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

Transcript
November 19, 2020 11:30 a.m. – 4:00 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

Call to Order/Roll Call

Rebecca Hines: Good morning, everyone. Welcome back to Day 2. Glad you could all make it for Day 2. I think we will just go ahead and get started with roll call, starting off with our chair.

Nick Coussoule: Good morning, all. Nick Coussoule, Senior Vice President and Chief Information Officer with BlueCross BlueShield of Tennessee, Chairman of the Full Committee and I have no conflicts.

Rebecca Hines: Denise Chrysler.

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

Rebecca Hines: Denise Love.

Denise Love: Denise Love, public health data public consultant, member of the Full Committee, member of the Standards Subcommittee, member of the Privacy, Security, and Confidentiality Subcommittee, no conflicts.

Rebecca Hines: Jamie.

Jamie Ferguson: Good morning. I am Jamie Ferguson with Kaiser Permanente, member of the Full Committee, member of the Standards Subcommittee, and no conflicts.

Rebecca Hines: Frank Pasquale.

Frank Pasquale: Hi. I am Frank Pasquale. I am professor of law at Brooklyn Law School and I am a member of the Full Committee, chair of the Privacy, Confidentiality, and Security Subcommittee and no conflicts.

Rebecca Hines: Jacki Monson

Jacki Monson: Hi, Jacki Monson, Sutter Health, member of the Full Committee, a member of the Subcommittee of Privacy, Security, and Confidentiality, and no conflicts.

Rebecca Hines: Margaret.

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

Rebecca Hines: Melissa.

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

Rebecca: Tammy.

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

Rebecca Hines: Valerie.

Valerie Watzlaf: Good morning. I am Valerie Watzlaf. I am with the University of Pittsburgh and the Department of Health Information Management. I am a member of the Full Committee and I have no conflicts.

Rebecca Hines: Vickie.

Vickie Mays: Vickie Mays, University of California Los Angeles. I am a member of the Full Committee. I am a member of the Privacy, Confidentiality, and Security Committee and I sit on the review section of the Standards. I have no conflicts.

Rebecca Hines: Wu.

Wu Xu: Hi. I am Wu Xu. I am adjunct faculty with the University of Utah. I am a member of the Full Committee, no conflicts.

Rebecca Hines: Deb.

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

Rebecca Hines: Rich Landen.

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

Rebecca Hines: Thanks, Rich. Jim.

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

Rebecca Hines: Thanks. Is that all the members? Did we get everyone? Okay. Lead staff now.

Lorraine, would you like to say good morning and introduce yourself.

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

Rebecca Hines: And Rachel.

Rachel Seeger: Rachel Seeger, Senior Advisor with HHS Office for Civil Rights, and I am lead staff to the Subcommittee on Privacy, Confidentiality, and Security.

Rebecca Hines: Maya, it looks like you are here with us.

Maya Bernstein: I am. Good morning, everyone. I am the Senior Advisor for Privacy and Policy at the department. I work in the Office of the Assistant Secretary for Planning and Evaluation. I am the lead staff to the executive director of this committee and staff to the Subcommittee on Privacy, Confidentiality, and Security.

Rebecca Hines: Wonderful. I think we are now done with roll call. We have a quorum. Nick, take it away.

Review Agenda

Nick Coussoule: Excellent. Thank you. Welcome everybody today. We have a few topics on a somewhat shorter day today, but they are pretty meaty topics so we will try to get into them right away.

The first one on the Subcommittee of Privacy, Confidentiality, and Security is going to report a follow up to the hearing conducted in September on data collection and use during public health emergencies. Some of that actually will lead into discussion of priority topics that will also be covered a bit in the work plan this afternoon, but it is a nice lead in depending on how much time we have this morning to cover the follow ups for that subcommittee. We will take a break for lunch and then the Subcommittee on Standards and Rich will follow up specifically on the letter of recommendation based on the CAQH CORE ask as we discussed yesterday. We will take public comments and then we will have a discussion more around specific items on the workplan or potential items for the workplan for the next year plus.

With that said, we will get started right away with Frank on the Subcommittee on PCS Subcommittee.

Subcommittee on Privacy, Confidentiality and Security

Frank Pasquale: Here are slides for the PCS Subcommittee Report. We have two main topics today. One is to give the Full Committee and all of our audience today a sense of the September Hearing on Data Use in Public Health Emergencies. That was a big focus of the Subcommittee since the COVID emergency. You can see it in today's agenda. My rough sense of the timing is going to be that we are going to review the issues and hearing report to about 12:05 that will have some takeaways and have further discussion of the hearing report. If it turns out that the hearing report is pretty well received and that the takeaways seem relatively uncontroversial then we may be able to get earlier into the longer term PCS priorities because as we were simultaneously always working to close out present projects and to finalize those and then we are also thinking about longer term priorities and we have a really rich list of potential longer term priorities that we want to hear the Full Committee's view as to which would be best to prioritize. We have had a good discussion about them and we will share some of the developments of our discussion with the Full Committee.

Just to review, this is a slide we have seen earlier actually in our June meeting, I believe, about data use in public health emergencies. Some of the issues that we, as a Subcommittee, were tasked with exploring were issues like what are fair information principles for a pandemic. We have a public health emergency. We are in the midst of it. And we have some promise of being able to use data to better address that emergency. But we also face significant risks because the potentially stigmatizing impact of COVID, the impact on individual's work on their ability to – how this health data could be used – we want to be sure that we enhance data liquidity and availability and access and usefulness, but also try to ensure that we have a really robust framework of privacy, confidentiality, and security around that.

A second question, what data should we be collecting? How far should data collection go in the context of a public health emergency? There are many exceptions to privacy laws in the context of emergencies. That is going to be another issue there.

And that introduces us to this third bullet point. What rules are all right to override to advance public health, and what should remain in force, and perhaps inalienable? And that term inalienable is an unusual one. But it means that one is not even able to – you always have the right no matter what contract you were to sign. I think that is an ongoing concern as we think about the future of public health data and data use and emergencies that we really have to address squarely and not just reinvent the wheel each time an emergency comes up.

Clearly, there are many folks in HHS that have done incredibly hard work in terms of issuing notifications and enforcement discretion and other issues like that in terms of exceptions that can be made or discretion with respect to enforcement in the context of emergency.

And I think that what also needs to be done is longer term development of templates or other approaches to rapidly be able to respond to increased demands for data in the context of public health emergencies. We know that although it sounds a bit paradoxical or oxymoronic. We know that emergencies are a certainty. We know we are going to be facing them even if not with pandemics like COVID, with hurricanes, disasters, other issues like that.

A fourth point, our fourth bullet point is the level of identification of data that is appropriate for which purposes in public health emergencies. When do we need identifiable data? When should that data become more liquid, more available? When is aggregate data more appropriate? And is case-level data without identifiers an adequate compromise?

Finally, how do our standards differ at the local, state, and federal levels? What we are going to see with the takeaways is that there were a lot of comments in our hearing, particularly by experts and professionals in public health about concerns about the way in which a patchwork of law even if well meaning could potentially impede effective response.

I will go over the speakers in the slides, their writings, research that were available were recommended as pre-reading or for the record. We had first with respect to data collection use, we had Ashkan Soltani, who was a Former Senior Advisor to the US CTO at the White House OSTP and also a Chief Technologist for the FTC. We really wanted to reach out to experts that had both academic expertise and governmental experience. Ashkan is certainly in that mix.

Commissioner Allison Arwady of the Chicago Department of Public Health and Robert Grossman, the Co-Chief of the Section of Computational Biomedicine and the Biological Sciences Division at the University of Chicago.

In that panel on data collection and use, we really got into – I think if I were to summarize some themes there, Ashkan really warning us about technosolutionism, saying that it is easy to assume that technology is always going to be advancing the solution to a problem via a public health emergency or other health issues, but that we need to be cautious because we have to really look for proof of efficacy. Just as with drugs, we want to safety and efficacy. With respect to apps and other forms of novel data collection in the midst of pandemics, we are responsible for trying to make sure that the benefits would be commensurate to risks imposed.

I think with respect to the commissioner, I think one of the key things is that we really heard a lot about advances in public health monitoring and need for public health monitoring in the context to the pandemic and similarly with Dr. Grossman. We have with respect to new modes of analysis. This hearing we really got a lot of input and also a robust discussion among the panelists, among the subcommittee as well.

One of the other themes – and so our second panel of the September hearing involved technology and ethics. Professor Danielle Allen, Dr. Loonsk, Director Kate Goodin of the Surveillance Systems and Informatics Program at the Tennessee Department of Health, and Stacey Katz, who is the director of Healthcare Privacy and Human Protections at the Maine Department of Health and Human Services. Each provided really helpful perspectives on the nature of technology and ethics as when it comes to health data collection.

I was particularly – one of the take homes that I think is worth highlighting for the Full Committee – of course, you can get the take homes from all the speakers in the draft hearing report that we distributed in the eAgenda book before the hearing. One thing I just thought was so helpful from Professor Allen was the ways in which the context of data matters. Of course, echoing Helen Nissenbaum's point, she also has advised our committee or testified for our committee that the context of data collection matters and particularly its context within a larger pandemic response plan.

We have to always really be able to understand the larger pandemic response plan in order to then be able to ask the second order question of what health data is useful, what is less useful. And of course, given the diversity of those plans across different states, that does make our task more complex. There are some places where – we have seen the unified national response, which has sometimes led to very good outcomes as in Taiwan, South Korea, Australia, New Zealand, Vietnam, China, and sometimes the response has been devolved as in like the EU to member states or in the US to states. I think being able to understand that distinction is really critical to being able to see the full scope of questions raised by health data policy in the context of a public health emergency.

In Panel 3, we talked about bias and discrimination, which I think is really critical to the overarching themes here. I would note that in terms of both Mary Gray, who was, I think shortly after our hearing, named MacArthur Genius Award Fellow or MacArthur Fellow, Sean Martin McDonald from the Centre for International Governance. Both of them really emphasized the importance of being aware of the

downside risk of novel technology in these areas. We were, in part, inspired to be thinking about these issues in light of debates about contact tracing apps. If we go back in time just the spring of 2020 and the summer, there was a lot of enthusiasm for contact tracing apps as a way out of the pandemic or exposure notification apps as a way in a more targeted manner ask people to quarantine or to isolate as opposed to having generalized lockdowns with their larger economic effects.

I think that both Gray and McDonald offered some very well-informed skepticism about the efficacy of such apps beyond the questions of if there is a centralized data collection model or a less centralized data collection model, all those sorts of debates. I think they sort of transcended those debates and really focused a lot on the question of what exactly are we trying to do here and is the app capable of being part of a coherent, larger strategy.

I think that Dr. Wang really gave us a sense of what a larger strategy that is successful looks like in his very interesting and compelling presentation on Taiwan's response, which is summarized in JAMA. But I think we got a lot more detail in his presentation.

As someone also who is on the ground in Taiwan, when we spoke, I believe he was speaking with us at 3 a.m. his time, which I thought was just tremendous service on behalf of Dr. Wang. And I think he really helped contextualize how this sliding scale where perhaps in a society where there is a more robust overall response. There seems to be more of a social contract for more data collection whereas when the response is lesser, fragmented, less effective, the social contract seems to fade in comparison. That is sort of an important point.

And finally, Dr. Karras, the Chief Informatics Officer at the Washington State Department of Health, offered I think some very important perspectives here on the overarching response.

In terms of trying to think about the overall issues raised out of the testimony and the related materials that were submitted by this very august group of speakers, one is data and data stewardship. The role of our committee, others in the Federal Government, offering guidance on data and data stewardship in the midst of public health emergency.

The second is coverage gaps. Where are there data sources, data uses that we are not getting to and where do we really need to focus on gathering more data?

Public trust I think is critical, sort of the idea of how do we build public trust? Is there a lack of public trust? Certainly, some of our public health speakers were very concerned about a lack of public trust in something as simple as contact tracing. We have seen new stories and emerging academic research on people just refusing to pick up their cell phone. Some of this is a much larger problem than perhaps we can address, but we can at least highlight in terms of robocalls, spam calls and the failure of regulatory authorities to really deal with those effectively.

But part of it is also I think a larger suspicion or mistrust in the public health system that has to be I think addressed head on in terms of trying to ensure that exposure notification, contact tracing can work in a high-touch, high-expertise model, not something that we automate into software, but I think something that we work – has to be complemented by the experts.

And then finally laws and policies. The next four slides – I will go over some takeaways in the draft report on each of these issues.

With respect to data and data stewardship, one of the issues here is that case examples can be really critical. In terms of case examples, it can be applied to needs and gaps in data and data stewardship, trying to understand from different cases what worked, what did not work, trying to find those best practices.

Deidentification is the backbone of much of current public health data collection process. However, given some forms of re-identification or advancing abilities in those areas, there was concern expressed by some of our speakers about potential for need for alternative models – privacy.

There was a bit of interest in master patient indexes, but also a sense that they were not a realistic goal as a focus for current efforts.

There is, of course, a lot of emphasis on increasing liquidity of data. Just to summarize and going further that there are smartphone apps that require sign-up and download, providing some form of consent. But there are some concerns about secondary uses that are not anticipated by users. Prohibition of secondary use of data may help build public trust, if well enforced and well targeted. That is going to be a part of the plan here. And that we want to know in our larger report about the work of the Subcommittee on Standards.

In terms of coverage gaps, one of the issues that we definitely heard concern about was lack of payment coverage for testing. We did have some legislation on that matter. But of course, there are always ways around and ways to avoid the spirit of the law. That was something that I think is sort of the theme there about trying to ensure that there would be coverage for testing.

Some gaps in HIPAA privacy protection coverage. There was some concern raised that alternative health care providers such as things that are just providing tests were being seen as not covered by HIPAA or were not following proper or fair information principles or relevant state laws. That was a concern.

And disparate impact on individuals partially caused by misidentification of individuals due to missing data in the analytical models. The idea there is that there could be if we have analytical models in terms of contact tracing or exposure notification, are there ways in which this could disparately impact individuals?

Just to give a very concrete example of this, you might have, for example, an exposure notification app that is looking for 15 minutes of exposure to anyone within 6 feet of you. And it may turn out that that person is someone who is across a wall from you. You may be in an apartment and there is someone on the other side of the wall. That might be an over detection of exposure, et cetera. And the problem there of course would be that could indeed have a disparate impact, given who lives closer together in more crowded housing versus who does not who would not be more subject to that type of – I think that is an issue with coverage gaps. I think those were all very interesting issues raised by the committee hearing.

Public trust, I think, is also critical. Without public trust, no interventions or data collection efforts will be successful. We talked in the hearing about building a data trust, how data trust might be part of the solution. Building public trust in general requires better ways to communicate the complex processes of data collection and storage.

Just to pick up on a theme that I think comes out of Mary Gray's work and out of some of our discussions that this may well be high touch. This may well require counseling for individuals or better ways of people understanding exactly what is going on with data and the reliability of data.

Just in terms of something as simple as COVID tests, do people understand the false-negative rate? Do people understand the false-positive rate of various types of tests – antigen or PCR and how does that data feed into a larger system? All of those things I think are critical to trying to build public understanding and trust of what is novel to lots of folks. A large-scale public health effort to combat a pandemic of this magnitude and extremity is relatively new. I think being able to take that on and to take on responsibility for educating individuals on the data side. That is our bailiwick but situating it within a larger framework and context is critical.

To go to the fourth bullet point here, opt-in for all data use is very complicated. I think that there has to be some individuals who I think are really very concerned about protecting privacy end of the scale are very committed to – and approaches, but opt-in is really going to be – it is worrisome to make that a default in many of these arenas because of the need for rapid action.

The point about public distrust being a longstanding, gradually worsening issue I think is key and that transparency is also important and making sure that there is both an effort of transparency, but also speedy access to relevant data is critical.

Effective and clear emergency response with a sound scientific basis is the cornerstone on which public trust can be built. Do we have that effective and clear emergency response and within that, having a data framework I think is critical to ensure that individuals know not only that there is responsible use of data, but also that irresponsible use does have consequences and that there is accountability there. Because if you create a world where it just seems as though anything goes in terms of data use then you definitely are creating more incentives for individuals to strategically avoid being part of that system.

In terms of laws and policies as a fanatic aspect of the hearing, one of the things that was really heard loud and clear from the public health community was that efforts should be made to create policies to address inconsistent, patchwork coverage across the nation by different state and local laws. We have seen some efforts on that front. But I think there is a lot of worry among public health commissioners that there is just too many conflicting or complicating overlaps among different laws and that at least in the context of a public health emergency, something more clarifying is needed in order to have the type of rapid and effective response that we want.

And that leads seamlessly into the second point that national-level guidance may foster more consistency at the state and local levels. But if we had some ideas about what would constitute the best practices here disseminated nationally, that could not only help individuals in the state and local level, but also could help for cross state responses. And certainly, speaking to someone in New York, given the

fact that effectively there is no way to have a New York policy that does not include New Jersey and Connecticut. They could say the same things in terms of a tri-state area. There are certainly many tri-state areas, quad-state areas, border areas that could immensely benefit, I think, from this sort of guidance.

And laws should balance the need for privacy and protection of the individual with the need to collect data. We need to always have that balance in mind. In fact, we might – those balances we are going to discuss more when we discuss further some of our future priorities.

And work recently completed by NCVHS on Next Generation Vital Statistics could be used as a model to consider how working parts are being forced into an incomplete whole and how federal leadership can be supported to create a structure that can hold the disparate pieces together because we really want to ensure that there is proper levels of academic research, industry input, stakeholder input, word from and participation of those who have felt that their voices have not been heard or that they have been hurt by the current system. All of those voices are necessary, I think, in future considerations here.

The first 12 slides presented – these are some summary take homes, giving you a sense of what happened in the September hearing and what the draft hearing report is taking forward as takeaways from that hearing and potential foundations for future work in the area.

There are also other potential future work topics for us at PCS. One of the things that I thought would be great to take advantage of as an opportunity in the Full Committee Meeting is to have a pretty robust discussion about where the Full Committee sees the most value added in our future work as a Subcommittee. I wanted to just give you a brief description of each of these six items and then also to – probably we will kick off the discussion with members of the Subcommittee with commentary on the items, what they feel is very important or potentially less important. And then I think we will be able to have a larger committee discussion about all of them.

The first part in terms of Point A about deep dive on Beyond HIPAA, just to refresh everyone's recollection of the Beyond HIPAA report, that was a report that we issued as a Full Committee in 2019 that provided I think some excellent guidance with respect to the issues raised by health data that is not created by covered entities under HIPAA and is not data business associates or subcontractors connected to covered entities.

Under HIPAA, there is a pretty robust federal framework with respect to the privacy and security protections for the data of covered entities and business associates and their subcontractors. And a lot of people assume that any sort of health data that they are generating is covered by HIPAA. But in fact, nowadays, there is tons of health data being created that is not covered by HIPAA. Therefore, what the Beyond HIPAA report did is it looked at some of the – data exchange, data use, analysis – and gave a sense of what are the risks here and what might need to be done in the future. In terms of that report, a lot of work was done in it.

But much more could be done particularly in terms of specifying the types of provisions and perhaps minimal provisions that should be in data use and service agreements for things like wearables and M-health because if we have literally thousands of apps and app stores that people are downloading to

their phones that have some – ranging from general wellness to much more specific data collection about specific health issues. That there really is a bit of a vacuum there in terms of proper guidance, support structure both for consumers and interpreting the risks they are taking on, but I think more importantly in terms of trying to make sure that there is some baseline standards and some redlines, some redlines in terms of types of data collected, types of data sharing or transfer, types of use. That, I think, is something – a potential area for future work topics.

A second is health information security. There was a recent HHS/FBI memo on ransomware and malware in health care. There has been a real explosion of ransomware. Just to give some background on that problem, we now have lots of cryptocurrencies out there. The most successful or famous is probably Bitcoin. The idea behind many of these cryptocurrencies is that they can help individuals anonymously transfer money. We are still working out the implications of that with respect to know your customer and anti-money laundering laws as I think, Ed, you presented to us in our March meeting. We have a lot of problems in terms of the new capabilities afforded by cryptocurrency, allow for profitable hacking, profitable freezing of data, threatening to delete data, threatening to encrypt it forever and throw away the virtual key, et cetera.

Because of that, because of these new threats that I think where cryptocurrency is a real critical aspect of it, we have an increasing need to develop health security measures. There is probably a lot of low-hanging fruit there in terms of some very basic guidances.

A third aspect and Part C is data linkage stewardship. I mentioned earlier about some of the issues about de-identification and potential re-identification. One of the issues – one umbrella way to think about further work here would be to think about data linkage.

Part D is on further HIPAA guidance related to accounting for disclosures. Accounting for disclosures is an issue of long vintage. And of course, going back to the 2009 Health Information Technology for Economic and Clinical Health Act, it has been something that has been on the minds of many for some time. There is some need for future guidance with respect to this type of accounting.

To give the general committee the sense of what is at stake here, essentially under rights of access under HIPAA, you have a right to your health records. Accounting for disclosure goes further to give you a right to know to whom your records have been disclosed.

For some individuals, they say why would I care. I trust my hospital. But as mentioned earlier about some issues related to trust and also with respect to the proliferation of concern about privacy and about potential data transfers and sharing that would not be agreeable to many patients, there is increasing interest among some to know about this type of sharing. And even if it is a relatively small group of people, it still is something that could lead to better understanding of how our health data system works.

I know many might be familiar with the computer scientist, Latanya Sweeney's work on the data map, which mapped the surprising diversity of – if we were to think further about Latanya Sweeney's work and then also about the various surprises that may lay in store for people that could be exposed by, for

example, non-profit organizations or others in the same way that subject access requests in Europe pursuant to the GDPR have led to some very interesting data journalism and other discoveries.

E is about approaches for dealing with civil monetary penalties resulting from HIPAA enforcement. To make a long story short though, that was something in our parking lot, but we have learned that OCR has been addressing it. But if the Full Committee wants to talk further about it, we are happy to do so.

And then finally, the NPRM on the HIPAA Privacy Rule, changes to support and remove barriers to coordinated care and individual engagement. That is something that is on the horizon. It has passed through some of the relevant hurdles at OMB or passed over those hurdles that sometimes – in place of regulation of significant economic impact at OMB. It is something that is on our horizon.

With that, that is really the core of the issues that I wanted to present today. I think in terms of structuring our deliberations, I first should ask the Full Committee or of course members of the Subcommittee if there are any points to be made about the September hearing. And then once we have dealt with that, we can get into some of the potential future work topics. With that, I we can end the slide show and we can get into – actually, let us keep up the potential future work topics because I think that is actually a good slide to keep up for a lot of our future discussion because that may be the main focus of discussion for many today. Thanks. I will watch the participants here in terms of if anyone has – wants to raise their hand, please feel free to do so.

Nick Coussoule: Frank, thanks. Going back to the hearing a bit, it covered a lot of ground. That is one of the challenges was to share the amount of ground covered. Obviously, it was focused on data collection in public health emergencies. But there are other themes that came up in the discussion of the meeting, which I think are clearly relevant to thinking about the priorities going forward.

One thing that came up in that hearing and just happening in the ecosystem – issues of transparency, issues of interoperability, issues of individual engagement, patient engagement in there. I think the relevant point you talk here are good not only from the feedback that we got at the hearing, but also to inform what we might undertake going forward from a PCS perspective.

And the other item I guess I would toss out for discussion is how this might impact also activities that are going on whether they be in the Standards Subcommittee or other items that the committee might undertake. I would encourage everybody to be a little broader than just the feedback from the committee meeting although that is quite important to be thinking about the other challenges that are happening in the ecosystem.

Frank Pasquale: Thanks, Nick. I do think that is really important to give the broader context there because I think there was a real theme of that meeting of worries about or the idea that we cannot do it on our own and that things are a bit fragmented. It is not just about public health emergencies, but in terms of data in general in health care that there needs to be some more standardized approaches.

Wu Xu: I have a question from my experience in the state, not sure – public health, the hearing and the Subcommittee discussion. My question is the privacy and security policy are different in public health emergency situations on the regular routine public health practice. The reason I am asking is when the pandemic state announced as a statewide emergency, actually the command of chain became unified

command is under governor's office and lead by the public safety commissioner. It is a different structure. When it comes to data access, the health department, the privacy officers, the security officers apply the HIPAA rule, the routine, the public health rule, the regulation on the privacy, but from the unified commander, the governor's office really pushed our – lose a little bit. They are – under emergency, what is the high priority to make that call?

Frank Pasquale: I really like that perspective, Wu, I think that is a really important one. I think trying to get a concept of – by the way, this was something that I wanted to get more of a sense about international perspectives in this hearing and of course we only had a day so we did not have it. In having – what you are describing is sort of a state command center. It is something that I have been studying in terms of international Australian perspectives, New Zealand and other areas. I think that the state command center idea and the sense that there could be a distinctive approach that would be only for the public health emergency could potentially be part of building public trust here.

But I think one of the problems that also came up during the hearing is that once the data is collected, do we have a strong ability to monitor where it goes thence forth. Do we have provenance on that data? That, I think, is really interesting.

On the one hand, we heard a theme that having a strong command center that would be distinctive would be really helpful in terms of saying it is just for this pandemic response or it is just for this public health emergency response where we have these extraordinary authorities.

But then it seemed like another sub-theme coming out of the hearing, there was a tension between the public health approach and some of the privacy activist/privacy researcher approach that we were very concerned that we lack the infrastructure to make credible assurances that unwanted secondary uses would not occur.

But I appreciate your point about the state approach and the governor's – law enforcement. We may well need to have – we have to think in similar ways about this being a threat on the order of war or something.

Rich Landen: My sound is cutting in and out. Did you recognize me, Frank?

Frank Pasquale: Yes.

Rich Landen: Thanks. Two comments. One is I am very much in support of applying lessons learned from the pandemic so that we have a game plan and a recognized, well-discussed, and agreed upon nationally approach to data collection and privacy in a public health emergency. I am very much in favor of that.

Also, on the potential future work topics, your first on the list, Point A, the Beyond HIPAA. I just wanted to call out again that the HITAC's ONC federal advisory committee has Beyond HIPAA on its work plan. Much like the Standard Subcommittee work through the HITAC's ICAD Task Force, I think in the future, there is great opportunity and need to collaborate between us and ONC HITAC on the Beyond HIPAA issues. Thanks.

Frank Pasquale: Thanks for that angle, Rich, because I think that is going to be really the coordination. I am just going to make sure I take a note of that because coordination with HITAC will be really important to developing where we would be able to add value and where – and not to be redundant. Thanks.

Denise Love.

Denise Love: Hi. Thank you, Frank, for the -- every time you go over the hearing and the findings, I think of new things. That is happening today.

Following on Wu's model of a public health emergency, I also thought of Dr. Moyer's comments yesterday and how we can improve the – if not liquidity, but also the timeliness of the data. How good is good enough? Should we be releasing our public health data on a preliminary and how preliminary is preliminary and how to handle that? But also, this hearing really speaks to the downstream uses and the guardrails.

I still go back to how do we build guidances that do not lock out utility, the usefulness of the data, but also improve the access to the data to secondary users, academics, and others and yet protect it. I think that is our challenge going forward. But I wanted to bring in Dr. Moyer's comments of how good is good enough and how preliminary.

Frank Pasquale: I agree with you, Denise. I think that both your perspective and Wu's perspective are completely in line with what Brian Moyer was saying yesterday in terms of the timeliness and other issues.

One of the things I do not think we are able to adequately ventilate in the hearing, but is important is there have been ongoing concerns about are there ways of releasing the data, delaying the data, other things that might be politicized. That is, I think, is a really big concern. If we have to dig – I think there was New York Times story a couple of weeks ago about how some states do not include certain test results in terms of the number of cases, et cetera. Just for us to be able to have a broad sense of what is going on out there, that is a data issue as well, but that is where I would start shaving into I think more of standards – than privacy, confidentiality, and security – it is interesting to think about the relative competences of the different subcommittees.

Denise Love: But data liquidity in terms of having third parties appropriately access the data also I think instills a certain accountability to some governments that may not be transparent, but letting the data appropriately flow, I think also as a citizen adds some accountability factor that other people are looking at the data appropriately. I know that is a double-edged sword. But I think the liquidity part is important.

Frank Pasquale: Absolutely. Yes. And when I think about things like the environmental data governance initiative and others in the environmental field and being able to have that type of third-party review is really important. I think that is a really important thing as well.

Any other thoughts about the hearing takeaways?

Seeing no hands on that topic, now one thing I really would like to be able to do is to get a sense of the – for subcommittee members to be able to express their preferences and also for the Full Committee if it has feedback to give feedback on potential future work topics. If there are ones you think are particularly urgent as a Full Committee member or ones that you think are not that urgent. Of course, that is part of the deliberations as well. That is our slide that we have up, our potential future work topic slide. Anyone want to weigh in on those?

While I am waiting, I am just going to give one tension that I think is really interesting and that I think members of the Full Committee might be able to weigh in on as well, which is I think that with respect to health information security, it is a pressing need. But it is also one that is forbiddingly technically in many dimensions. And of course, standards have managed to weigh into some very technical areas as well. We do not want to underestimate our ability to do that. But I am wondering in terms of the broader committee –

But before going into that question, I see that Vickie has her hand up. Vickie.

Vickie Mays: Of the five things that we have here, I think a few that are intersecting with the things that we heard from our colleagues who presented. I think Denise just brought up what Brian Moyer wants. I think he is launching into this in a way in which having a partnership with him would be important. And to me, that is thinking about some of the things I think that are in our further HIPAA guidance.

The other thing is the data linkage stewardship. I think I heard that from Mary Greene. I think that again these are people who are just starting, who are very open to roles that we can play. I think the data linkage stewardship would be important.

And then for me, the third one which is the Beyond HIPAA we have done a lot of work on. I think that there are still some pieces that we could do. A is a shorter term. I think that C is a longer term. And then I think B – and I am assuming since Jackie got called on, Jackie may be the one to talk about this that there are some issues that I think could be in that space. I do not have a sense at all at E. I do not have a sense of where we are in terms of F. When I say I do not have a sense, meaning where those are in the universe in terms of whether it is a good time for us to weigh in. But on A through C, I do think it is a good time for us to weigh in.

Nick Coussoule: Vickie, can I just ask for a clarification? When you say some of the Beyond HIPAA work, are there one or two or three particular items that you believe would be more important or relevant?

Vickie Mays: In the Beyond HIPAA work for me, what was still there was ways in which things have moved Beyond HIPAA, but yet – the way in which the world has moved Beyond HIPAA and HIPAA is covering very narrow things. I think we need to go back to examining that and also trying to get some comment because the world just keeps changing. To me, that is the critical piece of the way in which the committee under Linda laid out some of the other things we should be thinking about. Beyond HIPAA was not just about regulation of slapping someone's hands for something negative. But it was also about the positive ways of thinking what should be protected. It may not be that it is HIPAA protected, but it still needs to be protected.

Did that help, Nick?

Nick Coussoule: That is very helpful. Thank you.

Frank Pasquale: Great. That is really clarifying, Vickie.

Jacki and then Denise Chrysler.

Jacki Monson: I suggested B and obviously many of you know what my day job is as both the CISO and the CPO. I spent about 80 to 90 percent of my time on security at this point, given the risk. That is very similar to what was in the HHS, FBI, and CISM memo that came out a couple of weeks ago. It is an area that I think the committee can add a lot of value in.

As many of you know, I was on the Health Care Cybersecurity Task Force a number of years ago and not a lot of movement has been made in this space. Yet the risk landscape continues to increase particularly since COVID. Just at Sutter alone, we have seen a 92 percent increase in cyber events since March. That number just continues to increase. It is just an area where there is a lot of targets around health care. And in addition to that, it is hard to figure out what to focus on from a risk standpoint. Because of COVID, a lot of health care is impacted budgetary wise and what they can spend money on and what they cannot. I just think it is a huge area of opportunity. I have been on the committee for a number of years now and we have not focused on information security as much as I think the risk landscape warrants it. That is just my opinion.

I think some of the other ones – previous reports have addressed. I would say A, for example. Our Beyond HIPAA report addressed it. We also have state laws that cover it particularly. In my State of California, we just had a new CRPA regulation that just passed on the ballot. That is going to cover scope. I think there is lots of intersection with state regulations in that area and our Beyond HIPAA report covered much of that.

And then the other one that I will comment on – we did a lot around de-identification. I actually was not a member of the committee at the time, but I had testified on the de-identification standards. If I were to be able to pitch one to you, I really think we should focus on B because of the risk landscape and I appreciate that. The committee does not have that level of technical expertise. But I do not think it is an area that we should shy away from because of the lack of expertise because we can leverage hearings and other aspects of it to get the expertise that we need to be able to perhaps produce a report.

Rick Coussoule: Let me make one comment – Jacki, that is a really good point. The committee has certain areas that we cover and lots of different expertise on here. But we will never have the expertise in every area. That does not mean it is not something that we should undertake. Part of our capability of being a convener and being able to bring the experts to bear and then using the people on the committee to help frame up what we hear – I think is really an important one. I want to make sure we do not limit ourselves only on things that we have particular very deep expertise in. I think that is a little too limiting. It is a really great point.

Frank Pasquale: I agree. Thank you. Denise Chrysler and then Rebecca.

Denise Chrysler: Sure. C, data linkage stewardship is the issue that speaks to me the most. I was trying to do a skim of the Beyond HIPAA report right now because I have been reminded that some of this work

had been done in that report. Even if it had, that was a year and a half ago. This area continues to march forward.

My day job is working a lot with public health data and especially the role of public health and informing the public. This has come up over and over again during COVID-19 when the public has felt there has not been – the public has felt that public health has not been transparent, that data has been politicized especially with regard to issues such as disaggregation of data around race and ethnicity.

What I find is public health feels like its hands are so often tied and that is because of risk of identification, a re-identification of data. The more disaggregated you make it, the more informative you make it with more and more characteristics, the increase in risk. Helping to provide solutions, to provide meaningful data, to inform the public, to provide data community organizations to use to benefit the community. That is where my priorities would be.

I want to mention – and the issue that just keeps – I just keep thinking about it and I do not quite know what to do with it. When I think of Beyond HIPAA, I get a little worried about are we going to expand what a reasonable expectation of privacy is. I hear more and more a sensitivity to any information that concerns me and what is it that is reasonable for an expectation of privacy and keeping that in mind, keeping in mind what do we mean by sensitive data. What do we mean by stigma? For me, sensitive data – my address is more sensitive to me than a lot of other information. The fact that I may have gotten a serious injury when I go down a flight of stairs, trying to escape a dog. My address is more sensitive to me, but we have no reasonable expectation of privacy and address. And it is, of course, sensitive because I worry about people finding me, especially when I used to do fraud work, that sort of thing. C again.

Frank Pasquale: Thank you, Denise.

I see Rebecca and then Melissa.

Rebecca Hines: Just wanted to note that in the Q&A, somebody noted the topic of patients opting out on data sharing may be an important area. I know this has been discussed in the past. Just wanted to add that to the mix.

Frank Pasquale: I did see that Q&A point as well. I think that is something that I think for our next meeting might be a valuable thing to put into the mix. It is a way to square the circle. It is a way to sort of say if we are on the one hand concerned about data quality access and comprehensiveness, but on the other hand, we have privacy concerns. Opting out can be a very valuable way to square that circle. Of course, I realize there have been debates about the degree to which that might bias the data or might lead it to be less useful. But on the other hand, that is another concern. That is great.

Melissa.

Melissa Goldstein: Thanks. First, I wanted to just note again my deep thanks for the very hard work that the staff did in putting together the September 14 hearing. The staff and you, Frank. It really was a well-attended and really helpful event to me and I am sure to many other people.

In terms of our future work, I agree with Vickie that we should continue our work on the Beyond HIPAA. Of course, the committee has adjusted and the HITEC committee may be addressing it as well in the future.

These issues continue to evolve in different ways. When the committee last addressed Beyond HIPAA, location data as we have seen used in the pandemic apps that are either sponsored by states and cities or independent was nowhere on our mind about being able to identify where people had gone, what events they had attended, where they might have been infected, who they might have seen along the way. I think that this area is constantly expanding and deserves close attention on an ongoing basis.

I would say that I feel the same way about C, data linkage stewardship. I think that the issue of re-identification, de-identification, the entire issue of risk analysis, what causes risk, what does not cause risk. Denise raised it a few minutes ago as a reasonable expectation of privacy. I would phrase it perhaps a different way as what is the risk. What is the risk to individuals, to groups actually, of releasing, disclosing, sharing, or the possibility that certain information may be re-identified without permission? I think we need to focus on risk analysis, and I think the ideas of linking data is very important in the stewardship.

I am a bit agnostic on the health information security side. I am not sure that we have the technical chops that HHS and FBI have. I would be happy to view it. I think it is incredibly important.

I also think that accounting for disclosures has been neglected for a very long time, not only by us. I think that it would be a good topic for us to address perhaps not first, perhaps not the most urgent.

The last two, the civil monetary penalties and the NPRM, which potentially has not yet been released as of this minute. It might be coming pretty much soon. I am not sure that they are ripe for us to deal with immediately. They might be soon and I think that the committee and the subcommittee should be vigilant as to where those stand because we may need to redirect our attentions according to importance of topics. But that is really just my quick sense about where we stand in terms of the –

I did want to note that I do think that Beyond HIPAA is still an important consideration that certainly has not been settled.

Frank Pasquale: Thanks so much, Melissa. I think those were all very important points.

Vickie and then Jamie.

Vickie Mays: One of the issues I want to revisit is the data linkage stewardship issue because I think when we talk about stewardship, we are also talking about issues of responsibility. One of the things that has been occurring more often than some of us would like is the notion of not linking data in order to prevent things like numbers being seen of hospitalizations or numbers, for example, not being coming up in terms of testing.

I think in this data linkage issue, it really should be also about looking at the kinds of data for the sake of risk of morbidity and mortality as well. It is not just we have all this good stuff, but it is like when we do not, for example. And COVID-19. There are clinical data and public health data – staying in different

places and numbers have been curtailed. And what that does is it affects people's morbidity and mortality. I think there is another side to thinking about this and not just risk in terms of identification, but risk in terms of disease and death.

Frank Pasquale: Excellent. This question of – I think that reminds me of – I think it was Katherine Taylor from MIT or there was a researcher was looking at – trying to analyze the potential effects of health privacy on morbidity and mortality in NICUs. It is really important to have a comprehensive risk framework as opposed to one that is only focused on the risks of data misuse, harms from data.

Jamie Ferguson: I have two comments. First is I wanted to support Jacki's comment on B and looking at cybersecurity in light of the changes in the cyber world that we are living through now.

I think in particular we have multiple different maturity models and frameworks that apply to different participants and stakeholders in the health sector. I think the committee could do important work to seek to come to either fewer number or a single maturity model or framework that would apply to different aspects of the health sector.

I would note in particular, the Department of Defense has launched I think this year what is probably the most comprehensive maturity model, the Cybersecurity Maturity Model Certification program, which is required of Tricare contractors. It does affect many health systems.

We might look at that versus the other models for maturity and certification that are out there to seek to strengthen our cyber defenses across the health care critical infrastructure.

And then the other thing I wanted to comment on is in terms of data linkage stewardship on number C, I think that what we are seeing is increasing data flows and integration of social services, community services along with public health and health care coordination data. When I talk about social services and community services, I mean addressing problems like food insecurity, homelessness, transportation needs for health care. Those data have in many cases different participants that are non-HIPAA-covered entities, different personal preferences and sensitivities about the data. And I would also add that long-term care facilities also need to be integrated. When we think about the data linkage stewardship, I wanted to put in a vote for that as a priority, but also for broadening the focus somewhat.

Frank Pasquale: Thank you so much, Jamie. I think those were really helpful – I think that point about the Defense Department for Tricare, that is a really interesting parallel. Thinking further about other models is going to really help us in terms of our ongoing deliberations. I am going to look into that guidance and the point about the social determinants of health and other forms of data that could be feeding into these systems is helpful as well.

Denise and Valerie. I do not want to go too far over our 12:45 limit. I think we have a bit of time to take in these last comments. Denise and then Valerie.

Nick Coussoule: Frank, let me just interject. Timewise, I think we are good. Why don't we give ourselves another 15 minutes because I think we have a little bit of flexibility this afternoon with part of the discussion. If we can do that, that would be great. Let us just try to plan on wrapping this one up at the top of the hour.

Frank Pasquale: Sure.

Denise Love: This is a wonderful discussion. It is such a vast number of topics that I find myself in the grouper rather than the splitter category. Following on Wu's comment and Jamie's and also maybe A, B, and C, I am really thinking – maybe some guidance or some vision of what a national data commons would look like in a public health emergency, but also a post-COVID world because we are going to have to bring these things together. How does it look? What are the guardrails? We heard at the hearing some call for data commons.

Frank Pasquale: I really like that vision, Denise, because I think it really helps us to integrate the topics and to see them in a larger framework.

Along those lines, I also wanted to make the point that one of the things – our discussion is sometimes sequencing is hard. On some level, we might want to know a lot about the current state of re-identification and de-identification in order to really specify A, which is the best practices for data use and service agreements. If we think that de-identification is a big threat then we might think it – bigger threat than – recognized in the relevant guidances then we might want to be stricter on that.

On the other hand, I think that there is also a way in which by making those data – by providing guidance that would make for better data use agreements and service agreements for wearables and M-health, we reduce the re-identification threat. There is this very interesting sort of chicken and egg like which is the first to take on.

But I think when you provide something like this overarching framework of the national data commons that would be useful in public health emergencies --

Denise Love: Dr. Moyer's – also some guidance to state and federal agencies. Preliminary releases of data are not a sin if it is not perfect, but how good is good enough. Those are big questions and I will end there.

Frank Pasquale: Great. Thanks.

Valerie.

Valerie Watzlaf: I just wanting to say that when I – I think these are all wonderful topics. I am not sure how many we can take on at one point. But I was focusing on data linkage stewardship. And when I look at that and hear some of the comments I think even that Melissa brought up about risk analysis, I do not see how we could not also undertake B, the health information security, since that is also part of it as well as possibly parts of A. I am seeing those – I guess those three combined is what I was thinking. Just because I do not think you can take one without the other two.

Frank Pasquale: I missed the three that were combined. Was it A, B, and C? Is that right? Or A, B, and D?

Valerie Watzlaf: A, B, and C. If you start with C, I guess if you really focus on data linkage stewardship, I am not sure how you couldn't also be looking at security and then moving beyond in relation to the privacy, looking at the data use agreements and so forth.

Frank Pasquale: Great. Thank you.

Wu.

Wu Xu: I really like the combined data linkage into A and B, but I propose also add D because when – disclosure is related data linkage.

Frank Pasquale: Thanks. You are right. It does take a wholistic perspective there. Maybe one of the challenges is trying to sequence and then also sort of organize them.

I think that the other point that I get out of your perspective, Wu, is that – even if we were to say, we really want to go deep on A, other elements of these work topics are going to be – inevitably, we are going to have to talk about them as well. We are going to have to think a bit about them as well, which I completely agree with.

Any other comments, questions, concerns?

Nick Coussoule: Maya, did you want to make a comment?

Maya Bernstein: I did. We have not really talked about the last item on this list so much. I just wanted to bring the committee's attention to two things that might cause you to think about that issue. One is that it is public information. That that rule making has gone to OMB and OMB has concluded its review, which is a time when the agencies then are free to publish the rule.

And the other thing is the timing of the Congressional Review Act, the 60-day period during which the Congress can take on a rulemaking and decide whether they wanted to go forward on it. They can basically vote a rule down within 60 days after a rule is published.

That 60 days – if you count back from not a random date, January 20, you will see that the 60 days is about coming this week. That rule and other rules you may look to – you may know the administration is shoving a lot of things out the door that are their highest priorities and that they want to make sure get into the Federal Register and implemented before the potential end of the administration. It is a time for people who are interested in those activities to look closely at what is being published and what is being output by the administration in terms of rulemaking in case there is something that you might want to comment on, not just health regs, but throughout the Federal Government.

Frank Pasquale: Thank you. Thanks very much, Maya. That is very helpful to hear that there is an increasing potential for --

Maya Bernstein: Frank, you are cutting in and out so we are missing pieces of your sentences.

Frank Pasquale: I just wanted to say thank you. Thanks for alerting us to that. Great.

Any other questions or comments?

Maya Bernstein: I guess the only other thing is that should this rule be issued, it is a notice of proposed rulemaking, which means they are looking for comment. If it came out in a timely way and the

committee wanted to weigh in on it, the timing might be good for the committee before its next meeting.

Frank Pasquale: Got it. Yes. I do think that is very valuable advice timing wise. Thank you.

Any other comments?

I will turn it over to Nick if that is okay with you, Nick. I think we can adjourn this part of the hearing.

Nick Coussoule: Perfect, Frank. Thank you. Actually, this was a very good discussion. Like all these, it takes a little while to get rolling and then once you get rolling, it is hard to stop. But very much appreciate everybody's level of engagement here. I think there was some really good work done.

We are now ready for a break. We are just before noon actually Central Time, so I guess 1 o'clock Eastern Time. Why don't we take a break until the middle of the hour so until 1:30 Eastern Time? That gives us a little over 30 minutes. And then we will come back and finish up the formal sessions with Rich, in regards to the recommendation letter and a little more work on the future workplan. We will also talk a little bit about how we actually decided that and the criteria that we have laid out. I think really good work here so I appreciate everybody's time. We will now be adjourned until 1:30 Eastern Time. Thank you very much.

(Break)

Rebecca Hines: I think we are ready to start the afternoon discussions. Rich, let me know when you are ready and we can display the letter. But I am assuming you wanted to start off with some preliminaries.

Standards Subcommittee Recommendations Follow Up Discussion

Rich Landen: I think we are ready. As Rebecca mentioned, we will pull the draft letter for the recommendations up in a second.

But first, just to recap yesterday, the Subcommittee on Standards is proposing to the Full Committee four recommendations coming out of the Operating Rules hearing. CAQH CORE proposed three operating rules to prior authorization operating rules and one operating rule on connectivity that affects more than just the prior auth operating rule. It affects – I think it is three, maybe four other operating rules that have already been adopted.

The rationale for the recommendations – the presentation yesterday. The Subcommittee had an anticipation of favorable reaction by the Full Committee, drafted a letter to go to the Secretary that would contain the recommendations and spell out a little bit more our rationale for why we are making the recommendations we do.

We are going to walk down the letter. Some of it is pretty much broiler plate. We will not spend too much time on that. But we do welcome and need the questions from the committee members and then we have gotten two emails this morning from – one from the American Medical Association, one from

CAQH CORE that reiterates some of the points that they made in their testimony and written submission. We will take that into consideration as we go through as well.

There were a couple of committee members who last night and this morning did send some comments and we will address those as we walk down through the letter.

I do want to reiterate that Operating Rules and HIPAA transactions are a – it can be a pretty deep dive. There is no expectation that every member of the NCVHS will be a technical expert in this. But it is very important for the process and I think I used the "cannot see the forest for the trees sometimes" analogy when the Subcommittee gets into technical discussions. Sometimes we forget that the rest of the universe has not lived in this space. We are relying on and expecting our colleagues on the committee to raise the questions because what essentially the Subcommittee is asking for you to do is sign off on these recommendations and we need to ensure that you have a comfort level with those that is consistent with your general responsibility and knowledge about the health care and health data and health informatics space, but without expecting you to be a deep dive expert.

Let me pause and see if any members of the Subcommittee want to add anything to that before we go through. I do not see any so let us walk on down through.

Again, I am going to spend a little bit of commentary for the benefit of those who are new or newer on the committee. These letters by our charter – they go to the Secretary of the Department of Health and Human Services. Once they get to the Secretary's office, that office then will disseminate these recommendations down to the appropriate agency or agency within the Department of Health and Human Services for a response.

We try and keep the letter itself at a high enough level that conveys to the Secretary the sense of what we are trying to get done. And then there is always a long discussion about how much detail and in what depth is required in order to give the Secretary and the management officials within the department enough information that they can really get their arms around what it is we are recommending and why. Of course, the door is always open for further communication. But it is an art and into deciding what the level of detail is and of course what language we choose.

Walking down, let me just go through the whole thing just briefly. The first page is pretty much broiler plate that we send to the Secretary. It gives a little bit of the history of what it is we are doing and then it highlights the recommendations.

On page 2, we get into background and supporting details. And, again, this is a middle level of details sufficient for management to understand what we are proposing, but it does not get down into nits and grits and nuts and bolts.

You see that we give the background. Then we spell out each recommendation and the language in each recommendation should be verbatim as to what you saw yesterday. The narrative under each recommendation is kind of a refined version of what I hope I presented to you yesterday, using the slide deck so Recommendation 1, Recommendation 2, 3, 4. We will walk down these in detail. And then the summary. Here is the conclusion and it talks a little bit more about where our head is at and relates to some other things going on in the industry.

With that being said, I just will remind you that the Subcommittee has had a lot of deliberations. We did use an evaluation template and that included not just looking at the rule itself, not just listening to the testimony or the oral testimony at the hearing in August or reading all the written testimony that was submitted, but also then proactively using our resources and our experience and in talking about the third criteria, the evaluation, is how this whole thing fits into the environment and looking at this again as – request for a rulemaking under HIPAA or in Operating Rules. That is, in effect, a federal national mandate. They require a significant investment of resources, time, workflow changes, and it is not a simple deal. It is not voluntary. The criteria that we looked at – the question we asked is essentially to use some of the language we used from the Subcommittee, is the juice worth the squeeze. Keeping those kinds of things in mind, let us walk through in detail here.

The first suggestion is right up at the top. Instead of recommendations for proposed Operating Rules for prior authorization and connectivity for HIPAA transactions, the suggestion is recommendations for proposed operating rules for HIPAA transactions related to prior authorization and connectivity.

I think from my technical perspective, the original version is more technically accurate because they are operating rules for prior authorization. They are not operating rules for HIPAA transactions related to prior authorization.

Nick Coussoule: Rich, I think the first point frankly from my perspective is more relevant because the second one – it reads as if there is a HIPAA transaction for connectivity. In fact, Margaret sent a comment about it. There really is not.

Rebecca Hines: Done.

Rich Landen: Moving down then, Recommendation 1. Again, just repeating the recommendations themselves so nothing to pause on there.

First paragraph of page 2, we found out that that was a versioning error we had in an earlier draft. We had this paragraph here, but we moved it up onto page 1. This paragraph that is now stricken through is repeated on page 1, as you may or may not have noticed. This is a redundant paragraph. We are proposing to take this out.

The background then goes into talking about the prior authorization transaction. Those in the industry were recognized. That is the X12 278. There is an English language title that is health care services review. Deb, you may want to help me out here. Health care services, request for review, authorization for referral, referral authorization. But that is the actual transaction standard for which a HIPAA rule has been adopted to which these two prior auth operating rules would pertain.

The point here is that in contrast to some of the other HIPAA transactions, namely the claim transactions, the eligibility transactions, the electronic remittance, and payment transactions. This transaction has the lowest implementation rate of all the mandated HIPAA transactions currently at 13 percent. That figure comes from the CAQH. They do an annual what they call CAQH Index. This is the 2019 CAQH Index. Since these transactions have been out in regulation for close to ten years now, a use rate of 13 percent clearly indicates that there are some issues here.

We talked then about keeping with priorities of HHS and the administration. Several efforts are underway to understand the challenges of prior auth, identify opportunities to increase the electronic prior auth and thereby reducing burden on providers, payers, and patients.

Melissa Goldstein: Hi, Rich. This is Melissa Goldstein. I had my hand up, but I did not know whether you have your eye peeled on the panelist list. When you just were summarizing, you said HHS and administration priorities, but that is not what the sentence says. I would clarify that that is what you mean because administration with a small A could mean many different things. If it is in keeping with HHS priorities, maybe say that. I guess you could say administration priorities, but this document will live on. I would say HHS, but that is clearly up to you guys.

Rich Landen: Let me see what others think about that. The priorities we are talking about include burden reduction and the HIPAA efficiencies. That is primarily, but I am not sure exclusively an HHS priority. I welcome any other insight and input into Melissa's comment here.

Debra Strickland: This is Deb. I think we could certainly entertain adding that or even just the capital A in administration because there are, as you mentioned, other offices interested in this.

Rich Landen: One of the concerns is the burden reduction actually comes from legislation. That would take it outside of administration. But again, the HHS and administration priorities are founded in that legislation. How do we want to phrase this? I am happy with keeping both if that is good for people. I see a lot of heads nodding up and down.

Melissa Goldstein: If you do mean administration priorities, it does need to be capitalized. I am putting on a very ancient editor hat here. It does need to be capitalized to specify which administration you are talking about. Any readers who are not groupies, know what we mean.

Rebecca Hines: If you want it capital, we have never done that before. It would be new for us. But if you would like it capitalized, we can do that.

Melissa Goldstein: The other phraseology is just the administration and it does not say who.

Rebecca Hines: Right.

Melissa Goldstein: That could be institutional administration.

Rebecca Hines: Which to some degree I think is the case in this case. I think it is both.

Rich Landen: Is this maybe a thing that we can just flag? And then typically what we do is we will vote on this. I am not necessarily assuming a successful vote. Typically, in our process at NCVHS, we can vote on this and make it subject to editorial cleanup later. I think we understand the concept here. Let us flag that and designate that for a looksie in the cleanup.

Nick Coussoule: Rich, this is Nick. Not to interject, but the first part of that sentence before the comma could almost be deleted and it does not really change the meaning. It does not actually change what it means. If we are really hung up on the reference point, the point is that there are several efforts

underway to understand that process. Depending on the point you are trying to make as a group, I would make sure that that is clear and then we could deal with the language.

Rich Landen: Nick, my reaction to that is one of the rationales we have down here or later on in the letter is there are multiple priorities that the industry is facing.

Debra Strickland: -- we had that in there --

Rebecca Hines: Yes. It is an important lead-in based on discussions I recalled.

Nick Coussoule: That is what I thought. Then the question really becomes just a language question and not a point question. We agree with the content. We are just trying to get the language right.

Rich Landen: I see heads nodding. Anyone object or disagree? Okay.

The final sentence there in the paragraph. The proposed operating rules are one effort aimed at mitigating some of the barriers in the workflow for prior authorization.

Next paragraph. In general, both oral and written testimony supported the proposed operating rules for prior authorization. The testimony – there was solid support for where CAQH CORE is trying to go with these. The key values of CAQH CORE rules are that they could shorten the payer prior authorization response time for review and reduce administrative burden by improving the consistency of information across payers. That is what operating rules are intended to do. As they relate to HIPAA and X12, they improve the consistency of information so that one of the trading partners does not have to face as much one-off in formatting and transmitting a standard transaction to different trading partners whether that be from health plans to multiple providers or providers to a provider to multiple health plans.

Most commenters agreed that these rules were a step forward on the path to automating the prior authorization requests, but they did not encompass a full solution for digital prior authorization workflows. This is one of the key takeaways that the Standards Subcommittee talked about. I mentioned it in the presentation of the recommendations yesterday. But these rules are an incremental step. There are still a lot of issues with the prior auth, thinking over to the ICAD report and to the testimony that we received as part of our hearing. It is very clear that this is not – if we adopt the rules, it is possible that the operating rules would move the needle forward, but it is clear that it is not in and of itself a solution and a lot more work on prior auth still needs to be done by others. It is not a question of – it is a larger question than merely waiting for future refinements of the operating rules. There are a lot of moving parts going on.

These rules – I think some of the language we talked about in the subcommittee and again others chime in if I am misstating or not completing the thought. We talked about these were necessary first step. In other words, whatever happens, something like this operating rule has to happen. But even with this operating rule in place, it would not solve some of the key problems in the industry.

Importantly, those testifying were emphatic that without an adopted standard for attachments to convey the related clinical information, use of the adopted HIPAA standard for prior authorization would

not substantially increase, even with the proposed operating rules. This paragraph is the key to our Recommendation Number 1. Before it makes any sense to adopt to promulgate regulations for the prior auth operating rules, the standard for the attachment would have to be promulgated.

With respect to the proposed operating rule for connectivity, many organizations stated that while the update provided consistency, there were concerns about the implementation costs for small providers, the current alignment with industry security best practices, potential conflict with the NIST standards, National Institute of Standards and Technology. And again, talking about editing, we need to spell these out in the final letter. And the burden of making certain system changes might not be necessary but would only be required because of the operating rules. Again, the thinking here is we have – if we recommend adoption of these operating rules and HHS does adopt them then they become national mandates. Again, to this paragraph, we have other guidance coming out of NIST and under other legislation requires adoption of different transport level security standards than what is here in this version of CORE's connectivity rule.

Further, based on our understanding of the proposed connectivity rule, use would apply when trading partners are exchanging four transactions: the claim, the X12 837, the prior auth, X12 278, premium payment, the 820, and the enrollment/disenrollment transaction 834. And CORE leverages a provision called the safe harbor, which means the operating rule would be used unless trading partners mutually agree to use an alternative. To state that in the converse, what the CORE rule allows is the trading partners to mutually agree to use something other than what the standard calls for. If the trading partners cannot agree then both partners must use and accept what is in the CORE requirement.

The currently adopted version of the connectivity operating rule would be expected to remain in use for the exchange of eligibility, claim status and electronic remittance advice transactions until the new connectivity rule is adopted by HHS for those transactions.

NCVHS analyzed the testimony and deliberated the proposed operating rules in light of current use of the prior authorization standard transaction, the rapid evolution of interoperability innovation and burden reduction, and the principles of HIPAA. There are ten principles of HIPAA. Let me just say on the side that the verb "deliberated" is one of choice. It was a very intense discussion. A lot of give and take back and forth, different perspectives among the subcommittee. A lot of input from the oral and written testimony as well as looking at the FHIR initiatives and other activities going on. AMA had presented the head of coalition that had come to a consensus about prior auth. There is just a lot of work being done on this and it is very clear that prior auth is a high concern in the industry. Our discussions were quite extensive as far as just getting a snapshot of everything that is going on and the potential impact. If FHIR goes forward, at what pace would it be? If we go forward these rules, these rules, of course, are predicated on the X12 transactions. Would we have two different ecosystems and how would we manage that? There is a lot of thinking behind this.

But the point is that we had to take an awful lot into consideration in really trying to determine the value to the industry of the proposed operating rules as a national mandate.

Rebecca Hines: Rich, this is Rebecca. Did you see that April Todd noted that the proposal was not for the connectivity rules to apply to claim premium, enrollment, dis-enrollment for adoption? The connectivity

was to apply to prior auth and prior federally adopted operating rules including eligibility benefits, claims, and ERA. I just want to make sure you saw that.

Rich Landen: I remember we have gone round and round about this several times because there was some – we were not always clear at all times on exactly which transactions they would apply – the connectivity would apply to and would not. Rebecca, is what you are saying is we should go back and doublecheck which they do or am I missing your point?

Rebecca Hines: I think in the cleanup phase, we should just make sure everything is spot on.

Nick Coussoule: I think that is correct. I think the ones that the rules apply would be the claim, the 278, 820, and 834. Those are the – I just think it is referencing the wrong set.

Rich Landen: Okay. Recommendations in the explanatory material. One, adopt an attachment standard. NCVHS understands that the adoption of a standard for attachments is a prerequisite to the adoption of operating rules for prior authorization transaction. Without an attachment standard, payers and providers indicated – that suggested language that I think looks pretty good – payers indicated in the August hearing and written submissions that an increase in the implementation or use of a prior authorization standard transaction would be unlikely. Unless we get an attachment standard, uptake of the 278 would probably be pretty minimal. For further detail on the value of an attachment standard, see our previous recommendations and that is footnoted at the tail end of the letter.

Recommendation 2. Support and encourage voluntary use of the two proposed operating rules for prior auth prior to an action for adoption. NCVHS recommends the Secretary encourage voluntary use of the proposed operating rules for data content in infrastructure for the HIPAA prior authorization standard transaction, in light of the strong support from industry. During the voluntary phase, HHS could identify meaningful measures to evaluate stakeholder use of the operating rules, and consider an objective evaluation process for the evaluation, data capture and final report. Based on the data and results of the voluntary adoption phase, HHS could consider adopting the operating rules through the notice and rule making process.

What that is saying is and again this is bringing in some of the concepts from our Predictability Roadmap that the operating rules are proposing solutions to some of the issues around prior auth. But we, as the Subcommittee – I think the language if I may quote one of our members – we see the promise of the operating rules, but we want to see the evidence for the promises. The communication today from CORE pointed out that there were several payers of their membership that did pilot these with good results. But the Subcommittee's view is it is one thing to run a test with a couple of trading partners. It is a very different proposition when we scale this up as a national mandate. We, as the Subcommittee, did not feel that the evidence was there to necessarily demonstrate that the operating rules would improve the uptake of the 278, uptake and use of the 278 transaction and the concomitant reduction then of the manual process is currently used by most of the industry for prior authorization.

This is also worded specifically so that once this voluntary use period wraps up and we do not define how long that is, we suggest later on a timeframe. But we are saying HHS at that point in time when it has the information that it needs, it can then proceed to rule making without coming back through

NCVHS for a new recommendation. We do not state that explicitly, but we think it is clear enough in what we got in language there.

We believe the proposed operating rules provide improvements in the prior auth process such as consistency in response times across payers. Response time is a big issue. It is raised by industry particularly when you are looking at it from the patient perspective. However, the lengthy rulemaking process, if initiated, would not provide immediate results. What that means, again, for those of you who are newer on the committee, the rule of thumb that if all goes well, it takes about four years from the time something is proposed for rule making. CMS drafts, clears, and publishes a notice of proposed rulemaking, gets in the comments, reviews the comments, publishes a final rule. And as we heard this morning, the six-day congressional review period. And then after the final rule is published, it is at least a year before compliance with that rule is mandatory. The rule of thumb is about a four-year process. If we would recommend the operating rule today and HHS accepted our recommendation, it would still be 2024 or 2025 before the industry would be mandated to be using that rule.

The value of a voluntary adoption purpose is you do not need to wait for rule making. It can be started immediately. And through the lessons learned in that adoption, we see will it move the needle. Can we demonstrate what are the cost of implementing? What is the value and efficiency and burden reduction? Those are the types of things in our Predictability Roadmap – those are the types of information that CMS needs for its fiscal impact in industry, impact analysis in the rule promulgation process.

The next paragraph gets us back to some of the ecosystem things we were talking about. The Committee is aware of the Secretary's prioritization of other initiatives, including interoperability, API implementation with FHIR, clinical decision support (which can be foundational for automating prior authorization), and improved public health reporting based on lessons learned in the COVID pandemic.

Supporting voluntary adoption of the proposed operating rules does not conflict with these other HHS priorities. Furthermore, HHS support for, and industry's subsequent action on operating rules, could mitigate certain workflow barriers related to the prior authorization process. For example, use of the operating rules in concern with the adopted HIPAA standard transaction for prior auth could reduce delays in approvals, once the provider has submitted the necessary documentation so getting into a fully digital mode, not the paper model.

The Committee has observed that there is significant innovation occurring around prior auth among multiple industry sectors and groups, including – when we drafted this, it was in the future. Now, it is the past – including recent released recommendations from HITAC and the collaborative work between NCVHS and HITAC on the convergence of administrative and clinical data. NCVHS understands that HHS must evaluate several promising initiatives and determine how to incorporate any recommendations into a larger strategic plan. Apropos of operating rules, NCVHS believes that a voluntary use phase would provide time to garner value while bringing clarity to the mid to longer term priorities for national interoperability. As such, we suggest a period of at least 12 months for this voluntary use phase.

One of the Subcommittee's concerns here was we have a lot of industry energy being focused on prior auth for different solutions. And one of the key and promising activities is the app-based world as

represented by HL7's FHIR. If the industry moves toward the ideal state for prior auth as articulated in the ICAD report, then we are looking at a very different world, a very changed ecosystem and we have to then be very cautious about what we recommend for these operating rules, which are X12 centric if indeed the future world is going to be FHIR centric or API centric. Again, remembering that we have a four-year lead time. That was one of the considerations that the Subcommittee spent a lot of time trying to digest and get our arms around.

I think where we came out and again any member of the Subcommittee wants to chime in on this. We thought that this concept of using a year for voluntary use will allow the industry to move forward in the X12 world and that will also give us time to see how the FHIR world evolves and have a much better sense of the uptake of the HITAC ICAD report and see where the industry is of a little bit down the road and have a better idea of whether we are going to be staying – whether industry will be staying with the X12-based standards for prior auth or whether it will be wanting to shift to the more FHIR-based thing. There are impacts on the return on investment if we recommend now that HHS consider making these operating rules a national mandate. Again, lots of moving parts. Lots of conversation among the Subcommittee.

Anybody want to add anything while I take a pause? I have been talking much too long. Either they agree with me or they are afraid of me and I do not think it is the latter.

Recommendation 3. Very succinctly, do not adopt the proposed operating rule for connectivity and encourage CAQH CORE to complete its new version of this proposed operating rule. This became a fairly clear consensus early on in the Subcommittee's conversation. NCVHS does not recommend that HHS adopt the proposed operating rule for connectivity. The Committee has decided not to recommend the proposed connectivity rule because it both adopts a security standard that has known vulnerabilities and it allows continued use of other obsolete security practices. That reasoning in and of itself was sufficient for the Subcommittee to say no. It does not make any sense from a national standpoint to mandate a security requirement that is known defective or to allow use of obsolete or obsolescent security practices. That just did not make a whole lot of sense to us.

We pointed out that the National Institutes of Standards and Technology, NIST, has already issued recommendations with a different security standard than what is in the current version of the CORE connectivity. The Committee suggests that CAQH CORE move toward the newer Transport Layer Security standards as put forward in recommendations by NIST. Base don industry input, CAQH CORE may wish to consider removing the safe harbor provision that would enable continued use of certain security practices that may be outdated. The Committee heard some testimony indicating that the change in authentication from Username and Password to the X.509 digital certificates will be too burdensome and costly, without demonstrable value for many smaller entities and thus will not enjoy widespread adoption.

One testifier representing a large stakeholder group indicated that because this was the only option for authentication, it limited stakeholders' ability to meet differing business needs and could impede EDI adoption. The cost of the X.509 digital certificates could be passed on to providers, which could be a shift in the transaction cost, increasing burden. One organization indicated that the proposed operating

rule could limit the inclusions of new and emerging technologies such as RESTful APIs, OAuth, SAML authorization and identify services. These are all standards within the transport realm of the data.

The Committee heard additional testimony from a variety of perspectives, including some positive testimony in favor of immediate adoption. Some testifiers indicated that the articulation of this rule was complex, and difficult to understand. We also heard from HHS that the change in the CAQH CORE new operating rule structure might require re-promulgation and adoption of already-implemented operating rules. That was significant to us because that would mean in addition to promulgation of the three new operating rules, CMS would also have to go back and re-promulgate rules already on the books because of the change that CORE made going from its – again, to the new members of the Committee, CORE used to have a structure that had all its operating rules in phases. Just this past year, it eliminated that phase concept to go with a more componentized versioning system. And the change of that structure within the CORE operating rules, CMS indicated that it would likely or could possibly require re-promulgation of the rules in the books and that means a lot more work for CMS and a lot of more lead time and rule development work in order to adopt.

The Committee understand that CAQH CORE is working on revisions to the connectivity operating rule. We encourage publication of a new version that takes the above considerations into account and that is written in clear language for a broader audience. Specifically, we understand that CORE has pretty much completed final drafting of the next version of the rule and that that version is out for ballot within CORE already.

Questions on that language under Recommendation 3? Moving along then.

Four. Increase visibility of enforcement information related to operating rules. Consistent with previous testimony, stakeholders requested that HHS act upon and publicize its efforts on compliance and enforcement for already-adopted operating rules. The Committee made recommendations in previous letters about publicizing enforcement data on an appropriate website, and we commend recent efforts by HHS to do so. That reference is footnoted.

Data on compliance and enforcement activity specific to operating rules, as well as de-identified case summaries on operating rule issues, could be educational for stakeholders. In other words, if there are stakeholders, trading partners that are having issues, knowledge of what those issues are could help other people in the industry, other stakeholders, who are having the same or similar issues.

Furthermore, in alignment with compliance reviews underway for standard transactions, the Committee suggests HHS consider implementing compliance reviews for the adopted operating rules to determine the level of compliance with those that have been mandated to date.

That is the gist of the recommendations and the rationale. I think I will not go through the reading of the summary unless there are changes that members really would like to suggest. I see, Rebecca, you have a couple of them highlighted already.

Rebecca Hines: That one was just for clarity – I think it is good. Instead of saying to address these, to address the challenges. That was it.

Rich Landen: Subcommittee members, anybody want to do what Alix used to call the colored commentary.

Debra Strickland: It is Deb. I think you have done a great job at reviewing all of the sentiment and the work that has gone into these recommendations. We deliberated. We discussed. We challenged each other to really come up with the best way forward for the industry. I think that this is it. It gives us a happy medium. It allows the industry right now and openly to go ahead and voluntarily test these transactions, test their worth, and make sure that it is really going to be an effective uptick for the industry before we spend the amount of money that would be needed to do this on a broad scale.

I think it also gives CAQH CORE and its members time to refine the communication rule and make sure that it aligns with the work of the industry.

Rich Landen: Questions or comments from the Committee members? Wu, did we get all your questions addressed?

(No response)

Rich Landen: Melissa, you are okay. I know you submitted a number.

Melissa Goldstein: I was really just focusing on readability. I think Rebecca added in the language for Recommendation 3, maybe spelling out all of the acronyms at the end of one of those paragraphs. I got a little bit lost in them and I did not know whether I had already read about digital something or not. I just thought maybe dropping a footnote to spell it out so it does not take up room in the text. Just something for the less technically focused.

Rebecca Hines: That whole list.

Melissa Goldstein: That whole list.

Rebecca Hines: What you are saying there is a footnote, Melissa?

Melissa Goldstein: A footnote would be fine or whatever is the most – whatever can be clearer without de-railing the meaning of the actual sentence.

Rebecca Hines: I think a footnote is a great idea. Thank you.

Tammy Banks: Rich, I just wanted to underscore – the Subcommittee really found CAQH's work, CORE's work on these operating rules favorable in support of the adoption of these rules. We also understand that a complete solution needs to be identified and that why the strong emphasis on the attachments so moving forward, taking into account in Recommendation 2 all the other activities around prior auth. I just want to underscore again that this is obviously a priority topic that needs additional thought for consideration in order to meet the business use case as well as get the adoption by providers. vendors and payers. So appreciate the discovery work and the work of CAQH CORE and again I have to underscore the new attachment rule in some fashion in order to --

Rich Landen: Alright, then. I, again, do want to acknowledge the comments we got in from AMA and CAQH CORE. I want to make it very clear that the Subcommittee and these recommendations are adopted and the Full Committee as well are really on board with this concept that there are issues with prior auth the impact on patients that do have burden aspects associated to it and we need some solutions.

What we are saying here is not in any way a statement that we do not like CORE's work. We absolutely do. We have some issues with the connectivity rule, as we pointed out. But we think with everything else going on in the industry, there just was not the compelling evidence to make this a national mandate particularly when there is no federal regulatory barrier to or prohibition of moving forward on a voluntary basis and we think not only CORE with its own members but others in the industry who may not be CORE members, but can voluntarily adopt. And with the industry consensus letter that AMA had mentioned a couple of times in their testimony, again, in their email today, there is a lot of industry agreement that there are issues here so a voluntary approach. Rather than holding people back, it allows them to go forward and really try and get that value without waiting for federal action.

As we pointed out, a recommendation is phrased that after the voluntary use period then assuming the outcomes of the voluntary use provides the data that is sufficient for CMS. It can go ahead with the development of the fiscal impact and the impact analyses and the NPRM.

Rebecca Hines: Rich, we have three people with their hands up, starting with Val and then Jamie and then Vickie.

Valerie Watzlaf: Yes, thank you. Thank you so much, Rich, for going through this. I really appreciate this as a new member. I just had a clarifying question. Under Recommendation 2, do you anticipate like a number that you would need to test this during the voluntary use phase or even looking at maybe a diversity of the groups that would be testing it?

Rich Landen: That is a really good question. We, as NCVHS – we are not an operating arm. We make the recommendations. What our vision is is that along the lines of the discussion that we hope the Predictability Roadmap recommendations make, it is really CMS who is responsible for writing the rules and performing the impact analysis. What we are trying to say here is in our recommendation to the Secretary, allow the appropriate staff within the Office of Burden and Reduction to engage in this initiative and work with CAQH CORE and those who are doing the implementations to ensure that the implementers know what data has to be collected and that CMS then gets the data it needs in order to soundly perform its obligations when it comes time to draft the rules. That is the concept here. It is not that NCVHS is trying to set those criteria. But we are trying to broker a conversation between CMS and the industry to try and establish what is the minimum data that the industry need to bring to CMS to get these rules promulgated and meet all the requirements that CMS must, all the boxes that CMS must take off when they do the rule drafting.

Jamie.

Jamie Ferguson: Hi. Thank you. I just wanted to add a little bit of color commentary on the recommendation for voluntary use rather than immediate adoption. Not to change the letter and just to

add on to what has already been said. We did hear conflicting testimony. For example, we heard testimony that the timing requirements in the proposed operating rules – some said that that would actually speed up prior authorization and others said that, no, it would actually result in more transactions being put into appending status quickly and they would stay there for a long time. One thing that the voluntary use period will do is it will provide data to be able to discern which of those courses is actually going to happen from the voluntary use.

Then the other thing is that because voluntary use is immediate, we thought that this actually was very supportive of the consensus statements that we have received from a number of industry groups from physicians, hospitals, pharmacies, health plans, medical groups, all of whom support moving forward with prior authorization. This voluntary use recommendation we think supports that consensus statement because it allows immediate use.

Rich Landen: Thanks, Jamie.

Vickie.

Vickie Mays: I think we are all zeroing in on the same thing because it is also about this Recommendation 2 in terms of voluntary use.

One of the things I am trying to make sure of is that – and it is what Jamie was saying. We heard some people who have a differing opinion on this. We know that there were different industries that were in favor of this. I do not know that we are giving that credit to some extent. It just felt like it then goes to HHS and they get a barrage of stuff. To me, it was less clear that we realized that there is this split and that we have waited. I liked what Jaimie said, which is we had this group and it was in favor of it. And voluntary use means this.

I guess my sense is that they came back on yesterday that in some kind of way, we need to put to rest when they respond again that we heard them and just a little more as to why after hearing them, we decided to do what we do. I think we dance around it in this.

I liked exactly what Jamie just said in terms of – I do not want to start messing up the letter, but I just think it is just not as clear and we are avoiding that.

Rebecca Hines: The question, Jamie, is can you on the fly, if not perfectly, because we have talked quite a bit in recent weeks. Could you propose something concise, a synopsis of what you described and where that might go? Which paragraph?

Jamie Ferguson: Let us see. Perhaps on the paragraph where your cursor is, just before the phrase during the meaningful use phase. We might insert there, the Subcommittee received conflicting testimony and the voluntary use period could allow HHS to determine which prediction is correct. That is not quite the right way to phrase it, but that is what I might insert there.

Rebecca Hines: Can you say that again? I am sorry.

Jamie Ferguson: The Subcommittee received some conflicting testimony. In order to determine which of the predictions is more correct, the voluntary use period will allow HHS to measure the results of actual implementation on a broader scale.

Rebecca Hines: Come again.

Jamie Ferguson: Will allow HHS to measure the results of actual use on a broader scale.

Vickie Mays: I appreciate the willingness to put that in because I think what it does is also for HHS, it gives them a sense of when they get these letters that we did our job. We recommended based on what we thought was best, but it is also up to them as they do this, to take those both sides into account. Then that way I think we are being – we are really doing our due diligence to the industries that we work with.

Rich Landen: I would like to add a little bit more specificity to that first sentence we added. The conflicting testimony was on just a few key aspects. The turnaround time that Jamie referenced was one of them, the use of the X.509 digital certificates was another.

Jamie Ferguson: I would be fine with that.

Rich Landen: The point of it is that some people said yes, this is a good value. And others said no, this is going to move the needle the wrong way.

Jamie Ferguson: I would just amend what is there, e.g., the turnaround time, use of X.509 digital certificates. I would add after that, and the potential for unintended consequences. And the example there that I am using is more transactions going into appending status faster and for a longer period of time.

Rich Landen: Rebecca, I think the language is more transactions being "pended".

Rebecca Hines: Thank you.

Debra Strickland: For a longer period of time.

Rebecca Hines: Thank you.

Rich Landen: Vickie, thanks. That was a good add.

Vickie Mays: I felt bad because we did our work, but I just – when people kept coming back to us, I just wanted to feel we decided for a reason, but we heard you as well.

Wu Xu: I want to really thank the Subcommittee for the detailed careful work and a good letter and thanks for each for detailed explanation and added on the current CAQH CORE is working on Recommendation 1 attachment and the connectivity.

I want to ask – first, I want to just talk about the public health clinics. They are small providers and usually the IT resources are lacking. It is good if you have a monitor use phase for Recommendation 2.

I have a question about this letter's procedure. Is attachment the standard we will come back as a rule for this Committee to review or is a part of operation rule or whatever – and the connectivity rule, the updated rule will come back or not.

Rich Landen: First, the attachments rule. No, the attachments rule will not have to come back to us. Our predecessors made that recommendation several years ago. HHS already has an attachments rule on what they call its unified agenda. It is scheduled for publication soon. But it has been in that status for too many years. No guaranty that they will be published, but the recommendation is there. It will not have to come back to us.

The connectivity rule, since we are assuming the Secretary accepts our recommendation on the connectivity rule, CMS would not engage in rule development or rule making for it. The assumption there is that CORE would come back to us with a new version of the rule and we would go through the same process again. That is the normal course of business. Any of the standards development organizations can come to us at any time with proposed updates. The process for operating rules is very similar to, but not identical to the process for updating the standards coming out of an NSDO.

Debra Strickland: This is Deb Strickland. At this point, I would like to propose that the Full Committee vote to approve the letter with minor editing as we have suggested.

Rich Landen: Mr. Chairman.

Rebecca Hines: Someone needs to second that.

Denise Love: I will second.

Nick Coussoule: All those in favor of moving it forward.

Rebecca Hines: Would you please use your hand in the box so we can actually see and count them please?

Margaret, are you raising your hand?

Margaret Skurka: Yes.

Rebecca Hines: It looks like it is unanimous, folks.

Nick Coussoule: Process wise, we will move this forward. We will clean up the letter, make any minor grammatical changes, i.e., commas, periods, apostrophes if necessary and finalize that through the standard process.

Rich, thank you for leading us through this exercise and thank you to all the members for your participation.

We will now go to a public comment period, Rebecca.

Public Comment

Rebecca Hines: You are right. We now have a public comment period. I have two written comments. I will read. But Sabira, if you would please give people the instructions who are on the line with us now.

Sabira Mohamed: Sure. Thank you. When submitting a public comment, please include your name, title, and organization. To participate in public comment, please use the Q&A box at the bottom of your screen to submit a question. If you would like to provide a verbal comment, use the raise hand button at the bottom of your screen. If your hand is raised, we will call on you and grant you speaking permissions. To raise you hand on the phone, please press star 9. To unmute yourself on the phone, press star 6 after being called on.

Rebecca Hines: While we are waiting, let me read – we have one public comment from April Todd at CAQH CORE. Here is the comment. As you discuss your recommendations at the NCVHS meeting today, CAQH CORE would appreciate specific guidance on the level of real-world evidence and industry support that is needed for a recommendation for federal adoption. As we shared in our testimony the three rules that CAQH CORE proposed, achieved an industry approval rate of at least 80 percent with every stakeholder group approving by at least 69 percent. Industry participation in this rule included health plans, representing over 208 million lives, Medicaid agencies with over 28 million enrollees, and a wide range of provider organizations and associations.

CAQH CORE supports the Predictability Roadmap recommendations that encourage the development of real-world evidence and faster time to market for standards and operating rules that can provide benefit to the industry and patients. In our testimony, we shared the real-world experience of Harvard Pilgrim and Cleveland Clinic. Some states already operate with a two-day response time for prior authorization including Massachusetts for which Harvard Pilgrim shared their positive experience.

The results of our pilot study with Cleveland Clinic showed an 80 percent reduction in staff time even without automation for attachments. As the industry focuses scarce resources on ways to improve administrative processes, including ongoing work with attachments and connectivity, more specific guidance would be helpful regarding the level of evidence and support that is needed to bring recommendations to NCVHS within a faster timeframe.

It does not look like anyone in the audience has anything.

We have a second written comment. I am going to read an abbreviated portion from Heather McComas, American Medical Association. She expresses appreciation for the Committee's consideration of federal adoption of these rules. She is following up on her public comment yesterday to share additional information, which was forwarded to the committee this morning after it was received. She says, as I stated yesterday, the AMA is extremely disappointed that NCVHS is recommending voluntary adoption of the rules. We believe this decision forfeits a clear opportunity to drive the industry to meaningful, near-term improvement in the PA process.

The AMA along with the American Hospital Association, Arthritis Foundation, and Medical Group Management Association sent the attached follow-up letter to the Subcommittee on Standards in early October, reiterating our strong support for federal adoption of prior authorization operating rules. As

noted in that correspondence, they reviewed formal support for the prior authorization operating rules at the August 2020 hearing among national organizations, representing patients and health care professionals as well as representatives of individual health systems. This is a key point.

As patients and health care professionals are the stakeholder groups that unilaterally absorb the harms and burdens of prior auth requirements imposed by health plans. We urge the committee to fully appreciate this clear breakdown along stakeholder lines on this issue.

We request that the Full Committee also consider the impact or lack thereof of recommending voluntary adoption of the prior auth operating rules. In January 2018, national health care associations and ensure trade associations release the attached consensus statement on improving the prior auth process in which these groups agreed on key prior auth reforms. Unfortunately, implementation of these important changes has been extremely sluggish as shown in the attached 2019 progress report. We urge the Full Committee to reconsider mandatory adoption of the prior auth operating rules given this clear evidence that the industry will not meaningfully improve PA without legislative or regulator requirements. Thank you for your consideration and I would be happy to answer any questions.

I would like to note that the October 7 letter referenced here is posted on the NCVHS website. It was added to the public comments' compilation on the August hearing page of the website. If you would like to see the AMA letter referenced here, it is posted and all of this in this email will be included in the meeting report summary.

Rich Landen: Rebecca, along those lines, let me also add that the other two documents attached have been available to the Subcommittee as part of the hearing. They were hyperlinked in the written testimony that AMA sent so the 2019 survey results and the industry consensus statement – two attachments. The Subcommittee was aware of those documents previously.

Rebecca Hines: Thank you, Rich. At this time, I do not see any more public comment either by email or on the phone or in the chat. With that, I think the public comment period is wrapped up.

NCVHS 2021 Workplan Review & Discussion

Nick Coussoule: Thank you, Rebecca. We will move on to the last item on our agenda today, which is specific to the workplan. We had a significant amount of this conversation earlier this morning from the PCS Subcommittee as a natural follow on to their thinking in the work that happened from the September 14 meeting by regards to the public health emergency data collection and use.

One of the things that we are trying to make sure everybody understands – we get the vision, mission, and scope of NCVHS. I think you all know this. These are all published. Part of what we wanted to talk about is to make sure that we are considering this as well as considering the general framework by which we accept and decide to do work. The vision here gets into a little bit of what we are – why we are going to do things. The vision gets into a little bit of how we are going to do things. But the idea is that we are responsible for trying to improve the health and well-being of the population. Our work effort hopefully all is aligned to that.

This is really a pictorial view of the strategic goals of the Committee. We developed a strategic plan in 2015. We updated it last, I believe, in 2017 with the following four goals. This document that outlines these is posted on the website. You can see a little bit more breakdown to the goals. But fundamentally, there are four of them. One is to improve data usability and analytic capabilities. Two is to accelerate the adoption and implementation of standards. Clearly, we have been talking a bit about that. Third is expand appropriate access and use of data while ensuring the relevant safeguards. Obviously, the topic this morning, or I should say earlier today or this morning, was quite relevant to that. And then fourth but certainly not least is to improve the health information and data policy by taking the long view. I did want to stress the long view portion of that.

How do we achieve those goals? Pretty typical flow of what we do is to assess the current state. There have been times – sometimes we will actually do an environmental scan or study. Other times, we would make that part of our general work effort into our scoping. To identify opportunities and threats and recommend actions. That is pretty straightforward.

But one of the things that we started to do a number of years ago and that is really led by Bill, our former chair, Bill Stead, was to create framing documents for each of our work efforts. And that is a really important stage because most of the topics we undertake are kind of like the proverbial elephant. You have to eat certain pieces at a time. We want to make sure that we create an understanding of what we are trying to accomplish and how that is going to work and what the end game that we are looking for is to guide our work. In almost every activity we undertake, the tentacles are many and long and we could very easily go and never, if you will, finish anything by virtue of perpetually getting bigger and more complicated. It is a really important part of our exercise is to create those scoping documents and framing.

With that framing in mind, the way we – the criteria that we have established to select those projects, which is also part of the strategic plan. If you look at that, this is the – the strategic plan covers those four strategic goals, but also goes into the selection criteria.

The first one is it has to be consistent with our mission and be appropriately scaled and that is what the point I was really getting to. I should have advanced the page before I kept talking. I think the mission part is pretty straightforward because our mission is relatively clear although it is quite broad.

The second part is appropriately scaled something that can be done in the framework of what the Committee both has the resources and the abilities to do.

Second is to be complementary and aligned with one another to advance the goals and objectives in the strategic plan. We had that discussion this morning. It was quite apparent. The work effort that has happened and potentially happened in the PCS Subcommittee is very complementary and oftentimes overlaps with what is happening in standards, which is often complementary and overlaps with what happened when we had Population and Health Subcommittee. It is pretty rare that things we undertake are isolated solely there. But the general purview gets done in one subcommittee because that is the way we have chosen to do the work and get it done through that framework and structure and then rolled up to the Executive Subcommittee for consideration and obviously to all the Committee members can weigh in on it when we do Full Committee meetings. And all the Committee members are also

welcome to participate in any of the subcommittees that they would like through that exercise to make sure that we create the appropriate broad input to those topics.

Number three is we want to make sure that our work results in information or recommendations that are actionable by HHS. That is the driver. That is our charter. And we are providing advice to the Secretary of Health and Human Services.

But the second part of that is also important. In partnership with state and local organizations when appropriate or actionable by the private sector. We do not do work in a vacuum. Part of our strength and part of what makes us effective is we have convening authority and we do bring lots of players into our discussions with lots of different expertise and points of view. And part of our challenge is to try to gel that into meaningful actions. Even though we make recommendations to the Secretary, much of what we do is also effectively recommendation or communicating to other partners.

The fourth is to fulfill our mandated requirements and we talked about that yesterday in regard to the 14th Report to Congress.

And fifth is to take into account urgency and resources available to ensure project completion. We talked about a myriad of different items in the PCS discussion earlier today. And frankly, virtually all of them are important and we could undertake practical realities given our resources and our really wonderful staff resources. I do not want to ever minimize the amount of work that our staff does for us and helps us with these exercises. It is invaluable to that process. But we have to also make sure we are setting ourselves up to be able to collect the appropriate amount of information to do the analysis and make recommendations as part of that.

The work efforts that we have underway right now are pretty straightforward, the 14th report, the follow up to the PCS hearing on September 14. And then the convergence of the administrative and clinical data through ICAD and follow up and some alignment with ONC and HITAC. And those are activities that underway. Obviously, some of those will close up in the not too distant future at least as far as the results.

Future, which is a little less clear and that is part of what we are here to talk about now. There are definitely some follow ups to the Predictability Roadmap. Again, we have to decide scoping and priorities of that. Transition to ICD-11 clearly something that the Committee will weigh in on very readily as that makes it way through that entire process by which it will get done.

Data access for communities. We have done a lot of work in that as far as some of the public health work that we have done outside or earlier in subcommittees.

And then any change requests that come through operating rules or standards or other ways that change requests from the DSMOs and SDOs to our group. We cannot always predict when that is going to happen, but we know that they will. We just do not know when and we have to make sure we account for that so that we can take care of that in an expeditious fashion.

With that said, we really reviewed this part this morning. Just the first thing I guess I would do is ask if there are any additional comments or thoughts in regard to the PCS work or potential for PCS projects

that we talked about this morning. I will open that up. Please raise your hand in the participant window. We can have that – obviously, call on you to have that discussion. And then when we get past this, we will open it up also to some of the same kind of thoughts from the Standards Subcommittee and work that might happen there and then anything else that we would like to talk about.

Vickie Mays: Thank you. I have a question and it has to do with PCS, our bandwidth, and the expertise we need. I guess the question is we have been operating at this point with one project at a time. In the past, we have had two or three that we have done. I guess the question is what do we have the bandwidth to do and whether there is additional staffing that we might be able to reach out so that as we make our decisions, we can have them aligned with the resources that are necessary.

Nick Coussoule: I think that is an excellent question – to comment on some of that. But I think there are two thoughts, and I will just give you mine and obviously, I would love everybody else to weigh in.

I think it is particularly good or it is very good, for us to have multiple things going on at a time. Now, with that said, we obviously – there are only so many hours in the day and so much time that we have and our staff has. We cannot set an expectation that we cannot meet.

But oftentimes our work efforts are pretty complicated and oftentimes take a long time. It may be possible for us to have multiple things going on. But we have to be very sensitive to our ability to actually get it done and to manage the resources and coordinate and communicate with our staff and staff support. As I said earlier, we have frankly and have had in the five years that I have been here very good staff support and we do not want to take advantage of that and try to create really crazy expectations that cannot be met. At the same time, we want to be able to make sure we are making progress and creating visibility into potentially more things, being realistic to what we can get done. I think that is a balancing act.

I do not know if Rebecca will want to talk a little bit about this, how we may get staff. In some cases, we have had people from other areas that have been part of this through topics that were of particular interest to other people. There are ways, I think, for some of that to happen, but I am not sure there is really a formal structure for that as much as it is an informal structure that we have been using.

Vickie Mays: Nick, the reason I actually said that is because if you look at some of the things like health information security and other things, there are some other groups that we might be able to reach out to. In the support of doing this agenda, it may also make sense to find out the support that we might be able to reach out to help us do the agenda.

Rebecca Hines: That is an excellent point, Vickie. For those of you who are new, when we did the ICD-11 project and the health terminologies and vocabulary and I see our colleagues at NLM is on the attendee list – not to put you on the spot or anything, Vivian. But it was great to have our – colleagues from other operating divisions to help us out because it aligned. It aligned with their work. It aligned with our work. It was a win-win. Vickie, you are absolutely on spot here.

I think what I would suggest you all do is prioritize what you think is most important and then we will go back with ASPE and the team and see what kind of interest there is in the OPDIVS to support a particular project.

Vickie Mays: Thank you.

Nick Coussoule: Other questions in regard to the PCS discussions and the priorities from this morning.

Let me go to the next page. Rich, do you want to walk us through this?

Rich Landen: Sure. The convergence of administrative and clinical data standards. We talked about that quite a bit yesterday, the ICAD report, revisiting our scoping document for that project. But that has been – our part of the process, the Standards Subcommittee process has been kind of sitting on hold until the ICAD taskforce finish its work. Now that ICAD is done, now we take ownership and move on to our own NCVHS project around convergence.

And, again, for the newcomers, that is just looking at the – how over the recent years and specifically since the HIPAA requirements for standard transactions on a national mandate basis – how those align with the flow of actual work and actual data within the health care ecosystem. And when HIPAA was passed in '96, there were very few electronic health records, electronic medical records. There were very few clinical data standards. Health Level 7 was working on them. But it is not like it is today. What made sense in 1996 to 2000 no longer meets industry needs and the question here is what do we want to do about it.

Semantic standards for public health, community health, and social services. I may need some help from Margaret or others here, Jim or Jaimie. Continuing the work that we did over the past couple of years in terminologies and vocabularies. Again, the emphasis on public health, community health, and social services that kind of is a reflection of the same changed ecosystem. We are no longer working in an administrative stovepipe.

Jamie, is there more you want to add to that?

Jamie Ferguson: I think it is the same thing that I think I mentioned in my intro yesterday and also today on the PCS Committee work. We are seeing more integration of social services, community health agencies and services along with public health with the hospital and physician clinical care services. Obviously, they do have different semantics. As I mentioned earlier, they have different privacy and security characteristics that also need to be considered.

Rich Landen: I think Census 2020 – that was from our discussion yesterday in terms of the changing nature of how the Census is being conducted and dealing with where the data does not really cover well so that the gaps that is created from that obviously.

Affordable Care Act Section 10109. I am afraid I am going to need help from Lorraine or Rebecca. Remind me of the content there.

Denise Love: I think I brought that up. And Lorraine will help me. Right? Again, I am close to the ground I guess in deliverables. But there is a section in ACA and I think ACA will be I am assuming revisited after a four-year sleepy time. It does mention some activities relevant to standards, but also financial transaction standards, which then touch on something close and dear to my heart, all payers claims

databases and the gaps in financial data that are incorporated as part of non-claims transactions. I am the one that kind of pushed that out.

Lorraine Doo: Right. There were provisions in here that HHS would look at, certain things that were specific to both the financial transactions and also that there would be a review of whether there was duplication in terms of what audits were being conducted and how to streamline those related to covered entities, also whether property and casualty should be brought under the fold. There was something related to the all-payer claims database. We are looking at what other aspects in the industry could be brought into some administrative and simplification provisions. There was supposed to an analysis and a review of how those elements could be incorporated and work needed to be done.

They were supposed to be some studies done and a report given back to whether HHS thought those should be work taken underway. There was some preliminary effort done. We have a little teeny tiny report that we had looked at CMS at the beginning of all of this. WE got some little blurbs done on it.

And then I think basically – the sense was there was not really a heavy lift. There were not further actions taken. But we have a little bit of something at CMS that we could pull out if there was interest there and then NCVHS could take a look at and determine if there were some work products out of that.

And then of course there was the Review Committee, both HHS and NCVHS would have to look at to determine if it would be the same Review Committee or how HHS would want to look at it as well.

Denise Love: And there is a lot of work out on the state side on the financial fields and transactions and they capitate how to capture capitation and some of those pay-for-performance financial data points.

My question, Lorraine, is do we wait to see if this is pushed out by HHS or do we take the lead. How does this unfold?

Lorraine Doo: I do not know that there is an action under 10109 for you other than the Review Committee. And then that might be a conversation between HHS and NCVHS of where would it go in 2021. I think you would look at the Review Committee because the Review Committee I think is a joint discussion between HHS and NCVHS of who should be delegated for that role, given that it is been fellow, but there was supposed to be meetings of the Review Committee to assess the program and there has not been those meetings. That probably would be a discussion you would want to have. I can give of that report that we had done several years ago on 10109 and what the outcome was of that. There were some earlier recommendations made. I can turn that over to my leadership and then why don't you take a look at that too and make a decision that fits in the workplan. Does that make sense?

Rich Landen: Lorraine, when you use the term Review Committee, were you referring to an external Review Committee or to the NCVHS Review Committee in which case we better explain that to our new members.

Lorraine Doo: Yes. It was the NCVHS Review Committee.

Rich Landen: For practical purposes, the Review Committee for NCVHS is synonymous with the Standards Subcommittee.

Rebecca Hines: Plus Vickie Mays.

Rich Landen: Plus Vickie. And with our change in personnel, we will have to look at that committee as well. But it has not been active for a year.

Rebecca Hines: For four years and that was – that was the instruction we got from HHS, Rich.

Lorraine Doo: The last report I have is I think from 2016 from the Review Committee.

Rebecca Hines: Right. I think they met one time, which I believe was June or late May or June 2015. There were 70 testifiers or at least a bunch of people totaling 70 periods of people testifying and a very comprehensive report came out of that. And then we had a change in administration.

Lorraine Doo. Yes. I am looking at the report. It was really wonderful.

Rebecca Hines: And to be quite honest, the Committee does not have the resources to do that annually unless there was internal support to make that happen.

Rich Landen: Next on the list is Evidence-Based Policymaking Act input and follow up. Does somebody want to take ownership of that topic?

Denise Love: I think I brought that up. I may be getting ahead of myself because this is involved with other discussions I have had outside the Committee. I think it leads into the possibility of national data service or ecosystem and what that looks like to support evidence-based policymaking. I just think there is a lot of overlap here on the Committee.

From a practical sense, these are things on this list that could drive some of our work. But I am sort of pushing that post-COVID, this Committee really has some opportunities that kind of bundle some of these things together. What would an ecosystem look like? That is what I am curious. How would we bring these data together? How would we expedite access? What is provisional data versus final data? These are all things that I think academic centers and, Vickie, I think research centers. I know Stanford and others are saying we need another field in the vital records – had a probability for cause of death. There are all these things swirling around. I feel it is so fragmented. But it might be an opportunity under evidence based or ACA to sort of envision where are the gaps and how can this Committee in its charge address some of these gaps or at least guidelines or guidances or use cases.

Rebecca Hines: Denise, yesterday we heard from Brian Moyer. We would stand to benefit from a follow-up discussion with him because he very directly based this as an area where the Committee could be particularly helpful to NCVHS and HHS.

Denise Love: The death index is a big deal to improvements to that. But I think he said clearly, and I wrote it down. If they are kicking out data more timely, which has to happen, what is provisional? Two years is not going to cut it or even a year anymore for some use cases. Other uses cases, yes. And those are things that I think people are seeking guidance on this Committee might at least give some advice and how to push that data out and to whom and what are the restrictions and downstream guardrails. I

am rambling. But I package it more to a very specific application. But the Evidence-Based Policymaking Act does start giving at data commons, I think. I think they want to.

Vickie Mays: Can I just comment here because I want to follow up on what Denise is saying? I think that it is one of those things where this is really now because of what happened in COVID. We have an opportunity. I think it is the same opportunity that Brian is looking at. You have the National Academy of Science and Mike Soto was actually on it and Charlie Rothwell, who just finished a report that actually talked about some of these issues around data and what happens in disasters and ways in which we need data to make decisions and sometimes that data has to be released quickly and kind of some of the things we need to do.

What Denise is actually talking about is – in other places is being done, but it is that I do not think that they have the overview – you are seeing these little pieces. I think what the Committee could really do as a service is to really put this together with recommendations – I like Denise's idea of the data commons and what have you.

My concern is that if we do not do things in this space, there is some talk about Congress actually standing up a group who will do this. There have been some circulations around some committees that they are proposing because they did not like some of the data stuff particularly that happen within CDC. We are kind of associated with CDC. We just need to, I think, get back into a space of some do-good because otherwise I think that there is some ground that is being removed and carved out that I think in the next administration may – they may move quickly.

The data issues are being talked about by the transition team and they want some fixes on some of these data issues. One of the places that they are hanging their hat is what it is that we have done in terms of Evidence Policymaking Act and can that help reform some of the experiences we just had particularly in terms of as I tried to point out before, this race and ethnicity stuff kind of PO'd certain people so I have got an administration who is wanting to stand this up. There are some things for us to think about. I think Brian Moyer is spot on with what he is trying to do to kind of lead NCHS, which is under CDC to have a very credible presence going forward.

Denise Love: And new kinds of governance models perhaps, but anyway I will be quiet.

Nick Coussoule: Other comments, topics that would fit into at least the general framework of the Standards Subcommittee?

Rich Landen: Is this the last slide or do we have page 2 to the Standards Subcommittee?

Nick Coussoule: That is it. We consolidated them on the one page.

Rich Landen: The one I would call out and ask Margaret to talk a little bit more is ICD-11. About a year ago, we made recommendations for research in a communications plan. When COVID-19 hit, nothing is done. When we submitted the recommendations a year ago, we figured about now we would have the results of – CMS or HHS – a contract would be starting to have some results. We do not.

The other issue we have been watching is the US withdraw from the WHO. That looks to be on its way to resolution. But certainly in 2021, we will have to take up ICD-11 again and not just – we will have to resurrect the research type and then communications plan, but also maybe have to start taking a look at adoption, time tables, and doing more work, making some assumptions about what the research will show.

Rebecca Hines: Rich, two slides ago, that was there under the – Kim, can you back the slides up? Rich, it is there under we are not quite clear what we are doing, but it is on the list.

Rich Landen: It is on the list, but we are not exactly in the waiting mode anymore.

Rebecca Hines: Okay – waiting.

Margaret Skurka: I sent Rich an email about this earlier today. On November 25th, we sent the letter to Azar. A little bit a year on Wednesday with no response. I came on in March and I have not seen anything after that, and I do not think there has been anything before that. I think one year later we can – I do not know the process politically if we resend or if we do something different. And we asked for research. We asked for stuff to start. And other countries are going strong as always. As I said in my remarks yesterday morning, we do not want to repeat some of the mistakes that we did when we took the very long class list and we were the last civilized country to adopt ICD-10. We just want to be more efficient. We want to look at it. We want to study it. We want to see the benefits and the time is now. It needs to be on the workplan, I hope, in the second quarter.

But I think the WHO stuff will work out now. I think that will be a non-issue going forward. I have a seat at that table representing the international association, not the US. I hope we do this.

Rebecca Hines: Duly noted.

Nick Coussoule: Denise, I see your hand up.

Denise Love: I kind of forgot that my hand is up, but I will take the floor. I am just throwing out that there are novel data sources too. I am looking at Wu Xu. We have some – speaking of all-payer claims databases, maybe an update to the Committee on their developments in anticipation of any ACA or national data commons' effort. I just feel that they are gaining an importance in the states and for price transparency – I know several years ago, we had a hearing. But dusting off maybe – and I am trying to articulate what the Committee's interest might be. Just an update or a report about their use for public health, ACA, and price transparency.

Rebecca Hines: Okay.

Denise Love. Wu, do you have anything to add on that?

Wu Xu: Actually, the APCD can also be used to support pandemic control like we can see the telehealth use. Then we can see the visit, compare the COVID visit and all testing and also the primary care visit. It is really a useful data source.

Denise Love: And back to Moyer, maybe find out where there are gaps in their surveys where the APCD could fill or enhance. But anyway, that might take some work with Dr. Moyer. But I do think that post-COVID – it does require some novel data sources.

Wu Xu: And related to the Committee's mission and the strategic goal, data use, data policy, APCD can fit into that goal.

Nick Coussoule: Vickie, your hand is up.

Vickie Mays: Yes, it is. I want to thank Rich for one of the things that I was going to make sure we talked about and that is ICD-11. My suggestion is that we just wait – second quarter and not send the letter now, but instead send the letter a little bit later when there are some different plans, different structures in place. But I think it is critical that we get back on this.

I hear what you are saying, Margaret, but I just would not send it right now.

Margaret Skurka: I thought I said second quarter. I agree.

Vickie Mays: That was the work. I thought you wanted the letter to go like it is one year so let us send it back out again.

Margaret Skurka: I was just saying one year that we have not heard, which is sad. I thought at the end I said second quarter. We need to let the administration settle in and what not before we go forward.

Rebecca Hines: I did want to let you know that our colleague at the National Library of Medicine and NIH has noted – ICD-11 that NLM is still working on an exploratory study of replacing ICD-10-CM with ICD-11 – morbidity coding in the US. I think it is part of a project – National Center for Health Statistics – do not have a completion date, but that is something we should track closely. Maybe invite NLM for our next meeting. I will put that on the list. Perhaps that could be a good update to figure out what is happening because clearly, something is going on. That certainly came out of our work. Vivian had a very good role in helping us with that work. Vivian, glad to hear from you and it sounds like we need to – thank you.

Vickie Mays: My other piece was and it is interesting because – making the transition was the mortality piece and ICD-11 and a mortality piece that came up with Brian and a mortality piece that was left over from when we were doing our vitals work. I think we need to revisit where we are with the improvements and the standards that need to be put into place around the mortality data.

There was the definitional piece that is ICD-11. There was the issue in terms of the improvement of mortality data particularly doing epidemics mortality, all of the issues in the collection of that data. That came out just – the National Academy has talked about it a little bit, but it still is not well settled. That can be part of our COVID as well as the Puerto Rico disaster.

I think mortality needs to get back on our radar. Fixing NDI is there, talking about NDVRS as on our radar. Again, that intersects with I think the work that Dr. Moyer was talking about.

And then my third thing is getting back to the issue of mental health. We brought this up and I do not want to see it dropped. This may be a standards issue. I am not just 100 percent sure.

One of the issues that we have is about the ability to have access to mental health data and kind of whether or not in the clinical record there is some – to how to do that. I do not know if that is exactly what you do or not. But we need to think about that.

We need to think about this issue of there been a big loss as cutbacks occurred in NCHS of the collection of mental health data. It was all given to SAMHSA. What we have is an inability to match physical health and mental health together. In COVID-19, the prediction is we are about to have syndemic. We are going to have mental health problems, suicides going up, and substance abuse going up. And the data is going to show that. But we do not have it in our basic surveys that enough of that mental health data. I think we need to look at that.

And in relationship to that and this came up in the Healthy People activity – these are all things we used to have a place in. In Healthy People, they have been discussing the issue of we are not measuring and thinking about well-being. In this country, we are not setting any standards around what it means to be a healthy person. Again, there used to be a few well-being questions. In Healthy People, if there are no questions in any of our surveys, it becomes harder for them to put that in as a goal. I just want to advocate that we kind of think seriously here about work we need to do on mental health. Where it belongs, I am less sure. But that it belongs I am definitely sure.

Lorraine Doo: Vickie, are you also tracking to the social determinants of health work that HL-7 is doing?

Vickie Mays: The social determinants of health is a little different than – no, I am not. I actually was not thinking about that when I was talking. But I think that that is a good piece to think about.

Lorraine Doo: It is just that all these things are happening like what you are talking about with the mental health and the wellness sort of the Healthy People. And there is a huge bolus of work going on also related to social determinants of health and all of these things are intersecting and converging in a body of work that is going on and people are talking. I just thought it would be wonderful based on everything brilliant that you just said that we make sure that all your – with those other – that are happening because I think those groups of people are talking, in particular, related to SAMHSA is doing some work there – who do know obviously and not to lose sight of the convergence of that work effort that is going on.

Vickie Mays: I think that is great. I see that Mary Greene has some interest in it when it got brought up. I think that it might be something that can be on Brian Moyer's plate relative to the surveys that we have. And then I think this piece that you are talking about – the convergence would be very good. Thanks, Lorraine.

Margaret Skurka: I have two quick comments after that. I am concerned also about our underlying cause of death coding today in light of COVID. What physicians are doing in hospitals is – we do not know how much COVID is listed as the cause of death when it was maybe not. They had – I think I am worried about that data.

I am happy to hear some discussion because there are codes now for SDOH, social determinants. And hospitals I think are using them. Homelessness is a code. You want to add that on and it does extend the length of stay because you cannot discharge the patient to the parking lot. It impacts the economics. Our hospitals, I think, are in ICD-10 using the social determinants of health codes and should be.

Nick Coussoule: Rebecca, can you skip to the last page or next to the last page just to tee up. Any other topics on the list that we should consider or any other particularly strong feelings of topics that should stand out as priority?

Jamie Ferguson: Hi. It is Jamie. As I mentioned yesterday, I think that artificial intelligence within the next two to three to five-year period will actually generate a majority of the vital health data that we are concerned with. It certainly is used to analyze it. I think that we need to be concerned with a broad national framework of national standards and measures and rules for these technologies that are generating, manipulating, and analyzing these data.

I would propose that we would put that on the list for things that we have not quite figured out yet. I forget what you called the second part of the list on the previous page. But I think that we need to be concerned with that sort of a framework. It does not neatly fit into the Subcommittee structure.

Rebecca Hines: I just want to say to folks do not worry about where it fits. I would say the most important thing is to find out – to ascertain what needs to be worked on and then we may need to do some ad hoc being subcommittees like we did over the last few years where there would be a small subset of members who would work on a project and report back to one of the subcommittees.

Vickie Mays: I just want to support what Jamie just said and to let you know that there is research underway that is being funded by NIH because this is such a critical issue. Like my group is actually funded to use AI to make sense of death narratives because we cannot do the surveillance that we need to do because they are narratives.

But the problem that we are being asked to address, which is where the standards come in because this issue of algorithms and the bias that can be in algorithms and the extent to which you want to set a standard in which an adoption of any of these things has to meet a minimum standard around certain kind of bias. This is very much being discussed and up and coming. I know that vital records want to use AI more because it will improve surveillance.

Jamie Ferguson: Just to add on a little more in this. I think as Vickie mentioned, there is a lot of work on bias of various kinds. But we also need to understand what objective measures can we have for the disparate impact of the use of these systems in different areas in different contexts.

And because AI technology, such as natural language processing, frequently is used to generate the data that we then use – models have biases built in. And we do not yet have a framework of standards for the data characteristics, measures based on those standards or rules for of fairness and how those measures can be applied in regulatory as well as industry frameworks. This is a big body of work, I think.

Nick Coussoule: I think at a risk of channeling Frank who I know had to step out for another commitment I know that is very high in his interest level as well.

Other comments?

Wu Xu: I would suggest the privacy, security, the priority A, (indiscernible) and the wearables. That as a priority target current contact tracing acts because they are in the development phase given the deployment (indiscernible). There are a lot of issues related to privacy there and security. And it really needed for the pandemic control.

Nick Coussoule: Great. Thank you.

Rebecca Hines: I think we have just given ourselves all a second full-time job here. This is great.

Nick Coussoule: I will wrap this one up. I think what will happen is we will probably ask the subcommittees to cogitate around this and maybe frame up a couple of scoping documents for what the subcommittees want to do. I recognize not everybody is on every subcommittee area, but on some of them. We will also try to do that and coordinate through the Executive Committee, but try to frame a few of these up so we can have a little more in-depth discussion and figure out which ones we are going to try to tackle and when.

Part of what I wanted to do really was to create a bit of an open forum. Needless to say, we cannot tackle all of these. We are going to have some different interest levels based on different people on the Committee. But we will try to settle on what we believe is important, what our federal partners believe is important, and hopefully come up with work efforts that are meaningful and help the industry. With that, I think we will close out that topic.

Rebecca, we had one other comment come in. I think public comment that I would like to be able to read in.

Rebecca Hines: Yes, we did. We had one more public comment. It is back on the topic of the letter to the Secretary that we approved about an hour ago. It is from Mike Dennison, senior director of regulatory and standards compliance of Change Healthcare.

He wrote, with regard to CAQH CORE operating rule development, involving health care standards, data content, we continue to strongly encourage the operating rule authoring entity to more effectively partner and align efforts with their standards development organization, SDO peers.

If CAQH CORE workgroups identified data content needs and enhancements, they should be formally submitted as timely as possible via the established data maintenance process to the applicable SDO for consideration. Data content rules created outside of and divorced from SDO guides and specifications create confusion and disparity in health care EDI standards deployment.

I do not know if, Rich or Lorraine, you want to just briefly let the rest of the membership know what that meant.

Rich Landen: I think if I digested it well, essentially, it is calling for a closer collaboration specifically between CAQH CORE, who is the operating rules authoring entity and X12, who is the standards development organization saying that better collaboration is needed so that the X12 implementation

guides, which are actually the thing that is adopted under HIPAA, tie in more precisely or more neatly with the operating rules and vice versa. That is a little outside of our bailiwick although it certainly is an issue that the subcommittees are well aware of. It is also – I think we mentioned a couple of times. It is pretty specific between CAQH CORE and X12 because the other standards development organizations, HL7 and NCPDP and in the pharmacy world. They generally build most of the operating rule functionality into their implementation guide or implementation specifications. X12 is a different design/philosophy than NCPDP or HL7. It is a little bit different world there.

I hear what the commenter is saying. At least, I hope I am hearing it correctly. But I do not see any actionable – any specific actionability coming out of that request, more just kind of continuing to encourage the collaboration that X12 and CAQH CORE have been doing. Again, for the non-Subcommittee members, we did have X12 and CORE testify at the August hearing on the operating rules. And both of those testimonies made some time and effort to describe the ever-increasing levels of collaboration between the two. There was good progress made over previous years. The trend is there. I think this commenter is saying that that trend needs to continue.

Lorraine Doo: And maybe just industry continuing to be aware that they can submit their request for updates to X12 directly so if there were things that they want the standard itself to do and as X12 iterates on its updates on the regular process that X12 has described, those things will get in on a more predictable basis, which is part of the roadmap. There are things that do not need to be part of an operating rule because they are not embedded in the standard. All of this is part of the roadmap that you have been working on for the past couple of years.

Deb, did you have your hand up?

Debra Strickland: I did only because Rich kind of covered what I was going to say. We did identify or at least through some of the testimony, we heard that there were things that were in these rules that maybe should have been addressed at X12 and so forth. We did have pretty extensive written testimony as well from X12 saying which ones they considered to actually move into the next version of the guide, which suggestions and so forth that they did. They were trying to do it after the fact.

I think Mike's comment is really prudent about let us get ahead of this and not bring them in later and get all of the things that people want if they have any data content relation that they should go to this SDO as was said. Just in support of that. If folks want to see what X12 said, you can actually go ahead and take a look at X12's testimony.

Nick Coussoule: Okay. I appreciate that, Rebecca – and the comments, Rich and Deb.

With that said, we have had a very busy couple of days. I want to thank all the Committee members and staff's support for helping us put this on. It has technically gone off very well. Thank you to our technical partners for also helping us to put this together. It is always nice when you do not have to think about that very much, but we do not want it to go unsaid.

With that, I think we are officially adjourned, and we will look forward to talking to everybody soon.

Rebecca Hines: I just want to say a big shoutout to Lorraine Doo for the incredible amount of work that you have done in shepherding us from the Standards hearing in August to today. It was an incredible lift. You supported the Subcommittee in ways that nobody else could. Big wave to Lorraine Doo.

I also want to thank Rachel Seeger for her follow up to the September one-day hearing. This really is team sport like you said, Nick. Without each and every one of especially the lead staff and chairs, this would not be possible. I just hope you all can have a toast tonight. We would be there with you if we could. And hopefully, we will be able to see each other in person some time in calendar 2021.

Nick Coussoule: Thanks everybody.

(Whereupon, the meeting adjourned at 3:45 p.m.)