National Committee on Vital and Health Statistics
Meeting of the Full Committee

Transcript
November 18, 2020 10:00 a.m. – 5:15 p.m. ET

VIRTUAL

SPEAKERS

NCVHS Members		
Name	**Organization**	**Role**
Nicholas L. Coussoule	**BlueCross BlueShield of Tennessee**	**Chair**
Sharon Arnold	**DHHS**	**Executive Staff Director**
Rebecca Hines	**NCHS**	**Executive Secretary**
Jamie Ferguson	Kaiser Permanente	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
Tammy Banks	Providence St. Joseph Health	Member
Margaret A. Skurka	Indiana University Northwest and Principal, MAS, Inc	Member
Melissa M. Goldstein	The George Washington University	Member
Valerie Watzlaf	University of Pittsburgh	Member
Richard W. Landen	Individual	Member
Vickie M. Mays	UCLA	Member
Wu Xu	University of Utah	Member
NCVHS Staff		
Name	**Organization**	**Role**
Maya Bernstein	ASPE/OSDP	Staff
Lorraine Doo	CMS	Staff
Rachel Seeger	HHS Office for Civil Rights	Staff
Marietta Squire	NCHS	Staff

Geneva Cashaw	NCHS	Staff
Presenters		
Name	**Organization**	**Role**
Brian Moyer	NCHS	Director
Sheryl Turney	ICAD	Co-Chair
Alix Goss	ICAD	Co-Chair
Mary G. Greene	CMS	Director, Office of Burden Reduction & Health Informatics

Welcome/Call to Order/Roll Call

Rebecca Hines: Good morning, and welcome to the fall meeting of the National Committee on Vital and Health Statistics. I hope everyone is staying safe and well.

My name is Rebecca Hines. I serve as executive secretary and designated federal officer for the Committee, and I want to extend a special thanks to our members here today, given this time we're living in. Many of you are doing double duty within your organizations, dealing with the pandemic, and one thing we're clear on, entering into this second and, some cases, third wave, is the significance of having good data and information on which to base decisions and operate in crisis mode. So we thank you for taking time out to serve on the committee.

Before starting rollcall, I want to take note that this is the first meeting with our incoming chair, Nick Coussoule. Nick has been with the committee since 2015, serving as co-chair of the Subcommittee on Standards during his first term, and Nick brings to the committee deep background in addressing implementation challenges of health IT, data management, data security. And many of you may not know this isn't the first time that Nick has provided strategic leadership to HHS; in his work in Tennessee BlueCross BlueShield, he provided leadership to HHS, leading a successful development and implementation site for the Federal Health Insurance Exchanges.

So we're so fortunate, Nick, you've agreed to take the baton to lead the committee, and today also is the first meeting for four of our newest members, Tammy Banks, Wu Xu, Valerie Watzlaf, and Jamie Ferguson. We look forward to hearing from you all this morning. A special warm welcome.

With that, let's take care of rollcall now, stating out with our new chair, Nick Coussoule.

Nick Coussoule: Thanks, Rebecca. Good morning. It's Nick Coussoule, Senior Vice President and Chief Information Officer for BlueCross BlueShield of Tennessee. Chairman of the Full Committee, member of the Privacy, Confidentiality, Security, and Standards Subcommittees, and I have no conflicts.

Rebecca Hines: We will go in alphabetical order from here. So starting off now with Deb.

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

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

Denise Love: Denise Love, independent consultant, member of the Full Committee, member of the Standards Subcommittee, member of the Privacy and Security Subcommittee, and I have no conflicts.

Frank Pasquale: Good morning. My name is Frank Pasquale, I work for Brooklyn Law School as a professor of law. I am a member of the Full Committee. I chair the Subcommittee on Privacy, Confidentiality and Security, and I have no conflicts.

Jim Cimino: Jim Cimino. I'm professor of medicine, director of the Informatics Institute, University of Alabama, Birmingham. I'm a member of the Full Committee and the Standards Subcommittee. I have no conflicts.

Jamie Ferguson: Good morning. I am Jamie Ferguson. I work for Kaiser Permanente. I'm a member of the Full Committee, and the Subcommittee on Standards, and I have no conflicts.

Margaret Skurka: I am Margaret Skurka, Professor Emerita from Indiana University, and owner of MAS Consulting. I am a member of the Full Committee. I'm a member of the Standards Subcommittee, and I have no conflicts.

Melissa Goldstein: Good morning. My name is Melissa Goldstein. I'm a professor at George Washington University. I'm a member of the Full Committee and a member of the Privacy and Confidentiality Subcommittee, and I have no conflicts.

Rich Landen: Good morning. Rich Landen. I am a member of the Full Committee, co-chair of the Subcommittee on Standards, member of the Executive Subcommittee. No conflicts.

Tammy Banks: Good morning. I am Tammy Banks, with Providence St. Joseph Health, member of the Full Committee. I'm on the Standards Subcommittee, and I have no conflicts.

Valerie Watzlaf: Good morning. I am Valerie Watzlaf. I work for the University of Pittsburgh, and I'm a member of the Full Committee, and I have no conflicts.

Vickie Mays: Good morning. I'm a Distinguished Professor at the University of California, Los Angeles. I'm a member of the Full Committee. I'm a member of the Privacy, Confidentiality, and Security Subcommittee, I'm on the Review Committee for Standards, and I have no conflicts.

Wu Xu: Good morning. I am Wu Xu. I am an adjunct professor with the University of Utah, and a member of the Full Committee, and have no conflicts.

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

Rebecca Hines: Let's move to our staff, beginning with our executive leader, Sharon Arnold.

Sharon Arnold: Good morning. This is Sharon Arnold, I'm the Executive Director and part of the Office of the Assistant Secretary for Planning and Evaluation. Thank you.

Maya Bernstein: This is Maya Bernstein. I am a senior advisor for privacy policy at ASPE, I work for Sharon. I'm the lead staff to her as the executive director, staff for the Subcommittee on Privacy, Confidentiality, and Security.

Lorraine Doo: Good morning. This is Lorraine Doo, with the Health Informatics and Interoperability Group at Centers for Medicare and Medicaid Services, and lead staff to the Standards Subcommittee.

Rachel Seeger: I am Rachel Seeger, I'm a senior advisor with the HHS Office for Civil Rights, and lead staff to the NCVHS Privacy, Confidentiality, and Security Subcommittee.

Rebecca Hines: Thank you. And behind the scenes, we have Marietta Squire and Geneva Cashaw. And before getting started, I think we have here with us, Brian Moyer, the new Center director at the National Center for Health Statistics, and he has a special introduction for us this morning.

Brian, are you here?

Brian Moyer: Yes, I am here. Thanks so much, Rebecca.

Good morning, everyone. I'm very pleased to be here this morning. I want to take just a moment to introduce Ms. Kiana Morris, who is on detail as the new NCHS director of our Office of Planning, Budget, and Legislation. Ms. Morris comes to us from CDC's Office of Science, where she serves as the associate director for policy. So I just want to welcome Kiana to NCHS, as well as welcome her to our meeting this morning.

Kiana Morris: Good morning, everyone. Thanks so much, Brian, for that warm welcome. Glad to be here and looking forward to this journey with all of you and being a resource as well, to you. As he said, in my home office, I am associate director for policy and risk management, and just recently started here in OPBL, serving as the acting director. Thank you.

Rebecca Hines: Thank you all. Nick, the floor is yours.

New Member Welcome

Nick Coussoule: Thanks, Rebecca. Welcome everybody. I'm going to walk you through the agenda, first. We've got a busy couple of days, so we appreciate your time and attention and all the committee members. The first thing we're going to do is go through a new member welcome. We have four new members that weren't here with us for the last meeting. So we're going to give them an opportunity to introduce themselves, kind of across the committee but also publicly. So we will cover that, and then we will get an update from Sharon Arnold in regards to an ASPE update.

And then Brian Moyer, who was just speaking a second ago, will give us an NCHS update. Then we'll have a work session where we'll go through current status and where we're at in the 14th report to Congress. I will lead that.

We'll take a break for lunch, and then we will have an update on the ICAD task force, the Intersection of Clinical and Administrative Data taskforce from HITAC, from the two co-chairs of that taskforce, Sheryl Turney and our own Alix Goss, at least formerly our own Alix Goss.

Then Mary Greene, who's a new director of the Office of Burden Reduction and Health Informatics will give us an update on that organization. Have a break, and then we'll wrap up this afternoon with Rich Landen, talking about the update from the Subcommittee on Standards, which includes findings in particular from the August hearing on the CAQH CORE operating rule request for federal adoption. We'll wrap up with public comments and adjourn for the day.

Tomorrow, we will get started at 11:30 a.m., with the standard rollcall and agenda review. We'll then have a session on the Privacy, Confidentiality, and Security Subcommittee. Frank will lead that effort, really to talk about the follow-up from the September 14 hearing that we conducted regarding security considerations for data collection and use during a public health emergency. Not that that's anywhere relevant at all today -- that's a little humor, just in case you were wondering.

We'll take a break, and then we'll have a follow-up on the Subcommittee on Standards, again, in regards to the recommendations specifically in regards to the follow-up from the hearing at CAQH CORE's request for update. We'll have public comments, and then we will finish up with sort of a roundtable discussion on our work plan. This effort is really geared toward creating some visibility into potential topics that we will undertake, what's either on our work plan or things that we may want to undertake, so it's a little more of a roundtable discussion from the members to input on things that we believe are relevant.

Obviously, we take lots of guidance from our federal partners in this, but also we want feedback from the members in regards to things that we believe over the next few years will be important for us to undertake across the industry and ecosystem.

The next two meetings are scheduled already, coming up in this fiscal year, but in 2021, the end of March and early September, as you see below.

So that's our agenda for the day. Are there any general questions from the membership in regards to the agenda?

(No response.)

Excellent. So then I wanted to do some new member welcome. Let me start first, I do want to cover one other brief topic. We have new members, but that also generally means we have members that are no longer with us. I know Sharon did a really nice job at our last meeting talking about the outgoing members. I wanted to reiterate that. We have three members who rolled off because they were term limited, and so they rolled off after a long and excellent service to the committee. One is Lee Cornelius, University of Georgia. Personally, I really enjoyed Lee's insight and almost more especially his sense of humor, which helped keep us on track and tossed in some great idea throughout all the work efforts, even when he wasn't involved in the subcommittee work, he's always very engaged.

Secondly, with Alix Goss, who although she is no longer with the committee, we're not going to let her go permanently. She's even coming back today. But Alix was really a workhorse, as Rebecca indicated, I was cochair of the Standards Subcommittee for the first few years I was here, and partnered up with Alix, and in that I learned an enormous amount from her. She's been very helpful across the work of the committee over the last certainly five years, I know, that I've been here.

And then finally, our illustrious former chair Bill Stead, who actually I think really helped us get a little more discipline with some of the things that we were doing, and put out an enormous volume of work over the last few years. I'm personally indebted to Bill's service and guidance, and hope you all will also go with me and recognize the contributions these three folks have made to the committee over the last eight or so years.

In regards to the new member welcome, I just wanted to do a little bit of an introduction for myself as well. I think Rebecca did a more than generous job of giving you my background. I am honored to be given the opportunity to lead the committee. This is, again, as I've watched the two different chairs since I've been a member of the committee for the last five or so years, I hope I can do an adequate job of supporting the members and our work effort to provide advice and consent to the Secretary, as well as being a good guide for industry input and feedback.

A lot of really good work done over the last five years, as I indicated, and I really want to try to continue that. As I said, I have been on the committee since 2015, so I'm in my second term now. And I've been not only part of the Standards committee but also part of the PCS Subcommittee -- Privacy, Confidentiality and Security -- for the last five years, as well. So hopefully I've got a little bit of insight into what's happening around the committee, and will try to guide that work over the next couple of years during my tenure, as long you all will have me.

With that said, I want to give each of the new members an opportunity to introduce themselves. We've asked them to do this to give us a little bit of an insight into their background, area of expertise, what they're particularly enthusiastic about, so you can also get a flavor for the new members that we have. We have an incredibly diverse group of really smart and accomplished people, so I think it's useful to hear from the new members directly in regards to their own perspective.

So I will start with Tammy Banks. Tammy, if you can tell us a bit about yourself, and your intro to the committee.

Tammy Banks: Thank you, Nick. You asked me to share my past experience, and really my aspirations for my tenure. As a long-term contributor and presenter at NCVHS on behalf of organizations that include the American Medical Association, Optum, Cooperative Exchange, and Healthcare Administrative Technology Association, I really appreciate and recognize the crucial role of NCVHS as the national forum to bring key stakeholders together to collaborate on health data issues, and I'm honored to be a member of the esteemed committee.

I've served over 20 years in three medical associations, including the American Medical Association, really focused on setting and implementing strategies to promote fair payment, efficient practice management, industry certification in the private sector, serving as a representative at X12 and other organizations, my focus was to advance the exchange of complete administrative and clinical data in the fee-for-service world. This allowed obviously for the secure exchange of billing and medical information between payer, providers, and the consumer, to reduce unnecessary administrative burden and hassles experienced by all of the stakeholders, and I have to continue to really reiterate the impact on the patients.

In my current role as the vice president Medicare Strategy for the Medicare Value-based Care Programs for Providence St. Joseph Health, the transition from the fee-for-service world to alternative payment models is a reality. At Providence, our value-based care portfolio currently includes more than 130 agreements with between 50 to 60 payers that cover about 1.5 million lives. And these agreement include both government, Medicare, Medicaid, and commercial payers. So I see there's considerable

opportunity to replace this manual work that's currently undertaken every day by providers participating in value-based care agreements.

While our agreements are increasing by a significant proportion across our lines of business, the variability in manual effort to access information across APMs really impose significant administrative burden.

I really look forward to adding this perspective to the predictability roadmap as interoperability issues addressing standards that are critical to meet the value-based care needs for scalabilities. And I'd be remiss if I didn't quickly mention how the impact of COVID-19 has heightened our awareness of the need for population health to be able to readily identify and help provide needed care for our nation's most vulnerable populations.

I look forward to the conversation to digitize the standard reporting of pandemic health emergencies including vaccine data to state and federal agencies as well as other organizations, utilizing current standards in a secure manner that preserves each individual's privacy and right to opt out as well as offset the current manual efforts to upload data into web portals or standardized terminology to remove the need to manually populate data to account for different definitions for the same data point.

More importantly, the digitizing and standardizing reporting increases the accuracy of this vital data that is relied upon by public health decision, including identification and prevention of health inequalities.

In addition to NCVHS, I also serve on ONC's FAST Coordinating Committee, the Certification & Testing Tiger Team, and the Da Vinci Operating Committee these groups are building the infrastructure for semantic interoperability. I hold a master's degree in business with a quantitative emphasis from Roosevelt University and am a Fellow, American College of Medical Practice Executive (FACMPE) through the Medical Group Management Association (MGMA) certification program.

I look forward to working with and alongside all of you. Ultimately, we must all work together to make healthcare more digitized, affordable and patient-centered, which in turn will provide the population of the United States and its territories with affordable patient-centered healthcare. Again, I really thank you for the opportunity to serve in this role.

Nick Coussoule: Thank you, Tammy. Much appreciated with that. Next, we'll go to Wu.

Wu Xu: Good morning. I am honored to have the opportunity to serve on the committee. I'm a retired state public health informatics officer. Since my retirement, I'm an active member in the Utah Citizens' Council. I coordinate the health committee for that council. That is a voluntary policy advocacy group, a bunch of retired state, senior state, and local officials, and emeritus professors in that committee.

Before my retirement, I have worked in the state of Utah Department of Health for 25 years. I want to use this opportunity to thank Denise Love. She hired me 27 years ago, introduced me into the public health field. So I worked from the hands-on manager, hospital discharge database, to end as a director for the state Center for Health Data and the Informatics. In my last five years career, I'm one of the state department of health executive leadership team, and also I oversee the statewide health data and the informatics coordination work.

I also served as a state health IT coordinator, working with ONC and other federal agencies. I represent in the state, serve on the state HIE, that's Utah health information network, the board of directors, and also am the Association of State and Territory Health Officials and informatics policy committee member.

So over those years, I have worked with researchers and university colleagues on many different public health informatics innovative grants. I'm on the public health informatics fellowship training program, have several postdoc trainees working with me, so this made me have three department appointments as adjunct faculty with the University of Utah.

My area of expertise is state data policy, and the public health data integration and system interoperability, population health assessment and reporting. So I'm basically a state data person, and very happy to be able to combine the state perspective with a national federal perspective to enhance the health data and informatics in the field.

In terms of what I am enthusiastic about to serve on the committee, I'm still learning how the scope of the work for the committee and how you set up priorities and the projects. But personally, I really want to share two ideas I feel is really needed from my working background, and I think maybe able to do for us.

First, from a policy perspective, I'm interested in working on data sharing policy for states to share data with the federal agencies, researchers, health systems, and others, so we need to have an efficient and protected guided practice to have this data sharing in the nation. Currently it's a very diverse policy in the state data governance.

Second, from a population health perspective, I'm interested in helping the state health departments with federal agencies and the fundings to enhance the population data capacity building. So we can prioritize what data sorts are most important for population data, but just give an example, I do think the all payer claims database has very important, very valuable and promising, so if we can help develop, the all states can develop and use and share data, with the needed partners, we can make contribution.

So that's my personal thoughts. But I'm willing and ready to work on any committee assignments. That's all for me.

Nick Coussoule: That's great, Wu. Thank you very much.

Next, Valerie, please.

Valerie Watzlaf: Thank you, and good morning, everyone. I am so honored to be a member of the full committee, and just to give you a little background about myself, I am an associate professor and vice chair of education in the Department of Health Information Management in the School of Health and Rehabilitation Sciences at the University of Pittsburgh. And I also have a secondary appointment in the Graduate School of Public Health, also at Pitt. In those capacities, I've been there for over 35 years, I am involved very much in the teaching, research, and community service, so I just wanted to mention a few of the areas that I teach in and do research.

My teaching is primarily in what my background is in, which is in health information management and epidemiology. My master's and doctorate in epidemiology. I teach in the areas of statistics and epidemiology, quality management, research methods, and privacy and security. Also, my research areas have been in a few different areas; probably the most recent included what I did, what we did as a team, looking at clinical classification systems and really looking at the change going from ICD-9 to ICD-10. We did focus groups with healthcare providers, primarily physicians, to examine their concerns and some issues they have as they moved from ICD-9 to 10. And then we also did some research looking at productivity and workflow, and how that changed when we moved from ICD-9 to 10, and what we were able to do there was actually build some predictive models that healthcare providers could even use as we looked at coding productivity and workflow.

I was also very honored to be chosen to sit on the ICD-11 expert roundtable that was held here last year, and contribute there, as well. Another area of my research is involved in looking at telehealth privacy and security, and we've been looking at this for probably the last 10 years. What we did here is we built privacy and security checklists that providers could use to assess the different systems that they wanted to use to make sure that they were compliant in relation to privacy and security. At the same time, of course, we wanted them to be able to certainly use these systems, but of course also just take a look and make sure that they are compliant in privacy and security.

And then the other area that I was involved in with our research is something called the Neighborhood Resilience Project, and this is a project that we are doing right here in Pittsburgh, but it is expanding into other areas of the country. What we did there is we built an app called I Am Healthy, that was used to collect data from the community in relation to health and wellness and in trauma assessments, as well. We weren't the only ones that looked at this data. We provided it back. The results certainly went back to the community so they can see how they fared across different community groups, so we were very excited about that work.

In 2019, I was the AHIMA president. That's the American Health Information Management Association, and we serve over 100,000 health members that focus on health information management. I am finishing up my third year there, and I'll end at the end of this year, and one of the things I was very pleased to be a part of during my presidency was that we did build a new mission vision and a strategic plan for the association, so I was very pleased about that.

As far as -- I'm so enthusiastic about all the areas that the committee is involved in. But as far as what I think I can contribute the most is probably in relation to our change going from ICD-10 now to 11. I think based on the research that we have done in the past that I could certainly help in focusing on the research we need to do as we move forward with this change. And also around the education and training.

The other area I'm very passionate about and feel that I could assist with is when we look at new and emerging technologies. And making sure that we still move ahead and use them, but we also have a focus on privacy and security around them.

So, again, I'm very honored and pleased to be here, and I'm excited to move ahead and work with everyone here on the committee. Thank you.

Nick Coussoule: Thanks, Valerie.

And last, but not least, new member Jamie.

Jamie Ferguson: Hi, good morning everybody. I'm Jamie Ferguson. I'm actually thrilled and thankful to be here with you today and to serve on the committee. I've been the vice president of health IT strategy and policy at Kaiser Permanente for the last 18 years. I have a variety of experience that I think might be relevant to the committee.

I have had three previous federal advisory appointments. I was on the board of the pre-HITAC act health information technology standards panel. I also served on the HHS health IT standards committee, and health IT policy committee. And all of those positions included a variety of subcommittee roles.

Currently, I also serve on the board of Sequoia, which is the recognized coordinating entity for the trusted exchange framework and common agreement of the 21st Century Cures Act. I have some standards organization experience. I currently am a director on the board of ANSI, the American National Standards Institute, and I have previous board positions with WEDI and HL7, and I'm the past chairman of the board of SNOMED International.

Some other health IT policy experience of mine includes privacy policy, also security, interoperability, and artificial intelligence policy with industry groups. Those are -- I'm trying to remember them all -- but the Confidentiality Coalition, the Healthcare Leadership Council, the American Hospital Association, America's Health Insurance Plans, the Institute for Health Policy, and the Care Connectivity Consortium. I think this kind of experience will help me contribute to the work of the committee on some of the current challenges, such as clinical business integration, HIPAA rulemaking, and interoperability.

But in my mind, perhaps the most important thing is to look forward at how the committee may be able to address additional current and future problems, and these are really different, I think, from the problems of the past, so I'll highlight two areas that are particularly interesting for me. The first future area is, I believe, we have to address the combined functioning of information infrastructure for public health, social services, and community services, long-term care, and the safety net, along with the needs of hospitals and physicians for care coordination, population care, and value-based financing.

I think one important aspect of this broader coordination of information infrastructure will have to be integration of the semantic standards for terminology and coding across these very different service areas. Information coordination also will require coordination of the privacy and security policies for different kinds of entities that are serving individuals with very diverse needs and preferences.

The second future area for me to mention is a focus area on artificial intelligence. Over my term on the committee, I believe the department's focus on data sharing, interoperability, and standardizing health records will have to decrease relative to an increase in the focus on artificial intelligence. I really hope the committee considers its potential role to advise the Secretary on policies for artificial intelligence in healthcare.

The cost of healthcare can only be managed with a material increase in automation, and automation is based on AI. Automation frequently can be used to capture or to generate or analyze vital health information. Automation can assist consumers or clinicians in health decision-making, but it also has the potential to completely eliminate many administrative or repetitive tasks in the healthcare ecosystem.

I believe trust in autonomous and intelligence systems is going to be of paramount importance. Trusted systems can only come from trusted data, data with traceable provenance, data that's managed under trusted privacy and cybersecurity policies, specific to AI. And trusted AI also will need policies to govern it using objective measures of bias or the disparate impact of the AI.

So trusted AI also will need national policies for transparency and explainability. Building all of this trust will require a broad national framework of standards, measures, rules, and policies for artificial intelligence in healthcare. So I believe the committee can play an important role, an assistive, supportive, and coordinating role, in this future focus area on AI.

Thank you.

Nick Coussoule: Thank you, Jamie.

And thank you and again, welcome to the new members. I think you all will realize from the four individuals the kinds of expertise and background that we have now on the committee to hopefully advance lots of these challenges that they've mentioned, including other ones that they haven't mentioned. We very much welcome them to the committee. They've hit the ground running already, and in any case, this is just their full committee meeting, so I don't want to give the impression that they haven't already been fully engaged in a number of the initiatives that we have going on.

Next up, I'd like to introduce Sharon Arnold, to give us an ASPE update. As Sharon indicated before, she's our executive staff director. She's assistant deputy secretary of science and data policy in ASPE.

Sharon, I'll turn it over to you.

ASPE Update

Sharon Arnold: Thank you very much, Nick.

First off, I want to welcome you as chair of the committee and thank you for your willingness to step up and certainly acknowledge your leadership of the committee these past few years. We all look forward to working with you in this new role.

I also want to welcome the new committee members to their first official committee meeting, recognizing that you've all been very engaged over the last few weeks, months. Tammy, Jamie, Valerie, and Wu, we're grateful for your willingness to serve and for the expertise you bring to the committee's deliberations. We hope you find it a challenging and rewarding professional experience.

As you may be aware, the department is still working, but almost entirely teleworking, due to the pandemic. We continue to be open and running, even though we are all not necessarily in the office.

We're currently operating on a continuing resolution, until the Congress can pass a formal budget. The current CR expires on Friday, December 11.

We've submitted the department's FY22 budget to OMB in September. What usually happens is in the case of a change in administration, the outgoing President's team prepares a modified and simpler budget as the transmission of the budget to the Congress traditionally on the first Monday in February, which is shortly after the inauguration.

We have two public health emergencies in effect that are still ongoing. Secretary Azar renewed the one related to the opioids crisis, effective October 10, which expires January 7, 2021. He also renewed the one related to COVID-19 on October 22, and that one expires on January 20, 2021. We expect both of these declarations will continue to be renewed for the maximum 90 days.

There are three other public health emergencies that are currently in effect. One is associated with the wildfires in California that expires late next week. One is associated with Hurricane Laura, that also expires next week. And one is associated with the wildfires in Oregon, that expires early next month. We do not expect any of these to be renewed.

I couldn't possibly summarize all that has happened since June regarding COVID, so I'll just highlight a few particular milestones. At the beginning of October, the department announced the rollout of shipping 100 million rapid diagnostic tests to states through a public-private partnership. We're encouraging governors to use them in places like K-12 schools, supporting critical infrastructure and first responders, and screening or surveillance in congregate settings like group homes or certain workplaces.

HHS and the Department of Defense announced a $481 million contract with a biotech startup called Cue to support their production of a point-of-care test that provides results with similar accuracy to traditional lab-based tests, in just 20 minutes. You may have heard how Cue provided the tests that the NBA used to play their season safely this year. This contract will enable Cue to produce as many as 100,000 tests a day by March 2021, and the federal government is committed to buying 6 million tests and 30,000 instruments in the coming months.

HHS has announced a partnership with CVS and Walgreens to deliver and administer safe and effective COVID-19 vaccines to one of the most important populations for vaccination, older people and long-term care facilities. This includes folks in nursing homes and assisted living facilities.

Over the summer, the department launched an effort to create a next-generation strategic national stockpile, or SNS 2.0, to address many of the challenges we saw in the early days of the pandemic. This SNS 2.0 aims to cover a much broader range of medical products that may be needed in the event of a crisis, to provide deeper reserves of medical supplies, and to provide full visibility into the supply chain so we can know where shipments are needed and support manufacturing of these products here in the United States.

As you probably know, we continue to face rising COVID-19 case counts and hospitalizations in most parts of the country, which is why we need to double down on the effective public health measures that can keep us and our communities safe. These include washing our hands, watching our distance,

wearing face masks, and avoiding settings where we can't do these things. The department is working to get that message out as we approach the holidays.

We did have some good news recently. Pfizer reported its vaccine candidate, one of those supported by Operation Warp Speed, may be more than 90 percent effective. If this product receives authorization or approval from our colleagues at the FDA, HHS is guaranteed access to 100 million doses, that we've purchased for $1.95 billion, with an option for another 500 million doses. If the FDA gives the green light, U.S. distribution of the vaccine could start in increments of about 20 million doses per month.

That news was followed by similar news on Monday from the Moderna trials, the second vaccine to show the potential for very high efficacy in phase III trials. Operation Warp Speed has provided about $2 billion in funding and operational support for the development, manufacturing, and eventual potential delivery of the Moderna NIH vaccine. Secretary Azar said on Monday that this is an incredible tribute to American scientists and innovators and one more reminder that there is light at the end of the tunnel.

In other major news, the Department has been designated sector-specific agency for coordination of cybersecurity in the health sector. At the end of October multiple U.S. hospital systems were forced to use standby procedures after suspected or confirmed ransomware attacks on their information systems. The cyberattack has forced hospitals to revert to paper records, creating heightened workloads for healthcare employees and potentially affecting patient care. The attacks also affected some non-hospital county local governments. The government continues to assist these healthcare systems through a period of increased precaution and heightened cybersecurity.

In October, Dr. Harvey Alter, an intramural researcher at NIH, and two scientific colleagues, one an NIH grantee, were awarded the 2020 Nobel Prize in physiology or medicine for contributions to the discovery of the hep C virus. And Dr. Emanuelle Charpentier and Dr. Jennifer Doudna received the 2020 Nobel Prize in chemistry for their work in gene technology, and the discovery of CRISPR. They are both NIH grantees, and they are also the first women to share a Nobel Prize in chemistry.

The department continues to push out data and information through its Public Affairs Office. It's very important now to have accurate, timely release of information. Since our last meeting, the department has issued a number of different types of guidances. For example, CMS has issued guidance on mental health and coping during the pandemic, and on important flu information such as preventing measures, including getting the flu shot and safety tips for the upcoming holiday celebrations.

The Office of Civil Rights has settled multiple enforcement actions under its HIPAA right-of-access initiative, and they've announced this initiative as an enforcement priority in 2019 to support individuals' right to timely access to their health records at a reasonable cost under the HIPAA privacy rule. OCR also issued guidance on civil rights protections prohibiting race, color, and national origin discrimination during COVID.

OCR also issued guidance on the donation of convalescent plasma allowing covered entities, including providers and plans, to contact their beneficiaries who have recovered from COVID-19, to inform them

about how they can donate their plasma to help treat others. OCR resolved two religious discrimination complaints, ensuring clergy access to patients for religious purposes during the pandemic.

In September, CMS issued guidance on safe visitation in nursing homes. They've also updated their COVID-19 testing methodology for nursing homes, and they've announced that Medicare beneficiaries can receive coverage of monoclonal antibodies to treat coronavirus disease, with no cost sharing during the public health emergency.

And then yesterday, the department issued a final rule as part of a new department-wide regulatory cleanup initiative, the first of its kind using artificial intelligence and natural language processing technologies. Under this initiative, HHS was able to run an automated process that identified specific locations in the Code of Federal Regulations that warrant corrections, such as those with incorrect citations and outdated regulations that have gone unnoticed. The new rule provides for the correction of nearly 100 citations, the removal of erroneous language, and correction of misspellings and typographical errors, which comprise approximately 185,000 pages of the CFR, so a pretty significant amount of rulemaking.

This novel approach to regulatory reform will not only accelerate and augment subject-matter expert review of federal regulations but save employees valuable time and provide a pathway for future innovation. We're really excited about these activities.

Within ASPE, under the CURES Act, the Secretary has the authority to waive the requirements of the Paperwork Reduction Act for voluntary collection of information during the public health emergency, as declared by the Secretary, or when a disease or disorder is significantly likely to become a public health emergency. ASPE is responsible for managing this process, which allows data collection efforts for the specific preparation for and response to a public health emergency to avoid the lengthy public comment and review process associated with obtaining information from the public. Since January, we have processed 18 such waivers related to the coronavirus pandemic, and two related to the opioid emergency.

Within ASPE, we continue to work on implementation of the Foundations for Evidence-Based Policymaking Act, in coordination with our partners throughout the department. We have ongoing work on evidence act implementation; we've submitted our required evidence and evaluation plan to OMB in September; we're meeting regularly with CIO and CDO office to coordinate work with them. We have not yet received Title II guidance from the Office of Management and Budget, although we have seen a draft on which many agencies commented, so we expect that OMB is still working on this, and we hope to receive that guidance shortly. Title II is the section of the evidence act on making data available to the public.

The Title III guidance that reauthorizes CIPSEA and allows statistical agencies to request administrative data seems to be delayed, as well, and I'm sure Brian will talk about that. We haven't seen a draft of that yet.

I want to thank you for your attention, and I'm happy to take any questions at this point, if anybody has questions for me.

Nick Coussoule: Thank you, Sharon. It's good to know that there's not too much going on in your world.

(Laughter.)

Questions from the members, please? While they're thinking or queueing up, Sharon, one from me. I was being a little facetious; obviously, lots of different things going on. Given some of those activities and the challenges that you see, are there any particular areas that you went through that you believe NCVHS could be a big part of to start that process over the next year or so?

Sharon Arnold: I think that, as we've discussed, I think one of the really important things that we could use some guidance on is there's a lot of information that's been collected and aggregated as part of the pandemic, and obviously, in a public health emergency, we sometimes relax some of the privacy and security requirements because we need to act expeditiously, but I think that this committee will be in a really good position to think about what we do with this data going forward and how we think about applying the appropriate privacy and security approaches to this data, going forward. So that's definitely one area that I would like to see this committee work on.

I think we're potentially in a time of transition, and we'll be looking to see what the new priorities are in a potential new administration, and so I think that there may be some additional areas that we identify in the next couple of months. But that is the one that I'm really focused on right now.

Nick Coussoule: That's great. We very much appreciate the update and the insight. Any other questions from members?

Rebecca Hines: You've got Vickie, and then Denise Love.

Vickie Mays: Thanks, Rebecca. Sharon, I have two questions. This first one may be for you or may be for Brian, I'm not sure, but in the Heroes Act, what happened is that there was money put in for modernization of systems, and the modernization was specifically geared to make sure that we would have both the population side data, connected with the clinical data, so that you had test data and other data there, and it was designed to make sure that we were going from the state up be able to get better data on race and ethnicity. So I know it took a while to kind of get that down to NCHS. Do you know anything about the status of that?

And then my second question has to do with whether or not HHS is in a planning stage about not the vaccine, but as the new administration is talking about, getting people vaccinated. So we can put things in CVS, Walmart and community areas, but if we don't have those trusted sources -- whether or not the HHS is thinking about pushing out maybe the community sources, we have a great model in terms of ACA, community groups usually were the ones that went out and talked up the value and then got people to sign up. So those are my two questions.

Sharon Arnold: That first question I am going to defer to Brian Moyer, and he's up next, I believe.

The second question is, yes, there are a lot of people, particularly at CDC, who are thinking very hard about how to actually deliver the vaccine and about public messaging about vaccines. So that is a very active area of thought and planning.

Denise Love: Vickie, you read my mind. My questions were very similar, so I'll take it a step further and Sharon, thank you for the update. And my question also may be more directed to Dr. Moyer, as well, but aside from even vaccine distribution and administration, I sense that this committee might be able to provide input as far as the tracking of the outcomes. What happens after the vaccine is given? I think states with all payer claims databases can capture some of this, and Medicare fee-for-service surely can capture some of the populations that actually get the vaccine, but how are the outcomes down the road, and how are those populations faring? We won't necessarily capture CVS and workplace vaccines, so my sense is there needs to be an integrated, more data platform, to bring all of these pieces together, because there's nothing right now. There's little pieces of vaccination data all over our public health system, and sometimes not anywhere.

Maybe modernization is a key to answering some of these questions, or some of those investments. So Vickie, my question was similar to yours, but then the follow-through, long after the vaccination, how do we track and monitor?

Sharon Arnold: I know that there are folks that are very focused on tracking populations that get vaccines with a very potentially complicated delivery of different vaccines, two doses required, different timeframes between the doses. I think there needs to be a lot of data about the population, linked with who's getting it, and whether they've gotten their second dose, et cetera, and I think people are thinking about follow-up for that. Those thoughts are in the early, relatively early stages yet. I don't think there are final decisions about linking data and reporting.

But I will kind of circle back with the folks that are doing the planning for vaccine distribution and kind of monitor to see whether they think that this committee could be helpful. I think it's on a fast track, and so I want to make sure that, to the extent that this committee thinks about that and helps about it, it's helpful in terms of timing and input to the folks that are doing that work. So I will circle back.

Denise Love: Thank you. And I think also this is an opportunity for maybe public-private investments. I know there's some foundations who were in this space, and I think a coordinated investment response might be warranted, so we aren't moving on double tracks, and that's all I'll say about that. Thank you.

Sharon Arnold: That is a great point. And if there are any other questions, you all certainly know how to find me, and so happy to talk with you at any point, if you have additional questions or just to say hello. Thank you very much.

Nick Coussoule: Thank you, Sharon. Appreciate your engagement. All right. Next up on our list, Rebecca, did you want to introduce Brian?

Rebecca Hines: Sure. Brian has already said hello this morning, but I just want to emphasize he's a relatively still-new director for the National Center for Health Statistics. We are overjoyed with Brian's leadership already in engaging with CDC Atlanta around data modernization and strategic planning, and Brian, I will leave it there for you to give us your update.

NCHS Update

Brian Moyer: Alright. Thank you, Rebecca, and thank you, Nick. Nick, welcome to your new position. Good morning, everyone, once again. And I also want to express my appreciation to the new members joining the committee. Thank you for your service.

What I'm going to do today is give you a brief update on a variety of things going on at NCHS, and what I try to do in this quick talk is mix in a few areas where I think the committee could potentially contribute to some of the challenges that we face. I guess one of my goals going forward is to perhaps engage this committee a little bit more in NCHS work, so I would really value your thoughts as we go forward around where you see your talents fitting into the needs of NCHS.

At our last meeting, I mentioned some of my broad objectives for building a modern NCHS, and I just want to recap those, take a few minutes to recap those here. I think I said last time that we are really are in a unique time. There are many that say we are in the middle of a data revolution, and I think for an agency like NCHS, a statistical agency, there are so many forces that are converging all at once, and fundamentally changing that paradigm in which we operate.

We talked a little bit about the ongoing data modernization efforts that we have at CDC. We've also talked about the Evidence-Based Policymaking Act that's laying out new requirements for data sharing, linking, and privacy. And then we have that federal data strategy, that's asking us to take a hard look at our data lifecycle and to identify the skills gaps that need to be closed in order to make the most of our data assets.

So this sort of asks the question then, what does all this mean for NCHS? To me, what it means is we need to provide more timely, relevant, and detailed data for evidence-building and policymaking, and what that means in turn is that we need to be much more aggressive at harnessing new data sources. So, going out and harnessing things like big data, more administrative data, more private sector data. EHRs were already mentioned this morning. And the associated platforms associated with processing those data, whether that be AI or ML, or others.

I think what it also means is that we need to step up our statistical analysis and better connect NCHS data across the center, across all of HHS, and frankly, across the rest of the government, and in doing this I think we need to take an interdisciplinary, a more interdisciplinary, approach to data linking.

What's challenging, if all that isn't a tall enough order, we have to do this with a staff that is in some cases well-equipped, and in other cases we need to build greater capacity. So we need to continue to train, to build, empower our workforce, with the skills they need to make all of this happen.

To move that rather ambitious agenda that I just described forward, at NCHS we've embarked on a strategic planning process. We've identified a number of projects, case studies, if you will, to get some experience, to learn and to build some momentum around modernization. For example, we are evaluating and deploying data science methods more broadly across the center. We're improving data interoperability by focusing on central systems with common metadata, and we're working to improve remote access to protected data by both staff as well as researchers who want to use our data.

In all of this, a lot of what we're trying to do, I like to refer to it basically as breaking down silos. Like any organization, these silos develop over time, and what we want to do is see how we can better operate

across those in a more efficient way. The process is both a bottom-up and a top-down effort, and so we want to make sure that we have communicated to staff all the priorities that I just mentioned, but we also want to make sure that we've got buy-in and good feedback from the staff level up, that will influence these top-line objectives as well.

We're focused on programmatic goals, many of which I just described, but we're also focused on operational goals. How can NCHS work better together as a team? How can we do things in a more efficient and more cohesive way? Of course, one of the most important things about any kind of strategic planning process is to get stakeholder feedback, and here comes an ask for you guys. To the extent that you see an opportunity, you see something that relates to one of these objectives, one of these goals that I just described, that you think would be particularly worth emphasizing, putting a spotlight on, I'd love to hear that. We'd love to hear about that. So we want to incorporate your feedback, your thoughts, into this entire strategic planning process, as it moves forward.

Sharon spent a bit of time on the Evidence-Based Policymaking Act, and I think that I'd like to spend a little bit of time here as well, because I really do think that over the last several months, this entire effort has really heated up much more so than it has up to this point. I'm really impressed at the number of new committees that have been stood up, various workgroups that have been stood up, and the various work agendas that are starting to flow from those various committees and workgroups.

As Sharon said, OMB is now in the process of issuing implementation guidance. This is something we've waited a while for, but it is something that is starting to flow from OMB now. We've got draft guidance for Title II, and I can say, as a statistical official, we are starting to think about Title III guidance as well. As Sharon mentioned a moment ago, this Title III guidance is really focused around probably one of the toughest things in the Evidence Act, and that is figuring out how we implement this notion of presumption of accessibility, which means a statistical unit within a department can ask others to provide data for the purposes of evidence-building and policymaking. And when you're talking about data that have privacy concerns, confidentiality concerns, this can really be quite a challenge trying to figure out how we make this happen.

Nevertheless, this guidance is underway at OMB, and I'm really happy to be part of the discussions in terms of moving that forward. I'd like to hit on two things around the Evidence Act that I think would be of interest to you all and may spark some future efforts. First, the way that these various workgroups and committees that I just described are working, their M.O., if you will, is really the case studies. So there's lots of case studies being stood up around data sharing, data linking, and data privacy. And I think that it is vital that NCHS be at the table and contributing to these case studies. That's how we're going to learn.

So we've already been asked to engage in case studies around -- I'll just give you some examples -- for expanded use of EHRs, something we talked about just a second ago. We've also been asked to participate in case studies around better sharing cross-government data, or making those data more interoperable for key policymaking issues. So for example, around the opioid crisis. And then we've also been asked to engage in case studies that look at privacy concerns. In particular, we've been asked to think about how we might be using differential privacy platforms as part of greater data sharing and data interoperability, and just general better connecting data across the government.

As I said, my plan is to engage NCHS as much as possible, as much as feasible within resource constraints, to do this, to participate in these case studies, and I really would welcome your thoughts, your willingness to perhaps jump on board some of these potential studies. I know I've talked to our own board of scientific counselors, and they are also very interested in being part of these case studies. So, again, I extend that invitation to you as well.

The second thing around the Evidence-Based Policymaking Act that I want to highlight, that I think might be of interest to you is this notion of a portal for improved access to data. There's a cross-government workgroup coming out of OMB that's looking at how we can set in place a single application process, or it's sometimes called a portal, and this is part of the Evidence Act, so this notion is included as a requirement in the Evidence Act. But what it does is provide easier access, especially for researchers, to data across the statistical system.

Right now, as you know, if a researcher wants to gain access to protected data, what you basically have to do is you have to apply through the research data network, put an application in for all of the various agencies from which you want to receive data, and that process can be very complicated, very cumbersome, and very long. What this new approach, this portal, is trying to do is basically create a single portal with the intent to simplify this entire chain of events. So you basically put in one application, and all of the agencies -- for all of the data that you want -- and all of the agencies that would be providing those data, would think about, would consider that application, at one point in time, and then return a decision to the researcher.

Maybe it sounds straightforward, but it's actually turned out to be quite a complicated thing to get some traction on, not surprisingly. You can just think of all the various legal requirements across the various departments, all the different data, levels of data, privacy, confidentiality, and so on. But I will say that we are making good progress on this. We are moving forward. And I think this is something that we're going to see come to fruition in the not-too-distant future. And again I think this would benefit probably many here on the committee, and again, I welcome any feedback that you might have on that process. Also, your experiences in the past, what's worked, and what hasn't worked, with the current system that we can work into this new initiative.

I believe, at our last meeting, Paul Sutton, from NCHS's vitals group, came and spoke a bit about our mortality data, so I'm not going to repeat all the technical information here. I'm sure many of you have, are looking at these data on a regular basis, using them in your work. But what I really want to do is just to emphasize that NCHS in my opinion really has stepped up the timeliness, the detail, the quality of the data that are coming out of our vitals group.

What I want to spend a few minutes focusing on here is the one issue that does remain around these data, and that is how we best communicate about some of the more technical aspects of the data. Over the last several months, you've all read the newspaper headlines, you've seen where there's been some confusion around some of the NCHS data. The 6 percent example stands out, I'm sure you all are familiar with that.

There are challenges, there are always challenges communicating very technical concepts to diverse audiences, and I really think that one of the things we need to do a deeper dive into is how we best

approach communications and what are the best vehicles we can use? Is it a simple FAQ? Is it one-pagers? Perhaps more data visualizations? Targeting specific groups or doing special briefings might be a way of also doing that.

I think we've tried a shotgun approach at NCHS to better communicate, not just our mortality data, but other areas as well. And I think it's worked somewhat. I won't say it's been entirely successful. And I'd love to get your feedback on how we could do this in more efficient way.

As many of you know I come from the world of economic statistics, and this was certainly a challenge there as well, and if I learned one thing out of that adventure it was that there is no silver bullet. You just have to take each program, each set of data, and think about what your audience is and how to best target audience. But as I said, I would certainly welcome your input around improving communications, again, around the mortality data, but around even a broader set of NCHS products.

I do want to spend a moment on the Household Pulse Survey. The reason I want to do this is because I guess I'm very proud, I guess is the right word, to say that this is probably one of the most significant accomplishments of the U.S. statistical system in recent decades. For those of you that aren't familiar with this Household Pulse Survey, this is a cross-government effort to collect real-time data on the current pandemic. Seven agencies came together to identify questions and to field a web-based survey that covers a variety of aspects. So it covers economic, social, and health indicators.

For NCHS, we focused on things like mental health, access to medical care, insurance coverage, unmet healthcare needs, and a few other items. We've really been able to work closely with our partners across government, get these data collected quickly, get them processed quickly, and get them disseminated quickly. This is probably, as I said a moment ago, like no other effort in my time with the statistical system. So I think this is a major, major accomplishment.

I think it's not only a great accomplishment for getting more information around the current COVID experience, but I think it's a great example of where the statistical system should be headed. I think this idea of supplementing our core surveys, in the case of NCHS we're primarily talking about the National Health Interview Survey, but supplementing those kind of surveys with these kinds of additional data, sort of this more current tail, if you will, is really an important and innovative way of making the NCHS data products more relevant, and so the question we're asking ourselves now is, you know, how can we take things like the Pulse survey and connect them to the HIS, for example. How can we benchmark Pulse to HIS? How can we make adjustments to the various imputations that we would make to the Pulse survey to get levels in line and to think about creating that tail that I just mentioned?

My take is, you know, looking at this very quickly, is that the Pulse survey probably gets the trends right, probably gets the growth rates right. It probably doesn't get the levels right, given that the sample size is pretty small and it's a web-based survey. But in any event, this is all sort of in the research bucket at this point, but I think it's really -- it holds some promise for going back to my very first slide, sort of moving NCHS into a more modern environment in approaching things at a bit more productive way, if you will, and it may be harnessing some of those additional tools like -- this might be a great place for AI and ML, for example.

Finally, what I want to say about the Pulse survey is that because it's been so successful and because even OMB has recognized how successful it's been, we just recently got approval -- I think it was either last week or the week before, got approval to go through -- by OMB -- to go through the end of the year with data collection for the Pulse, and we're really hopeful that not only will this survey get us through the pandemic period, but we -- it may get approval to continue into the future as well.

Okay. The final thing I thought I'd mention today is the public health data modernization initiative, and I know that some questions have come up about this already. So let me just, a little bit of history, and then sort of where we are now. So as NCHS, you probably know, NCHS received about $3.4 million for data modernization back in the FY2020 budget, and we focused primarily there on improving our mortality data, and in fact, some of what you're seeing today in terms of that step up in the ability to provide these COVID death counts and excess deaths and other vitals related data are a result of that investment we made.

But now CDC is in the final stages of allocating $500 million in additional modernization funds provided by the CARES Act, and these of course are being allocated across the various centers within CDC, and I think Sharon mentioned this just a moment ago. NCHS will be provided some funding to continue to improve our mortality statistics modernization, including the processing systems that were mentioned a few moments ago, and greater interoperability across state data. So again, more of the modernization around consistent reporting state by state.

We're also going to be provided some additional funding to develop tools to provide improved access to NCHS data. So for example, when you or other users come to the NCHS website, what we want to be able to do is ensure that you get all of the relevant information on a specific topic, regardless of which survey that information is actually collected on. So this notion of a one stop shop, if you will, and again, going back to something I said a moment ago, what this is requiring is us to sort of work across those siloes, break down those siloes, think about how we can promote interoperability, greater consistent use of metadata, establishing in some cases metadata across the various programs at NCHS, in order to link all that information so that you can get it all at one time when you come in and ask, you know, a request related to a particular product or topic. So thinking more about products or topics rather than needing to know which survey you'd want to go to.

And I guess the other thing I would say about this is in terms of thinking about how this could be expanded to the broader CDC effort, if NCHS is able to figure out how we can promote this data interoperability and sort of promote this one stop shop, might we be able to extend this to a broader enterprise solution where we apply this kind of model to all of what CDC offers? So I think we also have that as a sort of a longer run agenda, a longer run role of this work.

So I will keep you up to date on all of this as the data modernization work moves forward. I hope this update was useful. I probably went on here for a bit longer than I had intended, so sorry for that, but hopefully mixed in, as I said earlier, mixed in all of this, hopefully there are some hooks that you see, the committee, you see yourself able to participate and engage, and I really would welcome hearing that feedback where you see yourselves in this broader NCHS agenda.

So with that, Nick, I will turn it back to you.

Nick Coussoule: Thank you very much for the presentation. Do we have any questions from the members for Brian?

Denise Love.

Denise Love: Thank you for the update, Dr. Moyer, and I have many questions, but I think those will be better asked as we move through the workplan and into our planning for NCVHS. But one of the things that as you were speaking that jumps out to me is COVID has really highlighted the need not only for more novel types of linkages and datasets, but the liquidity and latency of our public health data is really a problem. Some of the timeliness, I know, of hospital data through HCUP are two years out, and some of the other datasets, be it the death index or others, are lagging. So do you see improvements in that processing and the latency issues of the public health data that you oversee?

Brian Moyer: The short answer is yes. Will that all come at one time? No, but the idea is to -- there's a couple of fronts here. One would be creating better interoperability as we mentioned at the state level so that some of the stuff can flow in a more timely way, and we have to spend less time actually making sure that one state's data is in line with another state's data. So there's that aspect.

But the other part of this I think is just a more general better data linking. I think that is one of the things that we don't do enough of now, and I think data linking in combination with some of these more sophisticated platforms, whether it be filling in gaps with AI or ML or other platforms, may really close some of those gaps and give us more timely data.

You know, I mentioned the Pulse survey. There's also something called the Research and Development Survey, which is within NCHS, and both of those are aiming at trying to get more current real-time data, if you will, but as I said a moment ago, the trick is linking that back to the four surveys that we have.

You know, I'm still new enough at this that I can hearken back to my days as an economist at the Commerce Department, and one of the things that we always did in the economics world is we would have an advance estimate. That would be followed by a preliminary estimate. That would be followed by a final estimate. And everyone sort of knew in those various vestiges of estimates that there were strengths and weaknesses, and those early data, yeah, you got them, but there are certain limitations to those early data, and you know they're going to be revised with more complete data along the way.

And that was well understood and well incorporated into the financial market decisions and so forth. I get a less of a sense of that in the health world, and you guys can enlighten me, since I'm new to this, but I think that quality thing is really a bit of a challenge for NCHS. If we provide something early, that's great and it might help you, but you gotta also bear the -- we also, and the users, too, have to bear the risk that there will be greater volatility, greater error, in those earlier data.

So I think that's sort of one of those philosophical things that's hanging out there that we have to figure out where that optimal level of risk lies.

Denise Love: Thank you. And I just wanted to say that we have another dataset that has some common structure out in the states that I hope you'll look at in the future, called All Payer Claims Databases, and I

think that will help augment it, the surveys, so maybe even replace some of the current surveys. So anyway, we look forward to figuring out how we can help you. Thank you.

Vickie Mays: Thank you for a very exciting presentation. You are just -- I'm not sure even where to start. I think there's much that we can do, and I think this will be a great discussion to have as we do our data workplan.

I want to comment on three things that you talked about. One is I'm as excited as you are about the potential that we saw from the Pulse survey. One of the issues -- because my team used it, we're trying to get papers out, we're trying to work on it particularly in terms of minority issues -- is what it reminded me of is the need for small data statistical approaches, because following people over time, what the losses were like, we even talked to the Census Bureau, they wanted help, they knew some of the statisticians we had and they asked for help. In the past, NCHS actually was in a leadership role around issues like that, and then money kind of hit.

So I'm wondering if there's a possibility of taking that leadership role again and trying to really develop statistical approaches for small samples, statistical approaches for small areas. Those would be wonderful if you could think about undertaking that.

My second issue has to do with kind of the difference between expending resources on a data query tool versus expending resources on making data more research amenable. So typically if I'm going to a data query tool, it means I'm looking for a fact or something that I can use, but I can't manipulate it. Bang for the buck says to me, well, the public may get a fact, a bang for the buck would be the ability of a researcher or some large entity, to be able to manipulate the data.

So like here, at UCLA, we have the CHIS survey. A data query tool, which costs a lot of money, gives us very little, but when we can get the dataset, we can multiply that. So as you have this modernization data, I'm going to pose that as a return on investment question for you to think about in the preparation of the data, because in mortality data we still need NDI, need some work on it, we still need work on NVDRS, and particularly trying to harness how to use AI approaches with all those narratives. So there's some bang for the buck return on investment that I really want to put before you to think about.

And then my last one is I think that if you want this kind of linkages in investment in working with the committee, in the past we actually had a representative that sat on the Board of Scientific Counselors, and that also dropped over time, and it may have been us, because we were down a lot of people, but that's one of the ways to keep this excitement going so that we have a feedback loop. You had somebody with us, and we had somebody with you. So that's just on the table for you to consider in order to make this work for you.

So thank you very much for your presentation. Those are my questions or issues.

Brian Moyer: Thank you so much, Vickie. I agree. Those are all great observations. Rebecca is already hitting me up for this notion of sharing across the two committees. So that is something we're throwing around. We're not really sure why it ended up -- why it stopped. But we're certainly thinking about how we could start doing that again.

Yeah, obviously, you have lots of thoughts here. Let me just react to one of them. The small area estimation, or the small sample estimation. Yes, that is something that our Division of Research Methodology is actually taking on as we speak. So we are going to be engaging in that work and doing research there.

So this survey, the Pulse survey, since you referenced that particular survey, was the joint effort across all of the statistical agencies, and so it was really -- it truly was a joint effort. The Census Bureau did the data collection and initial processing, but it really was a collaborative effort. So there was probably not as much taking the center by group by group, as maybe there was in the past for certain things like this. But anyway, we are, just so you know, we are going to be working on looking at those small area challenges.

You know, the data, the question you had around investment and the data queries, and sort of what the public needs versus what researchers need and data sets versus sort of point estimates and that sort of things, my take is you need both. You need to be able to allow a member of Congress to get in there and access that one data point they need for a briefing, but at the same time, you need to provide an opportunity for the researchers to do their thing, and I think if we go back to what I mentioned about the single portal access effort that's being taken, that's really focused on the research data centers or the FSRDCs, and I think exactly what you articulated there is the spirit that's underlying all that is how can we make those datasets, especially those protected datasets, more easily accessible to the research community?

And as I said, it's proving to be a little more challenging perhaps than we had thought, first pass, but I think we are making some good progress there. So again, all your points are, thank you, well taken. I agree.

Nick Coussoule: Thank you. Any other questions from the committee members? Just a reminder to raise your hand in the window, and we'll make sure we get to you.

Wu Xu: So it's very good to hear the NCHS modernization efforts, so I wonder how the different centers in the CDC, how do you coordinate in your data modernization effort together with yourself and with the states, because all different centers, when you come grants or instructions come to states, will come to one place in the states, and also different requirements may cause the local planning effort.

Brian Moyer: That is a really good question, and one that CDC leadership has thought about a whole lot. So there has been -- and in fact, this is one of the reasons it's taken so long to get all of the various modernization plans sort of set in place is because we wanted to coordinate across all of the various centers and to make sure we had these broad themes of modernization that didn't just enhance the programs of one center, but sort of built an enterprise kind of solution and didn't just address the current COVID pandemic, but also addressed any kind of future similar event.

So really we really have thought a lot about that, and I will applaud CDC on doing that and also on the really robust monitoring and feedback mechanism that they all -- that's been set in place to go along with that. So each of the centers have their charges, have their areas of data modernization, but what

we're doing is we're reporting back almost on a weekly basis sort of what progress is being made and what midcourse corrections are needed?

That's proving to be -- I mean, we're at the very beginning of this now. So I'm sure we'll see more benefits as we go down the road. But already we're seeing some benefits from that kind of feedback across the various centers. And you're right, the state element of this is incredibly important and that's a theme that's running throughout all of the modernization efforts. So yeah, I think what you describe is exactly the philosophy that's guiding the management of the data modernization effort.

Nick Coussoule: Great to hear, Brian. It's interesting the sheer delta that's happening with what you're talking about, when we first started embarking on some of the statistical work years ago here is astounding. So I want to credit you for that kind of progress. Very complicated and very difficult tasks. So we're excited about that progress as well.

Okay, if no more comments from the members, Brian, I want to thank you again, very much, for your time. Very helpful, very informative. We look forward to continuing our discussions and our work together. So thank you again.

Brian Moyer: Yes, you are more than welcome. Just like Sharon said a moment ago, you know where to reach me. So if you want to take me up on any of those offers I just made, feel free to reach out.

NCVHS 14th Report to Congress

Nick Coussoule: Okay, back to our agenda, we have one more topic before we break for lunch, and that's an update on our 14th report to Congress.

Let me update people on how we're going to attack this a little bit. We'll walk through kind of a framing, a purpose framing and approach to it, and then we're going to cover some areas of the committee's focus over the last couple of years related to this, and we'll ask a number of members of the committee to provide a brief overview, synopsis, of some of the committee's projects so that it's easier to understand for all the committee members as we start framing up the actual writing of this report.

We will have a writer helping us with this, Susan Kanaan, who helped us significantly obviously with the last couple of reports. So we very much welcome Susan to this exercise, as well.

So let me just start out. So the purpose of the report was a statutory requirement to Congress to report regularly on the implementation and status of the administrative simplification provisions of HIPAA. So we are obligated to do that, and it's -- the reports over time have contained in some ways different amounts of information based on what's happening with the committee, but we also want to outline ways specifically in which HIPAA may need modernizing to enable the digital health system. So it's both a lookback to what the committee has done relevant to these activities as well as some ideas of going forward of what has to happen differently based on just the sheer change that's evolved in the industry.

While keeping this one front and center, the last sentence on the second bullet is while reducing costs and administrative burden. That's really the driver here was overall of trying to reduce administrative

burden and costs in the ecosystem focused obviously on patient health, but trying to reduce cost and administrative burden of the ecosystem.

So the approach we have, and it's both guidance from ASPE as well as the work effort we've had is to try to really adhere closely to our committee's mandate to address the actual act's requirements. The committee has over time in some of the reports, if you look at a number of the historical reports, has both kind of covered our statutory obligations as well as provided potentially a little bit more information and insight, just based on work that the committee has done that we felt would be relevant to making public to our congressional receivers of this information.

But to the extent that we deem appropriate the specific framing is the -- to the extent to which people comply with Part C of Title XI of the Social Security Act in cooperating and implementing the standards adopted. So really it gets into how well is that actually working? How well are we adopting those standards, and are we meeting the security standards adopted under this, including what penalties may be assessed for noncompliance with those standards. So again, it's not just are we meeting the standard obligations, but are we doing it in a way that's safe and protective of the information for individuals involved.

Then whether the federal and state governments are receiving information that's sufficient quality to meet their obligations. Any problems that exist that we are aware of, to the extent that timetables under those statutory requirements are being met. So again, to summarize, basically how well is the implementation working and how well are we protecting, the system is protecting the data of individuals involved in that?

So our focus on the report, it's activities, reports, and letters that we've done in calendar years 19 and 20. So technically I think the requirement is annual reports. Just given the volume of change in activity, in some cases not the volume of change in activity, we've been doing it every two years, and we anticipate that the next steps in the workplan will address this. So we have a little bit more work obviously to do before the time period is completed. So including work that we're doing today and tomorrow, with regards to some of the recommendations that have come forth, and other information that becomes available to us before the end of the calendar year. So the idea is that we would provide that information and deliver it in the next calendar year based on information from the last two, so 2019 and 2020 calendar years.

At this point, I'd like to ask a number of the committee members, or actually one each, to cover some of the significant work that's happened in the committee and work products that have happened over the last couple of years to be able to provide some context to the other committee members and the public around items that we believe are relevant and important to capture in this. So the first one would be the beyond HIPAA work, and so I'd ask Jacki to provide us a synopsis of that, please.

Jacki Monson: Sure. So, this would sort of be what we called the HIPAA or beyond HIPAA framework project, was really pretty expansive. We did an environmental scan really looking for mostly privacy opportunities with respect to something that's either beyond HIPAA or wasn't originally in the scope. The goal certainly wasn't to make any recommendations around any changes to the HIPAA regulation itself.

So what we did through a series of hearings and a lot of research and discussion is we were looking for frameworks, practices, technologies, that would essentially help us, and we really honed in on a very broad focus of key categories that included big data and really it expanded use of big data. We touched on cyberthreats and approaches. I will just mention with respect to that, during the time of this was when we had dedicated federal task force surrounding cybersecurity. So that was an area that we touched on but didn't necessarily fall in the scope of this particular report or the letter to the Secretary.

Also included personal devices and internet of things, while in really the scope of those domains, evolving technology just as it relates to privacy and security, and then also evolving consumer attitudes, patients, members, et cetera, and what their feelings are with respect to privacy.

So it was kind of what I would call boiling the ocean, and consolidation of what we could do beyond HIPAA. So that was really the scope of the report. The report is very large, almost I think 70 pages, and the letter to the Secretary really was a culmination of our recommendations based on what we identified through the beyond HIPAA report and work.

And that's my summary. I'll pause and see if there's any questions.

Nick Coussoule: Thank you, Jacki. Next is the work we did on the ICD-11 recommendations. So I would ask Margaret to please update us on that.

Margaret Skurka: Yes, thanks. ICD-11 is firmly on our workplan for NCVHS for 2021, and the work is also under way in many countries across the globe, because the whole planet will move to eventually will move to this next version of the coding system. No one can adopt until 2022. That's a WHO regulation. And some will be ready to move then, because many countries are involved in translations and that's well under way and that's something that we don't have to worry about.

No country as of yet has started to do a clinical modification, and the WHO is discouraging that. It's a comprehensive system. It's built to be used in an electronic environment. It is so comprehensive that the WHO is saying there may not be an ICD-12.

We have to adopt it for mortality, as cause of death reporting is a condition of our membership in the WHO, and then we will adopt for morbidity, because it's a HIPAA designated medical concept and it's used for morbidity and mandatory for hospitals, physician practices, and other healthcare providers and service settings.

The WHO does have a coding tool available for I-11. It's online and it's free, and it's very easy to use. So in your spare time, just google ICD-11 coding tool, and you can enter a word or a diagnosis, like a diabetes or hypertension or whatever, and have some fun with it.

NCVHS has stressed to the Department of HHS that research and evaluation of I-11 going forward is essential. We need to see if it gives us the opportunity to reduce provider burden, increase interoperability of electronic health information, because those are high priority goals for the United States. We realize that the adoption and implementation will be a years-long process, but we are encouraging HHS to move forward and avoid a repeat of the protracted and costly transition just a few years when we went from I-9 to I-10, and that was in 2015.

So we've identified challenges and lessons learned from this fairly recent transition. We last year did have that expert panel and began to identify steps forward. It is important to simplify the rulemaking process and describe a pathway forward for I-11, and communicate clearly to all industry stakeholders.

Thanks.

Nick Coussoule: Thank you, Margaret. The next area of work was the health terminology and vocabulary work, specifically their adoption and implementation of terminology and vocabulary standards and guidelines for curation and dissemination. I will cover this one a little bit.

The recommendations that we made, if you think about the terminology and vocabulary standards defining elements to ensure consistency, serve a broad range of useful purposes in the system. HIPAA directed us as NCVHS to study the issues related to the adoption of uniform data standards for patient medical record information and electronic exchanges, such information, it's been an area of focus for the committee for a long time. Back in February 2019, a culmination of this, there were two different chunks of work.

There was an environmental scan done in advance, or it should say in advance of the recommendations, but the recommendation is really twofold. The first was that the Secretary should approve the criteria for adoption and implementation of the terminology and vocabulary standards, and there was a specific group of criteria -- I'm not going to cover them all here. They're visible in the report. But that was the first chunk, which was the criteria for adoption and implementation.

The second recommendation was to approve the guidelines for curation and dissemination of the standards. So both of those pieces were very relevant, we believe, to dealing with the pace of change, the consistency across the standards, and the ability to create some predictability and simplification to both the adoption and implementation as well as the curation and dissemination.

As I indicated, there's a huge amount of work done on the environmental scan, great support from a number of our federal partners as part of this exercise, and as I said, you can see the very specific recommendations that will be part of the report but also in the letter.

Any questions generally about that work effort?

(No response.)

So next I would ask Rich to talk about our predictability roadmap work.

Rich Landen: Thanks, Nick. Predictability roadmap refers to the transaction standards and operating rules adopted under HIPAA and as subsequently modified by the ACA, primarily by the standards development organizations, X12, NCPDP, and CAQH CORE. Fundamentally, the issue is that the current HIPAA rulemaking does not meet industry needs. We have looked, NCVHS, in particular the Subcommittee on Standards, looked at the issues during a multiyear industry engagement series of events, and it builds on work of the subcommittee and the full committee and the experience that goes back even farther.

NCVHS issued some recommendations both in February 2019 and some follow-on recommendations in December 2019 to reform the HIPAA rulemaking process. Some of the fundamental recommendations are that once a transaction standard has been adopted by federal rulemaking, any modifications or updates to that standard should be industry-driven and not burdened by new rulemaking. New rulemaking tends to take a minimum of four years, sometimes a lot longer, and that is just not responsive to industry needs.

The second recommendation from the original letter was to promote and use voluntary testing of emerging standards and operating rules. The issue was that when rules and operating rules are promulgated, they haven't been well-tested, and if there are issues found with them, it's near impossible to get them fixed in order for implementation to proceed smoothly.

Recommendation three was to improve the visibility and impact of administrative simplification enforcement program, meaning that throughout the industry, some of the trading partners were not using the standards or not using them accurately or appropriately and this of course created some friction, and it was difficult to come to grips and get compliance going.

Recommendation four was to request more policy-related guidance from HHS regarding adoption and enforcement of the standards.

So those were the key recommendations. There were a couple of others that were not as fundamental. In December of last year, the follow-up letter clarified that federal rulemaking for these HIPAA transactions and operating rules is essential. Without federal rulemaking, industry adoption is problematic and unlikely to be very successful.

Current rulemaking processes do not meet industry standards or needs for timeliness, for responsiveness, for the digestibility, meaning because of the infrequency of when new standards are updated, it's usually a huge packet that's very difficult for the industry to handle at one time. So the thought was going to more frequent and smaller bites.

The other recommendations or the other concept was to move the end user vetting of the proposed standards earlier in the development cycle. Right now, public comment happens only after an NPRM is promulgated and any comments that come in, it's just very difficult for the standards-relevant organization to go back and modify the standard that's already been voted and approved. So in December of last year, there were three recommendations.

One is for HHS to provide guidance on the data needed to support adoption of the standard so that that data can be accumulated by industry throughout the standards development process, rather than waiting for the development of an NPRM. Second recommendation was to secure, support an evaluation of standards and operating rules prior to adoption, which I touched on earlier. And the third recommendation was to facilitate a more nimble approach to standards development to better support federal policy objectives, industry business requirements, and emerging technologies. It gets to the innovation and the importance of having a regulatory framework that is much more responsive to the needs.

I think we heard in several of the presentations this morning about specifically about the pandemic and the changes in reporting that are required, and yet if the reporting comes through a HIPAA standards, we're talking a minimum of four years before we can get the regulation updated.

So that's it in a nutshell on the predictability roadmap.

Nick Coussoule: Thank you. Rich, I would ask you again, we're going to cover this in a good bit, a good bit in a little bit, but the collaboration with ONC specific to the clinical administrative data integration.

Rich Landen: The issue of separate standards for clinical purposes and for healthcare administration, insurance and coverage purposes, has been a high priority both for us, NCVHS, and for ONC and its advisory committee, HITAC. Collaboration between the two groups was indicated in federal legislation, and a joint or at least coordinated approach is needed on the regulation development for the clinical side and the regulation development for the administrative side, because the two halves have to work together.

ONC is the regulatory body in the clinical space for EHRs and interoperability. NCVHS advises HHS on the HIPAA transactions and operating rules adoption, and CMS is the actual organization that adopts the transactions and operating rules.

Without coordination, there would be risk that conflicting rules might emerge or non-harmonized rules might emerge, and that would create adoption and burden issues for the entire industry. So working with ONC over the past looks like almost two years now, and developing a plan for how we address this convergence or intersection of clinical administrative, we chose to use prior authorization as an exemplar, number one, because prior authorization presents some real issues, rulemaking is not far along in those areas yet, so there is opportunity, and as a result of those discussions, ONC and HITAC created the ICAD taskforce of HITAC, and I need to point out very specifically that the ICAD taskforce is a HITAC advisory -- it's a taskforce, not an NCVHS taskforce.

Nonetheless, HITAC and ONC graciously included appointments for four NCVHS members and appointed one of them, Alix Goss, whose name has come up a couple of times, as now turned out, Alix was named as co-chair of the HITAC, or the ICAD taskforce.

So we'll go into more of the -- we'll have the full report later on. I won't go any deeper in that, but suffice to say that the ICAD final report talks about, describes, an ideal state where administrative and clinical standards come together, and made a series of recommendations, very high level, to initiate the directional movement toward achievement of that ideal state.

That's it, unless there's questions.

Nick Coussoule: Thank you, Rich.

The next area of focus was the recommendation for the updated NCPDP standard. Deb, I've asked you to talk about that, please.

Debra Strickland: Sure. Absolutely. This is a very important issue, and we have tackled it a couple of times. We did have a hearing from which the letter dated May 17, 2018. We presented three recommendations from that hearing, and one was for the NCPDP standard D.0 telecommunication standard implementation guide version F2, and the other was batch standard implementation guide, version 15, and the third was subrogation implementation guide for batch standard version 10 for Medicaid to replace version 3.

At this hearing, it proved that we had strong industry support, which is why we put forward these recommendations. We did get a letter back acknowledging the hearing and the recommendations, but that is all we heard.

So in 2020, we also embarked on an effort to solicit information from the industry, which prompted a letter dated April 22, 2020, where we had additional recommendations for HHS, and that was to then put forward the version F6 instead of D.0. We still support the other two recommendations we've made in the past. However, we're changing the D.0 to F6 in our recommendations.

This was gathered by a request for public comment through the Federal Register and direct outreach to the industry, again receiving strong support for the F6 version instead of that D.0 version. We also provided from the industry's feedback a timeline for adoption, which was dependent on an NPRM being put forward by the end of 2020. We did not -- we did get response and recognition of the letter that we sent. However, we did not see anything else. So it's not likely we'll see an NPRM by the end of this year.

Those are the efforts that I have highlighted.

Nick Coussoule: Thank you, Deb.

And then the review of the CAQH CORE's request for their operating rule updates. Rich, want to give us a little preview?

Rich Landen: Sure. We will talk about this at much greater length this afternoon, but the operating rules are -- let me take a step back. An operating rule is a series of guidances that wrap around a HIPAA adopted standard that was offered by ASC X12. The theory of the operating rule is it provides some more specificity than the adopted standard itself does and helps set some of the context, and I'll give some examples as I go through. But CAQH CORE has been designated by HHS as an operating rule authoring entity, and early this year, CAQH CORE came to NCVHS and proposed three new rules, operating rules for adoption.

The first rule was the prior authorization data content. That rule provides more detail around the X12 278 health service review or prior auth, HIPAA adopted implementation guide. What that data content rule does is it complements the X12 implementation guide and talks about specific techniques for patient identification, how to normalize patient names, use of decision reason codes. So it talks about things that are included in the guide. It doesn't add any data elements, but it clarifies the use of some of the things prescribed in the X12 guides.

The second operating rule proposed was the prior authorization infrastructure rule, and infrastructure refers to the transmission and processing systems requirements for handling the X12 278 prior auth

transaction. Some of the content of that includes differentiating between batch transactions and real-time processing modes, how to handle acknowledgments of a transaction, talking about the processing systems minimum uptimes, how many hours a week, days a week, it has to be up and running. Time requirements for decision-making or requesting additional information or providing requested information, and then templates for the companion guides, and the companion guide is something that an individual trading partner may publish to its trading partners to talk about the specifics of how the format of the transaction needs to be for it to be successfully processed within that trading partner's processing system.

The third operating rule proposed was for connectivity. The connectivity rule were general requirements for trading partners and this rule, unlike the first two, applied all the HIPAA adopted X12 transactions, not just the prior auth. The content of the connectivity rule talked about message envelopes, payload types, transport methods, enveloping and metadata, authentication, security protocols, error handling, audit functions, and date and time conventions, things like that.

So this is all operating rules are all designed to improve the processing, the successful processing of the HIPAA transactions to reduce burden, and you'll be hearing a lot more about this this afternoon.

Nick Coussoule: Thank you, Rich. Then, last but not least, in regards to the area of focus is the data access privacy and security during COVID. So, Frank, if I could ask you to talk about that a little, please.

Frank Pasquale: Yes, thanks so much, Nick.

In terms of our -- we had a September hearing for PCS that reviewed data use in public health emergencies. That was our critical topic there. At the September hearing, we had three panels. The first was on data collection and use. We have experts in that area and we really strive to get experts from computer science, policy, public health, to really broker a robust discussion. After that, we had panel two, which was on technology and ethics, again a good diverse group that will be talking more about their contributions and comments tomorrow.

And the third panel was on bias and discrimination, really trying to think deeply about what are the both current and actual and potential forms of bias and discrimination that occur, both with respect to the lack of data gathering, because we all know that data gathering can be a great boon, and also with potential disparate impacts in privacy harms. That was sort of a theme of the entire hearing was this balance between information being a good to inform good policy and also we must always remember that information can be used for more troubling purposes and that's the purpose of our privacy law, to prevent that, or one of many purposes of the privacy law.

So out of that hearing, we got at least four major issue areas. First on data stewardship, second on coverage gap, third on public trust, and fourth on laws and policies. With respect to data and data stewardship, some of the key things that we are going to be discussing and potentially have in the report are issues involving public health data and their security, the various smartphone apps that have been either proposed or implemented as ways of providing exposure notification or contact tracing, and the issues of secondary use of data, particularly the potential for troubling secondary uses of data to contribute to lack of public trust.

In terms of coverage gaps, the second of the four areas, there was some concern about the financial infrastructure for data gathering, and potential problems there in terms of lack of payment coverage for testing or confusion about that type of coverage for testing, and gaps in HIPAA privacy protection coverage. Some concerns were raised there about new facilities with these gaps.

So with respect to public trust, our third issue, one of the key findings was that building public trust requires better ways to communicate complex processes of data collection and storage so the public can understand, and creation of a role like a data counselor or someone that can better give person-to-person advice here may be a critical way of informing individuals, but of course, you cannot just expect the burden of privacy policy to be on individuals, right? The sort of consumer education, consumer notification effort, that's only the first step, and to the extent that we would only rely on that, that would cause some very serious disparities, and so we've got to take it further.

In terms of taking it further with laws and policies, there really is a need to balance the need for privacy and the protection of the individual with the need to collect data. So those are sort of some critical overviews, takeaways, from the discussions in the September hearing, and we look forward to working further with this report to Congress to make Congress aware that we have some great experts that we're able to convene and are willing to serve. Thanks.

Nick Coussoule: Thank you, Frank. So now I'm going to spend a few minutes covering the initial thoughts on the themes and takeaways from the meeting, and what I would say is that I've got four or five or six slides that I will go through. It's both the thoughts from the different subcommittees as well as the major themes and some takeaways, and then we'll follow up with the questions about are these the right points, what's missing, and what additional things do we think need to be in there.

So what I'm going to suggest is that I will actually walk through all of those thoughts initially, so please keep them in mind. We can go back to them if we need to. But I will walk through all of those relatively briefly, and then open it up for questions and comments in regards to are they the right ones, what's missing, what might not should be there in the first place.

So with that, some initial thoughts was the lack of action or recommendations the committees put forth in recent year related to the adoption of standards. I think Rich did a pretty good job covering that when he did his overview a few minutes ago. We also want to provide an update on the status of actions that were put forth in the 13th report really to take the recommendations or thoughts that we had had there and match that up against the work that's happened in the last couple of years to make sure that that's also visible.

And then it really highlights I think a very significant trend, which I think we would all agree to, it's been brought up multiple times today in regards to the movement towards integration of the administrative and clinical data, and we'll get a good bit of that when we talk about the ICAD work a little later on today.

So from the standards subcommittee, some of the initial thoughts that came through were that to update on the status of recommendations on the implementation of the administrative simplification provisions, and basically the impact of action or inaction on the furtherance of automation. So not only

kind of where we are but what's happened or what hasn't happened, and what kind of an impact do we believe that might have had on the successful implementation of that automation?

Second thought, or another thought, was that the original simplification regulations have certainly been an acceleration for driving transaction automation and reducing burden on payers and providers. Now, obviously, that doesn't come without pain to go through an initial implementation, but a number of transactions have had pretty significant take-up in automation and clearly have reduced burden over time.

But the third one is that the world has changed in a number of ways that challenge the existing regulatory process and the way that happens. Again, Rich covered a bit of that a minute ago.

So in regards to those existing regulatory processes, there is a belief that the current processes and structures do present a barrier to improvement instead of an accelerant. I think we draw a fine line between recognizing a lot of good progress and a lot of work made towards this, but with a lot of the changes that are happening across the industry and ecosystem that sometimes the processes may not be as effective in moving that along as they had been in the past to result in improvements in both burden reduction, automation, and the like.

Second, or another way it changes. HIPAA did create a floor and set of rules for privacy and security. We have been talking more about the administrative standards, as far as the actual transaction work, but the work has worked quite well from a security perspective to ensure that all the players in the ecosystem have a clear understanding of the rules and regulations to protect individuals' data.

One of the kind of a caveat to that is that there are lots more folks involved in the ecosystem now, at least visibly involved, and involved in a digital way, than certainly were when HIPAA was first envisioned. That creates some other challenges that may not have been envisioned by the HIPAA rules and frankly that aren't necessarily covered by the HIPAA rules if they don't happen to be a covered entity. So definitely some challenges with that.

Then also, from a semantic standards perspective, and I talked a little bit about that one earlier myself, the pace of knowledge development has increased, and yet the updates to those standards have not necessarily kept pace with that, and then they're not always consistently applied to recognize how they cooperate together or don't, and then making sure that with those standards, the same if we're looking at interoperability that we don't introduce decision bias by potentially using AI tools in their evaluations.

A few other thoughts on the themes and takeaways, that improved care integration, risk management, and payment models have essential a more cohesive integration between clinical and administrative functions. We even had a couple of the new members talk about that earlier on as ideas and themes that -- you know, the fee-for-service model, which was from a payment perspective quite transactional, as that's changed into value-based models and other kinds of risk-bearing arrangements, there's some significant interactions that need to happen between the clinical and administrative functions to make that work effectively.

The data just needs to be more integrated, and then the burden reduction driven by automation simplification must be looked at and can only be materially advanced by looking across the entire

healthcare ecosystem. So the thought process there, this is not a point-to-point question and issue. In order to look at the efficiencies, it needs to look at end-to-end use cases and not just a singular transaction that may be very beneficial to one player but not to others. So the idea is to look across the entirety of that ecosystem to make sure that the benefits are in fact in total positive.

And then it may require rethinking of the regulatory framework and then how the specific partnership between clinical and administrative standards development and implementation processes and technologies work. So more to come on that, as we'll hear a good bit about that in a presentation this afternoon.

Then the last page of the thoughts and takeaways, please. Not quite last page, one other page. The modernization efforts around vital records and births and deaths are foundation of vital statistics infrastructure. Is there an opportunity to include advances in that orchestration of state and territorial reporting capabilities? Again, we heard about this earlier obviously in the presentation that Brian gave us. Very important challenges inherent in that system, and modernization efforts are very, very important and can create significant benefits, and that the pandemic has definitely highlighted the criticality of the vital statistics system infrastructure.

And then lastly, also in the same relative topic in the vital records, it's important to focus on public health surveillance and the need for better linkages. Again, very apropos with what Brian was talking about earlier with regards to some of the challenges, modernization challenges, NCHS is facing.

A couple other kind of final themes, a little more generalized. One is that there is definitely a bigger role for the patient. Patient engagement has changed. New applications and new technologies, such as FHIR, convergence of administrative and clinical data, has put the patient much more in the center of things. Obviously, the patient has always been at the center of healthcare, but with the digitization and data access questions, very much more involved as kind of a partner in the entire delivery of the ecosystem. So that creates some different challenges.

The challenge to HIPAA in a pandemic, obviously we've talked about that a bit as well, and then living with that, the implications for the data ecosystem, which include disparities, communications, telehealth, working from home. Again, some of the changes that have happened in the general marketplace in the United States, really the rest of the world, but specifically in the United States in regards to dealing with those other factors that need to be considered in order to make the system function better, and then also that the contact tracing, again this gets into more of the privacy policy questions, with analytics. So some of the challenge, which Brian also brought up in regards to the challenge between making data more available and accessible and holding to privacy principles, keeping people's data secure.

So those are kind of high level and some level of detail thoughts and themes, as well as the overview of a good bit of the work products that have been developed and delivered by NCVHS over the last couple of years, and a couple that are obviously in the works. I would ask now for your input and feedback, in regards to -- and we can go back to any of these. I just thought it would be easier to go through them all to give you an opportunity to think through all of them before we ask those questions, but please, I'd love feedback from the committee members. Are these the right points? Are they articulated well?

We will have multiple opportunities to address this. In fact, let me do one thing. Let's go one step forward, and then I'll come back. So one more slide forward.

The way the process will play out here is that we will be provided and gotten input from the subcommittees, the executive subcommittee has provided some of guidance. We'll review it today obviously at the full committee meeting, which is what we're doing. We will begin to develop a detailed outline and drafting the early versions of this. It will be a very iterative process, the way this has worked in the past as we talked about at the last meeting.

We will go through multiple iterations, make sure the various subcommittees and the members of the committee will have an opportunity to weigh in to make sure it's appropriately framed up. Ideally, we would start doing that in the next month and a half or so, and then throughout the winter and early into the spring, we would refine it at the subcommittee, go through rounds of iteration, and then ideally at spring committee, do a full committee review and ideally approve it at the committee meeting we have scheduled for March.

There is not a formal and fixed timeline by which we'd need to do that. We will do it when it's ready and appropriate, if we've been able to get the feedback from all the committee members and staff, and I do not want to imply that we don't involve staff in those discussions as well. They're really helpful through all this process.

So that's the general sequence of events and timing. So go back one slide please, and I would ask for committee member input into again what I covered: are they the right points? Again, we can go back to any page if you'd like to. And are they articulated well?

What's missing, if anything, and what additional messages do you believe that we need to provide or that report to include that we provide to Congress in regards to the 14th report? So I'd open it up to other committee member feedback. Unless we've done such a good job with everybody talking already, that we are complete.

Frank Pasquale: Hi, Nick, this is Frank. I just think that the one other topic that may be of some interest is there are some proposals in Congress now for improving privacy, confidentiality, and security laws with respect to health data. So I just wanted to bring that up. It will be something that we'll have more room for discussion tomorrow, with respect to the PCS report. But in those terms, in thinking about reporting to Congress, it does seem that it might be something to make them aware, that we're following some of the proposals that are out there, because I think there is an increasing interest in Congress about how to modernize and further update privacy, confidentiality, and security laws, particularly just given the fact that there are so many new threats, both new opportunities with data, but also new threats, that I think do warrant some responses. So just an idea something maybe we can discuss further as a full group.

Nick Coussoule: Thank you, Frank. Appreciate that feedback.

Others? I just want to make sure we're giving everybody an opportunity to input.

Denise?

Denise Love: Thank you for the overview. It's pretty dense, and I think it covers all of the points that I'm aware of, but I just have a question. Maybe this is more for Rebecca or staff. I mean, I think this report serves as an archive of our work so that that is documented, but does Congress ever respond to it? What happens to it when it goes to Congress?

Rebecca Hines: So, since I have been on board, I have not seen a formal written reply, Denise. I do know that some members, committee members, have brought it to the attention of staff of certain members of Congress. So it has been received and reviewed, and probably included in their policy development discussions.

We've gotten informally, emails from IMIA(?) and other organizations that our work is very helpful when these discussions are under way, and I wanted to note, Frank, you talked about down the line in addition to responding to the mandate of where are we as of December 2020, the report is certainly within scope to include future looking, and so, Frank, you've pointed out basically future looking point to include, and to the degree that you all have the time and energy to write sections on what we think Congress ought to be looking at, it sounds like there's some interest there as well.

Denise, we haven't -- unlike the letters to the Secretary where we often, more often than not, get a response, we haven't seen a formal reply.

Denise Love: And so this could be an opportunity I think, what Frank was saying, is put some forward thinking maybe provocative, not too provocative, suggestions in.

Nick Coussoule: I think one of the things that we've not really made asks, if you want to call it that, as part of this report, so it's different than I think a lot of the reports that we've put into the Secretary, which is oftentimes make very specific recommendations of what we think might happen in this case. We don't necessarily ask Congress to do anything as much as we try to provide some insight and context to what's happened, while meeting our provisions and hopefully providing some thought-provoking things going forward.

But we don't necessarily make an ask, and I think that's part of why it's not something that would necessarily expect to get a formal response to.

Rebecca Hines: Maya just texted to remind us that this really is a report, rather than a series of recommendations. So it's not really designed to ask them to do anything more. It's our job, it's the committee's job, to give them a status. The committee has used the report as an opportunity in the past, you know, since they had to report to Congress, to put in some suggestions, but that's not really what the main scope and the mandate lays out.

Nick Coussoule: Okay. Other thoughts or questions or comments from committee members? Okay, then I think we'll wrap up this session. We are now scheduled -- we're about 15 minutes ahead of schedule, which is -- actually, no, I think we're right on schedule, now that I look at the calendar, which is awesome. We will take a break for lunch or if you're in the west coast, I guess breakfast. We will reconvene at 1:30, with an update on HITAC and the ICAD taskforce from Sheryl Turney and Alix Goss, but until then we are adjourned for about an hour.

Thank you, members, and we'll look forward to seeing you all back in an hour.

(Break for lunch)

Update on HITAC Intersection of Clinical and Administrative Data (ICAD) Task Force Recommendations and Report

Nick Coussoule: Welcome back, everybody. Appreciate your time and attention this morning. We're going to get started this afternoon with an update, as you see on the screen, on the ICAD taskforce, presented to us by Alix Goss and Sheryl Turney. So I will turn it over. I'm not sure who's going to start, Alix or Sheryl, but I will turn it over to you both. Thank you.

Alix Goss: Thank you, Nick. Sheryl and I are going to tag team on today's presentation. I'm going to kick us off.

Why don't we go to the next slide, and then Sheryl is going to round out some of my commentary with a deeper dive into the content of the report, before we have the opportunity to have a robust discussion with NCVHS. We are most appreciative of the opportunity to come present to you today the newly approved and newly officially transmitted report of the Intersection of Clinical and Administrative Data.

To help us with providing context on the report and the overview we'll give you today, we're going to start out with a bit of background context setting, and some of that will actually build on the remarks that you heard from Nick and team earlier in your NCVHS meeting today. We're then going to talk about the charge that was given to the ICAD taskforce, which is part of ONC's federal advisory committee, the Health Information Technology and Advisory Committee, or HITAC.

We'll showcase the taskforce members, including in that list will be some NCVHS colleagues, and then I'll be turning it over after discussing some of the industry comment submissions, to Sheryl, who will talk about the ideal state guiding principles and recommendations at a high level. This is a robust 100-page report, so today is really to give you an overview, providing time at the end for discussion.

To help us set some context, because it can be a little confusing as to who's on first and who has what roles and responsibilities, and also why we got to the point of actually creating a taskforce with NCVHS

and HITAC members, along with some industry members, within the ONC federal advisory space, it is good to point out some of the history, which is longstanding when it comes to the need to look at the intersection of clinical and administrative data, and this is really capstoned, if you think about the 21st Century CURES Act, inclusion of language when directing the national coordinator and its creation of a federal advisory committee, that they would take into account relevant and available recommendations for the National Committee on Vital and Health Statistics.

If you think about our history in NCVHS, we have -- you have tremendous responsibilities related to the HIPAA transaction standards, as adopted under the HIPAA act, but also under the Affordable Care Act related to operating rules and review committee responsibilities to do that retrospective review of HIPAA. So NCVHS has responsibilities for advancing new recommendations related to HIPAA transaction standards and operating rules, as well as obligations to do retrospectives upon occasion that help us really learn.

One of the things that we really learned in 2015 and 2016 when we did the review committee report was that there were -- the landscape was drastically changing, as you may have heard Nick refer to when he was covering the upcoming report to Congress.

The electronic health record capabilities have also advanced notably in the last decade, thanks to our work under the American Recovery and Reinvestment Act of HITECH and meaningful use, as some of us more affectionately refer to that phase.

What has been very clear from the work within the ONC realm and within the NCVHS realm and also along with our colleagues in CMS is that there is a lack of -- inefficient workflows, there's time-consuming discovery of payer-specific requirements, and there are technical barriers related to vendor support and integrated platforms. All of this really impacts patient safety and the quality of healthcare delivery.

The joint taskforce, as I like to think about it, although it was officially a taskforce under ONC, it really brought together ONC HITAC members as well as NCVHS members, and provides us with the opportunity to really take the vision of the 21st Century CURES to the next level. While all of the sort of authorities aspect may be clear to some, it may not be clear to everyone. The role that we have or you have as NCVHS is very HIPAA-related, and we work in partnership with the Office of Burden Reduction in CMS and their National Standards Group to update HIPAA standards and adopt new ones.

When we're looking at electronic health records and certification requirements related to the health record functionality and certified health IT, that's really under the authority of the Office of the National Coordinator, but along the way we're seeing an overlap between what we're doing, or NCVHS is doing, and what ONC is doing and what CMS is doing, especially when you think about the advancement of Fast Healthcare Interoperability Resources, adopted in 2020, in March of this year, related to the interoperability rule and also for the certified health IT program.

So understanding the transformation in the landscape and understanding that there are different authorities across programs, there was a need to be efficient in how we were going to move forward in

looking at this opportunity to harmonize our frameworks for clinical and administrative data exchange within the United States.

We're grateful that ONC provided us with a glide path and tremendous resources from their support team, as well as their staff, in advancing the charge. The charge was to produce information and ultimately a report related to the merging of the clinical and administrative data, its transport structures, rules, and protections, with prior authorization as a primary focus, and this was all to achieve a vision, and the vision is around improving data interoperability to support clinical care, reduce burden, and improve efficiencies, furthering the implementation of record once and reuse.

As we capture data, we should be able to use it in a variety of ways and, thus, reduce burden. However, we need to figure out how to advance that vision, and we wanted to take a look at not only the prior authorization opportunity, which is a longstanding inefficient administrative transaction that really is at the heart of clinical and administrative data, that we also wanted to look at the broader issue of what we needed to do as a nation to bring our standards, regulations, and frameworks closer together to reduce unnecessary burden.

In order to do that, we really wanted to validate and extend the landscape analysis. We are working on the shoulders of giants. There's been a tremendous amount of work within the industry to date that we were able to leverage, including the work of NCVHS. We also recognized that we needed to extend our understanding to what was happening in the marketplace. So we invited industry to help us through presentations inform our analysis and broaden our thinking as to what might be the recommendation path we'd like to advance.

All of this is really about patient- and process-focused solutions to remove roadblocks that we've all been frustrated with at one point or another. The body of work was to produce a report so that it can be advanced in several ways. First, within the ONC HITAC arena for them to think about what they can tackle as a part of the national coordinator's role and health information technology advisory aspects for ONC's areas of authorities. But it was also for NCVHS to be able to get additional insights from the industry to inform its convergence project that you will be undertaking, continuing to undertake, this fall and into next year.

We launched, as a result of the partnership with ONC, the taskforce in March of this past year, nine months ago we established a foundation of understanding in the approach that we'd be taking as a taskforce with extensive engagement with industry to inform our analyses that took a deep dive into the prior authorization use case, to consider standards alignment and capability opportunities, that led us to the ability to describe an ideal state to define guiding principles, to create specific recommendations at a fairly high level, as NCVHS is probably accustomed to. The body of work is about what needs to happen and how we need to focus our lenses, rather than how things need to be accomplished. The how will come in the next stages.

We were able to take this extensive body of work and synthesize it into a draft report and go through an iterative review and comment and modification process, ultimately resulting in a unanimous vote for approval on November 10. The report is formally available and I've included the link on this report and suspect it will also be distributed here.

Taskforce members are listed on this slide, and represent a combination of industry, individuals, and representatives, as well as federal advisory committee members from both HITAC and NCVHS. It's an honor to co-chair this body of work with Sheryl Turney, who is a standing HITAC member, and congratulations on her being renewed for three more years.

This slide represents a good portion of the half of the report in that we've synthesized all of the industry presentations and put it into an appendix of the report. Those who are listed on this slide came and brought forward their thinking, their demonstrations, and their partners to bear in showcasing their thoughts and opportunities related to the intersection of clinical and administrative data.

In addition to the industry presentation slide I just covered, we also received written and verbal comments from industry in response to the drafts of the report. We iteratively were providing status updates to HITAC, since we were a taskforce of theirs, and that also provided for additional public comment period that supplemented the weekly taskforce conference calls where we always had a public comment period, as well.

Industry took the time and effort to pay attention throughout our weekly calls, as well as our status updates to HITAC, and then had the opportunity to pull down and review the draft report, and then submit comments which the members of the taskforce reviewed, discussed, and then reconciled during our taskforce conference calls.

There was a really substantial lift by industry as well as the taskforce members in bringing this body of work to fruition. It was a labor of love for a lot of us, because we're very passionate about improving the healthcare system, but also recognize that we are all a patient at one point or another, and so it was a really tremendous opportunity to bring a diverse set of perspectives and considerations to bear in producing the report.

I'd like to give you an overview of the report structure before turning it over to Sheryl to take a deeper dive into the key components of the guiding principles and recommendations. The front matter provides the traditional sort of framing information. We have an extensive executive summary. Typically you keep those at one or two pages; it's a little bit meatier in that there was so much in the report we really wanted to give a strong synthesis and were very grateful for the work and contributions of being able to retain Susan Kanaan to assist us with this editorial final development of the report, and she really helped bring that executive summary to a really solid state that's a nice snapshot if you don't want to wade yourself through the entire report.

Following the executive summary, we do provide a framing and introduction section, followed by the analysis of the prior authorization landscape and standards, and opportunities. We then move into the taskforce findings and recommendations, concluding with a summary and sort of a call to action to all as a community to continue to collaborate and work together in defining the how things are going to be accomplished to fulfil the recommendations.

We envisioned that the federal partners, ONC, NCVHS, CMS and others, will continue to work together and use their tools and their toolbox to engage industry through meetings and opportunities to review and comment, because it will take the entire village to really bring together our clinical and

administrative frameworks so that we can reduce burden, improve patient experience and outcomes, and ultimately allow our precious resources to focus their time and energy in the most important parts of healthcare delivery and reimbursement.

So I'm going to turn it over to Sheryl, who's going to walk you through the rest of the deck.

Sheryl Turney: Thank you so much, Alix. I really appreciate that transition, and also I just want to say thank you to NCVHS for this opportunity to present our report findings. It's an exciting day for both of us. As Alix mentioned, it's a labor of love for many of us and me particularly. So thank you for this opportunity to be here.

You know, it wasn't easy to take this group of people and create an ideal state. I want to say that right at the beginning, because we all look at how we work through our own lens, and with this great broad cross-section of individuals that we have on the taskforce, it's easy to get buried in what EMR system I'm using, what's the admin system I'm using. So we really did push this group to reimagine what are we -- how can we work?

So we really looked at the ideal state as being an integrated system where the data we need is available when we need it, without us having to necessarily ask for it. That doesn't mean of course we wouldn't be interacting with the patient when we need to gather data or performing tests, et cetera, but the data that results from those all those actions being available to the individual that needs it to take an action at the time that they need to take that action, and trying to really reimagine if we have that state in place, what would that take and what would that mean?

So as a result of that, we looked at creating this view of an end-to-end integrated closed loop process that doesn't exist today. How can that process reduce the barriers on all our stakeholders. And then how would we look at that process in the future to be able to account for the majority of situations that would occur either in the patient journey, the clinical presentation of that, or the administrative journey, as we go forward.

For that, an example would be maybe we don't need a prior authorization in this case, because all of the data that's needed for the decision-making is already there, and maybe what we need to do is make that available to the appropriate parties so those decisions can be made under the covers, if you will, or the thought beyond the curtain, and then the process supports the decision-making.

And then leveraging all of these assets and investments where appropriate and identifying what are the gaps, what do we need to do, and how can we really innovate this process in the future?

Again, it wasn't easy to get here, but the ideal state that we sought is an example of an integrated workflow which depicts this integrated system that has administrative and clinical interactions among patients, providers, payers, and all of the other requirements within the healthcare journey. We can go to the next slide.

In the paper in the report, what you'll see is that we really express this ideal state through our guiding principles, and the guiding principles that we identified were nine that are represented here, and I'm

going to review each of these in a little bit more detail. These guiding principles really were the depiction of this ideal state, sort of removing the boundaries of what we are dealing with today.

The first one was a patient-centered design and focus. This one really is speaking to how can we remove the current roadblocks that exist for a patient and their caregivers and support their timely requirements for care and also the burden that they currently face related to the patient experience, especially as it pertains to prior authorization, because as we all know, in today's world, the patient often has to be the ones to remove the roadblocks, and in the future, we hope those roadblocks have already been removed and the patient becomes engaged in the process in being more aware of what's happening and when it's happening, but not actually having to be the quarterbacks to get those roadblocks removed.

Then the next one is transparency. So obviously, based on what I've already said, there's an increase in the patient and the providers access to some real-time information about the care and about all the tests that have been executed, maybe the prescriptions and the adherence to the prescription that have been included, any lab results that are needed, vaccinations that might be important, especially as we see those that are coming up, the status of any authorizations that are required in order to deliver care, and other information in order to minimize delays.

So the whole idea here is to provide clarity so that it's more clear to all the healthcare participants what is happening in the process, what needs to be done, who has the ball, as the ball is moving down the court, and what the next action is that's required.

The next one we talked about was design for the future while solving today's needs, and of course, we realize that our current ecosystem is very disparate. There's many different levels of maturity on the provider side, as well as on the administrative side. So trying to deliver an ideal state to that wide landscape is going to be no easy task, but there may be more capability to identify how can we deliver that if we realize that we need to have an evolving process and that process needs to happen over time, and that process needs to be able to mature over time. So to design a process that allows for that.

Then the next one was measurable and meaningful. Well, the process of reforming and improving prior authorization and clinical and administrative data really should be measurable. What does that mean? It means that today, you know, you often will see in a clinical environment a prior authorization might be presented and you get back a response that says pending. That's all you see until there's an outcome. It's either approved or denied.

Well, at the end of the day, measuring the progress from the current landscape to where we're going in the ideal state is going to be important for all stakeholders, because the hope is that as these recommendations get implemented, we'll be able to see measurable progress moving from the current to the ideal, and that's the idea behind this one.

Then continuous improvement. I spoke to this already, but we called it out as a separate entity with the ability to have evidence that allows us to be data-driven and show that continuous improvement as that process of continuous improvement can be built into the recommendations with metrics and goals and monitoring.

And then we moved onto real-time data capture and workflow automation. This is very important in terms of the ideal state, because in transactions where we have clinical and data and they intersect, clinical care should be supported by automated practices that reduce the time and effort used to document information for any clinical decision-making or prior authorization. So these processes should operate in real time in the background to improve usability and efficiency for all stakeholders, and then the processes should really focus on what information can be exchanged to make shared care decisions better, faster, and more transparent.

Next we have align to national standards, and here the prior authorization and the clinical process should leverage and align to existing national standards. We're not talking about reinventing the wheel, but we all know that there are some conflicting standards. There are some standards that have been put out there that haven't yet been adopted. There are standards that probably need to be advanced more speedily, and so we have a number of recommendations that will address all of these types of activities aligning to national standards and contributing to the community development of additional standards where gaps currently exist, rather than reinventing new methods.

Then we move on to information security and privacy. This is a very important aspect of the ideal state. Patient matching is an issue that we're -- everyone has talked about in many different venues, we did not try to solve that in this process. Again, we didn't speak to the how. But our ideal state is really grounded in the foundation that security and privacy considerations are very important to the design and the process. We need to be able to support that process as it matures within the ecosystem of clinical and administrative data. It needs to better be able to support the interoperability of the patient and the clinical ecosystem and especially as we try to move for more integration, and the more we integrate the data, the more important that patient identity, security, privacy, and consent is all going to be.

Then lastly, reducing burden on all stakeholders, and certainly this is not in priority order, because that is a major part of our charge, but the idea is that with a workflow-based design that we use to approach, the idea is that by having more ability to handle decision-making within the workflow, it's going to naturally, based on its design, reduce the burden on all the stakeholders, and through increasing transparency allowing for continuous improvement, being able to support things like primary and specialty care, public health, vital records, research, information that payers and policymakers need in addition to clinicians. We'll have the information we need without creating additional data capture or burdens on providers. The idea is to support a seamless exchange across the continuum of care.

This has great potential for reducing burden by furthering the implementation of recording once and reuse, which is one of the tenets that all of our recommendations were based upon.

So this is a list of each of the recommendations, which we're going to deep dive on on the following slides, but really the focus here is on what needed to change, not how we wanted to change it, and this list again is not in priority order. It's in the order in which we put it in the report. Then we really focused on the key opportunities where we actually needed action to take place in order to further the ideal state and the guiding principles.

So the following recommendations are discussed in the full report and really reflect the taskforce focus on the most important activities that we feel need to occur in order to achieve this ideal state and improve the overall ecosystem.

We'll go into each one. So the first recommendation is really prioritize administrative efficiency in relevant federal programs, and this is really focused on aligning the administrative efficiency objectives into relevant federal payment programs and through other joint type of certification that could occur with the interoperability rules and other things that are being also put into place. But also, look at providing targeted incentives to address the challenges for -- that small practices have. That was something that did come through in multiple avenues of stakeholders that came to ICAD, and I think is still very important in order to provide the support that's needed with that very broad spectrum of providers' ability to have the clinical support systems that they need.

Recommendation number 2 is really focusing on government-wide common standards advancement process, and here, again, the focus is on a single consistent process for standards advancement and really focusing on what are the relevant standards that are needed for moving the needle and then what are the processes that need to be put in place and accelerated in order to make this happen? As we all know, we have some issues relative to multiple standards right now today, and we are all working on trying to move those forward. So focusing on pilot projects and multiple rounds of development testing and even a later recommendation where we have perhaps some incentives where pilot testing is really going to accelerate the ability to adapt some of these standards more quickly.

This next recommendation is really focusing on the convergence of healthcare standards, again looking at the harmonization of standards to create this consistent set for code sets and content and services that are all evolved together to address multiple workflows, both from a clinical and administrative perspective, and we, although we didn't prescribe an underlying data model, we talked about the fact that if we have this imaginary underlying data model, that would provide the focus and the ability to serve both clinical and administrative needs in a very positive way.

So there was a lot of discussion around that, and then the focus of the patient-centered model, what does that really need in order to move the clinical and administrative workflow processes forward, and how can this new ideal system provide the transparency and information that patients and caregivers need, without putting additional burden on them to actually again be that quarterback through the process. So what are the standards that we need to put in place, and you'll see some of those coming up that may be supporting patients in a little bit in a further recommendation.

So the next one is really on providing the roadmap and timeline for the harmonized standards. This is really focusing on what is the roadmap, what are the priorities, what's not only the process of timeline but also what's the impact on the certification process, to put this timeline and roadmap into place?

The next recommendation really focuses on harmonizing code and value sets, and again, we spoke to this a little bit already, but there does need to be some decision-making regarding the value set authorities that are needed to harmonize code and value sets in today's world. There are standards that have been put forth by multiple groups that need to be harmonized and come together, and either

endorsed or moved forward in a way where we can as an industry adopt those standards and allow for the capabilities of the provider system to handle those.

You know, an example of this, and this is by no means a recommendation, but an example might be some provider systems because they're not overly mature might need to have this prior authorization standard on the X12 move forward, where others can utilize HL7 and maybe it's a matter of recommending both of them go forward and utilize one or the other, whatever is the capability of the provider system to deal with, but at the end of the day, we need to move that type of framework forward.

The next recommendation is really again making standards open to implement without licensing cost. As you can imagine, we got a lot of comments about this one. Really, the goal about this one is really to encourage future standards to be as open as possible. That doesn't mean that there is no income that would be generated, because obviously every standard has to be able to have some vital life to it, and that does require work and resources and efforts. So that's by no means what we're recommending here. But at the end of the day, making it reasonable and some sort of licensing model that can be adopted for both the small provider as well as large providers and payers is the idea and objective we're going forward with. So the idea being that as we move forward into the future, we really want to have that licensing model be scalable so that it meets the needs of the clinician as well as the big hospital system.

Recommendation 7 is really focused on the patient-centered workflows and standards, and really this is where we're getting to again the patient being able to be transparent and part of the process, but doesn't have to run and quarterback the process. That's really the focus of this recommendation, and there's a number of things that we can foresee that would be beneficial to patients to allow them to be part of the process without having to be the quarterback.

We can move to recommendation 8. Here, this is one where we identified adopting a member ID card standard. It was actually a surprise to me that we didn't have one. I actually thought we did have this already. When this came forward, this was something that a lot of the smaller providers especially felt would help their ability to match patients' identities and also be able to digitally ingest all of the member ID specifics for all the different payers, and since there already is an international standard, adopting that seems to make sense and will significantly help us as we move forward, because today based on the way it was explained to some of us what's happening today provides for a lot of mis-keying, which could essentially cause more issues with patient matching.

And then also, it sets the standard, sets the placeholder for perhaps a more digital ID card that could be adapted for other purposes, and you'll see that in another recommendation that we have that comes following.

Then we also talked about naming an attachment standard. This is one of all of our favorites. So we know that there are recommendations that are out there already, and we're saying name the standard so we can all move forward and make progress in this area.

Recommendation number 10 is to establish a regular review of prior authorization rules. This is really important, as we said, to mature the process, and what we've been recommending here is that payers would be requested to define what the rules are related to what's the data required to support the process, and those should be updated on a regular basis, and then that information should be able to be either pulled into the workflow or, once it's defined, part of the workflow so that the information required to support those prior authorization rules can actually be built into the workflow processes.

Recommendation number 11 is establishing standards for prior authorization workflows, and again, this one's really talking about what triggers an event, how the data would be communicated back and forth, and all of this will support the transparency and work that could happen within the workflow itself if administrative and payer systems were more integrated.

We don't necessarily want to have to rely on an EMR vendor to create a payer portal. Maybe it's a matter of creating the hooks that are needed for more of that integration so that third party tools can even be developed that would allow this to happen more quickly and also in a way that even the smaller providers would be in a position financially and otherwise to adopt those processes.

We can go to the next recommendation. So, 12 is really creating extension and renewal mechanisms for authorizations. A lot of the stakeholders spoke about this related to especially when you have a prescription and it's an annual prescription, why do you have to revalidate every year that you can't use the generic because it doesn't work for you? So some mechanism to allow renewals of previously justified prior authorizations that have been approved. There might be others for durable medical equipment or other things like that, but the example we used was for a prescription that might fit this bill.

The next one, which is 13, is including the patient in the prior authorization, and again, we specifically specified this out so that it would be known that we're not looking for the patient to have to be the quarterback, but we want to have entry points so that the patient has an opportunity to know, hey, my prior authorization is waiting information or it's waiting for me to get this test done or it's waiting for a lab, and once that's finished, then I'll know what the status of it is.

So it's actually a little bit more information from both administrative and clinical systems that tell the patient and the caregiver where are we in the process? Where today they have to make a phone call, because there's no -- they have no line of sight into this process at all.

The next one is really about establishing patient authentication and authorization to support consent. The idea behind this one is we want a standard to be developed that will allow us to support third-party patient identity development, and then also for a patient to be able to own their consent. So if we have a standard, then that means the patient can have an app that they can control where they have verified like clear ID does their patient identity, and that can connect to an administrative and clinical system, and they'll be able to sort of take their identity with them.

It will also, I think, in the long run, move us in the direction of where the patient security and privacy efforts are going, and it aligns to that, but it also allows the patient to control their own consent, where today that often has to be coordinated through an administrative paper process or clinical paper

process, which the patient, although they can request, usually again by phone call, but they don't control it, and this way, some sort of app where they have the ability to control their own identity and consent, they'll be able to control the process and hopefully speed it up.

Then this recommendation really speaks to the test data and we felt very strongly that we needed to have a test data platform, if you will, or test data bed with at least sufficient information that allows for integrated testing, because that is one of the things that's been a little bit of a difficulty in terms of furthering some of the standards especially for the APIs to move forward. We have testing processes, of course, already set up. But they're not really integrated, and you can't see the whole workflow.

So if we were able to have a test data set that sort of goes across the workflow, that would really help all of the stakeholders in the process.

Then from here, I'm going to turn it over back to Alix, who is going to provide the final summary, and want to thank you for your time today.

Alix Goss: Thank you, Sheryl. So I'm going to summarize the recommendations and then we're going to go ahead and open it up for questions. So Nick, you'll need to let us know how you want to manage that.

But to really kind of summarize all the substantive overview that you heard from Sheryl, in summary these recommendations are about patient-centered design approaches that get at the heart of the experience, the safety, and their ability to achieve the health outcomes that they've designed with their care team, that we really want to make sure that patient consent, privacy, and security are an integral part throughout the entire process, that digital capabilities automate manual time-consuming activities, to optimize approaches to achieve the record once and reuse.

These recommendations address key barriers to effective information exchange, to improve transparency and timeliness of prior authorizations and decision-making processes for all stakeholders. These recommendations build and extend on current standards to enable maturity and evolving processes and resolve conflicting standards which may be inhibiting innovation and adoption. We want to provide a path forward to harmonize today's national health care policies, vocabularies, and transport standards, because there's tremendous investments, but we really want to ultimately create an ecosystem that enables patients and caregivers to focus on their wellbeing rather than problem-solving administrative process complexities.

We look forward to your questions. We thank you for your time today and look forward to your ongoing involvement in creating a convergence of our national frameworks.

Nick Coussoule: Alix and Sheryl, thank you very much for doing this. I'm frankly kind of stunned you could cover it all in 45 minutes. So very good job of being concise with a very dense report. So lots of really good work.

Let me open it up to the other committee members. Please, raise your hand. Denise I saw first, but others go ahead and get in queue and I will call on you in time. Thank you.

Denise Love: It is so great to see Sheryl and Alix even if it is by Zoom. Thank you both. The report is comprehensive and I clearly have not absorbed it all. But I have some questions that may be obvious, but please help me out.

The first one is what is the implication for the 278? Does it or are there any implications? Does it make it more important or less important? That's one question.

Alix Goss: So I am going to start, and then Sheryl can certainly weigh in here, but from our standards subcommittee perspective, the 278 prior authorization X12 transaction has had a 13 percent adoption rate since its -- during its 20-year mandate. So we're in a situation where some have invested in the EDI standard of a 278, but a lot haven't. So when we talked about naming an attachment standard, that is also an ability to get that additional payload that might be needed in that prior authorization request, and so we need to have a proposed rule released as is envisioned by the unified agenda so that we can think about attachments and how that fits with the prior authorization process so we can automate it more.

But what this really also means is that we've stayed above the specifics of the 278 as a HIPAA-mandated transaction, as that's within the authority of NCVHS. So I think that what this means for the 278 is it's getting a lot more time and attention, as was envisioned by the review committee report in 2016, and that I would think that where we want to go with the 278 will really be chartered by the convergence product of the standards subcommittee.

So it's not gone. I think we have opened up the light of day on it to say things have changed, folks. Maybe it's time to change, but that means that we can do some things from a workflow policy perspective, but as far as the transaction standard itself, I think that will be something that this committee would be able to take a look at as a part of your convergence project.

Denise Love: Great. Thank you. A second one is clearly the prior authorization is a wonderful deep dive use case for how clinical and administrative could or should come together, and you've done a marvelous job on that. But because I'm a public health kind of orientation, I see that this could just be applied, and please, help my thinking, in a public health sort of way, be it COVID, an attachment from the electronic health record for a COVID encounter, say, in immunization. I just want to see if my thinking is along those lines.

So is that -- so this is a use case that could be applied more broadly to public health, correct?

Alix Goss: Yes, I think especially when you think about the record once and reuse objective, the idea that we could start to have a converged set of frameworks that would enable us to support public health uses above and beyond administrative and financial and clinical purposes is definitely within scope, and Sheryl, I don't know if you want to chime in here. I know there's a lot more work also going on within HITAC, the parent federal advisory committee related to COVID.

Sheryl Turney: Thank you, Alix. I absolutely agree with everything you just said, and do feel that there is great opportunity to utilize some of the recommendations that we have put forth here to support public health. As you know, one of the difficulties is that public health reporting tends to be very disparate. So every state has different rules, and Denise knows this well, and has different ways in which they want

the data and information communicated, and it's challenged not only for providers, but also for payers who support multiple states.

So having some standards around the clinical administrative data workflow, I think will accelerate the ability to share data for public health purposes and also help that data to be more usable, because at the end of the day, how that data then can come together if it's needed on the federal platform is going to be more accelerated if that data is consistent across multiple states, and today even that's been a challenge with COVID that the CDC has had when they're getting data from different states who get it in different ways.

So then there needs to be a time and process to normalize that data before it's usable, and we've already seen that happening with COVID.

Denise Love: And then just one more thing, and Sheryl, this is kind of for you, but as I read through the report, the key words that jumped out to me from my past life: price transparency, out of pocket expenses and benefits. I mean, those are huge informational issues related to all payer claims databases, and so any work on making that more timely and readily available is I think a worthy effort.

Sheryl Turney: Well, and of course, as you know, the price transparency rule came out October 29. So that data is going to be more standardly available because of the 500 shoppable services, and so again, that might resonate, since you brought up APCD, for APCDs to go back and say how do we want to look at these 500 shoppable services, because as you know, they don't collect data in such a way today that they would be able to actually align to that. So that definitely needs to be a discussion in that avenue.

Denise Love: On the list. Thank you very much. I won't dominate any more for a while.

Nick Coussoule: Thanks. I just have one quick question and then we'll turn it over, I think Rich's will be next, but you mentioned in the report a national ID card kind of nomenclature. How does that tie in with some kind of a potential for patient ID, national patient ID? Because obviously the national portion gets very complicated.

Sheryl Turney: We are not recommending a standard national patient ID. We specifically stayed away from that, but a standard for the data that's presented and how it can be ingested by all of the EMR and the provider systems is going to be very important, because we still have many, many issues today, especially with smaller providers, because the data is ingested as a PDF, their system can't make it digital, because all the data is in a different place, and so then there's someone transcribing it, and then there you already have patient matching issues.

So that to me is a simple one that we should really be able to solve. There is a national -- I mean, international standard, adopting this is going to allow all of the systems that providers, EMRs, and even we use to help that data be ingested in the right way that it can be digitized, and that's going to add one more step to getting greater patient matching.

There's still needs to be other things out there in order to do that, and as you may know, Karen has been talking about the potential for third party identity development, as well. So it's not something that's foreign. This is a subject that's in a couple of different venues being discussed.

Alix Goss: I do think it is important, Nick, to think about the fact that if the prohibition for addressing an individual identifier is really removed, the standards subcommittee specifically has that as one of its responsibilities, above and beyond transactions, standards, operating rules, code set and vocabularies, we also -- the identifiers are part of the responsibilities allocated to this body.

Rich Landen: I will start off with some comments as a member of the ICAD taskforce, rather than questions. For those of you reading the report, I would suggest that you spend some time looking at the appendices, and the reason I'm suggesting that is because the input from industry on this was really phenomenal. Call out and kudos to the American Medical Association and others for bringing forward presentations that really talked about what is the impact on the patient and on the workflows around the patient on both the provider and the health plan side, if something goes wrong with prior auth, and that was really, really fundamental to the work of the taskforce.

And then in addition, the presentations by so many of the people active in the industry about how they're thinking about prior auth, what they've tried, what's worked and what they rolled out and what's worked, what they tried to roll out, didn't work, they pulled it back. It was just really foundational to bring this thinking together of the taskforce.

My second comment is, again, thanks to HITAC and ONC for appointing the individuals they did to the taskforce. It was a really good group, dedicated people, passionate, knowledgeable in all sorts of different spheres, and all of us were able to come together and discuss ideas. We had people with very conflicting ideas, and yet we had very civil and productive discussions and came to conclusive outcomes.

I think I'll stop there. Oh, can't forget, kudos to the two co-chairs, Sheryl and Alix, for really herding the cats and coming up with such an incredible report in a relatively short time. Thanks.

Alix Goss: Thank you for your synthesizing and drafting efforts. You were a very strong contributor, Rich.

Jamie Ferguson: Thank you. Another quick question, it's on recommendation 8, about the ID card. Did you consider the need for federal preemption of state law in this? Because, of course, insurance being regulated primarily by the state insurance commissioners, in our experience operating across multiple states, some states have mandated specific ID card standards for insurance identification that includes or prohibits specific data that's in conflict with what other states require, and this includes both what may or must appear on the face of the card, as well as all the electronic features. So it's really a question about federal preemption.

Alix Goss: I would think that that would be addressed in the how. If they're going to advance that as a recommendation, we would, as you may recall, I noted using the various tools in the toolbox, I would anticipate if they're going to try to advance that recommendation in particular, they would put a proposed rule out and they would have to take into account the preemption dynamics.

Nick Coussoule: Other questions by members? Let me ask one more. What is the -- obviously, the report just got issued, and I haven't had a chance to go through it, but what's the next step for the report? What happens to it now?

Alix Goss: Since it was approved unanimously by HITAC on the 10th of November, it was transmitted, I believe yesterday, to the national coordinator. So what they did was they took the approved report, they put a formal transmittal correspondence on top of it, and they sent it off to Dr. Rucker. What I know from attending last week's HITAC meeting, Nick, is that ONC has already started to work on their draft workplan for HITAC. So maybe Sheryl could speak to this more than I. But they did indicate that there would be something next summer related to ICAD.

So I think what we need to understand is that they have to take and receive this report, ingest it and figure out how they want to work with the leadership of HITAC to start to address various pieces within their authorities. I believe that also coming here today as a part of the next steps in that we're anticipating that we are -- that we've now delivered a final report and that NCVHS has its own project for convergence and will pick that up and use it to start to figure out how to move forward with the applicable authorities and deep dives that need to occur.

Sheryl Turney: We're looking forward to that, Alix, and I think this is not unlike what's happened with USCDI and information blocking where once there was more activity and maybe a formal report or rule or guidance that came out from ONC, there was follow-on work where we looked at how do we mature the process, how do we go to the next steps, and I know in this particular case they're hoping that we will then expand what we've already done to build off of that in the work that is anticipated for next year.

Nick Coussoule: Excellent. We have time for one more question. Rich?

Rich Landen: Yes, I'm speaking from the perspective of the subcommittee on standards, we need to set the stage a little bit for what happens now with the subcommittee's work. ICAD's final report now becomes input to the subcommittee on standards for our own project about convergence, and this will inform the standards subcommittee as our first step is to redo our project plan and address the scoping to include some of the areas pointed out in the ICAD report from previous discussion among the NCVHS members, to rescope that and work on it, and I picked out a couple of themes from both the ideal state and the recommendations of ICAD, and that's kind of a bringing together the entire ecosystem in terms of aligning the standards, the terminologies and vocabularies, calling for essentially a reform of the way the HIPAA rules and other regulations are promulgated by the feds, that addresses the stovepipe issues and also tangentially picks up on the themes like Jamie raised with the preemption.

And brings that together and then it's back in our own bailiwick of where we go from here. Another influence is what we talked about earlier on, the predictability roadmap, where the industry needs some certainty. We need smaller bites. We need digestibility. All with a focus, with a newfound focus, on patient-centricity, because early HIPAA transactions were business to business. There was no role for the patient. The patient was not an actor.

Now when we talk about healthcare services, specifically prior authorization, the patient becomes an actor. So there's a lot of changes in the way rules are promulgated and the NCVHS will be getting a report and recommendations coming out of the subcommittee on standards as we get into that initiative. So we look forward to a lot of discussion and interaction with our colleagues as we digest the

ICAD report and then move that forward into our own plans and recommendations on the convergence of the administrative and clinical.

Alix Goss: Rich, I think you bring up a really good point. We are at an inflection opportunity to change the way we communicate. We've learned a lot. We have invested a lot in technologies. We've got good policy frameworks, but they need to evolve to modern capabilities, and this idea that we can automate where logical and change the way we have that chatty clinical conversation and administrative processes.

Nick Coussoule: All right. Sheryl and Alix, thank you again very much for bringing this. Sheryl, you are always welcome at NCVHS any time you want to come. Alix, you can't get away.

(Laughter.)

Sheryl Turney: Thank you so much. Really appreciate it.

Nick Coussoule: With that said, we will move on to our next topic, which is Mary Greene, who's the director of Office of Burden Reduction and Health Informatics. Welcome, Mary.

CMS Update

Mary Greene: I just want to say hello to everybody and thank you for giving me an opportunity to tell you what CMS is up to, and I think you'll find that some of what we're up to and some of what you just heard about over the last hour comes together pretty well.

This is what I want to talk about today. I'll tell you a little bit about our new Office of Burden Reduction and Health Informatics that was stood up just this past July, why the office was established, and what we do and how we're organized. Then I'll talk briefly about what we're doing to achieve -- what we're working to achieve through interoperability and just highlight some of the projects that we're doing, and then finally I'll give you a couple of updates on the HIPAA national standards.

CMS has been working for quite a while, for years really, on reducing administrative burden, and the focus has often been on clinician burden. That's what you'll hear. But it's really for all the stakeholders that we're engaged with, including burden on our beneficiaries, and we were just talking about that in the context of prior authorization and why it's so important to go forward with a very seamless prior authorization process that not only has the beneficiaries at the center, but also remembers that they're, as you mentioned, an actor but really the person, the entity that's really trying to get their healthcare attended to, and that process sometimes gets in their way. We'll talk about that more in just a minute.

So three years ago, reducing the administrative burden became an agencywide strategic initiative, and that's called our Patients over Paperwork initiative which some of you might have heard about before, and that initiative was focused on gathering input from clinicians, providers, beneficiaries, and other stakeholders as I mentioned, and the goal of getting the input is to really understand how our rules impact their day-to-day operations or potentially get in the way of great patient care, potentially somehow inhibit innovation in how healthcare is delivered.

Every component participates in the Patients over Paperwork initiative, either bringing in information from the external community or using that information to inform some of those solutions that we're working on.

So the CMS established a new office to institutionalize that work, to expand on the work, and actually coordinate the work even better across the agency. This is what we're charged to do. I'm going to give you a running list here. Reduce administrative burden in the health system to keep everyone focused on delivering high quality care. I want to emphasize our lens is the health system. There is other activity going on to reduce, to improve efficiencies within CMS, and those efficiencies I know some of them will help with the health system, with the external community, but our lens is really what can we do at our end to reduce burden in the health system external to CMS.

Our responsibility is also to advance interoperability and the use of national standards to achieve operational efficiencies, and we were just talking about that sort of thing, and make data available when and where it's needed. So people can gain insights from that information and make decisions, and again, that's beneficiaries having the information and clinicians having the information and others who need it.

We engage beneficiaries and the medical community to inform the work and the solutions that we might be working on, and we are charged with infusing a customer-focused mindset throughout CMS. That doesn't mean always keeping our beneficiaries front and center. We certainly have to do that. It doesn't just mean thinking about clinicians and providers, always having them top of mind. It means understanding their experiences and then their insights about things like, well, the pain points beneficiaries face navigating the complex health system or clinicians grapple with different prior authorization requirements across different plans. So even if you make it easier to get to those requirements, you're still dealing with a bunch of different requirements and decision-making happening in different ways.

Also even health plans and the challenges that they face, as well. A big one, and the one that was really foundational to this burden reduction work, really was the challenges providers face just keeping straight what our rules are, regulations are, and following them so they remain compliant with our programs. It's also about valuing those experiences and those insights and bringing that understanding internally to CMS so when we're having internal deliberations on policy changes, let's say, that information is informing those conversations.

We joined three existing bodies of work and brought their teams over to create the office. So one is the core Patients over Paperwork team that I was just telling you a bit about, which is really focused largely on burden reduction through policy changes. Then the national standards team that's responsible for implementing and enforcing the HIPAA administrative simplification regulations, and you're talking about that quite a bit in the last presentation. Then the interoperability team that was previously comprised, that previously comprised the Office of Health Informatics. That's now part of this office, and that team has really been the driving force behind CMS's interoperability policy and the push to develop APIs to liberate data, in particular.

So you might ask why did these three teams come together? First of all, if you just align the teams I mentioned to the list of things I told you we were responsible for, they're actually completely aligned with the work that we have to get done, but also at their core, all three are fundamentally focused on burden reduction, even if the emphasis is a little bit different or the scope is a little bit different.

Each by design has an enterprise view of their work. Patients over Paperwork and interoperability, that enterprise is across all CMS programs. For the national standards work, that enterprise includes HIPAA covered entities, whether or not they participate in CMS programs. We always have to take that into account as we're moving forward with the work that we're doing.

And the last thing is for all three of those workstreams, a customer-focused mindset is incredibly important and is really the way they operate engaging with the external communities, really critical to our successfully getting done what we need to get done and something that's successful in the eyes of the external community, not just our eyes.

So the staff that you -- I mentioned already that the staff came over with the work, so that even though they've been interacting with CMS before in the context of those three workstreams, those are the same people you'll be interacting with, and our current priorities haven't shifted and working together, we actually can get more done all of us being in the same office.

So we have five groups. The first one is the customer-focused research group, and that's the group that leads our human-centered design work and other customer-focused research work, and their job is to ensure the customer perspective, as I mentioned, is understood and it's accounted for in all the work that we do.

The second group is the governance and impact analysis group. That group leads our governance functions, such as our agencywide burden reduction steering committee that's a couple years old now. They also coordinate our office's communications and assess impact of our initiatives.

The health informatics and interoperability group, they lead the development of CMS's interoperability strategy. That strategy is about advancing the secure data sharing and use of health IT among payers, providers, and patients, and really again, other stakeholders that are in the mix, depending on the use case that they're working on. The goal is improve patient outcomes, drive down costs, and promote patient choice.

For the emerging innovations group, you can think about them as an incubator. That group leads cross-agency pilot projects that either explores opportunities to reduce burden or explores opportunities specifically to improve interoperability. So if a pilot is promising and CMS decides to go forward with it, meaning somehow advance and operationalize it, the project might actually go someplace else in CMS to actually operationalize. So think of that as an incubator doing pilot projects.

Then finally, the national standards group you know well. That was previously in OIT in the Division of National Standards, and they developed the regulations and policy to implement and support the administrative simplification provisions of HIPAA, but they also have an enforcement responsibility as well, enforcing those rules.

So let's talk about interoperability here. This slide is kind of the context to keep in mind as you think about how we look at interoperability and what we have in mind as we're taking into account what we're going to work on and how we approach it. So here's some context for it up front.

So the context is patient information is often trapped in siloed health systems, and some of this was discussed in the last discussion, too. That prevents patients from accessing their complete health information. This sometimes leads to providers offering treatments without having all the patient's health histories or complete histories, anyway, and potentially putting the patient at risk. So they might duplicate tests or duplicate treatments or suggest treatments that are more costly than they need to be, or unsafe for the patient because they didn't have the full medical record to take a look at. The clinicians would have made other decisions had they had the full record.

Because of the systems that can't share data, valuable insights that could improve outcomes and save lives are lost. That is the urgency behind improving interoperability. So MyHealthEData strategic initiative, which I think you probably heard about, too, that's an administration-wide initiative, and it aims to unleash data and empower patients by giving them access to the data and use of their data, their health information, and allowing that data to follow them wherever they are in the health system.

We're taking steps to make sure that they have that access and can get that data in the format that is practical, that's usable, and it's shared easily. Again, the expectation is this is about not only improving efficiency, but patient safety and outcomes, too, and that was mentioned a couple of times by Alix and Sheryl as well.

So the graphic here just shows the things that we take into account then as we're looking at our interoperability policy. So if you look at the top row there, and some of you might have seen this graphic before, but I already mentioned the first item, getting patient access to their data so they can make informed decisions about their care.

Second, healthcare needs to be connected through data exchange across the care continuum to get the data flowing and we talked about it being so important for patient-centered care and to get to value-based care. Third, we can't have interoperability unless the technology and standards are in place. So we're all speaking the same language.

But the other thing that we always need to remind ourselves and everyone else is this is a journey to get to interoperability. It's never-ending. That's the reason why you see the arrow at the end of the road in the picture there. There's no finish line that says we are done, we've achieved full interoperability. The journey will always evolve. Technology will change, and we'll need to be nimble and agile to innovate together. So some of the convergence that was talked about before and having a common vision of how, which direction we should be going and how we kind of bring all the parts together to get there is incredibly important.

Finally, this data exchange is built on the foundation of privacy and security at the end of the day, protecting patients' data is an absolute critical piece of the puzzle, and every time we talk about interoperability, we should talk about privacy and security and that's just like Alix and Sheryl were saying about that as being the foundation of the ICAD recommendations, as well.

So an example of a project, and again, I suspect you are familiar with this, and that's CMS's Blue Button 2.0. That project gives seniors more control over granting application developers access to their Medicare records so the information can be used to improve care and increase positive health outcomes ideally. There's about 3,600 developers working on new apps to serve seniors, and 63 applications are in production at this point. As part of that program, it's important to ensure the privacy and security of patient data, as we were mentioning, but it's particularly important because some of the folks who are involved in that ecosystem now, the app developers, the digital service companies, they're not covered under HIPAA. So thinking about privacy and security with health information in noncovered entities is going to be an important piece of this.

I just want to mention, we released the CMS interoperability and patient access rule last May, and let's go to the next slide, and I'll just give you some highlights about that rule. I won't go into it in too much detail, but we can -- if you have any questions about that, we can connect you with our policy folks to go into the detail there.

But the rule was proposed in 2019, and it was about a year later when it was finalized, and the initiative, the purpose of it, is to improve patient access and advance electronic data exchange and to improve care coordination across the health system. So it was approved around in early May of this year, and our vision is a future where open APIs allow seamless data sharing in all aspects of healthcare, and this is supported by innovative developers who can use that data to make customer friendly tools that empower patients, that help them to make decisions and to understand their care and to support care providers as well.

Our vision also includes a future where researchers and innovators have access to CMS data to support advancements in healthcare delivery and quality, as well as develop tools to support patients and providers in the decision-making, which I already mentioned. So the graphic depicts the key provisions of the rule and approximate timelines of when they become effective, but I'll just give you an idea of some of the provisions in there.

So there's two public reporting provisions in the rule to publicly identify doctors, hospitals, and other providers who engage in information blocking, for example, to publicly report those providers who don't have digital contact information include in NPPES, the National Plan and Provider Enumeration System. There are two API provisions in there, so all payers doing business in Medicare Advantage, Medicaid, CHIP, and through the federal exchanges are required to share health claims data and other important information with patients, and they need to share it electronically through FHIR-based patient access APIs.

As part of that, a payer may ask a third-party application developer to attest to certain privacy provisions that can help keep a patient's data private and secure. CMS regulated payers are also required to make provider directory information publicly available through a standards-based provider directory API. So it has more for the patient access API, then it has the provider directory API in there too.

There are three additional provisions to note, and then we'll move on here. First, the rule requires that all hospitals send electronic notifications to designated health care providers when their patients are

admitted, discharged, or transferred from the hospitals. That's the ADT provision, and second, a patient's health information should follow patient, as I mentioned multiple times before here, as they move from payer to payer, though. So creating a longitudinal record for the patient in their current plan. So there is a payer-to-payer data exchange provision that requires payers to exchange patient USCDI data upon request.

Finally, there's a provision to improve the dual-eligible experiences by increasing frequency of the federal state data exchanges so they're more up to date. Just want to note, too. People have asked us about whether any of these deadlines are going to be delayed. When we finalized the rule, at that time, we actually delayed some of the deadlines for implementation. So the patient event notification condition of participation, that ADT provision, that was delayed until 12 months after the official publication date, which was May 1, I mentioned, so that's effective in April 2021 now.

And then we exercised six months of enforcement discretion for both the patient access API and provider directory API, and so they will -- we won't enforce either API policy until July 1, 2021.

I want to mention COVID, and I'm glad Denise mentioned that, as well. So when COVID-19, when the public health emergency was declared, CMS put in place a number of waivers and rule changes and other kinds of flexibilities to help the health system address the surge of patients who had COVID-19.

So we gain a lot of insight along the way. For example, having the statutory authority to make some of the changes we did was pretty important, and frankly getting new statutory authority from Congress during the PHE was critical, and that's actually what allowed the medical community to use more telehealth. That's a good example of that.

Feedback from the field was also critical, both to identify what waivers were needed and how well they worked, and that pipeline of information came through numerous, numerous letters and tons of emails to a dedicated email box and very, very many listening sessions, and they were enormously helpful. I can't tell you how incredibly helpful that was.

But from my perspective, the COVID-19 pandemic is the quintessential call to action to achieve true interoperability and make clinical and administrative data readily accessible for care coordination and decision-making. That is a critical, critical lesson and call to action.

So just think about patients who had to move from skilled nursing facilities to hospitals and maybe to another post-acute care setting. Think about critically ill patients who appear in the emergency room with sometimes without records, or how about patients quarantined on cruise ships or who stayed with their family in a different state, separate from their usual care providers. At a minimum, a patient's data needs to follow the patient. The patient needs access to their information, as do the clinicians and the providers and their carers.

So this pandemic has also shown how necessary and critical it is to share data safely, securely, and quickly between the care delivery and the public health systems. So I agree 100 percent that if anyone didn't believe that this clinical systems and the public health systems need to communicate better what went on during the, what we've all experienced during COVID, is just ample proof that those communications need to improve. The interoperability needs to improve.

Let's talk about some CMS projects and, of course, the first one, of course prior authorization is top of mind at CMS. It came to our attention many times before, but when it was clearly emerging as a top source of clinician burnout, that really was the driver to do something and accelerate the pace of what we could potentially do. So there's no question prior authorization has a role in utilization management and promoting evidence-based care, but if it's onerous to get through the process, it's a problem. It's not just a problem of inconvenience, and some people say that. It's just inconvenient. So we need to make it better.

What should get all of our attention is that it can lead to patients unnecessarily paying out of their pocket or abandoning treatment, and that's one of the things that was described in the context for the ICAD report and delays in getting prior authorization. It also leads to some patient harm.

I could tell you that we had some patients come to some of our listening sessions when we were trying to get a better real-world on the ground understanding of what happens when somebody goes through prior authorization and it doesn't go well, and we had a patient with a severe seizure disorder who talked to all of us very passionately about how she's on a medication that requires prior authorization, it has to get -- the prior authorization has to get renewed relatively frequently, even though they know that she needs to be on that medication, and she literally worries that she is going to die of a seizure if there's a cap on her medication and she runs out of medicine in between.

There was another patient with a severe form of arthritis who said the same kind of story, and she said, again, it happened to be a very expensive drug, and she had to get the medication renewed every six months or so, and the process took a long time and it always ended up getting renewed, but she did end up with gaps in her medication always, and she did end up with decreasing the dosing, skipping days, so that she had her medication, and she was not worried about dying, but she was worried about losing functionality and not sure that she would get that function back, the physical function back, once she got back on her medication.

Most importantly, though -- not most importantly, but that definitely opened our eyes is when anybody says anything is more important, is a bigger challenge and more important to address than the electronic health record burden, then you know it's a big deal. So prior authorization unseated EHRs as the biggest burden, and that's an accomplishment that's probably not great.

So documentation requirements has also been consistently among the top burdens as well. We've been hearing about that quite a bit. We're told that our requirements are hard to find. This includes our prior authorization requirements, but this kind of use case or area of burden is much more general than just prior authorization.

Scattered across different kinds of documents like our regulations manuals, global coverage determinations, and scattered across different websites, our websites and our contractor websites. So requirements vary from region to region. It's not always clear what the most recent true requirements are. It seems that requirements may not always be interpreted consistently by our medical review contractors.

Now that, what I just mentioned, that was said about our requirements. So imagine having to find, understand, and comply with requirements across 6 to 12 plans you serve in your practice or facility, each with different rules and resources to find them.

This information maze has unintended consequences, and you can see some of the unintended consequences on the right side there. Whether it's documentation for medical review, or prior authorization, or anything else, this information maze has to get streamlined. You can note on there that delays to beneficiaries getting medically necessary services and barriers to interoperability are particularly important and particularly important to the conversation that we're having today.

You are quite familiar with this, I believe, but I just want to mention one of the -- we have been participating in a pilot project to create a documentation requirements lookup service. That's what we called the tool that we were piloting to make our requirements more accessible. This says documentation requirements, but it's really has in mind prior authorization requirements, too. And you know about the collaboration in the medical community and the health IT communities, to make documentation requirements available at the point of care, and electronic health record, or practice management system, in the workflow of the clinician or the administrative staff, whoever is doing this, or making available through apps on smartphones.

I remember I was talking to a number of optometrists, I think it was at the time, and I said how do you like to learn about our requirements? And they picked up their cellphones, several of them together, just in unison almost, picked up their cellphones. So that's how I like to get our requirements.

APIs like FHIR are the key to making this work, so that our requirements and other payers' requirements can be equally and easily discoverable, even if the requirements are different. The picture here depicts the use cases that are involved in the transactions there. There's two Da Vinci use cases in particular, coverage requirements, discovery -- that use case where the provider's EHR asks the payer system if there are prior authorization or other documentation requirements and receives a yes or no in response, and then the documentation templates and coverage rules use case, where the EHR can request, then receive, documents, templates, and rules from the payer's system.

We're currently focused on Medicare fee-for-service requirements, oxygen and CPAP requirements in particular. We've actually completed our initial pilot, and we're in discussions internally about what it would mean for CMS in terms of organizing our content and also in terms of technology to operationalize a more permanent solution.

Once you know that there's a need to request prior authorization, and you know the documentation that's needed, there's a third use case, and this, again, is the Da Vinci use case that I mentioned that can help facilitate the sending the prior authorization request directly from the provider's EHR, and that's the prior authorization use case. This use case not only facilitates the request, it also facilitates the decision flowing back to the provider's system. And this is all a system-to-system exchange.

Also, if you look in the middle of that graphic, just wanted to emphasize that the FHIR APIs and the information going back and forth, taking advantage of those in the context of the use cases, that's all done maintaining the integrity of the required X12 standards, as well, and that's what you see in the

middle of those transactions there. So sometimes people say we need FHIR, that we can do this with all FHIR. Sometimes people say we can do this with all X12 transaction standards. If we're really going to take a giant step forward now, we really need both of them to execute this.

I just want to mention one other thing, just to put it on your radar, and then we'll move to the next slide, and that is in June 2019, our colleagues in the Center for Medicare proposed that Part D plans would be required to use the NCPDP electronic prior authorization standard transactions, which will allow physicians to satisfy the e-prior authorization requirements at the time of prescribing. That's the goal, anyway. Keep that in mind; that would expedite prior authorization for sure. The particular burden here is avoid patients getting turned away from the pharmacy when they show up at the counter and find out that there was a prior authorization step that had to be done that wasn't done. So keep that project in mind, too.

Right. Let's go to the next slide, and this is going to be context-setting again, for the next project I'm going to mention to you. Again, this is a known story in the interoperability world, certainly in the clinical process improvement world, about the challenges patients face navigating the health system.

We know the system is complex, and it is tough to challenge and tough to navigate, and even some people with some clinical background remark at how challenging the system can be sometimes. So think about a patient experience that might go something like this: start with their visit to the emergency department, followed by a hospitalization, and then maybe they will need some home health services after discharge, and maybe when they're home they have a fall or experience a complication and they're admitted to a different hospital. Then maybe after that they need some time in a skilled nursing facility before they can go back home.

For a patient who is dually eligible for both Medicare and Medicaid, and it's maybe while they're at home, they need some home and community-based services. That's what's depicted in that journey for Mrs. Smith and her daughter, actually, who is pictured in the middle there. And if you just read counterclockwise, that's the journey that I was just talking about. So ow do we make sure that Mrs. Smith's data follows her on this journey and is shared with her along the way? And how do clinicians get insights about her health as she progresses through this journey? How do we get the right information, right person, right time, right format?

So let's go to the next one. This is a project that is led by our quality center, Center for Clinical Standards and Quality. It's called the PACIO project. It was launched in February 2019. It was launched in response to a provision of the IMPACT ACT, some provisions -- more than one -- in the IMPACT Act, that requires the use of standardized Medicare quality measures and assessment data in the post-acute care settings. Post-acute care settings, of course, are long-term care facilities, home health agencies, IRFs, that sort of thing. Each of those post-acute care settings have their own patient assessment instruments. So there's a SNF instrument, there's one for home health, et cetera.

These CMS patient assessments have been developed individually over time. They include administrative data and clinical data, in addition to data elements like general function, cognitive function, and impairments like, things like, incontinence. While each assessment tool collects similar

concepts, there's a variation in how that information is assessed, making it difficult to share information and easily compare outcomes across settings.

Meaning, you can use a SNF assessment tool, and if someone goes from a skilled nursing facility to another one to another one, you can get an idea of the progression of their -- the assessment of how they're doing. But if they go to different kinds of long-term care -- post-acute care facilities, you really can't compare one setting to the other setting.

So by standardizing the data in these assessments, and CMS is doing that by the development of a data element library, we can get a patient-centric view of the quality across episodes of care, and not just a view in a single type of care setting.

The PACIO project is a consensus-based project. It's a collaborative partnership. It's working to leverage FHIR and standards-based APIs to advance interoperable data exchange between PAC providers and patients and other stakeholders. The project is open to everyone, and participants include health IT vendors, providers, clinicians, researchers, CMS, ONC and B, are also involved in the project.

Let's go to the next slide. Another source of burden you've heard loud and clear is the burden of reporting data, such as for the burden of reporting many quality measures needed for various CMS programs. An important way to reduce burden is to make reporting seamless and easier, and that can be achieved with digital quality measures. Last February -- so this is February 2020 -- CMS committed to getting to all quality digital measures in 10 years. So that's by 2030. CMS has been working to advance digital quality measures, both electronic clinical quality measures and hybrid measures, which include clinical claims data.

That's an important effort, and envision this, if you think about the data that would need to go back and forth, system to system. Envision the opportunity to create a seamless connection between quality measures, clinical workflow, clinical decision support, in a feedback loop. Again, that's our quality center leading that effort, as well.

Let's go to the next slide. Let's switch to HIPAA national standards. The CARA Act, Comprehensive Addiction and Recovery Act, allows physicians and patients to choose to receive less than the full amount of opioids prescribed. And that of course is in the context of trying to reduce the number of opioid prescriptions, but also the amount of opioids that are prescribed for a given prescription. The existing standards, and these are NCPDP standards, the existing standards were not able to record the new way CARA allowed opioids to be dispensed. The new standards, in particular, had that ability, but the new standards that we're trying to get approved here have the ability, but there had to be an interim solution. So the change that was made here allows pharmacies to record partially dispensed prescriptions, and that was important.

Let's go to the next slide. That came out of the support guide, by the way. Slide 16 here, there are a couple of HIPAA standard regulations in development. One you've already talked about a bit, so that's the attachment rule, which will include both transaction and documentation standards to accompany the already-existing HIPAA transaction standards as recommended by NCVHS. And then there is the NCPDP standards, which will include the recently recommended F6 version, as well as the updated

NCPDP subrogation standard. Both of those are on the unified agenda. I encourage you to track the unified agenda for progress along the way.

Just one caution, though. The unified agenda version that's up there now is the spring agenda. I didn't check within the last couple of days, but the fall agenda wasn't up there yet, so please look out for that.

The next slide. The national standards group I mentioned has an enforcement function, it administers the ongoing compliance review program among covered entities. It randomly selects health plans and clearinghouses to be audited for compliance with the standards, the HIPAA administrative simplification rules. It's a proactive approach with a progressive penalty process. The goal is not to get ya; the goal is to remediation, to help organizations who are not compliant to become compliant, and that's done through working with the organizations, having them develop a corrective action plan, and then have them execute against the corrective action plan.

I mention that because the compliance review reports are available on a quarterly basis online on the CMS website, and you can see the link there, because it's a good place to go to get some idea of where organizations are not compliant, and they're all anonymized, so not the specific organizations involved.

We're close to the end, and there'll be a little bit of time for questions. Here's what I hope you would take away from this discussion. First is, it's really important for us to engage with you and you with us, and we value that engagement. It's an important source of information for us, and what you learn from others in the field, not only about the direction we should be going on burden reduction generally, clearly interoperability, specifically here and standards specifically here, is important. But what you also learn about the challenges of evolving standards and advancing standards, what are the challenges payers have or providers have, actually implementing them. Those kinds of insights are enormously helpful, as well.

We are actively working to reduce burden, to improve care coordination and empower beneficiaries, as I mentioned, and it's with their data, and it's through interoperability, and the right standards have to be in place for that to advance more rapidly.

When it comes to national standards under HIPAA administrative simplification provisions, the pilots that are done, the real world evidence that's generated, and the alignment that's achieved across the healthcare industry, and honestly, more alignment would be great, and I think that was brought up in the last hour, too, helps move the standards adoption process forward, which helps all of us. So that's absolutely critical.

So thanks. I'll end right there. And then we can go to questions if anybody has them.

Nick Coussoule: Thank you, Mary. That's a lot of activity happening. But really good stuff. I'm personally excited about it. Let me open it up to our team here for questions. I see Rich's hand up.

Rich Landen: Thanks, Mary. Very informative presentation. It's a ton of work you've got on your plate, best of luck, and however we can help with that, we will. I'd like to focus just on the HIPAA administrative simplification for a minute and talk mostly about the lessons we have learned from the industry in our hearings over the last three or four years. The bottom line, I guess, is that the industry

has told NCVHS loud and clear that the current HIPAA regulatory process just isn't working for them. When we've looked back and taken an arm's length look at that, it's really not surprising, because HIPAA in 1996 was based on low bandwidth, batch processing, mainframe computers, business-to-business, a healthcare industry whose leadership and processes had no concept of standardization and national standards. It was pretty much everything one-off. And it was not an atmosphere, HIPAA was very disruptive and administrative simplification was pretty disruptive to the industry.

There was not a lot of established trust between all the organizations that now suddenly had to interact. So the solution that we came up with as an industry, with CMS as a regulator, was good enough for then, but now, 25 years later, it's not working for us. The time is right to revisit, and when we think about the overall context of the interoperability and the ecosystem as described in the ICAD report ideal state, it gives us some guidelines to take what we've heard through the predictability roadmap and try to explore some things that will essentially update the HIPAA adoption process.

I think the key takeaways from our predictability roadmap are we need smaller, more digestible bites, we need dependable and reliable timetables for planning and budgeting relative to new adoptions and new versions, and one of the big changes we think we need to introduce is concurrent support of multiple versioning of standards as opposed to the concept we went with 20 years ago about everybody switches versions on the same day at the same time, with the concomitant floors and ceilings.

And then finally more visible enforcement, with the enforcement process used as feedback, not only for educational programs to the industry, but also feedback to the standards developers. So I'm hoping and looking forward to working with the appropriate folks within the Office of Burden Reduction to explore, as we go forward, both outright, as NCVHS does its recommendations on the HIPAA transaction, and as we collaborate with ONC and HITAC on the convergence. And I'm very much grateful to you taking your time today and sharing some of your objectives, because as I look at specifically the HIPAA components of that, they seem to be very well shared between your organization and NCVHS. So thanks.

Mary Greene: I look forward to hearing more and more specificity about, in addition to what seems to need to be updated, as you were talking about -- and thinking that was done with the technology in mind that long ago, anybody who even uses technology knows it probably has to be revisited.

But when it comes to the regulatory process, I appreciate the couple of things that you mentioned, but I'd love to understand where it really falls down, in more detail. The opportunity to talk to people about that, if you could help us with that, get to the right people to talk about that, that would be great.

There's also always this tension about some people who are ready to move forward fast, want to move forward fast, some people who aren't ready to forward fast, don't want to, part of what you described is a way, the version that you were talking about, is helpful to that, but we still get differences of opinion about which way to go forward, and I do regard -- we're partners in those discussions, but I do regard the standards development organizations and that infrastructure that's already in place is where a lot of that stuff has to get worked out, and we would be relying on you as you get all the information in, when you recommend changes, it's taking in those differences of opinion, it's taking that into account when you make your recommendations to HHS. So that's really important and valuable, too.

The other thing I'd like to hear, though, is when people are talking about even other specific changes to the regulations that they think would be helpful, what the solutions are. So not just X has to get fixed. What would be a way, a better way, of doing things? As I'm talking, I'm thinking to myself, this sounds like a good RFI to put -- but I would rather, we could do that, for sure, but really just having this conversation so we can have the more specific insights. Because I am open to looking at the process, for sure, there's no question, mostly because I know it's been around for a while, but also we are the Office of Burden Reduction, that's got to be for all of us, too, I would think, to help us all out.

So keep that in mind, because I really would welcome those conversations, and maybe we can -- unless there's some urgent issue during the holidays, we could maybe start fresh in the new year and really take a good stab at that.

Nick Coussoule: I think that is really good feedback, Mary. Just one comment I'd add onto that. I think you showed one use case for prior auth, and it's pretty easy to think about, if you just started from scratch, how might you do something, and the reality of it in most instances, we're not starting from scratch, so you have to take into account what exists today and how much of either a disruption that will be caused or leverage can be created. We try to capture that information, I think, in our work, and certainly with the industry input that we get, but that's really good feedback, and I think it challenges us to be both creative in our answers, and yet recognizing what it takes to get there and how that might best work over some reasonable time horizon.

Mary Greene: Let me tell you one more thing that I've heard a little bit, that slows the process down, and don't ask me to quantify how slow, the incremental slowness of it. But it is getting real-world information about the return on investment, and real-world information in different contexts, not just the best-equipped, the best, the largest health systems that might be ready for it. Because that's why I think the piloting is important.

You guys know this better than I do, but I'll say it anyway. Informatics pilots can be very narrow in scope. They can literally be can data go from one place to another and can both ends understand it? But going from there to figure out how you operationalize it, stay true to the content that's in there, and now we're talking about putting things into the clinical settings, active clinical workflow, the data has to be absolutely right for the absolutely right context, and the stakes are higher.

So that getting that kind of real-world data about how it's really helpful, what the pitfalls are, what the challenges are, I think is important as well.

Nick Coussoule: Thank you. Wu, your question next.

Wu Xu: Mary, thank you for your very informative presentation. I want to echo one thing you point out. The field needs integrated quality measure reporting. We heard the same thing in Utah. The clinics really tired to see their patient population, the quality reporting, Medicare, Medicaid, CHIP, and the private plans. So our APCD database, the office, again all the payers came together, providers come together, they come integrated quality measure reporting for the clinic, for the provider. So they feel that is more useful for them, because they cannot slice their patient into all small subgroups.

So I wonder, can you put back your presentation last page on the contact information. I want to follow up with you on that.

Nick Coussoule: We have the presentation deck that we'll send.

Denise Love: Can I follow up with Wu? When I was at NAHDO, we wrote on the IPPES and the MIPS comments with just about every state, with statewide hospital data, too. There were hospital measures that didn't have to be calculated individually, that could be used, some of those measures, calculated from a centralized state node.

Vickie Mays: I want to thank you for a great presentation. What I really like is the charge you have, as well as the vision, about what you're headed off to do. Which is pretty big, but I loved it. I want to ask a question that may be somewhat on the margins, but still I think is within what you're trying to accomplish. And that is, one of the things that COVID has taught us very well is that there are data we're collecting in public health that actually the healthcare provider needs in some way to be able to get, and we keep having these systems be siloed.

So part of what we're seeing is a lot of collection about tests, and different tests, and they don't always get to the clinician, and a lot of this is being done in, you know, CVS might do it, there are all these different entities right now that are all trying to help. And then when we get to the healthcare provider, they don't have this. They haven't gotten it, and they're kind of relying on the person to tell them.

The first time I had a flu shot through a drug store, I had to call three times because they kept sending the wrong information to my provider about which flu shot I had. I began to really understand, there's all this data, and I'm trying to figure out how the platforms that we're building we can begin to have some connections so that public health has just one more button to push in terms of where it sends it to, potentially to providers.

And the other is, we really know that we're about to have a syndemic as a function of COVID-19, in terms of mental health. So we're seeing an increase in substance abuse, we're seeing an increase in mental health problems, and we're going to see increases in suicide. Again, that system can be outside the system that we're talking about, but yet that information, kind of what's happening in mental health, and receiving specialty care that's outside -- it needs to get to the clinician. Can you see that any of this is kind of within what you're trying to do and that there may be a way to think about this?

Mary Greene: Remind me, I have a question for you about mental health data and clinical data mixing together. I honestly think, first of all, that coming up with -- that describing clinical scenarios and public health scenarios, and COVID is a great context for this because it touches both, coming up with those stories that anybody, whether they're medical or not, will just scratch their chin, that what is happening doesn't really make sense or there's inefficiencies, or there's so many opportunities for the ball to be dropped and care not provided, or whatever it is, or some lab result getting lost. That's what comes to mind when I was hearing what you were saying.

I'll tell you, when we were starting the prior authorization conversations, we had listening sessions of clinicians come in, and they'd all complain about the payers, and the payers would come in, and then we had them all mixed together and they would point fingers at each other. But they were pointing their

fingers at each other, so finally we said, okay, this is the way we want you to think about this. Prior authorization is a beneficiary workflow process, and there's a lot of stakeholders that touch it, all of us touch it, and our job is, whatever part we touch, we do it as efficiently and clearly as we possibly can, so that that process goes quickly.

When we change the lens to look at the patient, and not just your burden in the system, to you, suddenly they started asking each other what happens at your end, when I send you X, Y, and Z? Why can't you approve it? And this is like, 40-years-ago process improvement conversation. So I would say we should find what are those couple of compelling stories, which just galvanizes people, and then it leads to what are the right people to get into the room and move forward.

I'm going to -- Lorraine, correct me if I'm wrong -- but I know that some of this very granularly, one of the areas that we're working, clinical public health, is around the USCDI data elements, is that right? That's granular, but at least that's a place where we're at least involved in those conversations, so that makes sense.

But I'll tell you this, the vaccine, each state has vaccine registries, and then suddenly there's these new vaccines that are coming in, people want to track them in a separate way. So some state health -- some folks in the state are creating their own tracking systems instead of having them already incorporated into the interoperable systems that we have now. How does that make sense? It makes sense if you are the person responsible for the information and you want it at your fingertips. It doesn't make sense for a couple months from now, when you need more information from some place. So find those things, let's pick those -- things like COVID, that's just the obvious calling card for doing something different.

Lorraine Doo: Mary, you had a question for Vickie about mental health.

Mary Greene: Oh yes. So, always an issue about separating mental health information, right? But there's compelling reasons not to do that, especially if you're a clinician dealing with a human in front of you, because they all come together. Where do you think -- at the end of the day there are some statutory changes that have to be made, but where's the appetite for that, and is there -- are there protections that have to be put in place, other kinds of protections that have to be put in place, maybe for patients to give permission or whatever? I don't exactly what it is.

But at some point that we have to crack that one, too, because if you're sitting there talking, imagine you're dealing with a number of patients who have COVID, or a number of patients who come in and you didn't know that they had COVID, and they might not be forthcoming about that. I'm making this up, obviously. But a clinician really needs to have a holistic view of the patient. You can't just jettison, cordon off one aspect of their health, because ultimately, errors could potentially remain.

So think about that one, because I know it's an old topic. It came up a ton in all our conversations about the opioid epidemic, and not having that full understanding of who's even getting care for their addiction. But there's some interoperability pieces there, too, and I just know if there's solutions to at least make it a little bit more granular what's shared and what's not shared.

Vickie Mays: I think there is a difference between information being in a system and information being available to a clinician, and in that system, having that information available and having a rationale for

when you access it. This is the story that happened in terms of HIV/AIDS. Not every clinician can know that information, but it's in the system, so when needed, it's there and can be utilized.

So I think we should think about some of the mental health stuff in the same way, but part of what we do is the problem with the carve-outs of we have a behavioral health system that is totally outside the system, and whether the person even went to get the treatment they were recommended, what's going on, none of that has been available. So I think having platforms in which even when something is outside that has the capacity for a query, for transmission of information, is important. And then you have to have a rationale, and then we'd have to debate whether or not what we need is permission from the client to access sensitive information.

But when it's not built, it's not thought about, and it's not there, it makes it impossible both on the evaluation side, which means it doesn't have to have the patient. It's information on which there could be an evaluation of whether or not things or working at a population, a deidentified level. But right now we don't even have the capacity to do those things. SAMHSA sits over here, and then the physical health system sits over here, and if we don't have the NCHS systems, we end up not really being able to look at mental health issues.

Nick Coussoule: I want to be sensitive to Mary's time. We're running a bit late. One last question, Denise, and then we'll take a break before our final session of the afternoon.

Denise Love: In the spirit of time, I'll just follow on Vickie's comment, and I would recommend that we all think about working with SAMHSA. They were very helpful to states with their all-player claims databases, because this came up, that some states were getting everything and other states were getting filtered out claims that were inappropriate, and there are some good guidances out there and some workarounds. So this is just a big issue that I think has to bring in SAMHSA, and they were very good about working for the states, getting the data for their policy, and their research, and their public health purposes. They were quite supportive.

Nick Coussoule: Mary, thank you again very much for your time and effort. I think good presentation, a very good discussion. You'll find a team on this end that is very interested and engaged in working with you and your team. We look forward to that going forward.

Mary Greene: Thanks very much, everybody. Appreciate it.

Nick Coussoule: That said, why don't we take a 15-minute break, give people a little bit of a chance. It's about twenty of, so we'll come back at five of. And then we'll have a discussion from Rich on our standards update. And that will be our last session for the day.

Thanks, everybody. We'll talk in about 15 minutes.

(Break.)

Subcommittee on Standards Update

Nick Coussoule: I think we've got just about everybody, so we'll go ahead and get started for our last formal session of the day before public comments. It's our Subcommittee on Standards and subcommittee update.

Rich, I'll leave it with you.

Rich Landen: Thank you, Nick.

This will be brief, because half the topics we've either talked about or will talk more about shortly. The first item on the plate for the Subcommittee on Standards is the operating rules proposed by CAQH CORE. We held a hearing, and later this afternoon, you'll be hearing our recommendations. These operating rules are around prior authorization.

Next item on our plate is the report to Congress that we talked about this morning. Third item is the convergence of administrative and clinical in the standards world. We heard the ICAD this afternoon, using prior authorization as an exemplar, which is very timely, given the CAQH CORE proposed operating rules. You also heard that we, the Subcommittee on Standards, will be initiating our own project now on convergence, using the ICAD final report as input. We've got a draft framework for that initiative, or that project, that we reviewed several meetings ago. We are about to modify that to incorporate public health vital records, state use, patient-centricity, communities, disparities, additional users and uses, and the long-term and post-acute care implications, for the project scope.

In addition, on the convergence subject, we've got the ongoing collaboration with ONC and HITAC, and we will be applying the principles from the NCVHS recommendations that we approved over the last year on the predictability roadmap that we've talked about a couple of times earlier and from the vocabularies and terminology curation that Nick had gone through this morning.

Also on our plate is ICD-11. Margaret talked about that a little bit. World Health Organization has approved, has voted to approve ICD-11, so now we need, we've made research and communications recommendations to HHS, and it will be shortly time to follow up on those.

And finally, on our plate is a placeholder to be determined for any HIPAA changes that come through. We never quite know when we will be getting proposed version updates or proposed new operating rules, but we do expect eventually X12 to come up with a new set of versions. We understand the CAQH CORE is already balloting another version of some of their operating rules, and when those come to us, we will add those to our plate.

So that's what the Subcommittee on Standards is working on currently.

Nick Coussoule: Any questions for Rich in regards to the more general topic for the Standards Subcommittee? Seeing none, why don't you dive into the operating rules request, Rich.

Rich Landen: I'd be delighted. This is a major piece of work from the subcommittee that we're bringing forward. The returning members of the committee will remember the conversations we had about this at our last two meetings prior to our hearing in August -- the new members, this will be new to them.

The HIPAA process requires these operating rules to go through us. Today, we are looking at three operating rules proposed by CAQH CORE. CAQH CORE is the designated operating rules authoring entity -- ORAE -- under HIPAA, as HIPAA was modified by the Affordable Care Act. And the three rules are the prior authorization data content rule, the prior authorization infrastructure rule, and the connectivity rule.

Here's the way the presentation will go. First we'll talk about the background and our role, our charges, and cover the previous recommendations we made on this topic. We'll overview the subcommittee's strategy for evaluating the rules, and our decision criteria, then we'll look at the recommendations. Then we will open it up for discussion among the committee members.

The role of NCVHS for operating rules, HIPAA was amended by ACA so that the operating rules come to us from the operating rules authoring entity, and then we pass them on to CMS with a recommendation. Our role as described in the act for making these recommendations, first one is we need to make sure the operating rules authoring entity meets certain requirements. Two, that the operating rules are developed by a nonprofit entity. Both of those things are fine.

Determine whether the operating rules represent a consensus view of healthcare stakeholders and are consistent with and do not conflict with other existing standards and we did hold a public hearing; we have done the deliberation. Evaluate whether such operating rules are consistent with electronic standards adopted for health information technology. And then submit a recommendation to the Secretary.

What we've done in the past, too, earlier, recommendations on operating rules, we recommended that HHS adopt, and HHS did indeed adopt those operating rules. That was back in 2011 and 2012. The Federal Register citation is on your screen and in the deck that was sent to you. Those operating rules covered eligibility, claim status, electronic remittance advice/electronic funds transfer. And those were adopted by interim final rules almost a decade ago.

In February of 2016, we evaluated proposed operating rules for health plan enrollment and disenrollment, premium payment, prior authorization, and claims. Our recommendations to HHS at that time were to support and encourage voluntary use of those operating rules, rather than require adoption through federal regulation. And again, there's the link to the letter in the slide deck.

The background for the current rules. In February of this year we received the official request from CAQH CORE for the review of the three rules that I mentioned, the two prior auth rules and the connectivity rule. We solicited industry input through the Federal Register notice, which is required, and then we also did outreach to covered entities and invitations to selected cross-section of payers, providers, vendors, and patients for the hearing. And I'll stress that selected cross-section of payers, because we thought we needed to do that to ensure that we adhered to the requirement that we have a diversified group from the industry, that not all the testifiers would come from one camp or the other, so that we got a good cross-section of what the industry was really thinking about these rules. Finally, we held the hearing in August of this year, and because of COVID, that was a virtual hearing.

Here's the way that we tackled our charge. The first question we asked, does the proposed operating rule conform to the requirements of the law? That's what we visited a few slides previously. Second, does the proposed operating rule reduce burden? The third criteria is will the U.S. healthcare system be better off with the proposed operating rule to an extent that exceeds the cost of development and/or implementation? Essentially, what's the value proposition?

After the hearing, and after receipt of the letter submitted as part of the either as part of the hearing or in response to Federal Register notice, we had the subcommittee assessment of each of the rules -- meaning we as standards subcommittee members looked at and went in and asked questions about each of the three rules. We all reviewed the written submissions, and we had our notes from the hearing and a full transcript of the hearing to review. We met weekly to analyze, discuss, and try and develop a consensus, and then part of the weekly discussions meant that we analyzed what we were told, but we also asked ourselves additional questions, did some research into what else was happening around prior authorization in the industry. We've got the convergence work was going on, there were a couple of specific prior auth pilots that we looked into, and of course we had in process at the same time, parallel yet separate, was the drafting of the ICAD report.

So we looked around the industry in order to get a good sense of the ecosystem in which these three rules would live. Finally, we did come to a consensus as a subcommittee and we prepared draft recommendations.

Here's the recommendation, and then for each of the four, I've got a following slide that will talk about the detail. First, adopt an attachment standard. You've heard some discussion of an attachment standard today, and you also will say, well, CAQH CORE didn't actually propose that we adopt an attachment standard, yet it was the subcommittee's conclusion that our first recommendation is that we need -- if this prior authorization operating rules is going to be adopted, then we need an attachment standard to support that. We'll go into the reasons on the next slide.

Second recommendation, support and encourage voluntary use of the two proposed operating rules for prior authorization, prior to an action for adoption. So we're proposing not that HHS adopt the data content and infrastructure operating rules immediately, but that the industry engage in a voluntary adoption to test out these rules before they would proceed for federal adoption. Again, details coming two slides down.

Third recommendation. Not to adopt the proposed operating rule for connectivity, and that we would encourage CAQH CORE to complete the new version of the connectivity rule that CAQH CORE is already working on, and I believe is in process or has already balloted.

Four. Increase the visibility of enforcement information related to operating rules. And we'll talk about that down in the detail slide.

Attachment standard. Industry testimony was very strong that without an attachment standard, providers and payers would be unlikely to increase their implementation or use of an electronic prior authorization standard, specifically the X12 278. The 278 transaction itself is only designed to carry a certain limit of data internally. The clinical data payload is carried externally to the 278, and that would

use an attachment transaction, X12 275 of one version or the other, and that attachment transaction is robust enough to carry codified, noncodified, structured, non-structured data. For example, physician notes, lab test results, various reports, as well as images, waveforms, genomics, and other types of information that may be requested or needed by the health plan.

The next bullet is important. Without an electronic payload capability, then the whole process falls back to having to use phone, fax, portal, or god forbid, snail mail, and third bullet then, if providers have to use manual processes in some part of the workflow, then there's little incentive for the providers to purchase a system upgrade and the capabilities to use the 278. They're still going to be on the phone, they're still going to be sending faxes, so why go through the cost and the trauma of building in 278 capability?

Recommendation two, support voluntary use prior to an action for adoption. One of the aspects of the testimony that we heard from all parties is that these operating rules represent a step forward, but they fall short of a complete prior authorization solution. So it's a necessary next step, but it's not a solution to the PA issues that confront the industry. So it's a partial solution.

Many parts of the operating rules are promising; however, they're unproven. So some of the concepts in there, it is the judgment of the standards subcommittee that they will need some piloting and testing in order to provide some objective evaluation of whether the things proposed in the rules, in the two operating rules, will really pan out or not. There is industry and subcommittee concern with unintended consequences and the example there is the timeframes.

One of the things that the CORE rules on prior auth propose is a turnaround time of two business days. What we heard in the testimony is, yeah, that's a great idea, but if a health plan can't meet that two days, what the health plan would do is return a pending response to the transaction, to the prior auth inquiry or request, and it may turn out that the intent of the operating rule to speed up the decision process may -- and I stress may, not will -- may actually turn out to delay the response, because it gets pended in the bureaucracy rather than arriving at a decision.

So we don't know the answer to that, but it was not clear enough to us that what the CORE rule is proposing would indeed work as intended. Again, voluntary use, test it out, see what the empirical data is, what the pickup rate is, and what happens when providers and health plans try and adhere to that two-day timeframe.

Voluntary use and testing period aligns with our own recommendations on the predictability roadmap. Robust testing will serve to prove or disprove the value proposition. Testing will provide the data needed by CMS for the rulemaking's required impact analysis and the fiscal analysis. And again, voluntary use and testing will identify issues and feed back that information to CAQH CORE to either correct or improve the next version.

We also looked at completing industry implementation priorities of which there were more than few, and several of them very major. The new interoperability rules including information blocking, and everything going on with providers and health plans around the pandemic response.

We also noted in our scan of the industry environment there is significant innovation occurring around prior authorization among multiple industry sectors and groups, and we'll call out specifically the ICAD report that we've talked about today, we'll call out Health Level 7's FHIR, which has been referenced a couple of times. FHIR is recognized as up and coming, but it is not yet at scale that would be necessary for adoption as a federal standard for under HIPAA. Then also the clinical decision support evolution, and the increasing capabilities of EHR, both as they developed by the EHR companies, and as they respond to the new requirements from the ONC certification.

Recommendation number three. Do not adopt the operating rule for connectivity and encourage CAQH CORE to complete its new version. There were things about the proposed connectivity rule that the subcommittee felt were fatal flaws, and those are in the first two bullets. First, it proposes -- the rule as submitted by CORE proposes adoption of a security standard that has known vulnerabilities, and second, it allows the use, the continued use, of security practices that are obsolete. It goes into the transport layer security, and NIST has come out with a new requirement to move to a more recent security standard, but the CORE rule does not adopt the NIST standard. It stays with some of the older security standards.

So bullet three, there's also the possibility or probability that adoption of the connectivity rule could require CMS to have to repromulgate and readopt the earlier HIPAA-adopted operating rules, because the references and the names of some of the operating rules have changed, and it's rather unclear that the industry could adopt this connectivity rule without brand-new rulemaking. Now, that requiring the readoption of the existing operating rules is not a small deal, so this adds to, in our conclusion based on the two fatal flaws.

Finally, we observed that the articulation of the rule is complex and very difficult to understand. Not only to us trying to read it, but we also had comments from our testifiers and the submitters of the comment letters that described the same thing, that the rule is nearly impossible to read and understand.

And then finally, as I mentioned, we are already aware the CAQH CORE is already working on revisions to this connectivity rule.

The fourth and last recommendation is for CMS to e=increase the visibility of enforcement information related to the operating rules. CMS has enforcement activities, there is information, but from the testimony, we concluded that there is very low industry awareness of what CMS is doing, and stakeholders requested that HHS act upon and publicize its efforts on compliance and enforcement for the operating rules. So it's there, the enforcement is there, but the industry consensus is nobody is aware of it, nobody is learning from the activities of the CMS enforcement, no feedback loops for improving future editions, and that visibility needs to be increased.

Here's the link to some of the resources that we used, including the meeting summary, the agenda of the hearing, CORE request letter, and the testimony and public comments received.

And with that, I will first invite any of the subcommittee members, if they want to add some additional commentary, and after that we'll go to questions from the full committee. Assuming we get to a point

of committee agreement with these recommendations, what we will do is we will bring forward tomorrow morning a draft of a letter with these recommendations. We didn't want to bring that letter up today. We just wanted to get through the basics of the recommendations and get the committee's reaction before we get bogged down in actually putting that letter format.

So, any committee members would like to add to what I've said?

Denise Love: I don't have anything to add. I think you covered all of the details.

Rich Landen: All right, then, Mr. Chairman, open it up for committee member questions.

Nick Coussoule: Okay, if you have a question, please raise your hand. We are going to have that discussion.

Let me start, Rich, with one question, and it's really almost a point rather than a question. Part of the connectivity rule challenge that you mentioned is I think the general -- at least, from framing -- was that it would be very useful to have more stringent timeframes, but the components that were more challenging were the technical components and not necessarily the timing components. Can you elaborate, or another member of the subcommittee, elaborate on what I'll call the good and the challenge within that specific rule?

Rich Landen: I will defer to subcommittee members.

Denise Love: Can you restate that question?

Nick Coussoule: In regard to the connectivity rule, some of the feedback, and I know it's a mixed opinion, but some of the feedback we got was, I think, there was general consensus on the theme, if you will, of the connectivity rule, but the challenge was more around some of the technical specifications and issues that created that challenge. I think the practical reality of how quick a turnaround can be -- and I think we even talked about this earlier today, which is immediate is a better turnaround than two days, and the idea that two days was sufficient was, I think, clearly not stated that it was sufficient, but it was basically a starting point by which hopefully you'd accelerate into much more real-time or close to real-time.

DR. LANDEN: Let me take first stab, and then reinforcements may arrive by then. First, I think that was in the infrastructure rule, not the connectivity. The 48-hour response time. Accelerating when a provider submits a request for prior authorization, the proposed rule said 48-hour business-day response time for either a yes-no decision, or there are certain allowances for pending a decision, based on the need for further information, and then there were timeframes in the rule for submitting that further information, and it got, as Nick alluded to, rather complicated and a little bit unclear about whether those timeframes would work out or not.

We recognize that, again, from a patient-centricity viewpoint, CORE achieved a lot in getting its membership -- and I'll stress it's the CORE membership that voted to approve this rule -- they came to a consensus after a lot of hard work and arguing back and forth, about this 48-hour turnaround time. So it was a very reasonable compromise, but again, it is a compromise among that group and it's not a

proven concept that we know -- we don't know whether it will work, we don't whether it will not work, but because of that uncertainty it seemed to us that it's not ripe for promulgation as a national mandate under HIPAA.

There were other things about -- that the CAQH CORE discussed, argued, fought about, came to compromise, like the system availability time. How many days a week, how many hours a day, a health plan system had to be up and running. Again, they achieved a hard-fought compromise. The compromise was substantially less than 24/7. Providers argued that prior authorization happens not just Monday through Friday, but over the weekends and on holidays, as well.

So again, what was in the rule was a well-vetted compromise that is intended to be an improvement over the status quo, the term that we used, and I'm not technically accurate, but it moves the needle. It gives us some inertia, it starts moving us forward as a necessary first step, but it's not the last step. There still needs to be more to go.

Nick, does that get to your question? Were you looking for more?

Nick Coussoule: It does, Rich, I was just trying -- and I apologize, I mixed up the connectivity and infrastructure rule, I've been going through my own notes backwards. I just want to try to make sure that people get the full picture, that everybody on the committee gets the full picture of, you know, that the recommendations are one thing, but kind of the rationale behind everything to support with both positive and challenges I think, I just want to make sure that that's visible there.

Other questions from any of the committee members or any other feedback from the standards subcommittee members in regards to that?

Denise Love: I just think this whole process, and I commend you all for wading through this, these operating rules were kind of mind-numbing to read through. What brought home to me is just the high variability within the industry, the provider view versus the payer view, and the low adoption rate without attachments. So it does move the needle. I think CORE did an excellent job of bringing these disparate people together to kind of coalesce their, I guess, roadmap, but it's just still not quite ready for primetime. That's my opinion.

Rich Landen: Let me just pile on there, with Denise's comments. I think the figure that -- I think it was actually Alix Goss that cited earlier -- the adoption of the 278 is about 13 percent, and that's been a HIPAA regulation for how many years now? So if you do the subtraction, that's 87 percent of the prior authorization transactions are done by phone, by fax, or by portal. And trying to use these operating rules to get more of the industry into 278 is the challenge that CORE obviously was trying to address here and get this process more automated and reduce burden, particularly on the provider side, but also, again, citing from the ICAD report, for the reasons that Dr. Greene mentioned, there are real implications on patients' health and on patients' pocketbooks from this prior auth process.

Nick Coussoule: Other committee members' comments? Rich, I guess what I would suggest is that we could put up the single slide that has the recommendations, and basically ask any of the members if they have any particular concerns with a letter that would put these forward.

Based on obviously the members that were at the hearings, which many of us were, the discussion that's happened in the interim, the feedback opportunities here, are there any particular concerns with these recommendations? If there are, please raise them, even from a framing perspective, and we can then I think ideally, Rich, get a draft letter to everybody to review, and assuming there's concurrence, we can try to get through that in the morning.

Denise Love: Can I just add that, for the committee members not on the standards, just that the standards committee spent quite a bit of time wading through these nuances, and if that helps, these recommendations, I think, reflect a lot of painful consideration based on evaluation criteria. I just thought might help some committee members who weren't involved.

Nick Coussoule: Vickie, do you have a question?

Vickie Mays: I do. I don't have any objections to what we're proposing, but I just want to ask about number three. Do we expect there to be objections to number three? And if so, have we written it in a way in which we try and counter that?

Rich Landen: Vickie, that is a good question. The short answer is no, we're not expecting -- we don't expect CAQH CORE to be happy, because they've done a lot of work. On the other hand, as I mentioned, CAQH CORE is already balloting the next revision, so it's not going to be a long time in HIPAA time terms before CORE could bring its next version back to us.

Vickie Mays: Okay. I understand why we are doing what we're doing, and like Denise, I waded through some of this stuff, but I also know that some eternal sources, sometimes, may be vexed at us, and if there's anything that we can do in the letter anyplace to kind of assuage that, then that was all I was going to bring up. But it sounds like you all have got it covered, so I'm good.

Rich Landen: We've discussed that. Whether we've chosen the right path or not, I don't know, but I will also point out that the next agenda item is public comment, and we may very well hear what different people in the industry have to say about that, and indeed, we welcome the input that we expect to get from the public comment period and we will take that into consideration.

Vickie Mays: Sounds great.

Nick Coussoule: If there are no further questions or comments here, Rebecca, it's more of a process question of can we go to public comments earlier?

Public Comment

Rebecca Hines: We can. I would hope that anyone who's interested in making a public comment is already on, so I apologize, we're ahead of the agenda schedule.

Greg, do you want to give the instructions?

MR. RICHARDS: Sure thing. When submitting a public comment, please include your name, title, and affiliation to participate in the public comment. Please use the Q&A box within Zoom at the bottom of

your screen to submit a question. If you'd like to provide a verbal comment, use the raise hand button also located at the bottom of Zoom. If your hand is raised, we will call on you and grant you speaking permissions. To raise your hand if you are on the phone, please press star-9. This will raise your hand within our Zoom, and then if we call on you, use star-6 to unmute yourself. Once again, if you're on the phone, that is star-9 to raise your hand, and then star-6 to unmute yourself.

Rebecca Hines: And then you can always email us, and I can read it into the record. While we're waiting, we did get a question. I don't know if there's inclination to answer it live, but the question comes from David Wilderman as follows: would the recommendation adopt an attachment standard aligned to the attachment standard recommended in 2016, or a different version?

Rich Landen: Let me respond to that. This is Rich Landen. We talked about that extensively, both in the subcommittee discussion of the operating rules hearing, and also our conversations around the ICAD recommendations, and our conclusion was to let NCVHS's prior recommendation stand, and leave it to CMS at this point, as to which version of an attachment standard should be adopted. The way we look at that is that our recommendation is several years old. We recognize that it may no longer be the best solution, and we simply don't know, it may not be even a viable solution.

So we're on record as advising HHS to adopt an attachment standard and our view is that CMS, through the comment period attached to the publication of the notes of proposed rulemaking, that the industry itself can advise CMS as to which version to adopt. For us to go back in and revisit that situation would take quite some time, probably a year, and we really saw no compelling need for that, because that's something that CMS itself can do through the NPRM process, which it's required to do anyway, to promulgate an attachment regulation.

Rebecca Hines: Let's wait another minute. This is your opportunity to submit public comment, either written or oral.

MS. MCCOMAS: This is Heather McComas from the AMA. I am director of administrative simplification initiatives at the American Medical Association. I thank everyone who is engaged in formulating these recommendations and all your work. It sounds like it was a lot of effort, and there was a lot of materials to review. I will say that on behalf of the AMA at least, I express a lot of disappointment, frankly, in the recommendation that the prior authorization operating rules just be left to voluntary adoption. As was referenced multiple times today, prior authorization not only is an administrative burden and waste issue in our healthcare system, but it really directly impacts patient care in a way that a lot of issues in the standards world don't.

I will draw to the full committee's attention that the AMA, along with the Medical Group Management Association, American Hospital Association, and the Arthritis Foundation, sent a joint sign-on letter in early October, as a follow-up to all of our testimonies in August at the hearing on the operating rules, where we echoed and restated our strong support for federal adoption of the prior authorization operating rules, because, again, we think it's a patient care issue, and we think that the rules have real benefit in shortening delays in care and are a real step forward.

I hear the multiple references to these rules are a necessary kind of first step, and unfortunately, as many of us in life know, if you're not required to do something, people often don't do it. So I would just flag the fact that leaving these rules as voluntary will leave us as an industry stuck as we have been for many years with prior authorization.

Thanks for consideration. Appreciate it.

Rebecca Hines: Thank you, Heather. And I also want to just make note that Cathy Shepherd did write that she wants to say thank you to the subcommittee for your thoughtful assessment of the information you collected.

Anyone else want to speak or submit a written comment at this time?

(No response.)

With that, I think our public comment period for today is over. If someone's trying to and for some reason not able to reach us, please write into the Q&A and we'll call on you.

I just want to emphasize to the full committee that the four recommendations that you saw that were laid out for us so clearly by Rich have been drafted into a letter, and if you have no concerns, then the plan is tomorrow we will bring this letter forward for full committee approval to be signed off on and sent to the HHS Secretary. So I just want to make sure, since we have a number of new members, that you're clear that you have no further questions about those four recommendations. If you have any dialogue you want to have among yourselves, given the input we just heard, or anything else.

Wu Xu: I just have a procedural question. I have no question on the recommendations, but do we have time to read the letter tomorrow?

Rebecca Hines: Yes. We actually, our plan would be to take the results of today's discussion and send something out this evening so that you would have time to review it, and tomorrow afternoon there is ample time for further discussion. We actually in case budgeted 90 minutes total for standards, and we can use whatever of that to discuss the letter, Wu, so yes, thank you.

I just want to make sure everybody's comfortable with where we are. Nick, I don't see any further questions or public comment, and that was the -- Rich, were there any other topics you wanted to touch on this afternoon from the standards perspective? I know you mentioned earlier we need to take a fresh look at the convergence project. I know the scoping now is ready really to be basically rewritten now that we have the fruits of the labor of the ICAD taskforce.

Rich Landen: No, there is nothing that I think would be germane to go into today. I think the subcommittee has to be the one to take the first steps to essentially talk about amending the project scope as it exists today, and then we'll bring that back to the full committee once we've done the markup to it. Obviously, if the committee members want to take a look at that and send us comments, that would be absolutely wonderful and more than welcome, but I don't see taking time to do that today.

Nick Coussoule: I would agree with that, Rich.

Rebecca Hines: So I have shared the link with the committee about the letter that Heather referenced, which is now on the NCVHS website, added to the public comments page of the August hearing.

So I do believe today's agenda is wrapped, Nick, unless there's anything else you'd like to touch on.

Nick Coussoule: No, I don't I think there is anything from me. Unless there's any other points that any of the committee members would like to bring up, I would say that we are adjourned for the day. Tomorrow we will start at 11:30 eastern time.

Rebecca Hines: And you can use the same link.

Nick Coussoule: Okay, we are then adjourned for the evening. Thank you all very much for the time and attention today. I think it was a very productive day.

(Whereupon, the meeting was adjourned at 4:45 p.m.)