National Committee on Vital and Health Statistics

Transcript
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Virtual

SPEAKERS

NCVHS Members		
Name	**Organization**	**Role**
Jacki Monson	**Sutter Health**	**Chair**
Sharon Arnold	**DHHS**	**Executive Staff Director**
Rebecca Hines	**NCHS**	**Executive Secretary**
Debra Strickland	Conduent	Member
Denise Chrysler	University of Michigan	Member
Denise E. Love	Individual	Member
Jamie Ferguson	Kaiser Permanente	Member
Margaret A. Skurka	Indiana University Northwest and Principal, MAS, Inc	Member
Melissa M. Goldstein	The George Washington University	Member
Richard W. Landen	Individual	Member
Tammy Banks	Individual	Member
Valerie Watzlaf	University of Pittsburgh	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
Grace Singson	ASPE	Staff
Presenters		
Name	**Organization**	**Role**
Cason Schmit	Texas A&M University	Assistant Professor & Director, Program in Health Law and Policy
Kin-Wah Fung	National Institutes of Health/ National Library of Medicine	Staff Scientist

Mary Stanfill (ad hoc)	International Federation of Health Information Management Association	Representative to WHO Family of International Classification

Call to Order/Roll Call

Rebecca Hines: Good morning and a warm welcome to our members of the National Committee on Vital and Health Statistics, NCVHS. Welcome to committee staff and members of the public in attendance with us here today. This is our winter meeting of the committee. My name is Rebecca Hines and I serve as Executive Secretary and Designated Federal Officer for NCVHS.

Once again, we meet virtually. There is a possibility that in 2023 post-winter conditions permitting, the committee could convene in person. The next upcoming meeting is scheduled for January 18 and 19. The Subcommittee on Standards is holding a virtual hearing to receive input on recent requests from X12 and CAQH CORE for updates to standards and operating rules under HIPAA.

The committee has put out, and it is still active, a request for comment, an RFC, that members of the public can respond to until December 15. It is published in the Federal Register. It is a November 1. Details are also posted on the committee's website. I am going to put that in the chat as well for members of the public just as a reminder. If you have not already, you can sign up to receive email notices from the committee to subscribe. You just visit the home page of the website. It is on the front page there.

Let us take care of roll call now, starting off with our chair. Remember to state your name, your status as a special government employee, and any potential conflicts with today's agenda. Starting off with Jacki Monson.

Jacki Monson: Good morning, everyone. Jacki Monson, Sutter Health, Chair of NCVHS, no conflicts.

Rebecca Hines: Deb Strickland.

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

Rebecca Hines: Denise Chrysler.

Denise Chrysler: Good morning. Everybody. 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, the Committee on Privacy, Confidentiality, and Security, and I have no conflicts.

Rebecca Hines: Denise Love. You are not coming through.

Denise Love: How is that? Denise Love, independent health consultant. I am a co-chair of the Standards Subcommittee, member of the Full Committee, no conflicts.

Rebecca Hines: Thanks, Denise.

Jamie Ferguson.

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

Rebecca Hines: Margaret Skurka. Margaret, you are on mute.

Margaret Skurka: My name is Margaret Skurka. I am Professor Emeritus from Indiana University Northwest Campus and I run a coding business. I have no conflicts and I am a member of the Standards Subcommittee.

Rebecca Hines: Thanks, Margaret.

Melissa Goldstein.

Melissa Goldstein: Good morning. My name is Melissa Goldstein. I am a professor at George Washington University. I am a member of the Full Committee, Co-Chair of the Subcommittee on Privacy, Confidentiality, and Security and I have no conflicts.

Rebecca Hines: Rich Landen.

Rich Landen: Good morning. I am Rich Landen. I am a member of the Full Committee, Co-Chair of the Subcommittee on Standards and member of the Executive Subcommittee. I have no conflicts.

Rebecca Hines: Tammy Banks.

Tammy Banks: Good morning. Member of the Full Committee, Co-Chair of the Subcommittee on Standards, independent consultant, and no conflicts.

Rebecca Hines: Val Watzlaf.

Valerie Watzlaf: Good morning. I am Val Watzlaf. I am a professor at the University of Pittsburgh. I am also a member of the Full Committee, Co-Chair of the Privacy, Confidentiality, and Security Subcommittee and I have no conflicts.

Rebecca Hines: Vickie Mays.

Vickie Mays: Good morning. Vickie Mays. I am a professor at the University of California, Los Angeles. I am a member of the Full Committee and a member of Privacy, Confidentiality, and Security. I have no conflicts.

Rebecca Hines: Thanks, Vickie.

And last but not least, Wu Xu.

Wu Xu: Good morning. My name is Wu Xu. I am Adjunct Faculty at the University of Utah, a member of the Full Committee, and no conflicts.

Rebecca Hines: Thank you, Wu.

Let us move over to our staff with our director, Sharon Arnold.

Sharon Arnold: Good morning, everyone. I am Sharon Arnold, the Executive Director of NCVHS and also the Associate Deputy Assistant Secretary of Science and Data Policy at ASPE and HHS. Thank you.

Rebecca Hines: Thank you, Sharon. And Grace Singson.

Grace Singson: Good morning, everyone. My name is Grace Singson. I am an ORISE Fellow within ASPE in the Office of Science and Data Policy. I am here, assisting Sharon, Rebecca, and Maya.

Rebecca Hines: Thank you, Grace. We also have other ASPE staff who will be joining us. Moving over to CMS, Lorraine Doo.

Lorraine Doo: Good morning. Lorraine Doo, senior policy advisor in the Health Informatics and Interoperability Group, lead staff to the Standards Subcommittee. Thank you.

Rebecca Hines: Thanks, Lorraine.

We have Maya Bernstein on. Good morning, Maya.

Maya Bernstein: Good morning. I am Maya Bernstein. I am the senior advisor for Privacy Policy at ASPE. I am lead staff to the Executive Director of the Committee and at the moment, acting as lead staff to the Subcommittee on Privacy, Security, and Confidentiality. Good morning.

Rebecca Hines: Good morning.

Before we get started, I just want to note. It is possible that the timing on the agenda might shift. This afternoon the public comment period is scheduled specifically for 5:10 p.m. Eastern, depending on the extent of discussion needed for each topic. This time could shift earlier. If you are planning to participate in the public comment and we have gotten word that some people are interested, please be attentive, starting maybe around 4:30 p.m. Eastern. We do not know how things are going to ultimately evolve around the agenda when we get to the end of the day at that time. You are welcome to make a comment orally. We will provide detailed instructions. You also can send a written comment to the NCVHS mailbox, NCVHSmail@cdc.gov.

Last, before turning it over to our chair, the agenda is posted on the website. I will place a link for that into the chat. And all of the slides will also be available on the website shortly here today.

With that, I will turn it over to our chair.

Agenda Review and Comments on NCVHS 2023 Report to Congress

Jacki Monson: Good morning, Rebecca. Can we pull up the agenda? Let us go through the agenda. The first item is getting an update from Sharon Arnold and what is going on in ASPE. The next will be an update from the Subcommittee on Privacy, Confidentiality and Security, an update on the most recent activities and the environmental scan that was done by Cason Schmit.

Then we can take a break. And then at 12:15, we will have tribal epidemiology centers data access and privacy recommendation discussion. It will be a draft. We are hoping for approval today.

We are going to take another break and then we will move into at 2:15, the Subcommittee on Standards. We are going to talk about Convergence 2.0 update, an update on the proposals to NCVHS for the new HIPAA Transaction Standards and Operating Rules.

And then next we will talk about the developments in the transition to ICD-11. We will take another small break and then we will move into NCVHS 2023 Report to Congress. And then we will transition at

4:40 to the tribal epidemiology centers access and privacy recommendations, again, for approval on that today. At around 5:10, we will move to public comment and then we will wrap up and adjourn.

Just other comments for the committee members today. We are going to be discussing later today the 2023 Report to Congress. Please be contemplating that today as we discussed, what specifically you are interested in highlighting and specifically what you would like to share in that Report to Congress. I will go through a slide deck later to remind us where we have gone, what we have provided in the past, and what I think we should focus on but certainly want all of your opinions. Please be thinking about that today.

With that said, I am going to turn it over to Sharon Arnold to provide her update on ASPE.

Assistant Secretary for Planning and Evaluation (ASPE) Update

Sharon Arnold: Thank you very much, Jacki. Welcome, everyone. I am going to talk a little bit more than ASPE. I am going to provide an update of select items around HHS. But starting off, I want to say how pleased I am to be with you at this meeting. Although we considered meeting in person, the pandemic has not let up enough for us to do that. But we are considering whether to meet all together in Washington in the spring, fingers crossed. Hope that will be possible and that I will be able to greet you in person at that time.

As you probably know, we are always looking to identify new members for the committee as existing committee members roll off. We are always looking for well-qualified members and have now updated our website to include some information about the qualifications we are looking for and the membership requirements. We allow individuals to self-nominate or you can always nominate colleagues. If you know of anybody that might be appropriate for membership at NCVHS, please see our website for more details and nominate individuals. We prepare materials and make recommendations to the Secretary for the majority of the members. There are also two members that are appointed by Congress.

In the meantime, I am very pleased to announce that Denise Love's term on the committee will be extended for 120 days until June 13. There is significant work ahead for the Standards Subcommittee over the next couple of months and having Denise's expertise throughout the spring will be incredibly helpful as the subcommittee conducts the hearings scheduled for January 18 and 19 and reviews the written comments received from the request for comment, which will form the basis for the development of recommendations on adopting updated standards from X12 and CAQH CORE.

I mentioned the pandemic before. It is important to acknowledge that we are not quite finished with it or maybe it is not finished with us. When I last spoke with you, the Omicron variant of COVID-19 was busy mutating and its offspring circulating. We are continuing to discover new strains regularly.

We continue to rely on the science and the best available information, including guidance from the CDC to plan our health care and public health policies that affect the nation and regular cadence of work of the department continues.

At this time of year, that cadence means we are thinking about the budget. HHS submitted its FY2024 budget request in September to the Office of Management and Budget. After review, this request will eventually form a part of the President's budget that is generally released on the first Monday in February.

We still do not have a 2023 budget. The government is operating on a continuing resolution that expires on December 16, a week from Friday. We do expect Congress to fix that situation during this lame duck session by either passing a final appropriation for another continuing resolution. But of course, if they should not do so, there could be a lapse in funding, which results in a government shutdown. Of course, we hope that will not happen.

At the July meeting, I shared that ASPE had published the 2022 through 2026 HHS Strategic Plan. The plan consists of five strategic goals that focus on HHS' major priorities to protect and strength equitable access to high-quality and affordable health care, to safeguard and improve national and global health conditions and outcomes, to strengthen social well-being, equity, and economic resilience, to restore trust and accelerate advancements in science and research, and to advance strategic management to build trust, transparency, and accountability.

The Strategic Plan document includes an overview of the progress the department is making towards the plan goals and the five agency priority goals for behavioral health, child wellbeing, emergency preparedness, equity, and maternal health. There is also a section on looking ahead to 2023, which highlights how HHS will address important health care, public health, human services, and research challenges that impact all Americans.

While I normally would not remark on the result of elections, in November, four states voted on ballot initiatives regarding the legalization of marijuana, which is regulated by the department.

There are a number of states where the outcome of the election affected abortion rights in that state following the Supreme Court's decision in Dobbs v. Jackson Women's Health that struck down Roe v. Wade and returned decisions about abortion rights to the states.

Related to that, back in August, Secretary Becerra and the administrator of CMS, Chiquita Brooks-LaSure, issued a letter to US Governors inviting them to work with CMS and apply for Medicaid 1115 waivers to provide increased access for women from states where reproductive rights are under attack and women may be denied medical care. The letter also underscored that current or proposed abortion restriction laws do not negate providers' responsibilities to comply with federal laws protecting access to emergency health care.

Along with these announcements, HHS issued a report and plan of action in response to Dobbs' decision. Both actions further support President Biden's Executive Order protecting access to reproductive health care 14076 and Executive Order 14079 securing access to reproductive health care.

Getting back to COVID-19, since the July meeting, several notable developments have occurred in the COVID-19 realm. First, on October 13, Secretary Becerra renewed the determination of public health emergency exists and has existed nationwide since January 27, 2020.

The secretary previously indicated to governors across the country that HHS will provide states with 60 days' notice prior to the termination of the public health emergency declaration. Everyone will have at least a couple of months' warning before the PHE is lifted. The current extension ends on January 11, 2023.

In mid-August, the CDC relaxed COVID-19 guidelines and quarantine requirements for those exposed to COVID-19, including in schools. The CDC continues to recommend vaccination, masking when indoors

and public places, self-surveillance when exposed to COVID-19, testing, and isolation when ill with COVID-19-like symptoms.

On the vaccine front, the CDC has recommended Novavax Monovalent COVID-19 Vaccine as another primary series option for adults 18 and older. This brings the total number of approved or authorized vaccines in the US to four for adults and three for children aged 6 months and older.

Over the summer, the FDA granted an emergency use authorization for an updated bivalent booster that targets both the original virus as well as the BA.4 and BA.5 Omicron variants. And on September 1, the CDC recommended bivalent boosters for adults and children aged 12 and up. These were first available after Labor Day. On October 12, the CDC expanded that recommendation to include children 5 to 11.

On November 22, the Health Resources and Services Administration announced a new 350-million-dollar initiative for HRSA-supported health centers to increase COVID-19 vaccines in their communities with a specific focus on underserved populations.

In September, FDA updated its COVID-19 test policy to encourage developers to seek traditional pre-market review for most test types instead of emergency use authorizations while also ensuring continued access to tests.

NIH established a new website for self-reporting COVID-19 test results in November, MakeMyTestCount.org, developed through NIH's RADx program, allows users to anonymously report the results of any brand of at-home tests.

In response to requirement and the President's April memorandum on addressing the long-term effects of COVID-19, HHS developed two reports that together pave an actionable plan forward to address long COVID and associated conditions. The first report, the National Research Action Plan on Long COVID, details the status of current research and charts a course for future study to better understand the prevention and treatment of long COVID.

The second report, the Services and Supports for Longer-Term Impacts of COVID-19, highlights resources for health care workers and those affected by broader effects of COVID-19, including not only long COVID but also affects mental health and substance abuse and loss of caregivers and loved ones.

Last year my office and ASPE released a report on the impact of COVID-19 vaccinations. This report used a regression model to estimate reductions in COVID-19 cases, hospitalizations, and deaths associated with COVID-19 vaccinations across counties in the United States from December 2020 to July 2021. Our estimates suggested that COVID-19 vaccinations were associated with reductions of approximately 25.3 million cases, 1.3 million hospitalizations, and 213,000 deaths.

A more recent report from ASPE released in October estimated that the administration vaccination program, which has gotten over 90 percent of seniors fully vaccinated and over 70 percent of seniors a booster shot is linked to more than 650,000 fewer COVID-19 hospitalizations and more than 300,000 fewer deaths in 2021 among seniors and other Americans enrolled in Medicare. The study underscores the importance of Americans, particularly seniors and others at high risk getting an updated COVID-19 vaccine this fall.

ASPE has also been examining the medical supply chain, which has shown significant vulnerabilities during COVID, and we have just released a report examining the causes of medical device shortages in the last decade.

Of course, COVID-19 is not the only infectious disease requiring the department's attention. I want to touch briefly on three others that have been in the news: mpox, influenza, and RSV. On August 4, Secretary Becerra declared Monkeypox a public health emergency and renewed that declaration on November 2. Last week following a series of consultations with global experts, the World Health Organization began using a new preferred term, mpox, as a synonym for Monkeypox. Both names will be used simultaneously for one year while Monkeypox is phased out.

Moving forward, US federal public health agencies, including CDC, will adopt the mpox name in correspondence with the medical community and the public. This change will enhance the US response by using a less stigmatizing term.

To address the Medicaid mpox outbreak, HHS has taken two major actions. First, the CDC launched its mpox Vaccine Equity Pilot Program in which state or territorial health departments, tribal governments, federally funded tribal health care facilities, and cities currently receiving mpox vaccines through the Strategic National Stockpile and may submit proposals for projects designed to find innovative ways to reach populations disproportionately affected by mpox.

The other is that ASPR made at least 1.1 million vials of JYNNEOS, the mpox vaccine available, to states and jurisdictions for use against the current outbreak and purchased 5.5 million more to arrive over the next several months.

Last week Secretary Becerra announced that given the low number of cases, HHS does not expect that it needs to renew the emergency declaration for mpox when it ends on January 35 but that it does not intend to take our foot off the gas. HHS will continue to monitor the case trends closely and encourage all at-risk individuals to get a free vaccine.

During the last two years, viral respiratory illness activity has been impacted by the COVID-19 pandemic such that circulation of other respiratory viruses besides COVID has been atypical. For example, there has been little circulation of flu, which is usually responsible for a large portion of respiratory diseases in the fall and winter. However, right now, the US is experiencing a surge of respiratory viruses and SARS COVID viruses may continue to circulate at high levels this fall and winter. Flu hospitalization rates now are higher than the rate at this time of year during every previous flu season since the 2010-11 flu season. And RSV activity remains elevated but varies by region. RSV is the leading cause of hospitalization among children less than 1 compared to previous years. There are also more RSV-associated emergency room visits and hospitalizations among older children.

Turning to our Overdose Prevention Strategy, on September 29, the secretary renewed the public health emergency regarding the opioid crisis, meaning we are now entering the sixth year of this crisis. In early November, CDC released the clinical practice guidelines and includes new evidence and recommendations on acute, subacute, and chronic pain.

SAMHSA awarded nearly $1.6 billion through the State Opioid Response and Tribal Opioid Response Grant programs. We are also working with international partners. For example, Canada and the US recently published a white paper, Substance Use and Harms During COVID and Approaches to Federal Surveillance and Response.

I now want to turn to some other important activities of the Department that are directly implicated by the Strategic Plan and our agency priority goals, starting with health coverage and access to care. In August, HHS released a new report based on research by ASPE, showing that the national uninsured rate reached a historic low of 8 percent in early 2022 with 5.2 million people having gained coverage since 2022. With the enactment of the Inflation Reduction Act on August 16, even more Americans will have health insurance through the Affordable Care Act.

The new law reduces drug costs for more than 63 million people across the country with Medicare and 13 million people covered under the Affordable Care Act will save about $800 per year on their health insurance. Millions of people with Medicare coverage will benefit from lower drug prices, a $35 monthly copay cap for insulin, a limit on out-of-pocket expenses in Medicare Part D, and reduced costs under Medicare's new ability to negotiate drug prices.

In addition, the enhanced tax credits for the Affordable Care Act marketplaces will continue for three years to help people afford their premiums and connect to coverage.

In September, HHS approved a 12-month extension of post-partum, Medicare, and CHIP coverage in Hawaii, Maryland, Ohio, Indiana, North Carolina, and West Virginia under the administration's American Rescue Plan.

In concert with previously approved state extensions, an estimated 360,000 Americans in 27 states in DC are now eligible for 12 months of essential postpartum medical coverage.

Additionally, as of October 3rd, that is as of October, all 50 states and DC now offer dental coverage for Medicaid enrollees who are pregnant and postpartum for at least 60 days after pregnancy.

In October, Secretary Becerra issued a final rule to fix the so-called family glitch, a provision that make family members of an employee ineligible for premium tax credit even though they needed it to afford high-quality insurance coverage through the Affordable Care Act's marketplace. This step will help about one million Americans either gain coverage or see their coverage become more affordable.

To strengthen and expand access to high-quality comprehensive health care for all children, CMS announced three key actions. First, a new guidance document reminds states that their mandate to cover behavioral health services for children in Medicaid and urged states to leverage every resource to strengthen mental health care for children.

CMS issued a second guidance document that urges states to expand school-based health care for children, including mental health care. As part of a third action, HHS issued a proposed rule that for the first time ever would require states to report certain quality measures to strengthen Medicaid and CHIP to ensure that millions of children and families have access to the highest quality of care. CMS has also provided a roadmap for states to help connect children with complex medical conditions to Medicaid services.

I will now turn to mental health care, which is an extremely important issue. Just prior to our July meeting, the federally mandated crisis number, 988, became available to all landline and cell phone users, providing a single three-digit number to access a network of over 200 local and state-funded crisis centers.

In September, HHS released new data that shows that over the first month of the transition to the 988 Lifeline, there was a 45 percent increase in overall volume and a substantial improvement in answer rates and wait time compared to in August. The administration has also increased federal funding for the 988 Lifeline 18-fold in FY22.

On September 12, HHS approved the first Medicaid mobile crisis intervention services program to be launched in Oregon. This new Medicaid option, created through the American Rescue Plan, will strengthen behavioral health care and make communities safer by ensuring law enforcement can focus more on accountable policing and less on work that is more appropriate for mental health counselors or social workers.

HHS released a roadmap for behavioral health care integration on September 16. This roadmap details policy solutions that would help to better integrate mental health and substance use care into the larger health care system and other systems.

A few more announcements. At the end of July, HHS and Department of Justice issued guidance on non-discrimination in telehealth in the week of the 32nd anniversary of the Americans with Disabilities Act. This guidance provides clarity on how federal non-discrimination laws require accessibility for people with disabilities and limited English-proficient persons in health care provided by telehealth.

On September 8, the US Department of Homeland Security issued a final rule applicable to non-citizens who receive or wish to apply for benefits provided by HHS and states that support low-income families and adults. The rule details how homeland security will interpret the public charge around of admissibility and will help ensure that non-citizens can access health-related benefits and other supplemental government services to which they are entitled by law without triggering harmful immigration consequences.

There have been a number of other activities that HHS has done in the last few months. But I am just going to mention one more of particular interest to NCVHS. Both OCR and SAMHSA announced just after Thanksgiving proposed changes to the Confidentiality of Substance Use Disorder Patient Records under 42 CFR Part 2, which we generally refer to as Part 2, which protects patient privacy and records concerning treatment related to substance use from unauthorized disclosures.

The proposed rule would improve coordination of care for patients receiving treatment while strengthening privacy protection to help ensure individuals do not forego lifesaving care due to concerns about record disclosure. This action fulfills requirement in Section 3221 of the Coronavirus Aid Relief and Economic Security Act, also known as the CARES Act, that requires HHS to bring Part 2 into greater alignment with certain aspects of HIPAA. The deadline for comments is January 31.

I think that is all I am going to talk about. There is a lot of activity, but I know that time is getting short. I want to thank you very much for your attention. Happy to take any questions.

Rebecca Hines: Members, remember to raise your hand so Jacki knows you would like to be in the queue for a question.

Sharon Arnold: I guess I was very clear and comprehensive if there are no questions.

Jacki Monson: I was going to say this is the first time I think I have seen no questions, Sharon.

Sharon Arnold: Well, I will be around. You know where to find me if you have any questions later on. Thank you very much.

Jacki Monson: Thanks so much for your update.

Let us move on to the next agenda item. I am going to turn it over to Val and Melissa to give Privacy, Confidentiality and Security Subcommittee update.

Subcommittee on Privacy, Confidentiality and Security

Valerie Watzlaf: Thank you. Thank you, Jacki. There are slides. Thank you. I am going to be giving our update for our PCS, Privacy, Confidentiality and Security Subcommittee. First, I just wanted to start by thanking everyone on our subcommittee, Denise Chrysler, Vickie Mays, our Co-Chair Melissa Goldstein, and special thanks to our staff, Maya Bernstein and Rebecca Hines and also thanks to Jacki too because Jacki was with us and was very instrumental in a lot of the developments this year and certainly in the past. Thank you very much for all of your support this year. I know that will continue into the future.

On the next slide, I just wanted to – we wanted to start with a listing of some of our past work that we are continuing to build on. As you can see and I will start with the second one there, we completed a recommendation letter in May of this year, and it was entitled Recommendations to Strengthen Cybersecurity in Healthcare. It was developed in response to the increase in the number of cybersecurity incidents that was affecting the health care industry as well as a hearing that was held in July of 2021 in which we had a panel of experts provide us with information that would help us better understand the cybersecurity landscape and also explore how best to protect health information in our patients.

That letter is available. It went to the secretary. It is available on our NCVHS website. We also did get a very supportive response from the secretary in relation to that to those recommendations.

And then the top one there. We are in the final review formatting stage of this letter and their recommendations that deal with, as it says, their privacy, confidentiality, and security considerations for data collection and use during a public health emergency. These were recommendations for best practices, methods, and approaches to collecting, using, protecting, storing, and sharing personally identifiable data during the pandemic or any other long-term PHE.

This letter was developed in response to a few different hearings and reports. One was held actually in September of 2020 on PCS considerations for data collection and use during a public health emergency.

And then we also heard from another panel in January of this year on COVID and its capacity gaps and quality in the collection of race and ethnicity data.

The goal of these hearings was really to get input from our public health practitioners and other experts so that we could explore data privacy and security in the light of the COVID public health emergency.

And from these hearings and public meetings as well as other published sources, the letter to the secretary has been put together. We are in the last formatting stages, and it should be ready to go very soon.

And then we also want to thank everyone on the committee who provided us feedback on both of these letters, and for everyone on our subcommittee for all their hard work on these.

And then we also have listed out some of the past work that was done that really has helped us and continue to help us move forward with new topics and ideas. These are just a few of them. There are several others on our website but the Beyond HIPAA work as well as the de-identification letter of recommendations. I am sure we will be hearing more about that a little bit later this morning when Cason does his presentation on the environmental scan.

We definitely want to get input from the Full Committee today on some of the areas of focus that we might pursue. We just wanted to start by giving you a bit of background about those areas. This slide provides more detail regarding the legislative development and update of a data privacy panel that we held in July of this year. You can see that we had a very expert panel that provided us with a wide perspective of the current legislation as well as legislation that may be forthcoming on privacy issues. We had representation from the Federal Trade Commission, the Future of Privacy Forum, from AHEMA, the American Health Information Management Association, as well as International Association of privacy professionals.

After that panel presentation or it may have been around that same time, we engaged Cason Schmit, who is with Texas A&M University and who is with us today. We are very pleased to have him with us. He developed and delivered the environmental scan. You do have that report. Again, he will be presenting that a little bit later this morning.

We did have three objectives in relation to this environmental scan. The first there was really to identify and analyze some of the current privacy and security legislative developments, some enhancements, some challenges, anything that might need updated in relation to privacy and security of health data. But you will see that he has a lot more in there as he presents it a little bit later.

The second objective is on the next slide. This is really to identify experts within and also external to government who might be able to share their expertise with our subcommittee as well as the Full Committee on any issues that may have surfaced from the environmental scan and from some of the panel presentations that we have heard from. We would love to get your input on some of those issues that we may want to focus on and then we may want to bring in some of these experts in future panels as we consider a particular issue or issues.

And then the third objective was really to outline the issues for Full Committee consideration and then be able to deliberate that to support future steps.

As we move ahead, we wanted to consider input from both the July Full Committee Meeting, the environmental scan and also the discussion that we will have today as well as in the future. We just came up with a few scoping issues here. These are certainly not set in stone at all just to give you some ideas. Some possibilities may include, again, what we have listed here that we found from recurrent themes. We heard from the panel as well as from the environmental scan.

They could include such things as de-identification. We may want to possibly revisit the 2017 NCVHS letter of recommendations on de-identification. It might include artificial intelligence and machine learning with a focus on algorithm impact assessments and transparency standards. We could possibly work together with the Standards Subcommittee. I know that they are very interested in this area as well.

Looking at law enforcement access to and use of private information, that could be another area. Consumer surveillance and data security, possibly working closer with the FTC with a focus on group harm considerations.

And then the last two here are kind of themes that we heard from the panels, how HIPAA interacts with broader privacy laws under consideration and then also very general, the availability of data for public health purposes. These are just some areas we definitely want to get your feedback on.

We also hope to do outreach with the Office for Civil Rights with periodic check-ins and discussions with them. They are very much involved in these same areas as well.

We were also able to focus on cybersecurity. We mentioned of course the one letter of recommendation that was developed. But we also felt the need to get a more current landscape on what was happening in cybersecurity. This is the cybersecurity panel that was actually put together in July of this year as well. You can see again that it is a very broad range of experts. Again, they were providing us with areas that we could consider in the future. We have come up with some of those areas here.

Some of them may include what is the impact of cyber-attacks on some health care organizations, maybe some best practices, looking at security principles, and safety for patient and consumers with a focus on medical devices, and any other type of health-related device.

We heard through I think every member of the panel talk about the need for education and training of workforce on cybersecurity and also cybersecurity flaws that might lead not only to the unavailability of data but also unavailability of medical devices and full systems.

Again, these are just some ideas to get your ideas flowing. We definitely need your feedback, and we value that as well. We hope to do that a little bit later this morning.

This next slide really demonstrates what our journey looks like, past, present, and then anticipated future. The two green blocks there are things that we have already completed. As I already explained, we had two expert panels on the developments of data privacy and cybersecurity that was in the third quarter of this year, and then the environmental scan, which we will be hearing about in a little bit from Cason.

Again, we value your input. We need your input to determine where we go into the future. But this is just something that we anticipate so that in the first quarter or first or second quarter of next year, we would like to discuss and frame some issues that we could focus on and possibly do projects in relation to those.

And then we would like to develop a project scoping document or documents depending on how many issues we focus on. The scoping documents are like a project proposal, very important to keep us on track. We hope to have those available in the second and third quarter of next year and then get Full Committee approval on those documents at the end of next year and then hope to conduct those projects and possibly be able to draft out some recommendations at the end of next year and also into the future. I keep saying this. We cannot do any of this without your input. We really want that today.

On the next slide, I do not want to forget that we did have some other potential topics for future consideration. We kind of put these in a parking lot in the workplan. Some of these we have already

mentioned. But others are new. You could think about some of these areas as well. The consequences of interoperability rules. Some of the other ones we did not mention. Privacy and security issues involving genomic data and even looking at data use and service agreements for wearables, mobile health, and so forth.

That is it for our update. Before we take any questions, I just want to ask if Melissa or any of our PCS Subcommittee members have anything to add or anything I may have missed.

Melissa Goldstein: I think that was a great summary, Val. Thank you. Thanks very much.

Valerie Watzlaf: Sure. I do not know if we have time to even – do we have any time to get any questions or we will just move right on to the next presentation?

Rebecca Hines: The agenda was to go ahead and have Cason present the environmental scan. Then we will have all of the information together and then plenty of time for --

Valerie Watzlaf: It sounds great. Thank you.

Melissa Goldstein: It sounds good.

Without further ado, I will introduce Cason Schmit, who is a professor in the Department of Health Policy and Management at the Texas A&M University School of Public Health. He is also the director of the Program in Health Law and Policy. Before Texas A&M University, he worked for CDC as a legal fellow and a federal contractor where his work focused on the role of law and health system transformation, including the use of electronic health information to promote public health. You can learn more about Cason, including his many publications and his full CV and everything that he wants us to know. His bio is linked on the agenda, which is on the website. You can click on his bio there. We are really excited that he was able to help us with thinking through these issues but also that he could be here today. Thank you, Cason. Please start whenever you are ready.

Cason Schmit: Wonderful. Can everybody hear me okay? Wonderful. Great. My slides are showing. Wonderful.

I will go ahead and skip my introduction and Val did an excellent job providing background on the environmental scan. I will go ahead and skip through that.

I do want to pause briefly. The scope of this environmental scan was to focus on developments occurring after 2018. While I did my best to cover as many as the developments as I could effectively, there was a pretty tight timeline for this environmental scan. Please do not consider this a comprehensive overview of everything that happened since 2018.

On a personal note, days after dropping this report, I had the birth of my third daughter. I have been on leave since. Nevertheless, there are a couple of issues that I highlight in this presentation that were not covered in the report because there is a lot moving in this space. Those are highlighted in red just to clarify those items that are covered and those items that are not covered in the report.

Very briefly, an overview of the entire environmental scan is here. There are six substantive sections. These by and large follow the specific requests for the environmental scan. Although those of you that

have had an opportunity to go through the environmental scan will probably note that there are some crosscutting ideas or themes that are applicable to many of these different sections.

For today, I thought I would focus – and with discussion from Melissa and Val, focus the presentation on a number of different topics, highlighting on those and talking briefly about each opportunity for the National Committee to provide some timely advice to HHS.

The first highlight from the report are those significant changes in the Privacy Landscape since 2018. You may recall in the July meeting, you had a wonderful panel of experts that talked extensively on many of the state law and federal law developments. I am not going to go into detail on each of those here because it was done in such – very effectively in the July meeting and in detail on the report.

I will note that the activity is still ongoing. There are at least four states in addition to the five that have already passed privacy laws that still have active privacy bills, comprehensive privacy bills -- the data of the report.

There are a couple of other developments on the state law front that I wanted to draw attention to. The first is the Uniform Personal Data Protection Act. This was introduced in three jurisdictions. It is a piece of model legislation. Although the prospects of this model legislation are probably fairly dim, I wanted to highlight it because there are a number of innovative provisions within it that are not really present in many of the other privacy bills or acts that I have reviewed.

One of those being –- actually, two of them being how the law approaches defining acceptable or as the bill describes, compatible data uses. These are the permitted data uses under the bill. The first is typical privacy laws will very clearly define what is an acceptable data use and what is not an acceptable data use. In order to satisfy the legal requirements for what is an acceptable data use, you need to meet A, B, and C requirements in the law.

The Uniform Personal Data Protection Act, at least in one place, has a much more flexible approach to what is an acceptable data use. They use what some legal experts call a factor test. That is they will provide a number of factors and all you need to satisfy is just one of those factors sufficiently in order for the practice to be in acceptable or compatible data practice under the act. This provides a lot of flexibility in an area where technology is rapidly advancing. That can be both good and bad, depending upon how you look at it.

The other innovative area in this act is the use of a voluntary consensus standard approach to defining new compatible or acceptable data practices on the act. This is an approach that requires collaborations between industry, businesses, community members, and other advocates, and other stakeholders to come up with a new standard for a specific data practice or data practices that are going to be deemed compatible or acceptable data practices under the act.

The Uniform Act provides a very detailed description of what this and I am not going to go into that here. But just know that this voluntary consensus approach is something that you do not typically see in data production laws.

On the federal side, there has also been quite a bit of activity but not very much in the way of new or enacted laws. You may recall in 2016 that there was the passage of the 21st Century Act. Being in 2016, that was outside of the scope of this environmental scan. However, the regulations that provided

additional clarification on what constitutes information blocking are more recent and covered in the report.

One issue not covered, and I will talk in more detail about it later, details that the Common Rule revisions, which became effective in 2018.

In addition to these new federal laws, there are a number of many different federal privacy laws that are under consideration, the most significant of which was covered in quite a bit of detail in the July meeting is the American Data Privacy and Protection Act. Since that July meeting, there have been some developments that have increased some skepticism that that act will reach or that bill will reach the finish line and actually become law.

There is also the FTC Advance Notice of Proposed Rulemaking on commercial surveillance and data security. I will talk a little bit more about that in the next coming slides.

Going back to the Common Rule, the new regulatory text for the Common Rule or visions includes provisions that require the reexamination of the meaning of identifiable private information. That presumably is happening right now based upon the timelines within the regulations.

In addition, the FDA has issued some Draft Guidance on Cybersecurity in Medical Devices. You may recall that in 2014 and 2016, the FDA issued final guidance on both pre-market submissions and post-market management related to cybersecurity and medical devices. The 2022 Draft Guidance is replacing the existing 2018 Guidance on Cybersecurity in Medical Devices. That is another thing that unfortunately did not make it into the final report but should be on your radars.

Next, I want to focus briefly on the FTC Advanced Notice of Proposed Rulemaking. In terms of status, the public comments on that advanced notice have closed as of November 21. Right now, the next step is the FTC will review those comments and decide whether it will proceed with the rulemaking process. If it does decide to proceed with the rulemaking process, there will be a Notice of Proposed Rulemaking. This will include proposed regulatory text and potential alternative language for different provisions. There will be a new public comment period, providing an opportunity for various stakeholders and members of the public to provide their input and thoughts and criticisms of the proposed language.

After that public comment period, there will be or there may be a final rule. What is important to realize here is that challenge to any final rule language is going to be likely, whether from the consumer perspective or from the industry perspective. There is no doubt going to be some quibbling with whatever final language may come out of a potential rulemaking process. The bottom line is that we may be years away from new regulations taking effect.

Notably, the FTC has broad jurisdiction, which as you recall from the July meeting, does include HIPAA covered entities. There is potential regulatory overlap between HIPAA and future FTC regulations. This could both create some confusion on the compliance side. It could also have some unintended impacts on beneficial data practices, both on the health care and public health side.

We have a potential opportunity for timeliness advice to HHS on this topic. Early collaboration between HHS and FTC could mitigate some unintended consequences. Some potential topics for input could include discussion of potential or beneficial data practices that we want to be preserved and not impeded by future FTC rules. These could include learning health systems, precision public health, and private sector assistance in public health surveillance.

Other things. Clearly, we need to – it might be useful to talk about harmful health-related data practices and whether or not the FTC rules could address some of those. Also, looking very carefully at whether or not there will be conflicts between potential rules and existing privacy frameworks like HIPAA. Also, closely examining group harms that may come from future FTC rules or that future FTC rules could help address.

Next, I want to talk briefly about the Common Rule issue I alluded to in the prior slide. There is the potential opportunity for the National Committee to provide some timely advice to HHS on the Common Rule definitions for what constitutes identifiable. The revised Common Rule directs Common Rule agencies to – uses the word shall reexamine the legal definitions of what constitutes identifiable private information and identifiable biospecimens, specifically saying within one year and regularly thereafter at least every four years.

As you may recall, these regulations came out in 2017. It went into effect in 2018. I have not seen anything. It does not mean it does not exist. But I have not seen anything suggesting that there has been any change or what the outcome of any reexamination has been. But the agencies are empowered to alter legal interpretations of these terms if appropriate and permitted by law.

And in this, my focus here was the definition of identifiable but this directive also includes an assessment of analytic technologies that can generate identifiable private information or biospecimens, which would include reidentification methods.

Notably, any input in this process given the timelines above would be timely. This includes recommending that no changes be made to these definitions or the existing regulations. It is worth consideration.

Next, I wanted to highlight several different approaches to privacy enforcement that have come up in recent years in the literature. First and foremost, this should be familiar with most of us. One of the predominant approaches to privacy in this country is the consumer protection approach. This is the idea that consumers are in the best position to protect themselves by exercising their privacy rights. Most commonly, we see this in notice and consent frameworks where businesses will post their privacy practices and consumers will provide their consent to those postings or provide authorization for their data to be used in such a way.

Next, there is a data protection approach. These approaches tend to be principle-based protections. You see these in the EU, for example, and the GDPR in terms of purpose limitations, data minimization principles.

Notably, with data protection approaches, these protections tend to follow the data. When data is disclosed from a regulatory entity, those protections may follow that data as it is disclosed to another entity.

Next, there is increasing discussion of an anti-trust approach to privacy. And one of the hallmarks of an anti-trust approach is focusing oversight and enforcement on entities that are of sufficient size however that is defined by law. This could be entities that have data on so many individuals, data that derive so much of their revenue from the sale of personal data. These could be rules that focus on entities that take in so many millions of dollars in revenue on an annual basis. However, this is defined in law would describe the scope of that oversight and enforcement.

Finally, this is somewhat of a new development and is the discussion of an information fiduciary approach to privacy. Under this approach, there would be legal duties of confidentiality, loyalty, and care that are imposed on data controllers and processors. In this way, to put this in stark contrast with the consumer protection approach where the consumer is in charge and the consumer can in theory consent to whatever data practice is provided. The information in the information fiduciary approach – it is the controller or processor that is responsible for acting on behalf and to the benefit of the data subject. In theory, the consumer could not consent to certain practices that would be against the interest of that data subject. These are some of the alternatives that have come up to the consumer protection approach.

Next, I wanted to go over some different approaches to enforcement. There are the traditional enforcement approaches that you are all familiar with. These are enforcement through government agencies. Some privacy laws are empowering existing agencies. Others are creating entirely new agencies to deal with these privacy issues.

Another and perhaps a more contentious enforcement approach is by empowering individuals with a right of action. You will see this is a right to sue or perhaps class actions against those that violate privacy rights.

There are some notable alternatives to these traditional enforcement approaches that have been described in the literature and indeed exist in some privacy bills. One would be to deputize private intermediaries to help enforce standards. Another would be to scale the legal standards and penalties with the scope of the data activities that the controller or processor is engaging in. This one rests on the theory that the harms associated with privacy and data practices are not linear and that they scale potentially exponentially with the size and scope of the data controller or processor.

Third, what is being increasingly discussed and included in the FTC Advance Notice of Proposed Rulemaking is profit disgorgement. This is a relatively severe penalty where that would deprive the violator of any profits from the potential violation. And another, which is also a relatively severe penalty, is imposing personal liability on executives.

The next report highlight I want to talk about is de-identification. Now, one of the things I think it is important to discuss at the onset is there are two reasons why we de-identify things. One, we de-identify things because it is a legal mechanism. Perhaps less identifiable data under the law is permitted to be used for more things. We de-identify the data in order to be legally able to do those other things.

The second reason why we de-identify data is as an ethical protection. We are simply de-identifying data not because the law requires it but because we think it is a good thing to do to help reduce the harms associated with data uses. Notably, neither of these, neither of the legal mechanism nor the ethical protection should be equated with mathematical de-identification.

One of the consistent aims, both in the literature and in your July meetings, was that it is becoming increasingly difficult for those in the field to use these existing standards, the legal standards. This is a rapidly changing environment. There has been described an arms race between de-identification and re-identification techniques. And existing guidance from 2012 is increasingly outdated.

Another theme that came up in this area is the unintended consequence from de-identification. De-identification in some ways still enables group harms and as we heard what some groups have described as data genocide where suppressing some data to ostensibly to reduce the individual harms associated

with data disclosure may in effect prevent certain groups from being represented adequately in the data to the extent to where those groups may be subject to increased harms.

Notably, the National Committee provided recommendations on de-identification in 2017. Twelve recommendations, none of which included specific suggestions to update or change the standard. And you see those 12 recommendations summarized here in this table.

Nonetheless, there is an opportunity for timely advice here. It is not clear that there have been subsequent actions on those 2017 recommendations. But those recommendations are still relevant. As you heard in the July meeting, there is still a lot of clarity being requested from various stakeholders in de-identification. It is a major issue.

Existing operational and technical guidance specifically has been called out as being increasingly out of date. The National Committee might reconsider exploring considerations of both individual and group harms related to methodological approaches in data aggregation and de-identification. These would be opportunities for timely advice, including revisiting and potentially reissuing those 2017 recommendations.

Next, a highlight from the report is our issues associated with artificial intelligence. Artificial intelligence poses a number of quite significant challenges from a privacy, confidentiality, and security point. First and foremost, it is a moving regulatory target. There are rapid technological advancements and definitions of what constitutes as artificial intelligence and are difficult to make and often quite murky and ambiguous.

Next, artificial intelligence poses some real significant transparency challenges, not just for the public, not just for regulators, but also for developers of artificial intelligence algorithms and tools and users of those tools. It is often very difficult for all stakeholders to understand exactly what the artificial intelligence algorithm is doing within the black box and what the consequences of that algorithm might be without taking significant and meaningful steps to really understand the impact of those automated tools.

Moreover, the ubiquity of AI in all sectors raises legitimate concerns about the use of AI or the role of AI in both maintaining existing structural inequities and exacerbating those structural inequities or creating entirely new structural inequities.

One of the key aspects to be on the lookout in terms of artificial intelligence is our group harms. In the literature, these have been described as having two main groups, which have three subgroups between them. Those are the comprehensible groups. There are some comprehensible groups that have expressed protections in our laws. We have legal protections that prohibit discrimination based on sex, race, and religion, for example. But we also have -- artificial intelligence can group individuals in other ways such as dog owners and video game players. These groups can help businesses and health care providers make meaningful decisions and predictions that nonetheless may raise some questions about fairness and harm, for example.

But in addition to these comprehensible groups, artificial intelligence can group individuals in ways that are incomprehensible to everyday people, to lay people, and most people, even sophisticated people. For example, an artificial intelligence tool may be able to group people based on the way they move their mouths. We can imagine an artificial intelligence school quite easily distinguishing Parkinson's

patients from the general public based upon how they are interfacing with the website or how they are clicking.

The data in distinguishing these groups within the systems may not permit the developers or the users of these algorithms for understanding that they might actually be discriminating against somebody for this health condition.

Since I provided the report, there have been some important updates here in the universe of AI. First, the White House released the Blueprint for an AI Bill of Rights in October of this year. This included five principles: safe and effective systems, algorithmic discrimination protections, data privacy, notice and explanation, and human alternatives, consideration, and fallback.

Another notable update for the report that was not in the report is the release of the Draft AI Risk Management Framework from NIST. Comments for that closed in October 2022. But this is intended to promote – it is a voluntary tool, intended to promote and improve the ability to incorporate trustworthiness considerations into the design, development, and use.

All of this I think highlights the potential for an opportunity here for timely input. Notably, federal laws do not currently distinguish between automated and traditional manual data uses, practices, and processes. However, the risks associated are very different both in scope and scale. I think this presents an excellent opportunity for a new convening to explore different issues particularly around standards and requirements. These could include those four, impact assessments, for AI transparency, and looking at whether or not standards should be scaled depending upon the size and sophistication of data controllers and processors.

Finally, the final report or highlight I want to talk about today are increasing privacy threats. Specifically, the report focuses on the law enforcement use of health data. We have seen this in the use of commercial genetic databases and the use of commercial surveillance data that is purchased from data brokers by law enforcement agencies. One author described this as big brother surveillance on a budget. That was a rough paraphrase. I apologize for that.

But balancing the benefits and harms of law enforcement disclosure provisions and existing privacy laws presents a really tricky problem. In addition to these law enforcement uses of health data, their legal developments have highlighted new risks in the privacy sphere, specifically post-Roe v. Wade. Recall that this summer the Supreme Court decision in Dobbs v. Jackson permitted – which allowed states to place increased restrictions on abortion and has in effect prevented states to investigate and prosecute legal violations related to those procedures. This includes both HIPAA data and non-HIPAA data, and health data, but also data that is not about health but can be used to infer health status.

There are also increasing concerns that other privacy rights could also be at risk. For those of you without legal background here, there are a number of federal rights that have been established by the Supreme Court that are privacy rights. Abortion is one of them. Birth control is another. All of these are within this – what has been described as a federal right to privacy.

The recent Supreme Court decisions have increased concerns that perhaps the scope of these privacy rights that have been observed by the Supreme Court may contract in the future. Now notably, there is a new bill protecting same sex marriage and interracial marriages that I do not think has been signed yet but it is expected to be signed in the future.

With these increasing risks, there is a potential opportunity for timely advice on the law enforcement use of health data. Notably, drawing a line between appropriate and inappropriate law enforcement uses of health data could be quite perhaps exceptionally challenging. You might imagine a situation where an individual shows up to an emergency room with a gunshot wound. In the past, there has not been significant public uproar about disclosure of that patient's condition and treatment for law enforcement purposes where there has recently been quite a bit of uproar about the disclosure of somebody who is seeking care for abortions.

Defining and distinguishing the difference between inappropriate or appropriate law enforcement data uses in a legal provision or a legal exception might be quite challenging. That is one issue that could be explored in a future convening.

There is also consideration of imposing new data protection requirements on data that are disclosed to law enforcement for law enforcement purposes. These could include principles of data minimization or purpose limitations and also imposing higher legal standards when there are generalized law enforcement requests. Law enforcement agencies seeking disclosure of records pertaining to all patients with certain conditions as opposed to just I want information on Jane Doe.

That is it for my overview of the environmental scan. I would be delighted and happy to try to answer any questions that you might have at this time.

Melissa Goldstein: Thanks so much, Cason. That was so comprehensive, and we really do appreciate it. It was a lot of work that somehow you managed to do in a very short period of time with perhaps an internal deadline of a little one being born. We really do appreciate it.

Let us open it up for the committee now. I ask that you raise your fake hand so that I might see it. And if you cannot find the fake hand button, I am going to constantly scan the Zoom room for real hands as well. I am sure we have some good questions for you.

We did ask you to do a lot and I will preface this discussion for my colleagues on the committee with noting that this is a comprehensive presentation and a comprehensive report. Obviously, it is hard to take it all in at one point. But there is a lot of detail in the report itself, which we have circulated to you. It is not public yet but we have circulated it to the members for additional detail. Cason, you could even highlight pieces of detail in response any questions we get. But we are so appreciative and you have given us so much to think about, which really was our goal. Thanks again.

I see that Vickie has her hand up. Vickie, why don't you go ahead?

Vickie Mays: Let me just repeat what Melissa said, which is an incredible piece of work. I do not know how you did it with baby on the way and baby there, but I have to congratulate you and thank you because my head is just – I have now read this a couple of times. When you presented it, even more issues came up.

Here is one of the things I want you to help me understand better is the difference between what we can do about individual harm and what we can do about group harm. It is like most of what I can tell, we protect individuals and – of the law is there. But when we start thinking about things like IRB and you had on one of your slides like ethical issues, an individual – what happens with an individual can result in very significant harms for groups. I am trying to understand the space in which we can start addressing that if you can help me with that.

Cason Schmit: That is a terrific question. I certainly -- as I alluded to in the presentation and your question acknowledges, our legal framework right now is predominantly in that consumer protection model. It focuses on the individual, the individual's harms.

The data protection approach provides one way to try to mitigate some of those or it could be adapted to address group harms by creating specific principles that are intended to address those group harms.

Of the approaches that I provided, I think the information fiduciary approach is the one that most expressly deals with the group harm image in that Balkin, who is the primary advocate for that approach has expressly stated that data processors such as – the very large processors such as like Facebook or Google may need to take a population-based approach to exercising their fiduciary duties because of the scope of their activities.

Some ethicists have spoken to – for example, I, in the report, highlighted Megan Doerr of Sage Bionetworks, who has been critical of de-identification as a primary ethical protective method in some contexts, specifically saying maybe the focus needs to not necessarily be on running through the motions and doing these sorts of individual protections but rather engaging communities and seeking social license to undergo certain activities.

There have been some approaches that have looked at maybe a broader, collective approach to seeking community input as a better way than seeking individual consent. It is a difficult consideration. But right now, our laws are very clear that the individual is the focus of these protections.

Vickie Mays: I guess I am trying to understand how to get to the group whether or not – and, again, it kind of struck me when I was looking at the slide about ethical issues, whether some part can be through what we say the – that limits it because not everything is under IRB.

The other, I wonder about, is the extent to which we can come up with data governance or sometimes we call it data stewardship. If we cannot legally do it, I am trying to figure out if there is a structural thing, which this is where data comes from and in order to have it or do it or possess it, these are the rule, which a federal agency could do.

Cason Schmit: Right. One of the things that comes to mind is, for example, so many of HIPAA's disclosure provisions are permissive. There are so many instances where a covered entity might have the ability to disclose individual-level data. But for organizational purposes or whatever purposes, they have decided that even though they may disclose these identifiable data that they are going to go ahead and de-identify it.

There may be an opportunity to provide some guidance to highlight some of these other issues and other concerns to help these organizations understand that this ethical protection or practice that they are undergoing might not have the protective effect that they think it is having or the balance – there might be a different balance of risks and benefits that they should consider in this. I think some of these sorts of considerations and guidance could help inform some of these permissive disclosures.

I do see that there is a question in the chat.

Melissa Goldstein: I did want to mention that, Cason, but obviously, we understand that you are not 100 percent cognizant at all times of all laws and all proposed laws. We do understand that. But to the extent that you have considered, and I will read this question for the public because I do not believe that

they can actually – I do not know actually whether the public can actually see the question or not. The question is about linking data from different sources, which we know is called the mosaic effect by some people and the ability to de-identify data when it is linked when there are certainly different sources, different lists, different databases where different things about different people are de-identified but then when you can cross reference them, there is an ability to re-identify it so that there are questions about possibility – there is some possibility of requesting explicit link for linking this type of data from data researchers perhaps. And the question from the participant is are these issues being considered by any bill.

Cason Schmit: I do not recall seeing – my omniscience here is quite limited. But I do not recall seeing any that expressly address this issue. That said, I think that there is a lot of existing legislation and existing bills that implicitly address some of these issues.

For example, comprehensive privacy legislation, which more broadly provides blanket protections across different applications. I think it implicitly addresses some of these issues.

To take a step back, privacy laws in our country have typically been described as past work. In other words, they apply to a specific type of data, specific type of data custodian or controller or processor and they regulate specific purposes. These different laws that vary in these different ways may also describe protected data differently.

Those differences in rules might mean that data set protected by one law is de-identified in one way and data set protected by different laws de-identified in a different way and that provides increased – when you link those two, it provides increased risk of re-identification because there are new attributes or different attributes, assuming they can be linked.

Applying more blanket rules under a comprehensive privacy act allows for some more broader data linkage because there is a single set of rules. This applies to all sets of data. But it also eliminates some of the variation in how those data are protected or de-identified. That is an implicit way that some of these bills might be addressing some of those issues. But I do not recall -- it does not mean it does not exist but I do not recall any specific bill that specifically addresses the issues of data linkage.

Melissa Goldstein: Thanks, Cason.

Any other members of the committee, comments, questions? I am sure there must be some out there. Val. Thank you.

Valerie Watzlaf: Sure. And also thank you, thank you, thank you, Cason. Just such a beautiful job that you have done.

I just had a clarification question because I am so interested in the artificial intelligence and machine learning, and you did such a beautiful section on that. I know you added those new reports that came out from NIST and also the White House Bill of Rights. I just wanted to clarify. When you look at those, is there anything that you did not see there that we could focus on? I believe you were saying that it was more the algorithm impact. But I do not want to put words in your mouth. I just want to clarify. Are there other areas that you did not see there that we could possibly focus on in that area? I know there is a lot there.

Cason Schmit: I might need to get back to you on that. Certainly, I have been on family leave for the last few months. I have not been able to stay on top of many of those recent developments and thoroughly digest them as I probably would have liked to at this point. I might need to get back to you on that. My apologies.

Valerie Watzlaf: That is fine. I think you did mention some of the algorithm and impact assessments, the transparencies. And we can certainly look at those reports as well and clarify too. Thank you again. I just want to give my thanks to all the work that you did in such a short period. I really appreciate it.

Cason Schmit: You are welcome. My pleasure.

Melissa Goldstein: Thank you.

Denise Chrysler.

Denise Chrysler: Sure. I will echo everybody's thanks, Cason. Congratulations on your new one. You have presented so much food for thought and I am like I want to do it all. It is like I know it is impossible.

I kept thinking the place to be was de-identification. I am just thinking a lot these days about law enforcement and access to information and state laws that do govern when law enforcement collects DNA directly in their DNA databases.

When I thought about all the implications and where do you draw the lines and how hard it is and sometimes we do want law enforcement brought in. That is why we have probably in every state reporting laws related to gun shots, stabbing, and other incidents when you show up at a hospital and in an emergency department.

A few months ago in New Jersey, the police were able to successively subpoena – blood spots. This is a really important public health program where this is baby's first specimen. Babies are almost universally screened across the nation. Most states, it is mandatory. Some states will allow an opt-out.

These blood spots are analyzed for 60 metabolic and congenital conditions where harm can happen to the child and prevented by early intervention. They are also retained for years depending on the state and used for public health surveillance just as an example. Blood spots are used to monitor mercury in the Great Lakes and prenatal exposure. They are used for important research. They are a gold mine. But yet because of laws that allow police to subpoena, and it may not – for HIPAA, for example, may be permissive and – mandatory you release information. When you have a subpoena unless you can find a reason to defeat it, that may be mandatory you release information.

Thinking about just all the issues of – where HIPAA would apply. It is where I get a blood test and I do not know how long laboratories retain my blood. But implications are not just for me and Denise but also for my whole family that are genetically related.

That has been on my mind, as well of course as Dobbs. Different areas may rise to the top. What do you see as rising to the top as a priority if you were to address areas and knowing you probably cannot go down the road, this is my opinion, of addressing social media and how it is intercepted and used. But there are blood specimens for laboratories – different situation.

Cason Schmit: Thank you for that. That is, I think, a great question. Admittedly, it is a question that I have thought about a lot recently. In fact, I have written on it. This is me putting a bit of my personal scholar hat on and saying a lot of the oldest privacy and confidentiality protections that we have in law, the confidentiality between a person and a religious leader or a person and a doctor. Those exist because the law wants to recognize and protect the ability of individuals who are seeking help to be able to be open and candid so they can get the help that they need.

Very similarly in public health context, the individuals are in some ways creating a social contract with the government in that they are giving up a little bit of their privacy, blood spots perhaps, to enable a much greater public benefit. Arguably then, it is – you see this in – for example, the 2017 WHO Guidelines on Ethical Issues in Public Health Surveillance where they specifically come out against the disclosure of public health surveillance data to law enforcement, saying that no, these data should not be provided to agencies that could use these data to take actions against these individuals. It is an incredibly issue. I think it is something that needs to be thought a lot about.

I think it does become trickier once state laws start defining what legal conduct – what was previously legal conduct as illegal in terms of what might be a medically indicated procedure. That becomes a lot trickier.

Did I answer your question or did I completely hit a tangent?

Melissa Goldstein: Thanks, Cason.

Vickie.

Vickie Mays: Thank you. I want to go back to one of your all-red slides, which was the one on 45 CFR 46.102 because I think it is a really important issue. I want to try and understand. Again, I keep trying to understand if we do something, where do we do it and what is the most effective way to do it?

One of the issues that you raised is about the common rule agencies that are also required to assess analytical technologies or techniques that can generate identifiable information of biospecimens. Can you talk a little bit more about – I am trying to understand what we can do. The Common Rule just had a recent revision. I think it fell short. There are things that we could still do. Can you talk a little bit more about how we can address these concerns? I have ideas about it, but I would love to hear your thinking.

Cason Schmit: Let me try to answer this question without trying to take a specific normative stance one way or another because there are good arguments for a no-change approach and there are good arguments for a change approach. I think both sets of recommendations or both alternatives of the binary universe would be useful to HHS.

The directive is to – if appropriate and permitted by law to closely examine whether or not there needs to be additional guidance or additional rules on these issues. The recommendation could be looking at the legal standard. It could also be at creating informal guidance.

I think one of the things that HHS or the Common Rule revisions were really struggling with is the ideas that this is a moving target in terms of identifiability and the risks – they acknowledge that the risks are rapidly changing and knowable at the time of submitting that. That was one of the reasons for revisiting these definitions to see whether or not that risk balance was changing in ways that required new guidance or new rules.

I think one of the concerns with the analytic approaches is just to keep IRBs cognizant of the idea that although the data that the researchers are requesting to use is not identifiable under the scope of the act. They may be using processes that may take this non-identifiable data and for all intents and purposes make it identifiable data that would otherwise be subject to the Common Rule regs.

I do not know that I directly answered your question.

Vickie Mays: You did – it was – you gave me both sides. That is good. Thank you.

Melissa Goldstein: Thanks, Cason. Thanks also, Vickie.

Tammy Banks.

Cason Schmit: If I might say one more thing. I presented a change and no change approach. One change that you could suggest is that right now the definitions for what is identifiable private information in the Common Rule are different than the definition, for example, protected health information under HIPAA. There are some that could argue that you would simplify things by making those definitions the same. Now, you could also argue that there is good reason why you want those definitions to be different under the Common Rule and under HIPAA. HIPAA is far broader than the Common Rule. Their readily identifiable standard is presumably a little bit narrower but there are also lots of robust ethical protections in research. That is another approach I wanted to present that is perhaps more direct to your question.

Tammy Banks: I have to echo with my colleagues. What an amazing report. This is just so thought provoking. I almost hate to ask a question because there is just so much to chew on. But one of my areas of passion is the social determinants of health and the increasing priority and the collection of this data by the providers, by the payers.

But what I would really like to get your feedback on is the concept of they really need to treat the patient as a complete person so to speak is to look at the community service organizations who are providing the services and – really be the – point of a lot of the disparities that were seen out there. I understand the individual and group. I am not raising that question. But do you see anything that can be addressed in order to really make the community service organization partners because they are not covered entities in order to truly create where the social determinants of health priorities I think are really trying to get to? Any comments in that area to help us if we focus on supporting that priority effort?

Cason Schmit: That is an excellent question. Social determinants are also a passion area of mine. Particularly, social determinants data is a passion area of mine. I am not entirely sure if this made it in the report but I know there have been developments in the use of community information exchanges that exist to share a lot of the community service agency data and organization data between those various partners to try to create a more comprehensive view of an individual. This is a distinction with a health information exchange, which is between health care providers and such. I do know that there are some efforts by different organizations to try to do some of that work.

I know there are substantial challenges in the patchwork approach of the US privacy framework in sharing a lot of those data because those social – data come from different sectors that may be governed by different privacy laws.

Melissa Goldstein: Thanks.

Denise Love.

Denise Love: My head is spinning, and you gave me so much information. I feel a sense of urgency. As Rebecca says, I want to boil the ocean, but we have a committee that can only focus on a few things. My question is sort of a follow on to Tammy's but as I think of public health and my background in public health and data policy is really thinking about what is happening out there in public health not only the challenges and building public trust so that people trust our public health servants with their data and the use of that data. But we have big investments in data modernization and public health strengthening, public health infrastructure. Billions of dollars have just been disseminated across local and state governments. Having worked with some of these folks on the ground during the application period, much of that will go into data linkage infrastructure to make the capacity to link across data sources to enhance social determinants and other important data components. But that capacity is going to be stymied, I think, because our governance structures are not up to speed.

I think in this committee, and I am just going to lay this out, we can only do so much. But I think looking at the IRBs, the governance structures and guidances, to start updating former ones so that these people out in the local communities have a playbook. You have to keep that trust going but we have to keep the data. My mantra is for public data, we have to ready access. We have to have protections. But it has to be useful. And all of those have to be in balance. If one of those is balanced to protection and privacy, the public good is not served. Vice versa. If access is uncontrolled, then we lose trust in everything else. I spent 30 years trying to achieve that perfect balance. But I think this committee, and this is just my opinion for Privacy, is to start where we can with what we have and build out and not try to boil the ocean. That is just a random rambling thought today.

Melissa Goldstein: Thanks, Denise. It certainly was eloquent rambling. It was not rambling at all. Thank you also for hanging in there with us for another 120 days after your final day.

Cason, a last quick question and this is an easy one because we are almost out of time. I would like for you to talk a little bit out. You mentioned a Uniform Data Protection Act that is in bill form now and that has been introduced in three jurisdictions. I thought it might just be helpful for folks to review what a uniform act is and what it means and what it does not mean when it is only in three jurisdictions. That is not a lot of uniformity. I thought you might want to talk about that for a little bit just as a clarification.

Cason Schmit: Sure. Thank you. There are a number of organizations that produce model legislation and the idea behind model legislation is we are going to try to – is an attempt to simplify the regulatory structure in the 50 states through state legislation. These organizations will produce model legislation that – and make these available to states to adopt.

One of the more reputable organizations that does this work is the Uniform Law Commission, which is a bipartisan organization that goes through an extensive and deliberative and transparent process to create different model acts. Some of these you may be very familiar with like the Uniform Anatomical Gift Act, which I think is adopted in 47 states, the Uniform Commercial Code, which governs every single contract that you have ever signed is adopted in all states. These model acts, which were drafted by the Uniform Law Commission, have by and large achieved this simplicity in regulation across 50 states.

The Uniform Personal Data Protection Act has only been introduced in three states and not adopted in any. The purpose behind the act was to try to simplify a little bit of the US patchwork of privacy

framework. And admittedly by the Uniform Law Commission themselves, they prefer federal action on this. They prefer federal rules on this. But in the absence of federal rules, they undertook this work to try to provide an approach that more states could adopt. That saying, it is not going to be much of a uniform set of privacy rules if no states adopt it or even if very few states adopt it.

Melissa Goldstein: That was great. That was really helpful. I just wanted – I was wondering who had adopted it, where it stood, why it was not exactly – you just answered that question.

I know we have to pass the baton back to Jacki but I wanted to thank you again, especially for coming today when I believe you are still on parental leave. We edged into that. Thank you again. It is very helpful. We will try to leave you alone but I cannot promise that with more questions.

Jacki, back to you.

Jacki Monson: Thanks so much. Thanks, Melissa, Val, and Cason.

Rebecca, I believe we are now going to a break. We are breaking until what time?

Rebecca Hines: 12:15 is what is on the agenda. That gives us 14 minutes and we will return for the tribal data recommendations.

Jacki Monson: That sounds great. We will see everybody in 14 minutes.

Rebecca Hines: Remember not to log out. Thanks again, Cason.

Cason Schmit: Thank you for this opportunity.

(Break)

Rebecca Hines: We are back and it is 12:15, Jacki.

Jacki Monson: Welcome back, everyone. Let us go ahead and move to the next agenda item, which is tribal epidemiology centers data access and privacy recommendations. I will turn it over to Wu and Val to share their recommendations with us.

Maya Bernstein: Can you all see my screen okay?

Rebecca Hines: Wu, you need to unmute yourself. Someone needs to unmute themselves.

Tribal Epidemiology Centers Data Access and Privacy Recommendations

Wu Xu: Hello, everyone. The draft recommendations are a collective effort. I would like to first acknowledge the ad hoc group members. They are committee members and the staff. We worked on this draft letter for five months. They are Valeria Watzlaf, Vickie Mays, Denise Chrysler, Denise Love, Tammy Banks, Maya Bernstein, Rebecca Hines, Grace Singson and myself.

This letter is a follow-up action from our last July Full Committee meetings. The purpose is to recommend actions to improve the tribal epidemiology centers and other designated tribal public health authorities have timely access to public health data.

Here is some brief background. Federal law requires HHS to establish a TEC in each HHS service area to serve the public health needs of American Indians and Alaskan Natives. Among the 12 TECs, 11 serves the Indian Health Services geographic areas. The one TEC serves the public health needs of urban American Indians throughout the nation.

Under HIPAA, TECs are deemed public health authorities. Under the federal law for Indian health care and epidemiology centers, TECs shall have access to use the data, data sets, monitoring systems, delivery systems, and other protected health information in HHS' possession. Also, the state and local governments and health care providers may provide data to TECs and ODTPHAs. This is really a great learning experience for me and also for our groups.

We have learned a lot about sovereignty of tribal nations and also their relationship between the TECs and the tribal governments and the TECs with HHS and the CDC as well as the tribal public health practice and especially the scope and the definition of public health authority. That is why the definition of public health authority is in the letter. We would like to review it together as a collective learning practice here.

Under the HIPAA Privacy Rule, a public health authority is defined as an agency or authority of the US, the state, a territory, a political subdivision of a state or territory, or an Indian tribe, or a person or entity just like TEC acting under a grant of authority form or contract with such a public agency.

Just TECs and the ODTPHAs just like other public health authorities, they are responsible for public health matters as part of their official mandate. It is the same as the federal, state, and territorial local public health authorities.

And also as a public health authority, the HIPAA permits covered entities to disclose data, including identifiable data as reasonably necessary to TECs and ODTPHAs so they can do their public health functions.

Also, the covered entities can rely on the TECs and ODTPHA's reasonable representation of their legal authority and the needs for data. Basically, the other public health authorities should treat TECs and ODTPHAs as other public health authorities when they have data requests – should not put additional barriers or requirements for TECs and ODTPHAs.

In our last July meeting, we had a session on the tribal epidemiology centers and data access and privacy. That panel included broad representatives from the Tribal Health Board and TECs and the Government Accountability Office and IHS.

We heard through that panel that TECs continue to experience significant difficulty accessing their needed public health data from the federal, state, and local public health agencies as well as the health care providers, even during the pandemic time.

We also heard a very detailed presentation on March 2022 the Government Accountability Office report on this topic. Both GAO and HHS OIG reports confirm these challenges. They made the recommendation for those recommendations in Appendix A in the draft letter.

PARTICIPANT: Let me just say. The OIG is the Office of Inspector General in case people did not know that.

Wu Xu: Thank you.

During the public briefing, we heard a very strong voice from panelists. One panelist said I urge you to make recommendations to the secretary to take all of the recommendations that come out from GAO report. Every single one of those needs to be implemented. We need a timeline and the resources for that implementation to happen so that we can get access to the data that we need.

Although our discussion in that panel focused on the TECs, public health data access issue, we also learned that other designated tribal public health authorities also have the same legal authority to collect, receive, and disseminate public health data as necessary to do their work. They also experienced the same significant difficulty to access needed data. That is why in our draft letter we also included TECs and other designated tribal public health authorities in there.

The panelists during the public comment period, we also heard the federal, state, and local public health agencies are not aware of the legal authority of the data access by the TECs and the ODTPHAs.

This is the end of my very brief background introduction. Let me pass the presentation to Val.

Valerie Watzlaf: Thank you, Wu. And I also want to echo Wu's thanks to everyone also on the ad hoc group who helped bring these together today, the letter and the recommendations. We really appreciate all of your hard work on this.

On the next slide to begin, we wanted to give you some rationale for the recommendations. As noted by our panel members in the published articles and reports and the background that Wu provided, we do see some reports of some longstanding challenges to data access by the TECs and ODTPHAs that actually did contribute to delays and being able to respond to the COVID-19 public health emergency.

We also want to point out that the recommendations for this letter focused on data access. But we did discuss in great detail as a group that the TECs and ODTPHAs need in this second bullet meaningful, timely, and actionable public heath data in other areas as well, collection coverage and methods, data quality, data analysis, storage and use, and privacy requirements for data release. We are hoping that in the future, we could do additional letters of recommendations that could also include some of these areas.

Again, our focus for this one and today is on data access challenges. What we focused on was the timely access to public health data for the TECs and ODTPHAs, not just from federal authorities, but also state and local public health authorities and health care providers.

What we are going to do is I am going to read each one of the recommendations. I will pause then after each one of those and open it if there would be any discussion. You should have the draft letter in front of you and the recommendations are on page 4 and 5 of that draft letter, if you would like to follow on. And then if there is any discussion, please raise your button and we will make sure that we can get to any questions that you might have.

This is the beginning of – I just want to point out a couple of things here. We start off this way that based on the information provided to the committee by the expert panel, NCVHS concurs with and supports the GAO and OIG recommendations, noting though that these recommendations focus only on access by TECs to HHS public health data. Therefore, NCVHS makes the following five additional recommendations to HHS.

Recommendation 1 is to expand the December 2020 guidance regarding public health authorities under HIPAA to clarify that all AI and AN entities designated as public health authorities, including TECs and other designated tribal public health authorities, meet the definition of public health authority in 45 CFR 164.501 and should be able to access data on the same basis as any other public health entity so that they can carry out their mission to protect the public's health.

This guidance would clarify that covered entities may disclose protected health information or PHI for public health purposes without patient authorization to TECs and ODTPHAs as public health authorities under 45 CFR 164.512(b). The guidance should clarify that covered entities may rely upon TEC and ODTPHA minimum necessary determinations with respect to requested public health data, as they would with any other public health authority.

I just want to stop here. Are there any changes, any discussion around Recommendation 1?

Wu Xu: Sorry. I did not catch this when we drafted it. On line 2, "including TECs", we need to spell out TECs here because that is a formal recommendation.

Valerie Watzlaf: And I think, Maya, you are making – you are going to do this for us. I thank you.

Maya Bernstein: I am. In order for me to do that, I have to go out for a second and come back so that I can give you a non-video like a non-presentation version. Hang on one second. I can share again in a form that I can actually edit. Now you can see my editing version. Is it big enough for you to see?

Valerie Watzlaf: Yes. Any other discussion on this recommendation? I do not know if I am seeing everybody but if someone could let me know if they do have their hand up.

PARTICIPANT: They should rise to the top of your list of people.

Valerie Watzlaf: Great. Thank you.

We will move on to Recommendation 2. It is a little shorter. Given the importance of the GAO and OIG recommendations, prioritize their rapid implementation, determine any gaps in their implementation and develop a plan to fill those gaps to complete implementation quickly. Is there any discussion on this recommendation? Hearing none, I will move on then to Recommendation 3.

Lead a collaborative national effort to provide TECs and ODTPHAs timely access to all relevant public health data recognizing that their data needs are not limited to data provided by HHS Operating Divisions such as the CDC, IHS, CMS, et cetera. TECs and ODTPHAs have an urgent need for public health data from states, from local agencies, and health care providers to support and conduct public health in their territories. In its federal leadership capacity, HHS should identify constructive approaches such as distribute clear written guidance to make sure that all federal, state, and local public health agencies clearly understand that TECs and ODTPHAs are designated as public health authorities and should promote their unobstructed, timely access to authorized public health data.

Any discussion around this? Yes, Rich.

Rich Landen: I fixate on the word territories and thinking in terms of the urban Indian TEC particularly. Territories are okay. I do not want to nit-pick or wordsmith to death. But territories I think is not really

the word to circumscribe where the TECs and the ODTPHAs can be getting their data from. We do not want to limit it geographically. We want whatever their jurisdiction is.

Valerie Watzlaf: If we said territories and other jurisdictions --

Denise Chrysler: I typically say – with territories, I always worry about we have territories that are connected to the United States. I just usually use the word communities, although that has its imperfections also.

Valerie Watzlaf: Vickie.

Vickie Mays: I was going to say to conduct public health in their – use the words jurisdiction but that may be – people cross lines and all this other stuff. Instead, it may be better to just say conduct public health in their areas of responsibility.

Valerie Watzlaf: Is everyone okay with that? Areas of responsibilities?

Rebecca Hines: Is it area or jurisdiction?

Vickie Mays: Well, jurisdiction – it is almost like the same thing Denise was saying. Jurisdiction as a geographic boundary, and it is a defined boundary. The problem is that an American Indian can be in an urban area, living in LA, but has to go to Montana to get their tribal resources. It is who they are responsible for is actually I think a much better way to think about it because it is not geographic. It is relatedness.

Valerie Watzlaf: Rich, does that answer – are you okay then with areas of responsibility?

Rebecca Hines: I cannot help myself. What about having our cake and eating it too and saying communities and areas of responsibility. We do convey kind of --

Valerie Watzlaf: Denise.

Denise Chrysler: I was just going to say I am breaking my neck agreeing with Vickie. I like your addition, Rebecca.

Valerie Watzlaf: It would be communities in areas of responsibility.

Vickie.

Vickie Mays: I am struggling with communities because they do not use communities. They will use different terms. That is us. And if it works, fine. But I am just saying that is not how they – I am just not seeing the response use that.

Valerie Watzlaf: Denise.

Denise Chrysler: I often will say populations so that entity is responsible for but that is pretty textbook-y and public health-ish. But there are problems with communities because you may have a feel of responsibility for a community but we are really talking about a stronger link that you have obligations to see to the public health and it may be within a jurisdictional boundary of a tribe or it may be much

broader communities. But because of your responsibilities and your roles, you need this data to do what you need to do, what you are required to do.

Maya Bernstein: We could put obligation in there.

Vickie Mays: I think that is actually great is to have obligation and responsibility.

Valerie Watzlaf: I like that too.

Anyone not in agreement with that change?

Melissa Goldstein: Val, this is Melissa. I was going to say this is related. Could you read the recommendation again. I am sorry. I cannot see it right now.

Valerie Watzlaf: Yes. I can read that again. This is Recommendation 3. It says lead a collaborative national effort to provide TECs and ODTPHAs timely access to all relevant public heath data recognizing that their data needs are not limited to data provided by HHS Operating Divisions such as the CDC, IHS, CMS, et cetera. TECs and ODTPHAs have an urgent need for public health data from states, local agencies, and health care providers to support and conduct public health in their areas of obligation and responsibility. That was the change right there.

Melissa Goldstein: In the federal leadership capacity and then there was a little bit more.

Valerie Watzlaf: There is more. HHS should identify constructive approaches such as distribute clear written guidance to make sure that all federal, state, and local public health agencies clearly understand that TECs and ODTPHAs are designated as public health authorities, and should promote their unobstructed, timely access to authorized public health data.

Melissa Goldstein: This is a little bit of legal mumbo jumbo and I apologize. The Federal Government – I would say Federal Government to clarify instead to make sure because you are talking about providers and even if it would be a state law that requires providers to report. I would say to clarify instead to make sure.

Valerie Watzlaf: Okay.

Melissa Goldstein: But I would also say – I would change the word obligations to responsibilities. It is a slight nuance but I think it indicates we are talking about a responsibility. It may not necessarily be required by state law. Am I clear or am I all muddled?

Valerie Watzlaf: I see that. Is everyone okay if we remove obligation? It would be their areas of responsibility.

Melissa Goldstein: That indicates to me, quasi-legal/quasi-ethical. They are both there. That is the importance of the word responsibility as opposed to some of them have a legal obligation and some do not. But all of them have a responsibility.

Valerie Watzlaf: Right. We are getting some thumbs up and then we do have – go ahead, Maya.

Maya Bernstein: You are asking to remove the word obligation and keep responsibility or remove responsibility and keep obligation.

Melissa Goldstein: Keep responsibility. Remove obligation.

Rebecca Hines: Because obligation may or may not apply, depending on the state.

Melissa Goldstein: They all have a responsibility. It may be legal. It may be ethical. It may be both.

Valerie Watzlaf: Thank you.

And Vickie, is your hand up?

Vickie Mays: Before I do my other question, let me go back to what Melissa just said. Melissa, what is the objection to having both obligation and responsibility? There is an "and". It is not "or". I just want to understand why not both.

Melissa Goldstein: Because when you get beyond a federal designation and you are just talking state providers providing data, obligation to me indicates that we are talking about law. I would rather talk about law and. I can get a stronger to use responsibility honestly. I would rather use the stronger term because it does get complicated to – the public health authority as a federal designation versus a state designating. Its relative public health authorities and whether you are talking about a state agency. It just gets complicated.

Vickie Mays: This is Lawyer 201. I could do 101 someday.

Melissa Goldstein: That is why I prefaced it with mumbo jumbo.

Vickie Mays: No. Do not apologize. Protect us.

Melissa Goldstein: And there are people that – there are people – lawyers clearly do not all have one mind. I know that Denise and Maya and Jacki – you all have I am sure – but that is just my two cents that I thought I would add.

Vickie Mays: On line 2, I did not catch this before, but I would like to raise it. It says access to all relevant public health data. Maybe we should say access to all needed public health data because that was a problem that they actually had is what they wanted versus what they were given. Needed is maybe a little more of what we want. It is them – again, sovereignty is them determining as opposed to relevant allows for there to be some subjective assessment.

PARTICIPANT: That is interesting because I would have thought the opposite.

Melissa Goldstein: It gets a little bit complicated too because of the definition of minimum necessary and who defines what is minimum necessary so the word needs. Public health authorities may need or think they need data that is not necessarily required to be reported to them. It gets complicated. I just would want to add that into the considerations.

Vickie Mays: But if you think about sovereignty, do they not get to request what they think they need as opposed to those definitions being applied. It was really that – I am trying to make sure that we have

that respectful – it is a government-to-government kind of interaction as opposed to there is one top-down asking the other.

Valerie Watzlaf: Denise just in what about essential, essential public health data.

Rebecca Hines: Essential to public health. Data essential to public health.

Melissa Goldstein: I like that.

Maya Bernstein: It seems like it is narrowing to me. What if it is not essential but they want it?

Rebecca Hines: And that is what we heard is that they were being second guessed and that is why we used relevant. I actually think the word needed gets at what we heard from the expert panel.

Melissa Goldstein: But the problem is that it is not a legal requirement that states report that – a state legal requirement. Do you see? All public health agencies might believe they need or want data that is not required that providers actually give it to them. Providers still – it is permissible for providers to report it. Unless it is required by law, there is no requirement to report it. Do you see? There is always going to be at some level attention there.

Valerie Watzlaf: What word would you want to use or did you give us a word?

Melissa Goldstein: Well, the word essential – they can ask for it. Let us think about perhaps not race and ethnicity. Think about disability data. Not all state statutes require reporting of disability data or language preference data, things like that. To change that, the state would have to change its state law to require a provider to provide it. But then a provider also has to want to require it. The provider could always choose not to if it is not required by state law. They might even choose not to – if it is required, of course, then they are not following state law. But if you are asking for providers to give the data too and you are asking it out of respect – sovereignty – which I absolutely agree, Vickie. I just want to be clear that what is required, what is not required but is essential, what is important, all of those things. That was my thought there.

Valerie Watzlaf: Okay.

Maya.

Maya Bernstein: Just to remind the committee members that HIPAA – as Melissa is absolutely correct, HIPAA permits but does not require a disclosure to a public health authority, but it permits the covered entity who is considering such a disclosure to rely on the representation of the requesting entity. For example, the tribe or the epidemiology center or whatever so that whatever they present is what they are requesting. A covered entity can rely on that request without going afoul of HIPAA. That is mostly what they are concerned about in these disclosures most of the time. They might have other reasons not to disclose. But most of the time, they just do not want to be in violation of HIPAA and they are afraid of disclosing. But it is important to recognize that they are allowed to rely on the representation of the requesting entity if it is a legit public health authority as to what they need. I do not want to limit what they might say in your recommendation, what they might ask for because my understanding of what the committee wants is for it to be broad.

Melissa cannot see. I have put a bunch of suggested words that have been in the discussion. All relevant or desired or necessary or requested or essential or needed. Those are all words you might consider.

Valerie Watzlaf: Rebecca has her hand up too.

Rebecca Hines: It is about the other edit and I think we need resolution on this one.

Maya Bernstein: If we are on this one – I put parentheses or brackets around everything that we are talking about. You will see that I put brackets around the things that have been questioned so that we are reminded to get through them. If you want to settle on this one first then I will make sure to get to those. Thanks for the reminder, Rebecca.

Valerie Watzlaf: Denise Love has her hand up.

Denise Love: I would avoid desired. Just from a political standpoint, I would take that out. The others – okay with.

Rebecca Hines: I think early in the conversation, we went from relevant to needed and I think needed is what I heard. I think given Maya's clarification, I think needed gets us to where we I think intend to be.

Debra Strickland: I like relevant needed. Can we keep them both? Relevant and then needed so that it covers – the needed covers what they need. And needed covers necessary and requested and essential.

Maya Bernstein: -- it is just like a typical lawyer kind of language that people understand what kind of what that means, our standards for what does it mean to be relevant and necessary.

Rich Landen: Love the discussion but this is a common headache of editing as a group. As we fix one thing, we inadvertently stumble into other things we have not through yet. My observation is that we need to stay high level here. We, as NCVHS, are not proposing a solution down at the technical level. We are at the thought leadership level. If we can avoid splitting these hairs, we should. Let me throw out that we scrap everything in those parentheses, the relevant, the necessary, requested, essential, and needed and then delete the all that precedes the opening parenthesis so it would read provide timely access to public health data. Solutions we are recommending. We are already recognized in the first two – one of the first two recommendations and that refers to the OIG and the other studies there. It is not our solution. We do not own that but we are encouraging the secretary to implement details identified by others.

Valerie Watzlaf: Thank you.

Vickie has her hand up. You are getting some thumbs up, Rich, too.

Vickie Mays: That really concerns me for lots of reasons. One, in terms of what we have heard is needed. I think this kind of sentence is what is already in some of the reports, and it is not going anywhere. I think it is not going anywhere because the issue of an urgency, a necessity in order to solve – well, in this instance it will solve COVID, is not as clear.

How do I say this? This set of recommendations was based on problems that were brought to us that we heard and that we were aware of. I think when it comes to data issues, we speak with a different kind of authority than others. I think using some modifier because here are some of the problems, the issue of

data being collected around tribal affiliations. Sometimes that is not there. They end up knowing what their tribal affiliation people are and will define what is needed and a state may not have the tribal affiliation but is able to produce data on that person. There are a lot of complexities here that I think necessary or needed helps to cover.

Valerie Watzlaf: And you do not see that included just by saying timely access to public health data?

Vickie Mays: No, because I think that that is what has been done in the past and it has not respected – this is why we have the problem is that – I will not call names but it is like certain federal agencies did not think that that data was necessarily what would help and a judgment was made. We are trying to really make sure we respect sovereignty, which means it is government-to-government, so you have a government saying this is what is necessary in my eyes to deal with this health issue.

I think it is different than what we are usually used to doing. For example, things like in race and ethnicity, it was not there, and it was okay to go ahead. They are saying things because of the way people are clustered in this small group is not okay to make recommendations and not think about that. If you cannot think about it then give them the ability to be able to handle the problem and they know what they need in order to be able to do that.

Wu Xu: I want to echo Vickie's comment. If we do not have added needs there, the reason is this is federal leadership for a collective national effort, not only give data access. Also, you need – collect, need the data. A lot of states do not have good information on the race and ethnicity. If they just say I open data for you but I do not have your needed dat. That is why I feel when we put needed there as an effort to give states in all directions and support them to collect the Native Indians' needed data. That is why I feel – from legal perspective is from data complete needs perspective.

Valerie Watzlaf: We could use just needed. Would everyone be okay? I think that was what Melissa though brought up with the state issue if we use needed.

Rich has his hand up.

Rich Landen: I would not object to needed but I went back and looked at it. I think the point we are discussing here is actually something we already addressed and had language on in Recommendation Number 1. Recommendation 3 goes more to the effort to provide access rather than answering the question of access to what. I think that access to what question we already resolved in Recommendation Number 1. That reads access data on the same basis as any other public health entity.

Valerie Watzlaf: We have a comment in the chat. Needed is the word I used in my public health work. It ties to minimum necessary. I think Denise Chrysler said that. I believe that Recommendation 3 is really – if we could have that back.

Rebecca Hines: I am hearing an overwhelming support for saying all needed public health data. Melissa, is that acceptable to you, given the conversation?

Melissa Goldstein: There is a context that I believe we have to recognize and it would be better to recognize it in our recommendations that the Federal Government has not control. They can lead and they can persuade and we can use our "bully pulpit" but it would be state laws that would have to require that of providers so at any public health entity whether it is a tribal epidemiological agency or any other. CDC can request it and say they need it but unless it is required by law, there is no way to

demand it. You can say needed and I think that is just fine, but there is a lot of nuances there that maybe –

I actually liked Rich's statement of just saying public health data. I think we express in Recommendation 1 that they are not getting it and this is what they need to be able to function and to work with their populations. I am not going to object to the letter on behalf of that one word. I do think it is important to recognize the nuance. If there is a footnote or something that we can add somewhere about the minimum necessary, if you all think it is appropriate, Maya, perhaps that is helpful. That is what I would suggest.

Maya Bernstein: Val asked to do it this way. But we could look at the recommendations in the context of the letter. Then I can add a footnote or a note that we need a footnote there.

Melissa Goldstein: I am sorry that I am not able to see it right now because I am on my way to class. That day job. Is this letter presented with the appendix with the details is the same way. Okay.

Maya Bernstein: No, it is not. That is not right. The only appendices that are planned to be in the letter are a list of recommendations. The letter itself has quite a lot of exposition if that is what you are asking, Melissa. That discussion is in there. The only appendices were a list of recommendations from GAO and OIG.

Rebecca Hines: No, that is out. That is out, Maya. There is a whole background and rationale. There is a three-and-a-half-page appendix.

Valerie Watzlaf: There are two appendices, the A and the B.

Rebecca Hines: We are going to get rid of Appendix A per your suggestion, and then there is a three-and-a-half-page appendix that goes through the background and rationale with footnotes.

Maya Bernstein: No. That is not right. That is not the letter that I circulated.

Rebecca Hines: It isn't?

Maya Bernstein: No.

Rebecca Hines: I guess I have the wrong one.

Maya Bernstein: Appendix B was added material that was part of the discussion. I am getting a nod from Vickie. That was part of the discussion that was taken out and is not ready for – unless a member decides that it is for some reason compelling, we can put it back into the exposition. But for this letter, the recommendations and the discussion of them are all in the letter.

Rebecca Hines: It is still there, Maya.

Maya Bernstein: I know it is still there but you see my cover note in the email is not intended to be in there unless you want to pluck up something from there. That Appendix B is not ready to be presented to anyone. It is just for us to discuss. If you found something in there – because these were materials that were taken out of the letter as being too detailed. However, if there is something in there that a

member wants to put back into the exposition, we can do that. There are, for example, quotes in there that might be useful or other material.

Vickie, I am doing too much talking. Can you talk to this?

Vickie Mays: In the email, what she asked is that if members would look at B, not to be the appendix, but to look at B to see if there is anything in it that they wanted to put back in because it had some very powerful quotes and things like that. At this point, it is not ready and should not be considered that it will go. But instead, it can be used in the exposition. Whether we get comments today or not we could still take things from it to put in the exposition not in terms of the recommendations.

Maya Bernstein: I am sure I confused Rebecca because between the time that we had the discussion that I thought it was very odd to put in the GAO and OIG recommendations, we copied their cover page in their own format. I just listed them so that we could refer to them. And I did actually keep them in there. It is up to the committee if you want to do that but just for reference, I just simply listed them, and I said, which is true, that HHS agreed with the recommendations from GAO and CDC. Also agreed that those two recommendations from the OIG to them. But other than that, just the text.

Valerie Watzlaf: Could we at least get through these because the recommendations are things that cannot change. We get to vote on these today. These cannot be changed. If we could get through these today -

Rebecca Hines: We are close.

Valerie Watzlaf: -there is only five.

Rebecca Hines: I would like to say that we have been given a little cue from the public that – and it is in spirit of what we heard in July's briefing, that this overall recommendation is basically a request for national leadership. It is not legal. It is not binding. It is a request for national leadership. And really what we heard is that tribal entities were requesting data and being denied. That is really the spirit of what this – of the intended spirit is.

Of course, Melissa, legally, there are things that do not have to happen. But the question is what should happen rightly so. The first recommendation puts forward the legal aspect. Now, this recommendation is not legalistic. It is more tactical, saying we do need some kind of leadership to kind of point the way, which gets me to the other edit that was suggested that said to clarify. The point was it was not that clarification was needed. People had the clarity. They were just choosing basically not to follow through on data requests. The whole point was to suggest to HHS to employ a constructive approach to ensure, make sure, whatever the word is, that public health agencies that are not federal but including federal, state, and local, understand that the designation of these entities and that they should have unobstructed and timely access.

My request is that you all consider getting away from the legalistic on this particular recommendation because the spirit of it is basically tactical for national leadership to move things out of their stuck place.

Maya Bernstein: I think it is just hard for Melissa to recall exactly what the language is because she is on the phone.

Melissa Goldstein: No, I understand exactly. Thank you. If the point is national leadership, then why don't we just focus on national leadership like Rich said, and call it public health data?

Maya Bernstein: The beginning of this recommendation says lead a collaborative national effort.

Melissa Goldstein: The recommendation already sounds like it is – honestly, it is long, the recommendation language itself. I would shorten it the way that Rich did, which sounded ideal to me.

No matter how much leadership the federal government does, a public health agency can still put in a data request, and if it is not required by law, they can get the answer no. That is going to remain the same. I do think we have to acknowledge that. Whether or not you want to focus on the law or not, we are held by the law just like everybody else.

Valerie Watzlaf: Vickie has her hand up too. Thank you, Melissa.

Vickie Mays: I want to embrace what Melissa is saying but in a different way. Let us go back to why this is necessary, why we are actually doing this. Some of that has to do with the fact that we do have under way in the Biden Administration these executive orders around health equity. There may be times at which a state is not collecting something that this group thinks it needs. If we only do what we currently have in the law, we do not get to see nor to encourage states to expand what their collection is.

The Federal Government cannot mandate unless it is something that they are willing to fund or to change the laws, et cetera. But I think if we do not say needed then we do not get to what is the ideal set of data that is needed to equitably address an epidemic. A state does have a responsibility to equitably address epidemics but may not have much guidance about how to do that.

I think in this collaborative leadership that the feds would do, it would be about what the needs are and coming to some sense of what those needs are and some states will meet it. Some states will not. That is like in the report card, the article that I had where we talked about what some states need and others do not. But if you are never brought aware then there is a problem about ever reaching equity.

I think that the issue of the legal part is probably a footnote or exposition to talk about it. But I think the goal, which is aspirational, is what is in the recommendation. I'm off my soap box.

Valerie Watzlaf: Thank you. We could put a footnote, which I think – you were going to do that, right, Maya? I think you wanted to get to the letter. We could go to the letter. We will probably then say we will do a footnote so it will just then say, to all public health data or no?

Vickie Mays: That is not what I said. I am saying do both. I am saying leave needed or requested in there and then an explanation of why it is there and that we recognize that that is like a demand on the state that a state may or may not have the capacity to fulfill.

Melissa Goldstein: You could even say encouragement for the states, Vickie.

Jacki Monson: -- to some of what has been raised. Maya, I think we should bring up the full letter so we have the full picture, making edits in it.

Wu Xu: There is a question in the – from public.

Valerie Watzlaf: In the chat?

Wu Xu: No. In the Q&A.

Maya Bernstein: In the Q&A, I'd like to draw your attention to that too. If it is okay with you, Val, I will go to the letter as Jacki asked me to.

Valerie Watzlaf: The question in the Q&A is --

Rebecca Hines: That was what I raised about was getting it what we heard in July, which is what the tribal entities were doing was requesting data and being denied so in the spirit of what we heard, using the word request, data that is requested.

Valerie Watzlaf: I think we will have then – well, let us wait. We can pull up the letter and go from there then. The recommendations are on page 4 and 5 of the letter. If you have it.

Vickie Mays: Can I just comment on the comment in the Q&A because maybe I am not understanding it as well because needed is about – it is not needed that goes directly to the state. It is needed that the Federal Government is having this discussion about in collaboration with the states. That is my understanding that what we are talking about is is it needed. It is like you have let us say some high-level meeting going on. They talk about what is needed. States talk about what their issues are.

At the end of it, the Federal Government would have some set of guidance in which it would say what it wants or what it encourages states to do in order to deal with this public health emergency or epidemic or whatever it is.

Maya Bernstein: I think the problem is who gets to decide what is needed, right?

Valerie Watzlaf: That is a good point that Rebecca made. I saw that too. Need is already in the sentence. Maybe it is requested. Need is later. See data needs are a little bit later there.

Rebecca Hines: Correct. The sentence already says recognizing that their data needs are not limited to data provided by HHS. Need continues again in that sentence.

Valerie Watzlaf: I have it twice actually, if we keep needed. This is the original so where we had relevant.

Maya Bernstein: So you were talking about putting –

Valerie Watzlaf: Maybe requested there rather than needed since we have data needs later.

Rebecca Hines: What do other members think about using the word requested? What is the general sense on that? Does that get at what we heard in the spirit of this recommendation?

Wu Xu: From the state data policy perspective, we will get nervous because a lot of requests for data we do not have so we cannot have timely access.

Valerie Watzlaf: From the state perspective you said, Wu.

Wu Xu: Yes. Rich has his hand up, too.

Rich Landen: I am okay with requested, assuming we are following through with that footnote that really talks about our discretion is we are not the arbiter of all the complex rules around the relationships between the federal, state, territorial, tribal entities.

Valerie Watzlaf: I think we are going to include the footnote. Thank you, Rich.

Tammy.

Tammy Banks: I was just going to echo as long as you have the footnote with the minimum necessary because I do not think we are saying all requested data. It is all requested data according to the appropriate regulations.

Valerie Watzlaf: Thank you, Maya. Thanks, Tammy.

Maya Bernstein: The point of that is that covered entities are supposed to disclose the minimum necessary, but they are also allowed, as I said before, to rely on what the tribes say is the minimum that they need. That is in the rule and the guidance.

Melissa Goldstein: They can rely on it. They are not required to.

Maya Bernstein: Yes. Right.

Valerie Watzlaf: Are you able to go back up to the recommendation, Maya, in the letter?

Maya Bernstein: Is that big enough for everyone to see?

Rebecca Hines: You could make it maybe 10 percent bigger.

Maya Bernstein: I'm trying to put in if we had any comments so you could see those too. How is that?

Rebecca Hines: So is our conclusion then timely access to all requested public health data?

Valerie Watzlaf: Yes, as long as we have the footnote. Correct? Good. Okay.

Rebecca Hines: My hand was up because of the second part of that. There was a suggested edit to clarify that all federal and again, fourth one from the bottom, Maya. What we heard was to basically – it was more of not to clarify but to actually ensure. It was make sure is what we heard. The question is do we really want to change the language of this since that is what we heard. I just want to remind everybody about that conversation we had in July.

Melissa Goldstein: The Federal Government can't insurance.

Rebecca Hines: No. It is to make sure that all federal, state, and local agencies understand. Again, it is –

Melissa Goldstein: How are you going to make sure about that like literally?

Rebecca Hines: By issuing –

Melissa Goldstein: You could clarify to them – you cannot make sure they understand it.

Maya Bernstein: But the sentence also does not read correctly with the word clarify because you cannot clarify that they understand. You cannot prove that anyone understands anything.

Melissa Goldstein: No, you are clarifying that. You take out the part about understanding. You take out make sure they understand that, and you say to clarify that.

Vickie Mays: Here is what we do because it really was about making sure there was something. It is the something that we should focus on and not their mind because it is about a piece of paper that is a practice, is really what it is.

Maybe what we want to say is make sure that all federal, state, and local public health agencies or entities. I do not know if it is just agencies or whether it is entities, are aware through guidance and policies, and then go on from that.

Valerie Watzlaf: Is Maya there?

Maya Bernstein: I am here.

Valerie Watzlaf: Did you hear that? Where would that –

Vickie Mays: Okay, make sure that all federal, state, and local public health – I do not know if it is agencies or entities. All public entities – now, I lost what the way I did it – local health and public health entities are made aware and provided guidance and practices – I do not know which – this is where the lawyers -practices, policies, or something.

Valerie Watzlaf: Then we would have to remove the other in the parentheses, distribute clear written guidance there.

Vickie Mays: No, -- written guidance is – I do not know if it is too narrow. We are in a different age now. I do not know if that is too narrow.

Maya Bernstein: What it says in the beginning is it identified constructive approaches. That could be anything. I do not think we need to specify them if you want to allow the department to decide collaboratively and that is what we said at the beginning, with the TECs and the other tribal agencies how best to present this material. It could be written guidance. As an example, it could be.

Vickie Mays: I just moved that as an example because the Federal Government has a tendency to throw stuff up on websites. Some of the groups will tell you that they do not have that capacity. Anyway, I would leave that.

Valerie Watzlaf: We are getting some comments in the chat. Current language is fine. Too much wordsmithing. A lot of people are okay with this.

Tammy.

Tammy Banks: I just need a little clarity, Vickie. These entities are already designated public health authorities and they have the right to this information.

Correct? In this sentence, we are just trying to say that there needs to be additional guidance written so that it is honored. Is that where we are going?

Valerie Watzlaf: Correct. I answered for Vickie, but go ahead Vickie.

Vickie Mays: The entities are federal, state, and local. The entities are not the TECs and ODTPHA – we are talking about the people that we want to know that these groups have the right or access to this.

Tammy Banks: This is where we want additional written guidance to ensure that they are able to get this information, right. I think making them known is something we cannot make sure of. But what the action is create more guidance to ensure they get the information. I do not know if you want to take that little bit out for clarity.

Maya Bernstein: Which part do you want me to take out? Can you see what is here? I was thinking about – in the discussion, I was thinking about Melissa's concern about the term make sure, and looking for something else that would give the idea that you are talking about like you want to promote that or you want to --

Vickie Mays: I think it is stronger than that because, for example, you can promote. It is up on a website. A person goes to talk to someone. They have nothing to give. I remember, I guess it was Denise Love talking about how we found this. You give them this. I do not that promote is it. The Federal Government has the responsibility I think, to ensure that there is clear guidance somewhere that can be utilized to make sure that these processes take place.

Rebecca Hines: And that is what your current language says. That is what this says, to make sure that all of these agencies clearly understand that TECs are designated as public authorities and that these entities should promote unobstructed, timely access to authorized public health data. You actually have here everything you all just said. It is right there in black and white.

Maya Bernstein: I think the idea was that you did not want to limit it to written guidance or just guidance, but it could be – example.

(Simultaneous comments)

Valerie Watzlaf: In the interest of time too, I do not know when we are – we are at a break at 1:45. We do have a couple more to go through. Are you okay because I think I am hearing from some that you are okay with the language the way it is? Can we live with the language the way it is here?

Vickie Mays: My only thing was is it just public health agencies or public health entities?

Maya Bernstein: I change that, didn't I? Sorry. I lost it. We could add public outreach as an example just so it is clear that you do not just mean – is that okay with people? I am seeing some nods.

Denise has her hand up.

Denise Love: I could really throw a bomb here. I do not like the word promote. I am saying comply or honor.

Vickie Mays: We took it out.

Denise Love: No. It is down below – promote their unobstructed, timely – I am a former regulator. I would say that they need to comply but maybe it is --

Maya Bernstein: But we cannot make the states do anything. We are talking to state and local entities. The Federal Government cannot make them do anything.

Rebecca Hines: Melissa put out 15 minutes ago, the word encourage.

Melissa Goldstein: Encourage is good. Comply is not good when they are not required to do anything.

Committee Member: It currently says promote.

Denise Love: How about honor?

Melissa Goldstein: Promote is good. Honor is good. Respect –

Vickie Mays: Honor then.

Rebecca Hines: We are going to have to take a vote on exact language. Can we all come to some consensus? Is it promote, encourage, honor, or respect?

Melissa Golddstein: It sounds like marriage vows.

(Laughter)

Valerie Watzlaf: How about honor? I like honor. How about honor their unobstructed timely access. Anybody against honor? Can we remove that then, Maya? Just put honor.

Maya Bernstein: Honor. It might not be really doing it.

Rebecca Hines: It does not make sense. I do not actually think grammatically it works. I think encourage – if Denise says promote is not doable, then --

Vickie Mays: I like facilitate.

Jacki Monson: What about support?

Vickie Mays: No. Facilitate. Like it or not is one thing, but if they facilitate it, then I think that will achieve the goal we are pushing for.

Rebecca Hines: I think we got it.

Maya Bernstein: I do not understand what Denise is -- I thought Denise backed off on her objection to promote.

Denise Love: I had a problem with it just because it seems to me – we promote a lot of things that we do not follow through with.

Rebecca Hines: I think facilitate alone – I think this is what everyone is good with and we have got it.

Valerie Watzlaf: Would you like me to read it again?

Rebecca Hines: Yes, please.

Valeria Watzlaf: Lead a collaborative national effort to provide TECs and ODTPHAs timely access to all requested public heath data recognizing that their data needs are not limited to data provided by HHS Operating Divisions (CDC, IHS, CMS, et cetera). There is a footnote in relation to requested. TECs and ODTPHAs have an urgent need for public health data from states, local agencies, and health care providers to support and conduct public health in their territories. In its federal leadership capacity, HHS should identify constructive approaches such as distribute clear written guidance and public outreach, to make sure that all federal, state, and local public health entities clearly understand that TECs and ODTPHAs are designated as public health authorities and should facilitate their unobstructed, timely access to authorized public health data.

Melissa Goldstein: I still do not like make sure that. I can try.

Valerie Watzlaf: Can you live with it?

Melissa Goldstein: Not really. I am sorry. You can give notice. You can instruct. You can help. I can teach all I want. I cannot make sure they understand me or do anything. I cannot ensure it. Ensure means the same thing as make sure. You can clarify it to them. You can work with them. You can support them. You can give them technical assistance. You can try as hard as you can. Negotiate, coordinate. We are asking them to do the undoable if we say make sure that.

Valerie Watzlaf: Is there a comment on what we could put in instead of make sure again? Go ahead, Tammy.

Tammy Banks: Could you just put that and struck it out and just say exactly what they are reinforcing. So it is written public outreach that the TEC/ODTPHAs are designated as public health authorities and should facilitate. And just get rid of the clearly understand because that is the outcome of what we are asking them to do.

Rebecca Hines: That is great. Get rid of to make sure that all federal, state, and local public health entities clearly understand.

Tammy Banks: No. Unless you want to add a sentence at the end with those entities. That is an outcome. It is not an action.

Valerie Watzlaf: But that is such an important part that we heard over and over again.

Vickie Mays: How about HHS should identify constructive approaches, the e.g. is there, to instruct all federal – dah, dah, dah, dah, that - so take “make sure” and put “instruct”. Take “that” out and local public health entities clearly understand --

Rebecca Hines: Just get out understand. Just instruct all of these agencies that TECs are designated. There you go. You got it.

Vickie Mays: One more. Let us make sure that the territories – we do the same thing we did in the other one. Look up above – to support – in their territories. Can we just use what we used before?

Rebecca Hines: What is on the slide, Maya, that we used in place of territories? Was it areas?

Wu Xu: Areas.

Vickie Mays: Whatever that is. Exactly. Okay. I am done.

Maya Bernstein: If I switch to my slides, can you see them? Where was that?

Rebecca Hines: It was one.

Valerie Watzlaf: I think it is one.

Vickie Mays: Try another slide. I think it is here.

Maya Bernstein: In their areas of responsibility?

Valerie Watzlaf: Yes, we settled on responsibility.

Do we have this correct in the letter as well? I just want to make sure we are – because this is different.

Maya Bernstein: Trying to do it in one place so I would have one record. But I also have Grace in the background who is keeping track of what we decide.

Valerie Watzlaf: I think you do have it correct in the letter. I do not know that it is picking up all the changes here. Are we okay with 3? Do you need me to read it again or you are okay?

Rebecca Hines: Why don't you read that last sentence – in its federal leadership capacity?

Valerie Watzlaf: In its federal leadership capacity, HHS should identify constructive approaches such as distribute clear written guidance, public outreach to instruct all federal, state, and local public health entities that TECs and ODTPHAs are designated as public health authorities and should facilitate their unobstructed, timely access to authorize public health data.

Good? Anybody see any changes? We are getting some applause? Okay.

Maya Bernstein: The sentence reads funny if you say in its federal leadership capacity, HHS should identify constructive approaches to instruct and should facilitate. That is kind of what it would say without all the extra.

Rebecca Hines: In order to facilitate. Is that what you are saying?

Maya Bernstein: I guess it works. I just want to --

Denise Chrysler: To facilitate.

Rebecca Hines: I think "and should" could be to or in order to facilitate in the second to the last line.

Tammy Banks: Facilitate is in relationship to the -- federal, state, and local public health is not to HHS.

Rebecca Hines: No. It is actually to facilitate the TECs unobstructed, timely access to authorize. Maya, if you go to the last line where it says facilitate, instead of saying "and should facilitate", Denise Chrysler said to facilitate.

PARTICIPANT: You want this to say to facilitate?

PARTICIPANT: Or in order to facilitate, if that works better with the rest of the sentence?

Maya Bernstein: Constructive approaches to instruct in order to facilitate or to facilitate actually is better.

PARTICIPANT: It is long and it works.

Maya Bernstein: I am going to show you what it now looks like.

Valerie Watzlaf: Thank you. The last sentence. In its federal leadership capacity, HHS should identify constructive approaches such as distribute clear written guidance, public outreach, to instruct all federal, state, and local public health entities that TECs and ODTPHAs are designated as public health authorities to facilitate their unobstructed, timely access to authorize public health data.

Vickie Mays: But I think that in order than makes it –

Valerie Watzlaf: In order to?

Vickie Mays: Yes. Maya, are you okay?

Valerie Watzlaf: She got it. Everyone okay with that one?

We will move on to Recommendation 4. Thank you for your feedback. Four says investigate and determine the infrastructure, communication, and personnel needs necessary to improve TEC/ODTPHAs' data exchange systems, data modernization needs, and other data infrastructure capacity for a timely and quality response in meeting the public health data and surveillance requirements for AI and AN populations. This could include disseminating explanatory information to state and local public health agencies, facilitating the development of common templates for data sharing agreements, and providing consultation or technical assistance for specific data sharing issues.

Any discussion on Recommendation 4?

Melissa Goldstein: The only thing I would add is this could include, for example, because there are other things that might include.

Valerie Watzlaf: Do you see where that is, Maya, after the footnote. This could include, for example.

Maya Bernstein: I see. I just think includes means example.

Melissa Goldstein: You could say but not limited to.

Maya Bernstein: Lawyers say that. It drives me crazy I have to admit. Include means it is not everything.

Rich Landen: We have a footnote 22 there. Can we just briefly see what the footnote is?

Maya Bernstein: It says there is a suggestion somewhere that is not in the text – suggestion to look at the --

Rebecca Hines: No. Actually, the footnote is in the version that was distributed. It is the best practices.

PARTICIPANT: Footnote 23.

Rebecca Hines: It is best practices for American Indian and Alaska Native data collection and there is link to the UIHI.

Maya Bernstein: That is in the discussion, which is down here.

Rebecca Hines: The footnotes are off because of the editing or maybe it is supposed to be used twice.

Maya Bernstein: There is no footnote in the – there is no footnote here. That was a suggestion. The footnote is correctly over here where we are talking about Urban Indian Health Institute, which recommends its best practices. The footnote for that part of the discussion links to the best practices document that comes in the exposition. There is not supposed to be a footnote in the recommendation itself. It was just a backup note that was leftover.

Valerie Watzlaf: Any other discussion on Recommendation 4?

Maya Bernstein: It does lead me to a question, which I hope does not throw a stick in the spokes, which is this footnote that you want to add into the recommendation for number three has not been drafted yet. It is just going to say what the HIPAA rule says about minimum necessary and so forth. Are you guys okay with that? It is going to be factual. Thank you. Do not make me nervous.

This now just looks like this.

Valerie Watzlaf: We just added "for example" and then – in the last sentence.

And then the last recommendation is to identify and publicize a process within HHS from which TECs and ODTPHAs can seek redress should barriers arise for the timely access of such data.

Rich has his hand up.

Rich Landen: I apologize. Can we use through which instead of from which?

Valerie Watzlaf: Through which. Thank you. Yes.

Rich Landen: -- something from a process.

Valeria Watzlaf. Good comment change.

Any other comments?

We have gone through all of the recommendations. I am not sure – is there any interest in going through the text of the letter or do we vote on the – can we have a motion to vote on the approval of the recommendations?

Maya Bernstein: You have some time. I would like to see if anyone had any comments about the rest of the letter.

Valerie Watzlaf: I know we did not receive any from you. But if anyone does have any comments from the letter, we could address those now. None. We have a comment in the chat. Rich just said good recommendations. Thank you.

I guess we need a motion to approve the recommendations. Would someone like to do that?

Wu Xu: I make motion to approve those recommendations.

Rich Landen: Second.

Valerie Watzlaf: All in favor, please raise your hands.

Rebecca Hines: Maya, can you unshare your screen so I can – one, two, three, four, five, six, seven, eight – eleven. Margaret, are you a yes? Okay. Margaret says yes. That is unanimous, 12 out of 12 members approving the five recommendations with the edits just implemented on Maya's version of the document. Congratulations with three minutes to spare.

Maya Bernstein: You might want to make a program note about later this afternoon.

Rebecca Hines: That is a good point. For those who are on, we are now headed into a break and this afternoon right now there is a half an hour for the Report to Congress and a half an hour to revisit the letter. I am imagining we might actually need more than half an hour for the Report to Congress. But for those who are interested in public comment, it could very easily end up earlier because we do not need an extra half hour for the tribal epidemiology centers. Although, again, we might need more than 30 minutes for the Report to Congress. Thank you, Maya. Good point.

Jacki Monson: We are scheduled to be back at what time, Rebecca?

Rebecca Hines: 2:15 Eastern. Please do not log out if you do not mind, or just log in early before 2:15 so we can get started on time.

Jacki Monson: We will see everybody at 2:15. Again, congratulations in getting the recommendations done.

(Break)

Subcommittee on Standards

Jacki Monson: Welcome back, everyone. We are going to kick off what feels like almost afternoon for me in California, the Standards Subcommittee. So I am going to turn it over to Tammy, Rich, and Denise.

Denise Love: Okay. Thank you, all. What I will do is update the committee on the Standards Subcommittee work. I will refresh your memories on the Convergence 2.0 update. You have heard this information before but I think it is a good to level set and bring that up again so it will set the ground for what is going forward.

I will do part of this and then Tammy will give you a preview of what the next six months might be looking like in the Standard Subcommittee world. As we meet today, there are even new NPRMs in play or proposed rules with the F6 pharmacy rule and yesterday a proposed rule for prior authorization. A lot will be happening. But first – and then ICD-11 will be covered in the next session.

Let me just say a few words about Convergence. You have heard a lot about it. You may already know this, but I felt like before we went on, I would just do a quick refresher. And Rich and Tammy and my wonderful subcommittee, anybody can jump in if I miss something.

But the Convergence 2.0 is really the framework or the structure for the committee's work for two years. The scoping document is titled Burden Reduction and Post-Pandemic America. It is really a work plan that was informed by the June 2022 listening session and written comments at that time. And it also builds on the previous Standards Subcommittee work.

The Convergence document is geared towards actionable recommendations around the HIPAA ecosystem, the regulatory aspects, standards, harmonization across data sources, data exchange, and of course privacy and security issues. There is some overlap with the Privacy Subcommittee as we move forward on some of these issues.

The Convergence 2.0 recognizes that technologies, use cases, and health care delivery have evolved and that the workplan should highlight and does highlight opportunities for the standards and supporting structures to advance as well.

Year 1 or Phase 1 of Convergence, as you recall, was dedicated to assessment, gathering information from stakeholders, and really laying out what the standards landscape looked like in 2021.

And Phase 2 now is looking at data needs and standards across sectors and data sources, including social determinants.

I will quickly go over this current work and then Tammy will brief you on the fun that we are all looking forward to as the new standards proposals and updates have come forward and request. Convergence 2.0 really is branching out and the first accomplishment or task that was involved or one of them was the Joint Electronic Prior Authorization RFI Task Force and our wonderful committee members, Tammy served as co-chair and Rich Landon and Deb Strickland participated as members to develop an RFI, request for information, in response to ONC's electronic prior authorization request. The responses are due I believe March 10, 2022. That is active right now.

Some of you participated in the June 2022 subcommittee listening session where we had industry stakeholder roundtable discussions and topics related to the adoption of HIPAA standards and discussion of new drivers in health care data exchange. This resulted in a letter to HHS, which I will review in a moment with some recommendations that you all participated in and we carefully wordsmith on that one if you recall.

Another exciting aspect of standards that has really been helpful to me and I know the other committee members has been we have established regular committee engagement with leadership from the ONC, Office of National Coordinator, and the Office of Burden Reduction and Health Informatics at CMS. It has really helped educate me how the system works, how we are all needing to work together and these folks are the implementers, the conveners, and thought leaders. We all can pull together to get to the next level.

You have seen these before. I am just reviewing. These were recommendations sent in a letter to HHS in June 2022, I believe. If you recall, the subcommittee went through dozens of comments and letters and input and really there was a whole list of dozens of potential recommendations but the subcommittee chose four that we felt were priorities and that had good consensus among the subcommittee. These were actionable and seemed the most pressing and intended to improve health data flows and HIPAA transaction standards in some sort of alignment or configuration that led to efficiency and relevance to new business cases.

These four recommendations are on the slide. There are other long-term recommendations you will hear about later in the next year or so. They are not lost but they need some work as far as some of the recommendations or input that we got from the industry.

The first two here, Recommendation 1 and 2, address HIPAA regulatory adjustments to reflect new technologies and evolving business needs.

Recommendation 3 really gets at the heart of integration of multiple data sources beyond just the HIPAA transactions. It is recognizing that multiple agencies and activities are collecting and using social determinant data from multiple data sources. There really needs to be a nexus or a more coordinating effort to bring these efforts together, reduce variation, and eliminate what I consider dangerous data gaps affecting policy and health decisions. This one was to build on ONC's existing authority and expand it to include state and local and tribal and private health care systems to really broaden the lens here on gathering social determinants and other non-transaction data under HIPAA.

Recommendation 4 acknowledges the challenges and opportunities in assessing the readiness, cost, and value to the industry and really the entire ecosystem of new standards and how we measure that and how we communicate that. And capturing this information in a better way may help facilitate the adoption of new standards in the future.

I do not know, Tammy, if you have anything more to add for these recommendations.

Tammy Banks: No, you went through them well.

Denise Love: Before I turn it over to you, next slide, we do have some big requests from X12 and CAQH CORE to discuss. Tammy will cover that.

I just wanted to revisit before we get into the HIPAA transactions, the role of NCVHS and all of this. The roles and responsibilities for NCVHS are to receive requests for new or updated standards and operating rules from SDOs or the Standards Development Organizations and Operating Rule Authoring Entities or ORAEs.

For these standards, our role is to obtain input from industry, including the DSMOs or the Designated Standards Maintenance Organizations and they are listed here, I do not need to them, regarding the requested modifications.

And then for updated and new operating rules, obtain industry input on how these operating rules support the mandated, adopted HIPAA transactions.

Then after understanding all of the above, then it is our role to make a recommendation or recommendations to the Secretary of HHS.

I think I can turn it over to you, Tammy. But first, I wanted to ask Rich or anyone else on the committee. I went through just a really quick blast of our previous work. Did I miss anything? Is there anything that I should have pointed out?

Rich Landon: This is Rich. No, I think you did a good job. Thanks, Denise.

Denise Love: I covered what we have been doing but now Tammy will get into what we will be doing. It will immerse us quite a bit. This is a big lift, and it is a wonderful subcommittee. Take it, Tammy.

Melissa Goldstein: I think

Tammy Banks: Thank you, Denise. This is exciting. But before I get into the proposals, I would really like to just give you a little bit more additional information as conveyed on the slide. For those of you who are not in the weeds with the standards, just a little refresher. The HIPAA transaction standards are rules to standardize the electronic exchange of patient identifiable health-related information based on electronic data interchange or EDI standards, which allow the electronic exchange of information from computer to computer without human involvement. This is all pure HIPAA.

Per the Affordable Care Act Operating Rules are defined as the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications or implementation guides. Business rules and guidelines that do not duplicate what is in the standard nor are operating rules inconsistent or in conflict with the standard and operating rules typically go above and beyond the standard in terms of data content and other requirements.

The reason that is important is we, again, as Denise said, received two requests, one from X12 in regard to updating standards and one from CAQH CORE in regard to new and updated operating rules.

With that background, I would like to share the proposals received. The X12 request is personally to update the current version of 5010 of the professional, institutional, and dental claims with a proposed version 8020. Claims are typically sent from the provider to the payer for services performed. These transactions are widely adopted. Per the 2021 CAQH index, adoption rates are 97 percent for medical, which includes both the professional and institutional claims, and 84 percent for dental claims.

Secondly, update the current version of 5010 again of the claim payment advice that is typically set by the payer in the response to the claim with the payment information. These transactions are also widely adopted. The 2021 index adoption rates are 76 percent for medical and 84 percent for dental.

Keep in mind, Version 5010 was balloted by X12 in 2003 and adopted under HIPAA in 2009 and then finally implemented in 2012 so ten years ago. And then all other adopted transactions would remain on Version 5010.

As shown on the slide, X12 has reported the professional claim have over 1000 enhancements. The institutional claim has over 1100 enhancements. The dental claim has around 333 enhancements. And the claim payment/advice has 259 enhancements being reviewed by the health care industry. X12 indicated that each of the X12 implementation guides, including in the recommendation, has a corresponding XML Schema Definition or XSD that supports the direct representation of the transaction used in XML Syntax.

XML noted that it mechanically produces these representations from the same metadata used to produce the EDI Implementation Guide, ensuring there are no discrepancies between the two different syntaxes. Therefore, X12 also recommends both the Version 8020 EDI Standard Representation, the former implementation guide, and the XML Representation be named as permitted syntaxes under HIPAA because both would be contained within the implementation guide. X12 also indicated that it intends to provide FHIR crosswalks for the proposed Version 8020 transactions submitted for consideration.

The second request from CAQH and the proposed updates to adopt operating rules. First is an updated Eligibility and Benefits Data Content Rule that requires data related to telemedicine, prior authorization, remaining coverage benefits, tiered benefits, and procedure level information.

An updated federally mandated Infrastructure Rules. This update to the current mandated infrastructure rule for eligibility claims status and payment and remittance specifies an increase in weekly system availability and requires the use of the most recent version of the Connectivity Rule.

The updated Connectivity Rule establishes connectivity requirements for data exchange across all mandated transactions included in the existing operating rules. Specifically, this rule is intended to improve security through stronger authentication requirements including the use of 0 auth 2.0 and requires support for SOAP, REST, and other API technologies.

The new Eligibility and Benefits Single Patient Attribution Data Content Rule specifies uniform data and codes for the exchange of patient attribution status between a health plan and a provider to enable seamless notification of an attributed patient to a provider under a value-based care contract with the eligibility workflow.

Please note that NCVHS does recognize that there is no standard transaction adopted for attachments at this time. Discussion of the following proposed operating rules may be informational since they are not able to be adopted under HIPAA or ACA at this time. New attachment operating rules establish an infrastructure and data content requirements for attachments sent to complete prior authorization requests or health care claims submission to support the convergence of clinical and administrative data.

On the next slide, I would like to give you an overview of the subcommittee's workplan to meet the roles and responsibilities that Denise discussed based in HIPAA and ACA to address both of these proposals. First, the subcommittee invited and heard an overview presentation from CAQH CORE and X12 in August. The subcommittee continued its collaboration with the Workgroup on Electronic Data Interchange or WEDI, who was named advisor to HHS. WEDI held informational sessions, performed a WEDI industry survey, and held a member position advisory event in November to obtain feedback on these proposals.

To obtain additional industry feedback, the subcommittee published a request for comment that referenced specific questions that were placed on the NCVHS website to assist those providing feedback. The comment period is still open. If you or your organization has not already considered sending in your perspective, please do so by December 15.

Additionally, the subcommittee had and will continue to have consultative conversations with CMS OBHRI National Standards, NSG, and ONC throughout this process. The subcommittee appreciates this collaboration since interoperability is a team effort.

And the two-day virtual hearing is scheduled for January 18 on X12's proposal and January 19 on CAQH CORE's proposal.

The subcommittee is focused on obtaining industry input consensus through the request of comment and January hearing. Information requested includes all the various bullet points on the slide but basically in a nutshell to understand the impact, the cost, how these perspectives or proposals support HIPAA and ACA as well as we expect other priorities that will be provided through the oral and written comments, which may include the burden on providers' health plans, industry, subsegments, relation to other terminologies, vocabulary's code sets, interoperability and downstream health data flows like reporting for state data uses, public health reporting, repositories, health information exchanges, and impact on patients and consumers.

Specific questions separate from the RFC were shared with the presenters to keep the testimony focused. Registration information is located on the NCVHS website. We optimistically plan to review all the feedback from the request for comment and hearing testimony and provide a recommendation or at least update the next Full Committee meeting. Obviously, we are very excited that Denise will be able to be with us for another 190 days.

And then I will ask the Full Committee. Does anybody have any questions or comments? I know this was a lot of information but just to prepare you with what you can expect in the next Full Committee meeting really thought it was important to go through the specifics of these requests.

Denise Love: I just wanted to add. This subcommittee is quite active. We are meeting biweekly if not more and offline even more. That is important to know as well as our ongoing discussions with OBRHI and ONC and others because as we discussed in Convergence as these standards move forward, it is not a silo anymore. It is starting to overlap into other areas. Bringing those partners on but also excellent collaboration with WEDI who is helping us gather information from the industry itself because these transactions – there is a lot of them and it is really not known right now – quantified the impact on the industry. We are gathering as much information through WEDI and through these hearings as possible to determine what that impact will be and what the efficiencies gained can be.

Tammy Banks: Is there any other additional feedback that the subcommittee or Rich would like to add and any questions from the Full Committee before I wrap up?

Denise Love: And the last update was when? That last major update.

Tammy Banks: Ten years ago, for the standards, not the operating rules.

Hearing no comments, if you want to go to the next slide, we just gave you some supporting information. These are two work products that inform the subcommittee's Convergence 2.0 work and are located on the NCVHS website. For those who may be interested and as Denise said, we will look forward to picking up the Convergence 2.0 work after the review of the two proposals that we received.

If you go to the last slide, it just contains the URL to the NCVHS' website so that you can access information for the hearing and any other of our subcommittee or actually the NCVHS committees in general.

With that, I will pass it back to you, Jacki, unless again if there are any questions that have arisen. We really look forward to diving into this work.

Jacki Monson: Thank you. We are a quiet group today other than wordsmithing approval documents.

Denise Love: We do not have any of that today or any action items, but we did want the committee to be aware that these big update requests were coming down the pike. You will hear a lot more about it.

Tammy Banks: We are saving our time for the ICD-11 --

Jacki Monson: Let us move on to ICD-11. I will turn it over to Margaret, Val, and Jamie.

Developments in the Transition to ICD-11

Rebecca Hines: Sherri, can you bring up the slides? Damon or Sherri, do you want me to bring them up or do you have it?

Margaret Skurka: Okay. There we are. I cannot tell you how happy I am to see this on our agenda and --

Sherri Greenwood: Please excuse the intrusion. Would you mind speaking up? You are not very clear.

Rebecca Hines: Just get a little closer to the computer if you might.

Margaret Skurka: I am more than happy to be able to deliver this update on I-11. I am happy to see it on the agenda and we will do our best to keep it there until implementation.

Here is a little bit of background. We were ICD-10-CM for a while and we moved to – it was adopted – I-11 was developed by WHO. We did that in 2019. It made it effective for countries in the world just this year, January 1. I am the one who went through WHO comments. There were about 35 countries that have already adopted. They are smaller ones, I believe. We, like Canada and Australia, are studying it and everyone is hoping that there are no modifications. And that if something is glaringly missing, it should be submitted to the WHO now for review.

We will have to adopt for mortality. It is required by WHO and it is not an option. It is non-discretionary. Morbidity is another part. That is what we will adopt it for because we have to also for death certificate coding and public health. And we also use it for health care billing and payment. The US adoption would have to be a HIPAA-mandated medical code set.

We want to avoid a repeat of costly and protracted US transition from ICD-9 to ICD-10 by developing a shared understanding of lessons learned from the previous planning process and transition and then highlight what are the differences between ICD-10 and ICD-11.

We want to be able to reach consensus on research questions to be answered in the evaluation of the cost and benefit of transitioning from 10 to 11 for mortality and morbidity and to identify the impacts of not transitioning to I-11 for morbidity.

We need to identify some key topics and messages to communicate to the industry to foster early stakeholder engagement, that is now, and in preparation for the transition to ICD-11. We are going to do it better this time is the takeaway.

This activity started back in August of 2019. And NCVHS hosted an expert roundtable meeting in Washington. I was lucky enough to attend that meeting and several HIM people were there, and Linda Kloss was on the committee then. There were truly a lot of experts at that meeting for the kickoff.

And then in November of 2019, of course this was all pre-pandemic, the NCVHS recommended that HHS evaluate the impact of different approaches to the transition and implementation of I-11 in the US for morbidity and mortality. They told us several years to start evaluating now so that we could provide timely leadership and strategic outcomes to the health care industry about the transition.

We get to September of 2021 a couple of years ago, NCVHS a year ago. NCVHS recommended that HHS conduct research to evaluate the impact of different approaches to and for implementation of ICD-11 and that we conduct outreach and communicate regularly to the US health care industry about the ICD transition. I certainly know that HIMA is doing their part in the journal articles and all kinds of outreach to the HIM population and know that those of us in this field will take that to their hospitals and health care institutions and we can get widespread support without modification of adapting ICD-11.

Jamie Ferguson: I will take this part. Thank you. As a reminder to everyone, the purpose and the goal of this section of the meeting is to consider and vote to approve a proposal to establish a workgroup intended to inform HHS policy about ICD-11. The full project proposal has been distributed to the committee members so you all have that.

If this vote approves the recommendation, then the next step proposed by the Standards Subcommittee will be to continue our coordination with multiple federal agencies, including NCHS, CMS, and ONC to establish the specific charge for the workgroup and to invite members to the workgroup comprising really a wide range of public and private sector subject matter experts. We also propose that the workgroup convene an expert roundtable meeting.

Many of you will recall that in our national transition to ICD-10, there was a RAND study and several HHS agencies were involved to support that transition. In this case, we proposed to build on that successful analysis to get the same agencies involved in the analysis of ICD-11.

Right now, there are many independent threads of analysis and research of ICD-11 in the US but these efforts are not well coordinated. We propose the workgroup could provide an important coordination function. We anticipate that the outcome of this coordination and analysis would improve the US work with WHO to ensure that the US requirements can be met by the ICD-11 classification system.

The overarching goal of the proposed workgroup will be to draft recommendations that should inform US policy decisions for ICD-11. To reach this goal, we anticipate the workgroup would help to coordinate the national agenda for research on ICD-11 use in the US.

And as a reminder as Margaret said, implementation of ICD-11 for mortality reporting is a UN treaty obligation that is embodied in US membership in the WHO. But our use of ICD-11 for other purposes such as payment or health research is voluntary therefore gaining an understanding of the associated costs and benefits is crucial.

In this case, I am just going to read this slide because overall we want to understand how well ICD-11 meets the US needs as the HIPAA code set. What are the benefits of our adoption and implementation of ICD-11? What are the costs of implementing it? What are the costs of not implementing it? And then diving into some of the differences of ICD-11 versus ICD-10, a post-coordination or cluster coding is a

major feature of ICD-11. What coverage can we get of the codes that we use, the codes that we need in the US? How many can be managed in ICD-11 natively just using the existing stem codes? Or with cluster coding with existing extensions or if we were to device new extensions to ICD-11 specific to US needs, then what kind of coverage could we get of all the codes that we need and that we use in ICD-10-CM?

How does this code set coverage in these different scenarios of post-coordination – how does that vary by use case? For example, how does that vary between Medicare payments versus public health reporting versus clinical research studies? These are some of the questions we anticipate that the workgroup should be able to come up with and hopefully would coordinate research to answer these kinds of questions.

Next, I would like to introduce Dr. Kin-Wah Fung from the National Library of Medicine who will speak to several of these issues. After his presentation, then we will entertain committee discussion and we want to hold a vote on the proposed action to establish the workgroup.

And now, I think I will pass it off to Kin-Wah.

Rebecca Hines: Sherri, can you please bring up the next set of slides?

Kin-Wah Fung: First of all, let me thank the committee for inviting me here again to tell us a little bit about what we have been doing since our last report to the committee in April 2021.

Today, I am not going to present all the full results of what we have been doing. I just want to give the committee a sense of what we have been doing since representing our findings of our previous study in April 2021.

This is a collaborative work between the National Library of Medicine and the National Center for Health Statistics. We have been collaborating on ICD-11 research for almost two years now and we have been studying various aspects of ICD-11, in particular, how it can be used in morbidity coding.

Just first of all, a quick recap on what we presented in our previous research. This is a preliminary feasibility study of whether ICD-11 can replace ICD-10-CM in morbidity coding based on the contents itself. The full report was published in JAMA in August of that year.

This is just a summary of the findings of that study. We analyzed about 900 codes that are frequently used of 10-CM from every chapter of ICD-10-CM that would cover at least 60 percent of usage from each chapter. And then we tried to map those codes to ICD-11 to see whether they can be represented fully in meaning.

The first step that we looked at is to see whether all the stem codes in ICD-11 – whether they would be enough to represent a full meaning. We found that about 24 percent of the ICD-10-CM codes can represent it fully. And if you use post-coordination or code clustering, as Jamie mentioned, which is a new feature in ICD-11, we can increase the coordination of full representation by about 8 percent. But note that the post-coordination in ICD-11 is not particularly catered to capture all the nuances and meaning in ICD-10-CM. If we tweak it a little bit so by adding a few extension codes, we can increase the coverage of post-coordination to 35 percent. And the rest we can only do partial representation.

In order to compare the impact of moving to ICD-11, we look at the transition from ICD-9-CM to ICD-10-CM. You use the general equivalence maps published by CMS to study the rates of equivalence between

ICD-9-CM and 10-CM. We found that only about a quarter of the codes in 10 and 9-CM have exact equivalence in 10-CM. We conclude to say that actually it is not more disruptive to transition from ICD-10-CM to ICD-11 as compared to transitioning from 9-CM to 10-CM.

Based on that, we think that ICD-11 should be considered a serious candidate to replace ICD-10-CM. That means without a clinical modification like we have done with 9-CM and 10-CM. If we are not going to do a full clinical modification or not a clinical modification at all, there are several possibilities here that now for consideration.

The first one is can you just ICD-11 as a basis and then generate an ICD-11-CM based on the foundation layer of ICD-11 and basically ICD-11-CM would be a linearization of ICD-11, the same as the MMS, the mortality morbidity statistics set, is generated from ICD foundation as the core component of ICD-11.

The second possibility would be to use post-coordination of code clustering. But we also noticed in our previous study that the existing post-coordination capability of ICD-11 is probably not enough to cover all the requirements of ICD-10-CM. We envision the US may have a set of post-coordination capabilities like extension codes or even ways of combining existing and extend codes that is specific to the US that we will maintain. I would call this an extension to an extension of ICD-11.

And the last possibility, which is probably the more heavy-handed approach, would be if we find cases in which the ICD-11 stem codes or even with post-coordination can now represent certain meanings, we need new stem codes in ICD-11, which are US specific.

This approach is different from creating a whole new ICD-11-CM from scratch. This is just the idea of maintaining a small subset of ICD-11 stem codes that are use specific that we maintain ourselves as a supplement to the other approaches.

This is what we have been doing. We have been looking at the practical strategies to replace 10-CM based on the three scenarios that I presented. In this study, we have expanded a way of finding several codes. In the previous study, we took the 900 commonly used codes from all chapters. This is similar to the diagram, the figure on the left, like taking the top layer of a cake. This is just a horizontal sampling.

In this new study, we also adopted another way of sampling. That means we tried to examine all the codes in the chapter and we have chosen the chapter of diseases of digestive system that has about 800 codes, which is manageable for our purpose to study. This is analogous to taking a slice of cake as represented in the photo on the right.

The two approaches of sampling are kind of complementary and will show us perspectives of what are frequently-used codes and how they could be managed by the three different approaches and also less frequently-used codes within the chapter.

What we have done is like a waterfall model of mapping. We started with 10-CM code and then we would look for the stem code in ICD-11. If we find an exact map, we stop there. If not, we look at the foundation layer, which if you can find an exact match, then we stop there. Both looking at the stem code and the foundation layer. If we can find an exact match there, this will mean that we can basically represent all the codes with exact matches at those two layers by treating ICD-11-CM as a linearization of ICD-11.

The next step we will do if we cannot find exact matches in the first two steps, would be to find post-coordination of code (inaudible). At this step, we also look at additional requirements for post-coordination whether we need new stem codes or other ways of combining stem and extension codes. And finally, if all fails, we look at whether we need to create new stem codes for the specific use case.

As I said, I do not have the results to present here. But I will be happy to share our findings in future meetings. Next slide. I think that is the next slide so please stay tuned. That is the end of my presentation.

Jamie Ferguson: Thank you very much. I think, speaking for the Standards Subcommittee then, we would be happy to take questions and committee discussion before the calling the question on forming a working group.

Valerie Watzlaf: I have a question for Kin-Wah if he is – is he still with us? Great. I know you had recommended I think for ICD-11-CM like, I believe I think in your previous study and the study you have completed. And I guess just so I understand this, were these like additional stem codes that you could actually send to the WHO that could even be added into ICD-11 or do you feel that they are just specifically for the United States.

Kin-Wah Fung: Yes. I think both scenarios I envisioned would be possible. For those – codes that we identify as gaps in ICD-11 that we need in the US, if we consider them to be more applicable even for other countries than the US, then I think it is reasonable and logical to propose them to be added to the core ICD-11.

But I can also envision that if there are codes that are very specific for the US environment, they are better maintained within the US extension of stem codes. Of course, if they are stem codes, I anticipate them to be able to be used in post-coordination like the other stem codes in the core ICD-11.

Valerie Watzlaf: And are you looking more at this in your present study as well?

Kin-Wah Fung: Yes. We have looked at the cases in which – there is always the adjustment cause sometimes on how much post-coordination you want to do until you tweak the model so much that it is almost unwieldy to do a post-coordination until you say maybe at this point, a new stem code makes more sense that that kind of analysis.

When I have the full results, I will be happy to share with this committee again. I will have more details about what percentage of codes we find. We will probably need some new stem codes to be added to the US extension.

Jamie Ferguson: I see Vickie. Vickie, before we go to your question, I would like to add some context on what Kin-Wah was saying. And this also is about our work with WHO and Margaret may want to speak to this as well.

From a WHO perspective, on January 1 of this year, we entered into a five-year support period for national implementation of ICD-11. We are in that WHO support period now. Especially during this period, WHO has invited member countries to submit additional codes and changes to ICD-11 that it requests. We can make these requests directly to WHO for additions to the classification system now in ways that I do not know if there is going to be equally – if that invitation is going to be equally supported after the five-year implementation period.

Margaret, did you have anything to add about working with WHO?

Margaret Skurka: Yes, except that I retired from that position a number of years ago or maybe a year ago. But Mary Stanfill – I hate to put you on the spot, Mary, but I looked at the participants and I know you are here. Do you want to be put on the spot and comment on – you have been to the past couple of meetings instead of me.

Jamie Ferguson: Why don't we come back to that and in the meantime, Vickie, let us go to your question next.

Vickie Mays: Thank you. I thought this was a great presentation. I think the direction that standards is having is one I am fully supportive of. I want to raise a couple of issues particularly in terms of the work that you are doing. One of the problematic areas in ICD has always been the psychiatric diagnosis, particularly trying to line them up with DSM. NIH, in particular – NIMH, I should say, in particular, has taken that RDoC approach and really talks about this trans-diagnostic. If you look in PubMed or all these other places, what you are seeing is a lot of discussion around the new disorders that got put in. I am just wondering kind of where you all are with kind of thinking about that and Jamie, for you, where you all are in making sure that NIH is at the table, that there is expertise in terms of psychiatric disorders.

Jamie Ferguson: Thank you for the question. Obviously, we would want the stakeholders and experts in that area to be represented in the working group and the stakeholders involved in the research.

Kin-Wah, do you want to make any specific comments about that being from NIH yourself?

Kin-Wah Fung: I do not work in psychiatry, unfortunately. There have been quite a number of papers about the way that mental health concepts or codes are handled in ICD- and apparently it is quite different from ICD-10. I think that is certainly an important area to look at.

Vickie Mays: Are you doing any of the stuff that you are doing now, are you also testing that? I am just wanting to make sure that the US, which is being very different about these disorders, that we are looking very early on about the coding and what is going to happen as we move to the electronic health records – et cetera.

Kin-Wah Fung: Yes. In our sample, we have a couple of old codes from all chapters. But not all chapters will contribute an equal number of codes. It depends on the pattern of usage in that chapter. We do have a sample, covering the mental health chapter. But whether that is representative of the whole chapter, that is a question that I cannot answer. Whether things that are outside the sample, the small sample that we have for that chapter, whether there are problems there that we might not have uncovered, I cannot say for sure.

Jamie Ferguson: Thank you very much.

Denise, I see that you are next up but I also see that Mary Stanfill has been added as a panelist.

Denise Love: Why don't you go to Mary and then I will ask my question?

Jamie Ferguson: -- to speak to Margaret's question about WHO – thank you. Mary.

Mary Stanfill: Hello. I did not expect this but I can tell you just real quick, the WHO, when I was attending their annual meeting in Geneva in October, they have a scientific committee established. They have the morbidity/mortality reference group. They have the committees and the structure in place to address any requests for changes to the code set to the classification itself and to the foundation. There are two distinct processes to do that. Most of that work is largely through volunteers but they have a very good process in place. They also have, as you may be aware, an electronic platform to manage that. Truly, anyone can submit updates and requests and that sort of thing.

Is that helpful to know what their intent is? My sense is that they are definitely in a place where they are trying to make sure that they can effectively manage a true globally used standard since that is the goal, the interoperability and the consistency of the code set.

Jamie Ferguson: I think that is very helpful. Thank you very much. I appreciate it.

Rebecca Hines: Mary, can you just tell for the record, because we will have a transcript, your organization and who you are with. Thank you.

Mary Stanfill: Of course. Happy to do that. I am a volunteer with the International Federation of Health Information Management Associations, IFHIMA, and I am their official representative to the WHO Family of International Classifications, the WHO-FIC. I sit as an appointee on the EIC group Ja the morbidity and reference group.

PARTICIPANT: Sorry to Mary that I put her on the spot but thank you very much.

Jamie Ferguson: Can I ask a question of Mary? Are these open-ended scientific committee structures ongoing or is there a time limit? What kind of timeframe are we looking at to submit updates to ICD-11?

Mary Stanfill: I have not heard anything from WHO that would suggest that that is a limited timeframe. I believe that is their intent to have an international standard that is supported for global use. I do not believe that that platform for submitting requests and that sort of thing is going to go away.

I do think that, as member countries, we have an opportunity to and probably we ought to, I guess, if you are asking my recommendation, we ought to talk with them and establish a process as a collaborating center. Just clarify that is what I mean.

Jamie Ferguson: Thank you very much.

Vickie, did you have another question or is your hand still up?

Denise Love: I had a question for Kin-Wah or anyone else. I have not done a deep dive in ICD-11. But what I understand is medications are handled differently. In ICD-10, one of the shortcomings was medications were more handled as poisoning or accidents. But isn't there a chapter or a whole different approach or structure for medications in ICD-11, which would be much more informative of the clinical picture?

Kin-Wah Fung: One significant difference for handling for medications in ICD-11 is that they have – because the ability of code clustering of post-coordination, they can put a lot of medication in the extension code. That is a clever way of expanding what you can say about medication. If we want to say something about the adverse effect or poisoning due to a sudden chemical substance, you have to have

a code or any medication. As you know, through combinatorial explosion, soon you will run out of codes if you want to include the various effects of various medications. But by putting it in an extension, you can just add medications in the extension and then you have stem codes that show whether there is a poisoning, under-dosing, or adverse effects or allergy or whatever in the stem code. Then you can have an easy way to combine the meanings that you want in post-coordination. I think that is the main difference in ICD-11.

Denise Love: Thank you.

Jamie Ferguson: Vickie and then Wu.

Vickie Mays: One of the questions I wanted to ask and I think this is probably for Jamie but I cannot remember if he was on the committee then. When we had a meeting and I think it was probably a couple of years ago, there was some urgency about making the changes particularly in terms of the studies we need to do, particularly in terms of mortality. I do have a sense that there are some deadlines that if we miss them, we are going to be longer in this process and we want to get these changes done by a certain time.

I think one of the groups that was particularly concerned was NCHS and NIH. I do not know if people know the deadlines but there is some urgency, as I understand it. I just do not know quite what that – or remember what that is.

Jamie Ferguson: I cannot speak to the timeline for mortality reporting. Perhaps – I do not know. Margaret, can you speak or Mary, can you speak to that?

Rebecca Hines: Actually, I can jump in and say that Bob Anderson in the Division of Mortality Statistics at NCHS is on top of that. We interviewed him about a year ago and gave an update to the Standards Subcommittee. Basically, they are having some assessment work done parallel to what we are suggesting, they are already doing. They're researching the mortality side and seeing if they can make it work. It is actually an international research effort. It is not just the US. There is an assessment going on. In fact, they were supposed to get results I think this fall. I have lost track of the deadlines, Vickie, but it is a separate process and there is a whole group at NCHS that is focused on it. And if this group would like, we can ask them to come present to this committee or if the workgroup happens, we can have them come present to the workgroup. But yes, there is a lot of attention on that, and it will be probably a shorter timeframe than for morbidity.

Jamie Ferguson: Thank you very much, Rebecca. I do think it would make sense for the work group to coordinate with that effort to understand it at least. Thank you.

Margaret Skurka: I am already so encouraged.

Jamie Ferguson: Wu and then Rich.

Wu Xu: I have a question for Kin-Wah. Thank you for your research team's work. My question – also, I like your cake presentation, the top tier and the slice. I assume you will do all the slides. My question is about the resources and timeline.

Kin-Wah Fung: Yes. Thank you for liking the cake. I think it is a good way to visualize what we are doing. The two questions are related. Whether we can do more slices or even the whole cake. It obviously depends on the results we can have.

The reason for choosing one slice, particularly that chapter on digestive systems, is we did not do it by random. It is because that particular chapter has some characteristics that are the average characteristic of the other chapters so they are not very far to one end in terms of whether they can be represented or not and to the other.

And also, the size if manageable, not too small and not too big because some chapters in ICD-10-CM – they contain tens of thousands of codes, which is probably too big for our purpose.

To answer your question, if we have the resources and we do see the urgent need to add more slices to what we study like maybe mental health chapter and so on, we can consider that in the future but it depends on the findings of the current study and also very much on the feedback we can get from the user committee and other stakeholders of ICD-10-CM where we might have overlooked some things in ICD-10-CM that would warrant more attention then we would definitely consider that. But again, this is a resource issue and also whether we have time to do the additional analysis or not.

Jamie Ferguson: Excellent. Thank you very much.

Rich.

Rich Landen: I would just like to add on a little bit to that response to Vickie's question about mortality coding. Unlike the morbidity coding where the providers actually do the coding and the provider – their staff maybe be trained in coding, mortality reported by the states and NCHS is done in plain language and the coding, the convergence of the plain language into ICD-11 will be done by NCHS, not by the states and hence the importance of what Rebecca was talking about with developing the algorithms to support machine coding there. I just wanted to add that. Thanks.

Jamie Ferguson: Thank you very much, Rich.

I do not see any other hands raised. Vickie, is your hand back?

Vickie Mays: Yes. I just want to say in relationship to what Rich said. This issue of AI and the mortality data is really very important to NIH. One of the funding I have is in terms of looking at causes of death. Again, that is one of those areas that I think you want to have some expertise in because I think NCHS – they need sooner rather than later is my understanding on that.

Jamie Ferguson: Thank you very much.

Before we call a question on this workgroup. I also wanted to add a little bit of extra context because this discussion has focused very much on the content coverage and strategies for ensuring appropriate content in the classification system. But there are many other aspects of cost and benefit that the workgroup would be charged with understanding and providing input on for policy to inform policy decisions. That would include the relationship of the classification system to electronic health records, its actual use in the various interoperability and administrative transaction standards. There are many different aspects of implementation that would have potentially cost them benefits that would be considered in scope. It is not all about content coverage but that is where we are starting.

If there are no other questions at this time, I think we are ready to call the question for a vote. Jacki, how do you want to do this?

Jacki Monson: Rebecca, do we just take a vote on establishing a workgroup for ICD-11?

Rebecca Hines: We do and as a reminder in case people have forgotten, you have the draft proposal in your materials. This is what we are basically saying. This was the introduction, everything we just discussed laid out in the intro and then we are basically voting on the proposal to form an ICD-11 workgroup in collaboration with HHS, including CMS, NCHS, NLM, probably ONC, and various other colleagues. But that is what we are voting on. You have that in your materials.

I see, Maya, your hand is up.

Maya Bernstein: Just briefly, Jacki, since you asked. Usually what the chair would entertain a motion of the sort that Rebecca just read, ask for a second, if there is any further discussion, and then you can vote.

Jacki Monson: Vickie, do you have a comment?

Vickie Mays: I just want to make sure that some of the things that came out in the discussion are going to be plucked out. I just want to make sure that we are just voting for the idea but what is in the proposal that there can be additions to it. Right?

Rebecca Hines: We are voting not on the idea. We are voting on the establishment of a workgroup. Yes, establish a workgroup. No, do not. Yes. Then we collaboratively have a charge that we develop.

Vickie Mays: I just want to make sure that it was not just what we were using.

Maya Bernstein: Whoever makes the motion will establish the parameters of that motion.

Denise Love: I was going to move to approve the establishment and originally thought of the project proposal because the project proposal includes the establishment of the workgroup. I did not sever those two out. My motion is appropriate to approve the project proposal and the ICD-11 workgroup.

Jacki Monson: Is there a second?

Committee Member: Second.

Jacki Monson: All in favor please raise your virtual hand.

Vickie Mays: Didn't we get to do friendly amendments? That was what I was questioning, Denise. I did not want the full proposal to be kind of set in stone as much as the idea so that some of the additional things that have come up today can make sure it is there. I am just going to make sure we do not vote on the proposal itself but the idea. And you are wanting the proposal and the idea.

Rebecca Hines: The proposal does not have the framework you are talking about. The proposal is basically to do this activity, which would start off with the workgroup. The kinds of issues you raised are not on the table because we are not there yet.

Jamie Ferguson: But the proposal would envision that they can be added. Part of the proposal is developing those ideas.

Vickie Mays: The proposal is not the chart – off the table, Denise.

Denise Love: We are just trying to launch today, Vickie. That is it.

Jamie Ferguson: But it is for approval of the project proposal including the workgroup.

Denise Love: Yes.

Jacki Monson: Any other discussion? Rick, do you have anything for discussion or are you pumped to vote too? I thought so. All in favor of our motion and second, please raise your hands virtually or physically.

Rebecca Hines: Eleven. Jacki, that includes you. 11 out of 11 present. That is a quorum. A quorum would be ten. Thank you all very much. I appreciate that. The motion is approved. We will move forward with this project and move forward with drafting a charge for an ICD-11 workgroup and identify members. Just for everyone's knowledge, a member must chair this. I think Jacki has some suggestions on that, which we will bring forward at another time. I believe this topic is ready to move forward.

Denise Love: Thank you for the workgroup for getting the proposal together and moving it forward.

Jamie Ferguson: Thanks, everybody.

Jacki Monson: Thank you for all your work and putting it together.

Okay, Rebecca, it looks like we have finished a little bit early and next up is a break. Do we want to break now and come back a little bit earlier?

Rebecca Hines: Sure. What time would you like to resume? Right now, it is almost --

Jacki Monson: Would everybody like a longer break to move about the cabin a little bit? Longer break, I am hearing. We will reconvene at 3:40.

Rebecca Hines: 4 o'clock Eastern, I believe, Jacki. Is that right? We will reconvene at 4 o'clock. Members, if you would leave your Zoom connection on or log in five minutes before 4 Eastern. Thank you.

(Break)

Rebecca Hines: Welcome back. I did want to note that Jacki and I were talking about the information in the Q&A. I do not know if we have the answer to one of the questions on the last topic. Most of this has to do with the last topic. I am just going to say that we answered all of these live to clean it out. Thank you, all, for your interest. I think a lot of the people actually who were on for ICD-11 are no longer in the attendee.

Everybody is back. Welcome back. I think Melissa will join us momentarily.

NCVHS 2023 Report to Congress

Jacki Monson: I might be done with the really exciting PowerPoint that I have to share by then, when we are in conversation.

Let us go ahead and get started. We have one topic left and then I want to finish with – we have public comment. Let us go ahead and get started. If we could pull up my slide deck.

The ever-exciting Report to Congress is upon again. Let us move to the next slide. Just to really set the premise for what our role is with the Report to Congress. We do one every two years. We are ramping up for our report that we will deliver in 2023. As we are going through this PowerPoint and as I mentioned earlier today, just really interested in your thoughts and feedback and how we teed up, what we are going to focus on in the report. Rebecca and I had the opportunity to go back and review the previous reports. I have some ideas but certainly we want to hear from your first. These slides – we will walk through a bunch of them to bring you down memory lane a little bit on what our scope is, what we have covered in the previous Reports to Congress and then I want to think forward about what we are going to cover in our Report to Congress in 2023.

First, NCVHS' role with this. I think most of you know all of this, which is we are a public advisory committee to HHS. We are charged with assisting and advising the HHS Secretary on health data, statistics, privacy, national health information policy, and the department's strategy to best address these issues.

We are responsible for monitoring the nation's health data and both needs and current approaches to meet those emerging health data issues, methodologies and new technologies, platforms, and models for managing health information.

And then we assist and advise the department in the implementation of the Administration Simplification provisions of the HIPAA Act and inform decision making about data policy by HHS, states, local governments, and the private sector.

More about our role. We are also responsible for advising on a couple of the provisions of the Social Security Act and study the issues related to the adoption of uniform data standards for patient medical record information and electronic interchange of such information and report to the Secretary recommendations in what is legislative proposals for such standards and the electronic exchange.

Specific to the Report to Congress, it shall address the following subjects to the extent the committee determinates appropriate. That is where all of you should be thinking about this because much of this is our discretion and our decision. To the extent to which persons required to comply with Part C of the Act are cooperating in implementing the standards adopted under such part, to the extent to which such entities are meeting with the security standards adopted under such part and the types of penalties assessed for noncompliance with such standards, whether the federal and state governments are receiving information of sufficient quality to meet their responsibilities under such part, any problems that exist with respect to the implementation of such part, and to the extent to which time tables under such part are being met.

Just walking us down memory lane a little bit into the recent history of the reports. We completed the 14th Report to Congress in 2021. That reporting period was January 1, 2019 to December 31, 2020. We included five major trends in health information, the progress and status of HIPAA implementation in

two parts: the HIPAA Transaction and Medical Code Set Standards and HIPAA Privacy, Security, and Breach Notification rule. Review of near-term national health information challenges and opportunities and did a preview of what the committee's proposed near-term activities to address some of these things.

The evolving context. We really highlighted five major trends in health information. We highlighted new technologies, platforms, and models as well as patients' roles in accessing and using their health data that have both expanded and evolved.

Patients' roles in accessing and using their health data have expanded and evolved. The COVID pandemic has exposed grave weaknesses in public health information infrastructure. The convergence of clinical and administrative data standards is gaining recognition and crossing the boundaries of traditional data and program silos.

The COVID pandemic has exposed critical weaknesses. That was a duplicate. And then health information privacy and security challenges have proliferated.

Specific to the HIPAA Transaction and Medical Code Set Standards. Transactions background, transactions status in 2020, the HIPAA transactions initiatives and actions from 2019 to 2020, the HIPAA medical code status related terminologies and vocabularies initiatives and actions, 2019 to 2020, and then other Administrative Simplification initiatives and actions with the same date expansion.

The HIPAA security, privacy, and breach notification. Proposed changes of the Privacy Rule, updated guidance on FERPA and HIPAA, guidance on HIPAA, health information exchanges, and disclosures of PHI for public health purposes, HIPAA and COVID-19, HIPAA breach notification, HIPAA enforcement, and HIPAA right of access enforcement initiative.

This we included in the last report specifically to highlight I think the area of focus that we had on security and this data, I believe, came from the Office of Civil Rights. This just is an illustration of the 500 plus impacting patient breaches that involved hacking and ransomware incidents.

We included a grid on the 2020 OCR HIPAA enforcement actions and the penalties involved in that. And then we took forward this efficiency index and included this as well on the percentage industry and implementation of the transaction standards.

Looking ahead to 2021 and 2022 and NCVHS' focus areas. The national health information challenges and opportunities, a need for comprehensive, integrated, national health information standards, need to address increasing challenges for privacy, confidentiality, and security, the need for enhanced data sources to support payment reform and price transparency, the need for equitable information technology across the last mile to reach all end users, and the need for nationwide, digitized infrastructure to enable pandemic information collection and sharing.

Focus areas in the period ahead. Promoting convergence of clinical, administrative, social, and public data, improving the health care industry's security posture, monitoring and advising on ICD-11 readiness, and identifying new approaches for data collection, sharing, linkages, and analytic methods to address health inequities.

Just the appendices that we included. We included NCVHS statutory reporting requirements for HIPAA, i.e., chronological order of the Administrative Simplification, summary compilation of NCVHS

recommendations, reports, and all of our activities during that reporting period, acronyms, and then membership of the committee.

That kind of set the stage and I covered it pretty rapidly, assuming that you all had read the pre-read but really want to think forward on here is where we are today. I shared with you what we included, the previous report.

Our reporting is January 1, 2021 to December 31, 2022, so a look back and a look forward, what have we done and what are we doing now. Topics to consider for this are notable changes and activities over the last two years, significant notable policy changes, and focus areas. One area that we have had discussion in the Executive Subcommittee about is revising Beyond HIPAA. A lot of that report although the report is a little bit date, the content is still very relevant. We saw that highlighted with the COVID pandemic and some of the data challenges and opportunities that we have there as well as some of the areas that Privacy, Security, and Confidentiality group have been delving into for the last several months. That is one area of focus. I want to hear from all of you on what you think other areas of focus are.

When I went back and read the Report to Congress and Rebecca and I worked on this presentation to bring it to you today, a lot of the stuff is still very relevant, still things that we are currently working on today. My general inclination is what if we focus on any notable changes and activities over the last couple of years, significant policy issues, and focus areas, both what we are focusing on today and what we want to focus on tomorrow and make it a little bit shorter than previous reports and reference back to the previous Report to Congress and all of the documentation attached to that. That is my general thinking.

But now, I am going to open it up to all of you and see what your thoughts are, what your questions are, what your areas of focus are. And this is really meant to be our brainstorming conversation about how we want to design the report and what we want it to look like and what we want included in it.

I will pause there and open it up for discussion.

Rebecca Hines: Can we also just look at the next slide just to remind people that the options are to do as you just suggested, which is to prepare a new shorter report. We could take portions of the current report. This slide showed three charts, for example. We could update the data and see if it is even worse, has enough happen to present new data, or we could even prepare a brief synopsis and sort of attach it to the last one. There are probably other ways to go about it. But in addition to the previous slide, which is most important right now, just also in the back of your mind, thinking about how we want to go about it once we figure out what information to provide.

Jacki Monson: Exactly. If we can go back to the previous slide just so we have some context for the conversation of what we are looking at. If we can open it up for comments, thoughts, questions, ideas about how we frame this, I would appreciate that.

Vickie Mays: I have a question. Should we be thinking about those things that are a high priority right now? For example, we know that cybersecurity is like driving everybody crazy. I do not know that that is our strongest suit right now to do the work. But I know that they are looking all over for answers. Do we want to align ourselves with potential successes that we know that they are doing or do we want to current just stick with our priorities? I am just putting that out for everybody.

Jacki Monson: It is a really good thought. I think we definitely need to think about it. My personal opinion is that we should do both. That is my thought. In previous reports, we have done both to highlight them. Although we only have a couple of cyber experts. But it does not mean that we have not done a lot of work already. And of course, there is almost more to do.

Tammy Banks: I was just going to say as an approach, I think your approach is great and I think if we go back and take a look at these three bullets, we may then decide a different approach on or we will be able to determine what the approach is because we do not really know how much there may be in notable changes and activities. Obviously, we know the policies how that changed. But this may be the first step to determine if we can do that shortened report or just update. I concur with your approach.

Jacki Monson: Thank you. Other thoughts from the group?

Rebecca Hines: Do we want to try to identify people who could update the data or at least maybe not make – take the time to make pretty graphs and tables but to see is there actually – has there been enough change to warrant republishing updated charts?

Jacki Monson: My thought is to task the subcommittees with looking at their particular areas and particular parts of the report and looking over the last two years of what we have done since then and coming up with the notable changes and activities and bring it back for discussion again. That is my initial thought on that.

Vickie, you have your hand up.

Vickie Mays: I kind of want to do something similar because I do not think we want to put work into something if the whole group does not necessarily end up wanting to do it. I am kind of on that thing but just a little less, which is maybe what we should do is each group should take what is their area. We should also look at our work plan and see how much we could coordinate across things so that we do not end up giving ourselves a whole bunch more work to do because we do not know if the stuff will go anywhere, as you know. We did a longer thing and as you say, Beyond HIPAA. We spent a lot of time and I think it is so important what is in there, but it did not get an uptake. I would suggest kind of a moderate – let us just look and if we still think it is important then we say that and if we can get a vote across the group, then we can delve in and do the work.

Jacki Monson: It sounds good.

Maya, you had your hand up.

Maya Bernstein: I was just going to say that that is what we have done in the past is spread the work around, have the other groups do it. We will help you as the staff to clean it up and make it sound like one voice afterwards if you do that.

Jacki Monson: Okay. Rich.

Rich Landen: I would agree. Let us not do as deep a dive as we did for the last biannual report but certainly the topics that rise to the top are the cybersecurity, the privacy, Beyond HIPAA, the Convergence, certainly ICD-11, and some of the others. I guess keeping it at a very high policy level issue, not getting down into the weeds. The gist of all the recommendations we have made. I also agree with the approach that, as we did last time, let us chunk it up into each of the subcommittee's areas.

Jacki Monson: Thank you. Other thoughts or comments? I am seeing random thumbs moving up the screen. I do not know who they are coming from.

Vickie.

Vickie Mays: Everybody is raising their hand. There is one thing that I am a bit concerned about when we chunk things up into the committees. There are a couple of things that have been just kind of out there. One of the things we have worked on from all these different angles is some of the data equity stuff. It is also big time on their agenda. I just want to make sure that I would add it to the list. I love Rich's list and I would add that to the list. I do not know – how to assign it. But it fits also with what is going on right now.

In particular, I do not know if it is a new thing but right now, the definition of race and ethnicity or the categories I should say of race and ethnicity differ between OMB and HHS and those really do need to be reconciled and to me that would be a great thing to talk about.

Rich Landen: Vickie, I agree with you. My list was not meant to be exhaustive and some of the other big ones we have not mentioned are SOGI and SDOH.

Rebecca Hines: One of the things that we can be sure to do is have this on the Executive Subcommittee agenda every month and to figure out little chunks each month what can we try to get done either in the formal subcommittees or in ad hoc clusters of members to move some of this forward.

In the last report, you did have a section on what is on the docket, and you will need to decide whether you want to do that again this time. It sounds like that is sort of what you are brainstorming now is the brief set of here is what we think is important.

Jacki Monson: Other comments and thoughts?

Denise Love: I like where this is going. And I may have missed it. It is late in the day. What is the general timeline for the subcommittees to fair it out what they want to say. I know it is iterative, but we start right away or --

Jacki Monson: Let Rebecca and I come up with a timeline and I think we can bring it to the Executive Subcommittee next week when we meet. Let us just try to pencil out what a timeline would look like because I want to give a reasonable amount of time for the opportunity to happen with the subcommittees. I know, for example, Standards, you are going to be heads down focused on your hearing probably until after that is over. Let us come up with a timeline for socialization and input and then we can bring that to the Executive Subcommittee for feedback and then we can roll it to the entire committee if that is okay.

Melissa Goldstein: My question was going to be similar just – is there an outer date when it does need to be done by because it helps me conceptualize how small it needs to be. Of course, we gave Cason Schmit a very short period of time and somehow, we came up with this masterpiece. I do not really expect that from us. Maybe we can channel him. But that really was my question, the outer date.

Rebecca Hines: For the last report, the reporting period was 2019 and 2020 and we got it out in October of the following year. We could try – if you really wanted to not rush it, we could give ourselves this next entire year. If you wanted to try to rip the band aid off, we could make a more compressed timeline. It is

really up to us. I can assure you that no one is going to be calling me in six months and asking for it. We have not had that happen.

I also believe there may be some clearance issue this time. I need to go back and look at some emails over the last year about a change in policy on that. That is another issue. But in terms of our part of getting it done, there really is not – nobody is waiting for this. It is the kind of thing that we are required to do but I have never received an email saying it is late. It is really up to you.

Melissa Goldstein: That is a great summary. Thank you. Super helpful.

Jamie Ferguson: Thank you. I think, Jacki, it is a question for you. If we are thinking about a skinnier status report, to what extent are you thinking this is just a retrospective status of HIPAA versus a forward-looking status of things that we see on the horizon for HIPAA just to inform Congress? Just as an example, we just talked about ICD-11, which has a post-coordination feature. And that post-coordination will require an entire new set of HIPAA transaction standards. We know that is coming. We do not exactly know the time or shape or how it will proceed. I would call that a forward-looking status item.

Jacki Monson: I would say, let us do both. Let us look backward and see if there is anything we need to enhance and let us also look forward to highlighting especially in that case. That is probably going to be seen as a policy issue. We want to highlight that. We have always looked forward and backwards at the same time even with a skinnier version and certainly could even focus more on forward looking and then just cite we have already included backwards because at least when I reviewed it, it is most of the same things that we are working on today that are still very relevant as they were two years ago. We might want to decide as a group as we look and this will be part of what I am interested in the subcommittee is doing is how much do we want to spend going backwards versus how much time would we actually want to spend going forward and thinking through what we see on the horizon if it is cybersecurity, if it is ICD-11. What else is out there that we know is on the horizon? That is different than perhaps what we have highlighted previously or maybe it is the same in some situations.

Rebecca Hines: And the other thing I just want to note is I think the audience for this is our usual audience, which is our audience of stakeholders because I think they look to this more than anyone else does. Just something to keep in mind. We use it as a reference the same as we used the last one as a reference document.

Jacki Monson: Any other comments, thoughts, or anything we want to discuss with respect to this? It sounds like we have a game plan going forward. Rebecca and I will put a reasonable timeline together around soliciting information from the subcommittees, knowing we are going into the holiday season. We have a standards period in January. We will be sensitive to those things and timelines around it and we will bring that to the Executive Subcommittee next week for further discussion on socialization. And then we will tee this up using the slides and using some of the topics that both Rich and Vickie mentioned as potential highlights when we send this out for the group to do a little bit of work and fact finding and then give us your feedback and then we can come back together and discuss further.

Any last comments? Okay, Rebecca, I think we are ready to go to public comment.

Public Comment

Rebecca Hines: Fantastic. Sherri or Damon, could you bring up the slide please? Thank you. We are now in our public comment period. For those of you in the attendee portion of Zoom, please click on raise your hand to have your audio unmuted or you can type in the Q&A to request an open line. But we prefer that you raise your hand and I see that we have somebody whose hand is already raised. You can also send me, if it is brief, an email to NCVHSmail@cdc.gov and I can read it. But we do have a line open. We request that you state your name, the organization you are with and keep it to three minutes.

Damon, can you open Sara Rosenbaum's line please?

Sara Rosenbaum: I know that you have had a full day and therefore I will be succinct. Thank you so much for the opportunity to supplement my December 2 letter with a brief statement. In an era of deep focus on reducing racial and ethnic health disparities, these efforts could be considerably aided by race/ethnicity data fields on the uniform billing form so adding these fields. This change would facilitate better understanding of such disparities and health care where they exist and more importantly from my view, they would help us understand the effectiveness of interventions whose purpose is to reduce disparities.

My proposal would rectify the notable omission of such data from today's universal claims forms. Furthermore, it would only minimally alter current clinical practice since patients are now routinely asked to self-report demographic information along with other personal health information. Furthermore, the billing forms here, the UB-04 CMS-1450 and the CMS-1500, are an established part of the national health care infrastructure and thus no new data collection method is required.

As the National Uniform Billing Committee representing payers and providers as observed, the UB data set is a critical tool to public health practice and research. Updating the forms to take race and ethnicity into account would add immeasurably to the effort to move toward greater health equity. No periodic individual survey disconnected from the act of health care delivery itself can substitute for real time claims data. The proposal assumes voluntary patient reporting and does not make provision of such data a condition of claims payment.

Finally, as reflected in statements from leading professional organizations, this proposal is consistent with the work of these organizations, ranging from health plans to hospitals, physicians, and other health care providers to embed racial and ethnic health equity directly into health care. Thank you very much.

Maya Bernstein: Professor Rosenbaum, would you please identify your full title and your organization for the record.

Sara Rosenbaum: Of course. My name is Sara Rosenbaum. My title is Harold and Jane Hirsh Professor of Health Law and Policy at Milken Institute School of Public Health, George Washington University.

Maya Bernstein: Thank you.

Wrap Up & Adjourn

Rebecca Hines: Again, for the attendees, we have 24 of you. Please feel free to raise your hand to have your line open to make public comment. I checked the inbox. I do not see any public comments there. I

do believe we are done with public comment. I do not see anything in the Q&A. With that, the public comment period wraps up, Jacki.

Jacki Monson: I just want to thank everybody. We had a very productive day. I want to thank our staff who do a lot of work behind the scenes to make this happen for us. Thank you so much for helping us today and all that you have done in preparation for it. I just greatly appreciate you all and want to thank all of the members. We had a very productive day. We had a workgroup approved. We had tribal recommendations moving forward. We fit a lot into this short but mighty day. I just greatly appreciate your time today and I hope you all have happy holidays, and we will see you soon.

Rebecca Hines: Thank you, Jacki. Thanks, everyone. Take care.

(Whereupon the meeting was adjourned at 4:35 p.m.)