we want to add some productivity into the process as well. Also make improvements to governments and oversight, what the subcommittee and looking at some of the data sets over the last couple of years, the code sets talked about stewardship, so improving the transparency of the processes and advancing industry needs and ensuring more value.

Since NCVHS put out those recommendations we've continued to evolve our opportunities for the roadmap and for the adoption of implementation standards. These discussions have led us to think about the evolution of technology and standards, specifically the convergence of clinical and administrative. Today we're going to focus on more the opportunities and challenges in that convergence.

What is prior auth? We talked about this a little bit. It's the process requiring providers to request prior approval from a health plan before rendering supplies, services, meds to the patient. As I mentioned, in advance, and then we've already gone through the health plan's purposes for this.

So it's an established process, there are reasons for prior auth. It does create a burden, but it well deployed that burden has some value to the system and to the patient. Poorly deployed and operated that value erodes, and some of the things we're seeing in the market actually contributes to the

detriment of the patient rather than helping the patient. So lots of issues there. And as we mentioned before there's separate medical and pharmacy standards adopted.

So our 2020 convergence process. We wanted to develop some recommendations to support the convergence of clinical administrative data, to foster, to help it happen, and we realize that the existing HIPAA approach may not be the best way to do that.

So in looking at this we're reaching out to the work of our colleagues at ONC and HITAC, and specifically evaluating opportunities, and as I mentioned before we're using the prior authorization transactions and the work flow as our exemplar in seeing how we can bring, we, NCVHS and through HITAC, ONC, might be able to bring some advantages into the prior auth universe within healthcare and across HIPAA and the clinical standards.

So the aim is to identify and recommend a path forward toward convergence, and using prior auth to get an example, get our hands around, and essentially propose something and kick the tires to see if it can work, and beyond just working it can work at scale. This is a difference in implementing a small scale initiative versus a national implementation.

Timeline as I mentioned, for the ICAD I said the final report target is to get that out by September, but for the NCVHS that ICAD report is only one milestone. So the project we expect for the NCVHS will run six to 12 months.

So at best it will be a few months, a month or so after the ICAD report to HITAC, at the outside it will be probably a year from now before we have a proposal for action by the Full Committee. And in that we would look to make some recommendations on one or more concrete approaches for consideration by HHS and for the industry.

So the project as we envision it at this point will consist of three phases. The first phase we're in now, gathering information, both from prior hearings and the predictability roadmap and some of the standards update testimony and comments we've got, but primarily from the endpoint received through the participation between now and September in the HITAC ICAD task force.

Phase two will be an analysis of what we've learned in phase one, and that analysis would be done primarily by the standards subcommittee, supplemented by the Privacy and Security Subcommittee and outreach to others on the Full Committee or the Executive Committee, as necessary.

Phase three then, after we've gotten the data and done the analysis, will be to develop some proposals, to deliberate those, to come to a consensus as NCVHS, and then submit those recommendations to HHS, and more likely industry as well.

That's it for the background. So before we get into the scoping document itself, let's open the floor to committee members for discussion of what we've just presented, make sure everybody is on a level playing field at this point. Any hands up?

Bill Stead: I just want to one, thank you for your marathon. You have handled the last two complicated sets of information with great clarity, so thank you. I just want to be sure the committee understands the distinction between the NCVHS project, which the scoping document relates to, and ICAD, because our members, some of our members are participating in ICAD, our work is going to be informed by it, but NCVHS has responsibility for advising the secretary around the administrative standards related to

HIPAA administrative simplification, and the terminology and vocabulary standards, whereas HITAC is advising ONC around the clinical record standards.

And what we're attempting to do is have each of our FACAs in our appropriate lanes while having us coordinate to make sure that the sum of the two efforts is more than the parts. And I just want to make sure that everybody is comfortable with that, because it's pretty complex.

Rich Landen: I am pausing to see if other committee members have a reaction to that, because what Bill just stated is a key point. It's easy to get out of our scope and into HITAC's scope and vice versa, and we have to be very careful about doing that.

So a while ago we authored a document about how we coordinate with ONC, and now we've got some rules of the road for the HITAC ICAD task force, and then this project scoping document that we'll be getting to takes all those guard rails and kind of enshrines them to make sure that we can take advantage of the work we're doing with ICAD and HITAC, but we don't encroach or we don't stray outside the charge of the National Committee on Vital and Health Statistics. So if there's anybody that's not clear on that --

Vickie Mays: Thank you Rich. I am glad Bill, that you brought it up, because I wasn't clear as to greater benefit versus the bandwidth problem that we have. So right now Alix is there. So I'm trying to understand what this means, because Standards has always been the most hardworking, the most demanded upon committee. So some of this is thinking about your welfare, but also for us we love having you.

So I'm just trying to get a good sense of what this means for us in terms of our bandwidth and what it is we get. I mean HITAC isn't coming over and joining us to help, but a bunch of you are going there. So I'm just trying to understand what the implications are for all of this standard stuff that you all are trying to do, other than you maybe won't have any sleep.

Bill Stead: Do you want to do that, Rich, or do you want me to take it?

Rich Landen: I'd love to start. You can deliver the knockout punch. Thank you for your complements Vicky, but I assure you that the members of the standards subcommittee, as hardworking as we are, are not the only ones. We don't have a monopoly on that. I've sat in on too many of the meetings of the other subcommittees, and they work just as fine. But thank you.

Now I've been derailed. What we see here, and your concept of bandwidth is important to us, but the concern of the subcommittee and by extension NCVHS about the HIPAA standards has for a long time recognized that administrative standards used to be separate, no longer are.

So part of our obligation, part of our charge going back to the kinds of things that Bill was talking about early this morning in his opening remarks about taking a long-term view, is we recognize that the value to the health status, health and wellness status of the American public and the long-term demands that we create some sort of a plan around how to more appropriately harness and reuse some of the data that has traditionally been in administrative silos.

Vickie Mays: I am getting it.

Rich Landen: So this companionship with ONC and HITAC actually brings resources that we would otherwise have had a very hard time finding. So that's my short answer. Bill, do you want to add to that?

Bill Stead: That is perfect, Rich. I just would expand it. The relatively early in the predictability roadmap work, the fact that the only way to really accelerate things involved getting the clinical and administrative pieces out of silos so that they could work together because neither actually scale by themselves. Independent of the various committee bandwidth it's actually a matter of how you end up with effective standards that work together so that we have the right data to remove the barriers and reduce the burden. And that's actually where it started.

Our standards committee, supported by the full committee, developed and really led the development of the scope of work around convergence of our work and HITAC's two or three years ago, when HITAC first started, before HITAC or ONC really had time to join with us on it, because they were heads down on some very time critical things that they had to do.

Partly as a result of ONC's engagement and others' engagement, and a year ago, December's hearing, the opportunity I think really caught Don Rucker's attention, and as we all were very pleased by, Don spent a complete day with us in our November meeting, it was really quite unprecedented.

And so there has been real effort to harness joint forces, and I think it is letting both committees to get more done within their limited bandwidth, and each of us, we at least already had this in our most important critical path. So we're not diverting resources. I think as Rich said what we're actually being able to do is harness resources, and that's a key part of our charter, and it's a key part of the connection that was written into 21st Century Cures. So I hope that helps.

Vickie Mays: It does. Rich sort of laid it out, and I think you raised it up in terms of the level at which it's happening. The only thing I would have suggested, and this is where, when the class kind of walks those two lines of being able to do privacy stuff, well she does lots of different stuff, but just listening today and listening to what Rich has said, it would have been helpful or can still be helpful to have one of the privacy people in their group as well. Because we have pieces of this that we're doing, and I think they should kind of hear those pieces. So again I think that same benefit of more with less really would occur in terms of the privacy look.

Rich Landen: Yes, we actually have two of the Privacy subcommittee folks, Nick and Jacki, on the ICAD task force. So, great idea, we beat you to it though.

Vickie Mays: That is fine. I don't mind being slow on something like that.

Rich Landen: It is absolutely critical. The other point I'd just like to make is what we bring to ICAD is people like Bev and Nick and Alex particularly have deep background in the X12, the EDI, the NCPDP, which is not that common of a skillset among the HITAC membership. So part of the value of the collaboration is that between us getting the clinical EHR side and HITAC getting the evidence side, we ensure that neither of the groups inadvertently diverges and starts getting into solutions that are incompatible with the needs of the other industry segment.

Vickie Mays: Sounds good. Sounds well thought out to me.

Rich Landen: Thank you. Other questions or comments? Let's get into the scoping document then. And I think we've gone over a lot of the background and the history component of it. So I won't dwell too

much on that. So we go back to HIPAA and then HITAC, and the differences in technology, and now the technology has changed, the telecommunication has changed, the cost of memory has changed, health plans have taken on a different role.

There are these things called ACOs, there's a thing called value based medicine payment arrangements. All this innovation and development goes on as part of the landscape. And I don't think I have to make the case any further than we've done for the good examples of merging the clinical data, but maybe I should just take a second and talk about prior authorization.

Prior authorization was chosen as an exemplar for several reasons. One, because the low adoption rate of the mandated standard. But two, prior auth is a transaction, to look at it from the administrative side, that is both administrative and clinical in nature.

It has two components. The administrative piece of it, and as you think back to how the X12 278 was developed, it was about compliance with an insurance policy requirement, or a healthcare coverage, health plan coverage policy requirement for this pre-approval, which is an administrative process.

But that administrative process couldn't happen without the clinical people at the health plan, or at the entity contracted by the health plan, to do a clinical review, and to do that clinical review there had to be clinical information communicated, not just administrative information.

So it's one thing to say that administrative transaction says okay, Dr. Smith is requesting a PET scan for patient Jones, and the insurance company then has to say yes or no, but has to have the clinical information to decide whether that PET scan is part of the coverage of the policy or not, and whether the evidence supports the need for a PET scan. And then if you take it a little bit further on, historically at least it has not been typical. There's okay, what alternatives are there to a PET scan. So that transaction demonstrates how the administrative and the clinical come together.

And so I'm still basically on page two of the project scoping document we're talking about over the last couple of years, past three years, there has been a lot of industry activity, AMA, I need to call out that they did a really bang up presentation for ITAC a year ago.

AMA has a working group of 17 state and specialty medical societies, national provider associations, health plans and patient representatives that they're working on, and it actually came out with a joint consensus statement on prior authorization principles. So that's part of the background of what's going on. Other events over the last three years, HL7 has been working on the FHIR application, and we now see that OCCMS, including FHIR in its most recent rulemaking activity.

Onto page three, ongoing issues related to prior authorization, there's progress, but there's still burdens, barriers, and opportunities, despite the many efforts this is still one of the most inefficient processes in the industry. So NCVHS has been aware of the work of WEDI, AHIP, ONC, CMS, and others, and we've been thinking about this for a long time.

So for this project, again this is a project we're proposing for the standards subcommittee, we want a way to address the challenges of prior authorization that can help garner workflow efficiencies and mitigate patient care risks. So it's not just efficiency, it's all we've been hearing about, the actual risk to patient care from prior auth that is not well and timely done. So, and this is an exemplar to evaluate a broader plan for convergence of administrative and clinical data policy and standards.

On to page four of the document. Let me read the description verbatim. NCVHS Standards Subcommittee will produce recommendations related to the convergence of administrative and clinical standards and improvement opportunities related to prior authorization.

The Standards Subcommittee Project will use the information from prior NCVHS hearings, reports, and recommendations, the center among them is the predictability roadmap series of hearings we did, and combine it with the current efforts of HITAC's ICAD task force.

What is the expected outcome? Our intent is to produce recommendations oriented toward improving delivery system performance through the convergence of the clinical administrative data exchange standards. So we're still focused on standards. Such standards may be existing standards, they may be emerging standards, or a combination of both.

Timing, as I mentioned previously, next 6-12 months. The three phases we went through already, discovery, analysis, and development and recommendations. Important to note that in the scoping document that we're looking at the subcommittee does not specify the types of recommendations that might resolve from the discovery and analysis work, because the output at this point is unknown.

We won't know what we're dealing with until we get all the input in phase one and we start doing the analysis in phase two. So specific output from this project is still to be determined. The subcommittee will evaluate the information produced by HITAC and elsewhere regarding standards technology processes, workflows, and patient impact.

Components. Not surprisingly continued collaboration with ONC and ONC leadership. Actively support and participate in the ICAD, evaluate the existing body of evidence, coordinate with NCVHS privacy, confidentiality, and security subcommittee to advance privacy implications, and invite PCS to review and comment on privacy implications at appropriate milestones of drafting.

So our intent is to include the privacy PCS subcommittee at each key step along the way so that we discover potential impact of the privacy earlier rather than waiting until the end and then reacting after it's really too late to change the course of the ICAD process. So determine the scope of recommendations that will be useful and timely for the secretary and to the industry to develop actionable recommendations, key word actionable, and present to this full NCVHS review and approval.

And finally, what we will use as input, prior NCVHS artifacts, HITAC and ICAD reports, current industry efforts and work products that we're aware of, that comes from our review of the landscape. And federal input. CMS and ONC interoperability rules, information from the federal agencies on SAMHSA, VA, DOD, Indian Health Service, Public Health Service, Center for Disease Controls, and others.

So that's the proposed scope of work that I would like to present to the whole committee for its approval. And the appendices to the document is in the agenda book, you've got a lot, further information of links, I hope some of you have at least looked at that and explored some of the things. But let me open it now to discussion prior to seeking the motion for approval.

Nick Coussoule: Rich, one question. Do you envision as part of this having any in person or other meetings that we need to plan into the calendar specific to either information gathering or other objective testimony?

Rich Landen: The short answer is no, not at this time. We will of course, have the full NCVHS meetings to use, but at least in this fiscal year we are not anticipating any need for in person meetings. ICAD does all its work virtually.

Depending on where this journey takes us, we may in the future look to an in-person meeting, but I at this point at least do not see any clear need for that. Most of the fact finding will be done by ICAD, and if we do need a hearing for NCCVHS purposes we won't know that until we get well into the analysis stage, so phase two.

Nick Coussoule: That was my expectation as well, I just want to make sure the rest of the committee understands that as we look to trying to plan our calendar for the next 12 months and what's likely to be consumed or not consumed based on our kind of funding and availability.

Rich Landen: Yes. Frank?

Frank Pasquale: I was just wondering, I think your example of the PET scan was a really good one in terms of focusing attention and helping us understand the real world implications of it, and it was just a suggestion that disseminating best practices might be really valuable, because I think that there is, and I don't know if that's going to be a special section of the report or if that's already planned to be in it, but I just thought that might be something that could help make what can seem a very abstract problem more concrete to the readers and others.

Rich Landen: Thank you for that input. I am not aware that we have specifically, I mean as we mentioned this is just the initial phases, I don't think we have settled into anything, but I will certainly make sure that the concept of best practices does get onto the table at ICAD, and also in this project as well.

Rebecca Hines: Rich, I don't think we need to take a vote in a formal sense, but I do think you're right, we need to take the temperature to make sure everyone is comfortable with your current trajectory before we close out this section. I don't know if you want to take sort of an informal show of hands that everybody is good for the standards subcommittee to continue as outlined.

Rich Landen: You are the official parliamentarian, so I will go with what I am told.

Rebecca Hines: Some hands are going up already.

Bill Stead: Informal show of hands.

Rebecca Hines: That is what I meant to say. An informal show of hands that what Rich has outlined this afternoon for the NCVHS Standards Subcommittee is okay, from your standpoint you have nothing to add or to suggest, any edits, revisions.

Nick Coussoule: And if you are willing to work on it.

Denise Love: You just said subcommittee members vote?

Rebecca Hines: Yes, absolutely. It looks like all members who are on right now are in agreement. So an informal poll suggests you are on the right track Rich.

(Applause)

Rich Landen: Wonderful. We have ourselves a project scoping document then. Thank you all very much.

Rebecca Hines: Thanks everyone. We are getting down near the finish line. We're moving to the 5:00 committee discussion topic. And there were some items in your e-agenda book, starting on page 88, and Greg I'll go ahead and show this if you want to stop sharing your screen, or maybe that's Kim.

Committee Discussion

Rebecca Hines: In your e-agenda book there was an email and a letter from WEDI to the Secretary of HHS, and we wanted to provide an update on this. Bill, do you want to take the lead on this?

Bill Stead: Yes, I will. Why don't you scroll down just a little bit? We received this on February 3rd, and it's a letter of really strong support from WEDI for the ICD-11 letter, a recommendation letter with research questions and communication plan.

Most importantly they bulleted out for HHS the three things they were prepared to help HHS do. So this is a nice example of the committee's work fostering cross-industry collaboration. Specifically they said they could identify use cases for ICD-11 and work on how well ICD-11 will meet those, evaluate the impact of the ICD-11 code structure changes in different environments and on other health information standards adopted under HIPAA, and to identify the potential of ICD-11 to support greater convergence of clinical administrative standards. So I think that's a very helpful on their part, and we really appreciate their stepping in, helping this way.

The second is a letter that we received from France, and they were offering in essence to have the people that they're working with there on their health terminology in their health terminology management center to be part of the collaborative effort and the specific things that they're doing. And we connected them to Donna and so that input is being coordinated through that sort of normal standard process. So again, it's a very nice intersection. Anything to add to that Rebecca, or is that adequate/

Rebecca Hines: That is great. I just wanted to draw members' attention to those two items in the e-agenda book, especially our three new members, to see that we put out a letter just a couple months ago, and already there has been some follow-up by stakeholder organizations.

Bill Stead: The key point of that is we, we're supposed to submit the letter. We made recommendations to HHS, and we basically said HHS needed to provide leadership and to engage the industry, and this is an example of the industry is in fact engaging. So it's a very nice sign.

Rebecca Hines: There are some hands up, and I don't know if they're hanging chads or whether Rich you had anything you wanted to ask or chime in.

Rich Landen: I am a chad, sorry.

Bill Stead: I am a chad also. I will lower it. We are eight minutes before our witching hour. I thought it might be useful in that brief time just to give people a chance to round robin to the degree they have things they want to share about their reaction to the day, both content and the way this process is working as we prepare for tomorrow.

Rebecca Hines: We invite you to unmute yourself and video yourself if you care to, and weigh in.

Bill Stead: I love actually seeing the people in person. Thank you for the video, I miss us being together.

Rebecca Hines: Did this format, as second best, work for you all? Any feedback? Anything you'd like us to do differently tomorrow?

Denise Chrysler: It worked well for me considering it wasn't in person and it was a long day.

Lee Cornelius: My smart remark is we could solve all our health problems by Easter.

Debra Strickland: It was actually well thought out as always, and we've been through a broad girth of information, but taken in good small manageable doses I think this was as good as any other meeting that we've had.

Lee Cornelius: Seriously, I think this was an effectively run meeting.

Rebecca Hines: Lee, I would like to thank you for your suggestion yesterday. I sent out a set of guidelines based on your input, so thank you for that. I think you tightened us up considerably.

Denise Love: Thank you Rebecca and staff for all the hard work. This was not without some pain on your end. Thank you.

Rebecca Hines: You are most welcome. It is ironic, but it's easier to do this in person, there's less up-front work.

Bill Stead: It's hard to believe it was only two weeks that we figured out we had to do this.

Denise Love: Unfortunately, I think it's the new normal, and I think we did pretty good for an inaugural --

Maya Bernstein: I am just finishing my other meeting, which now is going to get extended for 10 minutes. Can I call you back just when it is over? Okay, I'll do that, thanks, bye.

Bill Stead: This platform is far superior.

Maya Bernstein: Sorry. Was that me talking? I was on a phone call. I raised my hand because I wanted to know if Lorraine is really standing in her garden or not.

Lorraine Doo: Yes, I am in my backyard.

Maya Bernstein: Awesome. It looks like a green screen, with very big grass. Tomorrow I will be on video when we have our part of the meeting.

Rebecca Hines: Before we go completely into rubbing elbows remotely mode, I just wanted to say Nick asked if we are having public comment today, and we are going to have public comment again tomorrow at the end of the day, Nick. We had public comment earlier. And I haven't received any additional public comments on email, so I'm assuming people are satisfied and don't have a lot of additional points to add but thank you for asking.

Rich Landen: Let me just add that as well as this technology has worked and as successful as we have been today I don't want this to become our norm, I still much prefer the ability to rub shoulders literally with folks.

Rebecca Hines: I agree.

Bill Stead: On that note, if nobody objects, I'll move adjournment.

Rebecca Hines: We are going to start at 8:30 tomorrow. I apologize, I didn't think to –

Participant: 5:30 in San Francisco.

Rebecca Hines: I'm terribly sorry about that. You all have to keep me honest. I just spaced out on the fact that we're virtual now and 8:30 start time is uncivilized for our friends west of the east time zone. So please don't hesitate to speak up. And I see Jacki with the baby. So you get to start with us at 5:30 tomorrow pacific time, 8:30 eastern.

And most of tomorrow will be devoted to the Subcommittee on Privacy, Confidentiality, and Security. We have some very exciting presentations coming up I understand, and then we'll get to dive into work plan deliberation for the subcommittee.

Bill Stead: Jacki, do we actually have a new member now that's helping with our bandwidth?

Rebecca Hines: Thank you so much. I can't thank you enough. Take good care.

(Whereupon, the meeting adjourned at 5:30 p.m.)