National Committee on Vital and Health Statistics
Joint Meeting of the
Subcommittee on Privacy, Confidentiality, and
Security and the Subcommittee on Standards

Transcript

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Virtual

SPEAKERS

NCVHS Members		
Name	**Organization**	**Role**
Sarah Lessem	**DHHS**	**Executive Director**
Naomi Michaelis	**NCHS**	**Executive Secretary/Acting Chair**
Angela Alton	City of Hope	Member
Steve Wagner	Individual	Member
Jamie Ferguson	Kaiser Permanente	Member
Michael Hodgkins	Consultant	Member
Lenel James	Blue Cross Blue Shield Association	Member
Catherine Donald	Alabama Department of Public Health	Member
Tammy Banks	Principal/ImpactQue	Member
Valerie Watzlaf	University of Pittsburgh	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
Marietta Squire	NCHS	Staff
Shirley Castillo	NCHS	Staff
Presenters		
Name	**Organization**	**Role**
Tina Olson Grande	Healthcare Trust Institute	President and CEO

Lisa Myers	American Medical Association	Senior Washington Counsel
Mona Calhoun	American Health Information Management Association	President, Chair, AHIMA Board of Directors
Deven McGraw	Citizen Health	Chief Regulatory and Privacy Officer
Annie Fine	Council of State and Territorial Epidemiologists	Chief Science and Surveillance Officer
Micky Tripathi	Office of the National Coordinator for Health Information Technology	Asst. Secretary for Technology Policy
John Loonsk	Johns Hopkings Bloomberg School of Public Health	Adjunct Professor
Marko Mijic	California Health & Human Services Agency	Managing Director

Call to Order/Roll Call

Naomi Michaelis: Welcome to all our members and to members of the public who are joining us for the National Committee on Vital Health Statistics, NCVHS, the Joint Meeting of the Privacy, Confidentiality, and Security Subcommittee and the Standards Subcommittee. My name is Naomi Michaelis. I am the executive secretary and designated federal officer and acting chair for NCVHS.

We will begin with our roll call. Members, please state your name, your status as a special government employee, and any potential conflicts you have with today's work. Starting with Tammy.

Tammy Banks: Tammy Banks, principal/ImpactQue, co-chair of Subcommittee on Standards, member of the Executive Committee, no conflicts. Thank you.

Naomi Michaelis: Thank you.

Angela.

Angela Alton: Angela Alton with City of Hope, member of the Full Committee, serve on the Privacy, Confidentiality, and Security Subcommittee and no conflicts.

Naomi Michaelis: Jamie.

Jamie Ferguson: Good morning. Jamie Ferguson. Kaiser Permanente, serving as chair of the ICD-11 Workgroup, also a member of the Privacy, Confidentiality, and Security and the Standards Subcommittees. No conflicts.

Naomi Michaelis: Steve.

Steven Wagner: Steve Wagner. I am former Enterprise Architect, now retired. I am co-chair of the Standards Subcommittee and member of the Full Committee, Executive Committee, and I have no conflicts.

Naomi Michaelis: Michael Hodgkins.

Michael Hodgkins: I am Michael Hodgkins. I am a consultant. I am a member of the Full Committee, the Standards Committee, and the ICD-11 Workgroup and I have no conflicts.

Naomi Michaelis: Val.

Valerie Watzlaf: Hi everyone. Val Watzlaf. I am faculty emeritus with the University of Pittsburgh. I am a member of the Full Committee. I am chairing the Privacy, Confidentiality, and Security Subcommittee and I am a member of ICD-11 Workgroup and I have no conflicts.

Naomi Michaelis: Wu Xu.

Wu Xu: Hi everyone. My name is Wu Xu. I am with the University of Utah, a member of the Full

Committee. I have no conflicts.

Naomi Michaelis: Cathy.

Catherine Donald: Hi. I am Cathy Donald. I am with the Alabama Department of Public Health. I am a member of the Full Committee, a member of the Privacy, Confidentiality, and Security Subcommittee. I also serve on the ICD-11 Workgroup, and I have a conflict with any discussions on reproductive health. Should those occur, I will recuse myself. Thank you.

Naomi Michaelis: Thank you. And staff, Sarah Lessem.

Sarah Lessem: Sarah Lessem, executive director of NCVHS, regular government employee.

Naomi Michaelis: Thank you.

Maya Bernstein.

Maya Bernstein: Good morning, everyone. My name is Maya Bernstein. I am the senior advisor for Privacy Policy in the Office of the Assistant Secretary for Planning and Evaluation. I am lead staff to the Subcommittee on Privacy, Confidentiality, and Security.

Naomi Michaelis: Thank you.

Lorraine Doo.

Lorraine Doo: With the Centers for Medicare and Medicaid Services, Health Informatics and Interoperability Group and lead staff to the Subcommittee on Standards.

Naomi Michaelis: Lenel has joined us. Thank you. Sorry for any issues we had there with that link. Lenel, please state your name and status on the committee.

Lenel James: Thank you. Lenel James, Blue Cross Blue Shield Association. I am a member of the Standards Subcommittee, and I have no conflicts to declare. Thanks.

Naomi Michaelis: Thank you so much. And I want to acknowledge our other support staff, Shirley Castillo, Grace Singson, and Marietta Squire who are joining us as well today. Thank you, all.

With that, can we please bring up the public comment slide? Thank you. We will be having one public comment period. It will be taking place tomorrow on Day 2, somewhere around 3 p.m. Eastern. If you are planning on participating in the public comment, please be attentive to where we are in the agenda.

As you can see, there is an email address if you are not able to make it for the oral public comment. You can send it to NCVHSmail@CDC.gov and we will read it into the record. If you have not already done so, you can also sign up to receive email notices from the committee and you can go to our website to subscribe.

Agenda Review

Naomi Michaelis: We will now do a review of the agenda. We are going to start with an update from Sarah. We will then move on to our first panel, Privacy and Security in Health Data Access: Health Information Exchange Participant Perspectives led by the members of the Privacy, Confidentiality, and Security Subcommittee. We will then be taking our first lunch break. In the afternoon, we will receive an update from the Assistant Secretary for Technology Policy in the Office of the National Coordinator for Health Information Technology. We will then take another break before proceeding with our second panel, the Privacy and Security in Health Data Access: Public Health, Human Services, and Other Perspectives again led by members of the Privacy, Confidentiality, and Security Subcommittee. We will then wrap up our day with some planning for our 75th anniversary celebration.

I will now turn it over to Sarah.

Update: Office of the Assistant Secretary for Planning and Evaluation

Sarah Lessem: Good morning, everybody. I am glad to be with you at this fall meeting of the National Committee on Vital and Health Statistics. It was great to see many of you in person back in April. And we are continuing with our plan to meet at least once a year face to face while utilizing virtual meetings as needed throughout the year.

Before I start the announcements, there are three people who I want to thank, Maya Bernstein, Naomi Michaelis, and Lorraine Doo. They have all been working tirelessly to prepare for this meeting. Maya has put together two amazing panels with experts on privacy today. She staffed the Privacy Committee for many years and brings a wealth of privacy, confidentiality, and security experience to her work with NCVHS. Even more valuable to me is her willingness to share her experience, advice, historical perspective, and time as I have learned about NCVHS. Without Maya, NCVHS would not be where it is today.

Naomi has worked tirelessly not only as a designated federal officer but as acting chair. She is incredibly organized and put together today's agenda. She supported NCVHS nominees, new members, and retiring committee members as they transitioned on and off the committee and her dedication to NCVHS made this meeting happened and kept great members on the committee.

Lorraine has staffed the Standards Committee for years. She brings her experience with CMS and the complex standards process. She is a true expert on standards and is always willing to share her insights with me and the committee members.

In addition, I would like to thank committee members for your work to synthesize complex information and make recommendations to the secretary. This work brings new analysis and insights to existing policies and is vital to HHS.

Finally, thanks to Grace Singson for putting together these talking points for us today.

Let me tell you about some administrative priorities. In April, we discussed the 2022-2026 HHS Strategic

Plan, which continues to guide our actions with five key goals. One, protect and strengthen equitable access to high-quality and affordable health care. Two, safeguard and improve national and global health conditions and outcomes. Three, strengthen social wellbeing, equity, and economic resilience. Four, restore trust and accelerate advancements in science and research for all. And five, advance strategic management to build trust, transparency, and accountability.

The department has also made considerable progress to our 2024-2025 agency priority goals. These include behavioral health. We continue to expand efforts around mental health and substance use disorder treatment with a focus on prevention and access to care and advancing customer experience. We are committed to improving how the public interacts with HHS services, ensuring that our programs are accessible, responsive, and centered around the needs of the communities that we serve. I look forward to discussing these priorities and hearing your insights as we move forward together.

Now, I would like to call your attention to some relevant key stories and milestones that the administration has achieved in the past few months. Last month the US Surgeon General, Dr. Vivek Murthy, issued an advisory highlighting the urgent need to prioritize mental health and wellbeing of parents and caregivers. Stress levels among parents are significantly higher than other adults with 33 percent of parents reporting high stress, which can negatively affect both the mental health of the parent and the wellbeing of the child. The advisory calls for a cultural shift to better support parents through policies and program that promote paid family leave, affordable childcare, and accessible mental health care, underscoring the critical role that parents play in shaping society's future.

Earlier this month, the department in collaboration with the American Society for Nephrology, launched the KidneyX Sustainability Prize. This is a $7.25 million challenge aimed at improving the sustainability of kidney care. The initiative seeks innovative solutions to reduce the resource demands of maintenance dialysis, which consumes vast amounts of water and power globally. Hemodialysis requires billions of liters of water and energy and resource shortages from national disasters post life-threatening risks to patients. The challenge encourages diverse innovators to propose solutions that reduce water or power usage in dialysis and enhance equitable access to care with the winners to be announced in early 2025.

Two years after, the Inflation Reduction Act was signed into law. The administration finally announced agreements for reduced prices on ten of the most expensive and frequently used Medicare drugs, which treat conditions like heart disease, diabetes, and cancer. These prices effective January 1, 2026, will save Medicare an estimated $6 billion and reduce the out-of-pocket cost for beneficiaries by $1.5 billion. This initiative, part of the first ever Medicare drug price negotiation, fulfills the administration's promise to lower health care costs and improve access to essential medications for millions of Americans.

Last month the Interagency National Integrated Heat Health Information Systems developed the National Heat Strategy for 2024 to 2030 to protect communities from the growing threat of extreme heat.

CDC and HHS offices of climate change and health equity along with the National Oceanic Atmospheric Administration, NOAA, and FEMA, led the interagency comprising of 29 federal departments and agency. With heat now recognized as the leading weather cause of death in the United States, the

strategy underscores the serious health risks it poses to humans, animals, ecosystems, and broader economic and societal systems.

The National Heat Strategy will address the compounding environmental challenges presented by heat in tandem with other climate stressors and seek to mitigate its multisectoral impacts on industries like transportation, agriculture, and industry.

The strategy also emphasizes cross-sector partnerships and dialogue to develop solutions that account for both unintended consequences and co-benefits. A collaborative and integrated information approach is key to addressing the needs of decision makers and creating heat resilience.

The Administration for Community Living, ACL, released a strategic framework for the National Plan on Aging, which lays the foundation for creating age-friendly communities that fully support and include older adults. The framework encourages partnerships across the public and private sectors, including family caregivers and the Aging Services Network to advance best practices for aging support. It emphasizes cross-cutting values like person-centeredness, inclusion, respect, and collaboration, ensuring that the aging services and policies are developed with dignity and respect for older adults.

On April 23, the department through CDC and the Substance Abuse Mental Health Services Administration, SAMHSA, released the 2024 National Strategy for Suicide Prevention, a critical framework to combat the growing suicide crisis with an accompanying federal action plan.

Over 49,000 people died by suicide in the US in 2022, making it a growing public health crisis. The National Strategy outlines 200 actions to prevent suicide such as integrating mental health and substance use care in clinical settings and supporting survivors of suicide loss. Equity is a key pillar, focusing on populations disproportionately impacted by suicide.

HHS has also unveiled a national strategy aimed at addressing the maternal mental health crisis with recommendations developed by the Task Force on Maternal Mental Health. This strategy is part of a broader effort to address maternal health issues in line with the White House's initiatives.

The United States has the highest maternal mortality rate among high-income nations with mental health issues being a lead cause of pregnancy-related deaths. In the National Strategy, the task force vision calls for a seamless integration of perinatal mental health and substance use care across medical, community, and social systems that increase equity and access, improve federal coordination, and elevates culturally relevant supports and trauma-informed approaches. Each of these strategies underscore the department's commitment to tackling critical health issues and building a healthier future for all Americans through collaborative, coordinated, and equitable actions.

Turning to our work on opioids and the department's overdose prevention strategy, on June 25, the secretary renewed the opioid public health emergency for another 90 days. In 2024, the Biden health administration made a critical investment to addressing the overdose crisis by announcing over $1.5 billion in funding opportunities for state and tribal opioid response programs. This funding distributed through SAMHSA aimed to strengthen evidence-based holistic practices, including prevention, harm reduction, treatment, and recovery services.

By building on previous successes such as over half a million overdose reversals and the distributions of a million naloxone kits in 2024, the state and tribal opioid response funding provided states, territories, and tribal entities with resources to continue combatting the opioid epidemic.

This effort was aligned with the HHS overdose prevention strategy, ensuring that life-saving interventions like medication for opioid use disorder and overdose reversal treatments reach those in need.

In addition, SAMHSA's 2023 National Survey on Drug Use and Health highlighted the ongoing challenges of substance use and mental health across the country. The report revealed that 22.8 percent of adults experienced a mental health condition in the past year while 3.1 percent of individuals misused opioids. Notably, mental health treatment increases with more adolescents and adults receiving care compared to the previous years. These findings underscore the continued need for accessible treatment services while also emphasizing the growing importance of recovery with 73.1 percent of adults who experience substance use issues considering themselves to be in recovery.

The administration's funding and data-driven approach represented a comprehensive response to both the mental health and substance use challenges across diverse communities.

The last few months, the secretary has declared five national health disasters related to public health emergencies. In response to Hurricane Francine, Secretary Becerra declared a public health emergency for Louisiana on September 12. The department has deployed disaster management professionals and a health care situational assessment team to Baton Rouge, integrating with FEMA and state officials to address the medical needs of the affected areas. These teams will ensure hospitals, nursing homes, and other health facilities can continue to provide care during and after the storm.

In early August, public health emergencies were declared for Florida, Georgia, and South Carolina due to the health impacts of Hurricane Debbie. To support these states, ASPR deployed approximately 50 medical providers and disaster management professionals to assist with facility assessments, patient care, and evacuations. They remain ready to provide additional resources as needed.

The department renewed a public health emergency for Hawaii on August 1 in response to the continued effect of the Maui wildfires. ASPR remains on standby to deploy additional resources as needed to support public health and medical needs in the affected areas.

Following severe weather and Hurricane Beryl, a public health emergency was declared for Texas on July 12. ASPR teams have been working closely with state officials to address the combination of severe heat and power outage, which have impacted more than one million residents. The department continues to provide resources to ensure vulnerable populations have access to the care they need during the recovery effort.

Now I 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. Last month the Health Resource and Service Administration or HRSA announced more than $1.4 billion in funding for the Ryan White HIV/AIDS Program ensuring life-saving HIV medication and care for over

290,000 low-income individuals living with HIV. The funding provided through HRSA AIDS Drug Assistance Program covers medication costs, co-pays, insurance premiums, and related health care services. Helping people with HIV achieve viral suppression, which allows them to live healthier lives and prevents the transmission of HIV.

Without access to HRSA supportive programs, the cost of HIV mediation could exceed $40,000 annually, making it inaccessible to many. The Ryan White Program currently provides comprehensive medical care and essential support programs to over half a million individuals with HIV, addressing social determinants of health such as housing, transportation, and food access to ensure long-term treatment success. In 2020, 90 percent of Ryan White Program clients achieved viral suppression.

Ahead of the 24 Marketplace open enrollment, the Centers for Medicare and Medicaid Services, CMS, awarded $140 million to 44 navigator grants to help millions, especially those in underserved communities, access affordable coverage through healthcare.gov.

Navigators provide free assistance for health care coverage options, Medicaid and CHIP enrollment, and post-enrollment services helping reduce barriers to care for many Americans. This is part of a larger five-year commitment of up to 500 million, the longest and largest investment in the navigator program today.

During the last enrollment period, a record 21.4 million selected health care plans through healthcare.gov and state-based marketplaces, underscoring the success of efforts to expand health coverage. Most consumers qualify for zero dollars in premiums or significant savings due to subsidies from the American Rescue Plan Act and the Inflation Reduction Act.

Moving on to another agency priority goal, behavioral health. SAMHSA announced 45.1 million in grants with 15.3 million dedicated to services for children and youth. Key focus areas include mental health support in schools, services for children and families affected by trauma, and transitional age youth with mental health issues. Additional programs include homeless support, school-based mental health, trauma and grief support, supported employment for serious mental illness, substance use disorder treatment for minority populations and many more.

In recognition of September as Suicide Prevention Month, a time dedicated to raising awareness about suicide and spreading messages of hope, SAMHSA awarded $68 million in grants to address suicide prevention and mental health. Key programs include Garrett Lee Smith State/Tribal Youth Suicide Prevention to implement prevention strategies for youth in schools and juvenile systems, campus suicide prevention to enhance mental health services for college students, National Center for Mental Health at Stanford University for technical assistance in mental health services and comprehensive mental health services for children with serious emotional disturbances also known as the Children's Mental Health Initiative aimed at improving outcomes for children and youth with serious and emotional disturbances.

The Administration for Children and Families, ACF, launched new resources to support the mental health of young children and families and the early care workforce. The resources focused on promoting

healthy child development and integrating mental health into early education settings. Aligned with the Biden-Harris administration focused on mental health as a pillar of the unity agenda, these initiatives aimed to improve mental health and behavioral health care in early childhood programs such as Head Start and Tribal Home Visiting.

For maternal health, as I mentioned earlier, maternal health continues to be a priority for HHS. Our country's maternal mortality rate is the highest of any developed nation in the world and more than double the rate of peer countries. As part of the Biden-Harris administration's commitment to tackling the maternal health crisis, the department has dedicated over half a billion to improve maternal health outcomes across the nations.

The funding builds on the White House blueprint for addressing the maternal health crisis with more than 440 million directed towards expanding vital home visiting programs, an additional $118.5 million allocated to prevent pregnancy-related deaths. A significant portion of this funding will be used to expand voluntary, evidence-based maternal infant and early childhood visiting services. These programs delivered by trained health professionals such as nurses and social workers provide essential support to families from pregnancy through early childhood.

By promoting prenatal care, breastfeeding, safe sleep, early childhood development and school readiness, the home visiting initiative connects families to critical resources like affordable childcare and education, ensuring long-term health and wellbeing.

In a complementary effort, the CDC is investigating public health infrastructure aimed at preventing pregnancy-related deaths. This will expand the work of maternal mortality review committees. These committees play a crucial role in reviewing pregnancy-related deaths and identifying preventable factors and recommending actions to improve future maternal health outcomes.

In addition to the home visiting programs, HHS is dedicating 105 million through the Healthy Start initiative to more than 100 community-based organizations across the country. This funding is targeted at high-need communities where maternal and infant mortality rates are significantly higher than the national average particularly among black, indigenous and infants of color.

By offering culturally responsive care, transportation, food assistance, and other social supports, Healthy Start aims to close gaps in the health disparities and improve outcomes for mothers and infants in vulnerable communities. The combined investment and effort reflect a comprehensive approach to improving maternal and child health, ensuring healthier futures for families in the United States.

As part of the administration's ongoing commitment to strengthen the health care workforce and improving care for vulnerable populations, several important initiatives have been launched in recent months. On July 1, the administration announced an investment of over $200 million through HRSA to support 42 programs across the nation, aimed at improving care for older adults, including those with Alzheimer's disease and related dementias.

The Geriatrics Workforce Enhancement Program is at the forefront of this effort, training primary care physicians, nurse practitioners, and other health care clinicians to provide age-friendly and dementia-

friendly care. This initiative also equips families and caregivers with the knowledge and skills necessary to support their loved ones effectively. These investments underscore the administration's commitment to ensuring older adults receive the high-quality care they deserve as they age.

Additionally, HRSA announced the first ever Licensure Portability Grant Program, investment in a multi-state, social worker licensure compact. This 2.5-million-dollar investment aims to ease the barriers to licensure, expand telehealth services and increase access to mental health and substance use disorder treatment by allowing social workers to practice across state lines. By facilitating practices across state lines, the administration is addressing workforce shortages and improving access to care, particularly in rural and underserved communities.

Earlier this year, HHS in collaboration with the US Department of Labor announced two technical assistance programs to help states recruit, train, and retain direct care workers. This workforce is critical in providing home and community-based services for older adults and individuals with disabilities. This initiative also includes key data recommendations for building infrastructure to support future policies aimed at improving job quality for direct care workers.

These workforce initiatives represent just a portion of the comprehensive approach the Biden-Harris administration is taking to address workforce shortages, expand health care access, and improve care for some of the most vulnerable populations.

Now, I would like to turn to some recent rulemakings of interest. The Office of Research Integrity, ORI, has finalized the 2024 public health service policies on research misconduct, updating the 2005 regulations to reflect advances in technology and the evolving research landscape. These updates enhance institutional responsibilities, streamline misconduct investigation processes, and clarify institutional discretion in handling research integrity issues.

These changes also support the Biden-Harris Administration's goal of promoting cutting-edge research such as novel treatments and responses to climate-related health issues by fostering transparency in collaboration within the research community. A final rule will take effect on January 1, 2025.

A significant step to expand access to mental health and substance use disorder care, the Biden-Harris administration has issued final rules aimed at strengthening protections for more than 150 million people with private health coverage. These rules issued by the Department of Labor, Health and Human Services, and the Treasury clarify the requirements under the Mental Health Parity and Addiction Equity Act of 2008, ensuring that mental health and substance use disorder benefits are on par with medical and surgical benefits.

CMS has issued a final rule updating the Medicaid payments and policies for in-patient hospitals and long-term care hospitals, LTCHs, for fiscal year 2025. This includes a 2.9 increase to payment rates for certain acute care hospitals and a 3 percent increase for long-term care hospitals.

These updates, which support historically underserved communities, are part of the Biden-Harris administration's effort to promote health equity and improve emergency preparedness. Additionally, the rule enhances resources for hospitals treating patients experiencing housing insecurity and

promotes access to innovative treatments particularly for rural and underserved communities.

This rule also strengthens emergency preparedness by implementing streamlined data reporting for future public health emergencies, enhancing hospital safety initiatives, and advancing value-based care through a new episode-based payment model set to begin in 2026.

Further, CMS has issued three final rules to support caregivers, enhance care worker compensation, and improve care quality in nursing homes, aligning with President Biden's effort to boost care options and job quality.

These rules issued during Care Worker Recognition Month fulfill commitments to the president's action plan for nursing home reform in his April 2023 executive order on increasing access to high-quality care. They establish minimum staffing standards for nursing homes, improve Medicaid and CHIP access and create transparency in managing care, ensuring millions of Americans receive high-quality, equitable care.

CMS is also proposing rules to reduce maternal mortality and morbidity particularly in underserved communities through calendar year 2025, Hospital Outpatient Prospective Payment Systems and Ambulatory Surgical Center rule. Key proposals include expanding access to care in the Indian Health Services and tribal facilities, enhancing maternal health services, and improving access for formerly incarcerated individuals to Medicare coverage.

CMS is also focused on addressing health equity through baseline health and safety requirements for hospitals, expanding quality measures, and supporting behavioral health all in alignment with the Biden-Harris administration's commitment to health equity.

Earlier this month, the Office of the Assistant Secretary for Health and HRSA proposed to remove burdensome clinical research and IRB requirements for kidney and liver transplants between HIV-positive donors and recipients, expanding access to life-saving transplants. This rule, building on the HOPE Act, aims to reduce stigma in health disparities in organ transplantation, increasing the number of centers able to perform these transplants and improving overall transplant access for people with HIV.

On July 25, the department announced a major reorganization within HHS to streamline and bolster technology, cybersecurity, data, and artificial intelligence strategy and policy functions.

The Office of the National Coordinator for Health Information Technology will be renamed the Assistant Secretary for Technology Policy, consolidating the oversight of tech data and AI policy from the Assistant Secretary for Administration.

HHS' cybersecurity efforts including the 405D program will shift from ASA to ASPR's Office of Critical Infrastructure Protection, further centralizing health care cybersecurity. National Coordinator Micky Tripathi will be taking on the new role of Assistant Secretary for Technology on Policy and Acting Chief AI Officer. This reorganization reflects HHS' commitment to addressing today's tech challenges in health care.

As part of this reorganization, three positions, chief technology officer, chief data officer, and chief AI officer are currently open and being actively recruited. These rules will play a critical part in shaping the department's strategy for advancing data and technology initiatives across HHS. Filling these positions with top talent will be vital to ensuring the department's continued leadership in health care technology and innovation.

And finally, recruitment. As we look to the future, I would like to take a moment to acknowledge the transitions happening within the committee. Jacki Monson completed her term as chair, leaving the role of chair currently open. Naomi Michaelis, our designated federal officer, has kindly stepped in as acting chair while HHS Secretary works to appoint a new chair.

Additionally, we extend our deep appreciation to Debra Strickland and Denise Chrysler both of whom have completed their terms. Their dedication and contributions have been invaluable to the committee's work.

I am excited to share that three new members have been nominated and are currently going through the onboarding process. We anticipate they will be fully integrated into the committee by our December meeting, bringing forth perspectives and expertise to our discussion.

That said, there are still opportunities for others to join. We currently have five vacancies with both congressional appointments still to be filled. Five individuals have already been nominated for these open positions and two current members are being considered for renewal. These nominations are under review by the secretary, and we are hopeful to have them on board soon. Additionally, Wu Xu will be completing her term in January, which will open another seat on the committee.

As always, your ongoing involvement and insights are critical in identifying potential new members who can contribute meaningfully to our work. We look forward to continuing our collaborative efforts as we transition into this new chapter for the committee.

This brings us to the end of my prepared remarks and I am happy to answer any questions you may have.

Naomi Michaelis: Thank you, Sarah. Any questions from the committee? Hearing none, I will transfer it over to Val, who is going to provide us an overview as we start the work of the Privacy and Security in Health Data Access panels.

Privacy and Security in Health Data Access: Health Information Exchange Participant Perspectives

Valerie Watzlaf: Thank you. Thanks, Naomi, and hi everyone. I am just going to provide a little bit of background information as Naomi said about our project topic today, which is privacy and security and health data access.

But before I do that, I also wanted to do some thank yous, to do a big thank you to our Privacy, Confidentiality, and Security or PCS Subcommittee members, Angela Alton, Cathy Donald, Jamie Ferguson, Jacki Monson, and Denise Chrysler. I know Denise is no longer a member of our Full

Committee, but she has been very instrumental in our work for many years actually.

And then I wanted to also give a thank you to Michael Hodgkins for connecting us to some of our panelists today as well. I also want to thank our amazing staff, Maya Bernstein for working her magic again to getting our wonderful panelists together for today and special thanks to Naomi, Shirley, and Sarah for always supporting our PCS meetings and discussions. Thank you so much. We very much appreciate you.

Now I want to just give some brief background information on this project. The PCS Subcommittee has been discussing the issue of privacy and security and health data access very recently. The purpose of this project today is to hold panel briefings like the one we will have today that will focus on this topic and really enable us to learn more where it will include an examination from multiple stakeholders. We have two panels that will represent multiple stakeholders, and it will include issues that may arise with health data access when, for example, health data is shared across health information exchanges and the movement around networks under TEFCA and also particularly when HIPAA-covered entities and non-covered entities may be exchanging data, possibly with public health, human services, and social service entities.

We will also hear from the industry and consumer perspective in regard to release of information, the individual right of access, and the possible consequences for not providing needed health information when requested as well as the misuse of consent, authorization, or identity when PHI are disclosed. These are just a few of the areas that we will discuss today. I am sure there will be many more.

As I said before, we are in an information-gathering and discovery phase right now, looking to learn more. And we look forward to having a very robust dialogue with our panelists today. Please feel free to ask questions, participate in our discussions. We certainly want to hear from you.

Now, I am going to turn it over to Angela and Jamie, who will be moderating our first panel where the focus will be on health information exchange, participant perspectives on privacy and security of health data access.

Angela Alton: Good morning. I am going to start off with a brief introduction of our panelists. There is more information about their extensive backgrounds and biographies in the materials. I will start out with Mona Calhoun, president of the American Health Information Management Association, AHIMA, and chair of the AHIMA Board of Directors. Dr. Calhoun has over 40 years of experience in the profession and serves as chair of the HIM program at Coppin State University. She has led HIM departments in a variety of health care settings and has chaired several educational and policy committees.

Tina Olson Grande is the president and CEO of Healthcare Trust Institute, an alliance of leading health care organizations committed to promoting and implementing effective privacy and security protections. Tina has an extensive background leading organizations in advancing data interoperability, information sharing, and health care and advocating for consumer-centered health reform.

Deven McGraw, chief regulatory and privacy officer at Citizen Health, a consumer health technology

startup. Deven is a national expert on health data policy. Deven has served as deputy director of health information privacy at HHS Office for Civil Rights and served as acting chief privacy officer at ONC for Health IT.

Our last panelist member is Lisa Myers, senior counsel of the American Medical Association Division of Legislative Counsel. She provides legal advice and regulatory analysis on data privacy and cybersecurity matters with an emphasis on HIPAA, GDPR and Consumer Privacy Protections. Lisa is focused on patient privacy and health care and advises on proposes congressional bills and agency regulations. Welcome to all of our panelist members.

Why don't we go ahead and get started? I think, Deven, you wanted to talk about an overview of the landscape that we are in.

Deven McGraw: Thank you very much, Angela. It is really nice to be here. I am going to give a bit of a landscape overview. There is a lot that is going on in this space and there are probably members of you who know even more about this than I do. But I want to make sure that everybody is on the same page with respect to the way that exchange is being promoted and is currently facilitated today and some of the privacy issues that may arise in those contexts.

Obviously, we have been at this interoperability effort, the ability to exchange data for purposes for which the law allows, for multiple years. There is quite a bit of history that this all builds on. We have tools that are resident and certified electronic records, FHIR APIs that are purpose built for facilitating, kind of point-to-point exchange. But for some period of time even prior to the HITECH Act in 2009, there have been health information exchanges, networks that existed at the state and regional level that helped to facilitate the exchange of data mostly among health care providers for treatment purposes but also some of the early ones also facilitated exchange with health plans.

The effort to build these networks into more national exchanges has been over probably the last five to ten years, maybe a little bit off on their timing, and continues to date. I would say and someone can correct me if I am wrong that the kind of first effort to create national exchange was called the National Health Information Network, which then morphed into eHealth exchange. There are now national networks that exist that kind of grew out of that effort. Carequality is the one that is the most robust. At one time, there was – there is still eHealth exchange. There is CommonWell, but those exchanges have been – are now part of the Carequality National Network Exchange.

Again, that facilitates the ability for participants in that network to be able to exchange data in accordance with an agreement, Carequality participation agreement, as well as some policies and some technical specifications.

TEFCA, the Trusted Exchange Framework and Common Agreement is kind of the most recent iteration of national networks. It is voluntary and was required to be established by the 21st Century Cures Act. ONC was required to establish it.

Before I go into a little bit of detail on how these national networks work and maybe some of the privacy issues that came up, I want to say that one of the hallmarks of these networks and what makes it

different than the way that point-to-point exchange has historically occurred is there is an automated quality to it. Again, historically, when entities wanted to exchange data or you wanted to get data from one end to – such as for continuity of care purposes, you might approach the health information management department and ask for copies of those records to be faxed to you. There is an entire body as AHIMA knows very well of medical professionals that are accustomed to vetting and making sure that data leaving an institution in response to a request, was in compliance with law.

Networks work a little differently where the network assumes some of the – all of the work really of making that exchange happen and a good portion of the work around accountability for making sure that the participants comply with rules. There is a common set of agreements that bind everyone. It is not as though from a HIPAA perspective, the responsibility for complying with the Privacy Rule in terms of appropriate uses and disclosures is completely stripped away from the health care provider that sits on the end of one side of that transaction. But there are expectations around that the network operates in order to regularize or operationalize those transactions in a way that a lot of times individualized decision making by an institution whose record is being queried does not happen. That endpoint has signed up for the network and the data will flow in accordance with network rules. That is a very different environment than the one that we had prior to the growth of these networks in my opinion and creates quite a bit of distinction.

What about TEFCA/Carequality? We still have both. Do we really need both is going to really be an ongoing question. There are some differences in the way that they operate but they are increasingly becoming more alike with a recent announcement just a couple of months ago by Carequality, which has been in operation for far longer in exchanging data than TEFCO, which is relatively new. But Carequality is starting to move to align their policies to TEFCA policies. And I think there is perhaps an expectation at least in my mind that ultimately there will not be a need for any additional national networks other than TEFCA. On the other hand, again, TEFCA is a completely voluntary network. All these networks are typically voluntary. Sometimes at the state level, there might be requirements to participate in the statewide HIE. But for the most part, entities sign up for and participate in these networks because they see a value proposition to doing so in terms of facilitating the exchange of data.

The other thing that I think is worth noting is that with these national networks, there are intermediary actors that help to facilitate those transactions. You can call them Carequality implementers on the Carequality side.

On the TEFCA side, there is actually an effort to limit the number of entities who facilitate the exchange that happens in TEFCA. These are the qualified health information networks. They were required to submit to the coordinating entity for TEFCA, which is the Sequoia Project chosen and supervised by ONC. But the recognized coordinating entity that makes TEFCA run is a nonprofit organization called the Sequoia Project. Through a governance process, comprise the common agreement, make the rules of the road for who gets to exchange.

Those QHINs kind of sit at the top of TEFCA and then there are participants and sub-participants. You have to choose a QHIN. But the idea is you pick one and you will have the ability to launch a query for a permitted purpose, get to that in a second, and be able to get data from any place in the network in

accordance with the TEFCA rules again for a permitted purpose.

Carequality works in a very similar way except there are lots and lots of implementers. Many of those implementers are companies that provide a service, usually a paid-for service, to be able to connect an individual who is seeking to query into Carequality and to facilitate those transactions. This middle layer of implementers in these national networks – they often look very different from one another in terms of their architecture. Some of them cache or keep or retain a copy of every data point that passes through their networks whether it is being facilitated for one of their customers or they are grabbing data for their customer from someone who is not one of their customers but is another participant in the network that data passes through. It gets held there. They have repositories many of them as opposed to a pure passthrough model.

The permitted purposes in Carequality include treatment, payment, health care operations, public health in response to patient requests for coverage determinations, for care coordination, and where authorized by the patient such as through a HIPAA-compliant authorization. But the only required response through Carequality is for treatment and they have recently – they were following the treatment definition under HIPAA, but they have recently narrowed it in response to some issues of entities who are querying Carequality and very desirous of trying to meet a treatment purpose because that is the only purpose for which a response is required to be sent back. For all of the others, it is discretionary for all the other permanent purposes.

Consequently, we have seen, and I think this is going to be addressed by another panelist, an effort by a number of companies where it is a little less clear that there is a true treatment purpose going on there. TEFCA actually has recently acted to create a more narrow definition of treatment and Carequality again is aligning with those policies.

In terms of TEFCA's use cases, similar, maybe a slightly smaller list of permitted purposes, treatment, payment, public health, individual access to patients otherwise called individual access services, government benefits determinations, and health care operations. To date, the only mandatory response is again, treatment and it is only mandatory under the one class – they have created two different classes of treatment responses in order to address the issue that I just talked about.

Technically, it is also mandatory for there to be a response to an individual access request. That is usually not launched by a patient but an app or a platform or some entity that is working on behalf of a patient.

However, a response is only required if the entity who holds the data is able to successfully match that patient with the identity attributes that are submitted to the satisfaction of the entity that they have a unique match for that patient. This is due to concerns on the part of entities participating in these networks that if they send back the data on the wrong patient and it is going to an entity that is not covered by HIPAA, it is a breach under the HIPAA Privacy Rule. They are very reluctant to be unsure even if they get the query and it gets run through their records and only one match pops up without meeting their local matched rules, which they are permitted by TEFCA to apply, they do not necessarily have to send the data back. Consequently, there actually has not been a lot of data that has been sent back in

response to individual access requests that come through TEFCA even though it is one of the mandatory use cases. Again, there is the stability for the endpoints to decide if their local match rules have been met.

Some of the privacy issues that occur are again you need to have a permitted purpose to query one of these networks. But once that data comes into your environment as the entity that received the data, you could subsequently use it for any other purpose as long as that is permitted by HIPAA if you are a HIPAA-covered entity receiving that data. That means that that data can be de-identified and then subsequently sold or reused because in accordance with HIPAA rules, which is all permitted.

Similarly for the implementers at the middle layer that might be caching or retaining data from queries, they may have a business model that as long as their business associate agreement allows them, they can reuse identifiable data consistent with the HIPAA Privacy Rule and/or de-identify that data, again assuming permission in their business associate agreement and sell and reuse it.

One of the biggest concerns around these networks for individual access services for the patient request for data has been the apps who are not likely to be covered by HIPAA. As you all know, you have worked on this issue for some period of time, what happens to all this health data that is swirling around in our environment not covered by HIPAA. You cannot participate in TEFCA without at least contractually agreeing to abide by the provisions of the privacy and security rule for all of the data in your environment, not just what you are grabbing from TEFCA.

On top of that, you have to be identifying proofing your users if you are an app like ours. You have to identity proof them at NIST level 2 of assurance and be using a certified identity provider because most entities hire a vendor for this. They do not do it themselves. You have to be getting express consent from patients and you also have to have a visible and understandable privacy policy that has a number of elements to this. I am happy to explore with you in more detail or that I would encourage you to explore. They have done a lot of work at trying to create a trust environment in TEFCA that tries to equalize where all of the entities are in terms of what the expectations are and frankly place a bit of additional sets of expectations around non-HIPAA-covered entities particularly those that are serving patients.

I will stop there. I am happy to – I apologize that I did not have time to prepare slides. I hope this was not completely in the weeds for you all. Happy to talk more about privacy and networks and where we are headed and all things interoperability. Thank you.

Angela Alton: Thank you, Deven. I think we were going to move to Lisa Myers, who is going to talk more about attestations.

Lisa Myers: Thank you and thanks for the opportunity to present here today. That was an outstanding overview. That was fantastic. I really appreciate that.

From the AMA perspective, physicians have long supported patient access to their medical records because it enhances patient engagement. It equips them for partnership with their care team. You get better health outcomes that way. That is the point of health care. But the privacy and control of that

information is crucial to every aspect of the individual's life now more than ever. And medical providers too can suffer criminal penalties for rendering aid that meets the standard of care if the health information is not protected.

HIPAA has done a pretty good job. And when patients first ask for their records, they get a file folder of paper copies and then one worried about unauthorized disclosure from that point. Now no one, including us on this call -- no one wants a stack of paper. That is the rub. When the patient wants PHI sent to an app that is not an entity covered by HIPAA, we do not know if and how that app will protect the PHIs as Deven noted and the whole chain falls apart. The whole HIPAA structure is gone once PHIs are disclosed to a non-HIPAA entity.

The crucial interface is from the provider to the app and the part that is now missing in that interface is the flow-down clauses that are in BA agreements to protect the PHI and that void has to be filled not by the patient who may be vulnerable and not by the provider who is already complied with HIPAA, information blocking, CMS regs, and has now disclosed the data. The entity that can best control the risk for the sensitive information it now holds is the app. The app should never receive PHI without a basic query as to what its security practices are.

And to zero in further, the disclosure of PHI to the app is accomplished by the EHR vendor and that is where ASTP comes in. AMA has advocated that for a baseline determination of app security practices, ASTP, ONC should implement a basic privacy framework before the EHR vendor send PHI to an app. A certified health IT developer application programming interface, API, could check an app's yes or no response to attest to three things. That it adheres to a relevant standard, which could be established by the industry for privacy and security. Secondly, our statement of transparency and best practices and finally a model notice to patients. This query and attestation – it would not regulate apps and it does not extend beyond ASTP's authority requiring certified health IT's API to check for an app developer attestation would not be a significant burden on EHR developers and likewise apps would not be prevented from connecting to an EHR even if they attest no to the three attestations because the patient right of access is so important that even if it does not look secure and the patient says fine. Post it on a billboard. They have a right to their records and they have to right to designate their personal representative or an app to receive it.

Accordingly, ASTP's decision support interventions and transparency requirements utilize the same concept that AMA has proposed, which is requiring the certified health IT developer to request information from a third party and make that information available to users.

As Deven referred to, there is an open space for these apps that are outside of HIPAA. Past responses from regulators have been to put additional compliance burdens frankly, on physicians who are in a good position and compliant with HIPAA and learning about information blocking. But to add another layer at this point would be difficult. It is already quite a compliance burden.

As someone who explains privacy regulations to physicians to explain HIPAA and information blocking, it takes 30 minutes just to give an overview. It feels inappropriate to keep layering on that end of the equation when we are talking about information that is now post-disclosure and in the hands of an app

where we feel that with the right regulation, it could operate seamlessly, give patients the access they need, and also an assurance of security from the requester who is standing in the shoes of the patient.

With that, I will let the discussion move on to the next participant.

Angela Alton: Tina, we were going to talk about from the industry perspective inside TEFCA and some privacy vulnerabilities.

Tina Grande: Thank you, Angela, and thank you to all the committee members for inviting me to testify today. It is nice to be with everybody.

Just a little background on the Healthcare Trust Institute. We are an alliance of health care organizations committed to promoting and implementing effective privacy and security protections for health information to engender trust in the health care system and allow for the advancements of treatments, cures, and quality improvement in health care both for individuals and for populations.

Our members include companies and organizations from across all of the US health care system. And we all agree that it is high time that we have a national privacy standard put in place to protect sensitive data so that we can continue to spur medical innovations. That is who we are.

I thought today since we are somewhat new as an organization, I do have some slides I can share just related to the privacy principles that our organization stands behind. And then following that, I will briefly discuss an article that Deven McGraw and I co-authored related to these exchange networks and some privacy issues that we would like to see address through policy.

Our organizations have thought long and hard about privacy in health care and how we can do a better job to protect the information, what kind of policies are needed to be put in place to engender trust in health information exchange because it is important that that information be allowed to flow so we can innovate in the health care space.

First of all, we stand behind robust privacy and security protections for personal information. It is the foundation of making sure that people want to share their information to improve health care quality and treatments.

All personal information, health information, whether it is in or out of HIPAA should be subject to regulation. We believe that – its apps have been talked about quite a bit already this morning that that information does need to be regulated and that people should have the opportunity to opt out or change their information, depending on the situation if it is something that they want to do.

Entities holding and collecting personal information should be required to have cybersecurity safeguards put in place. And we referenced NIST and their framework is something that we should look towards.

Protections for all personal health information should be established at the national level so that we have consistency. There is a real concern among our organizations that the patchwork of state privacy laws – I am sure everyone here has heard a lot about that – is getting increasingly more difficult to

navigate. And on top of it, we have states that are now passing AI laws as well and just this patchwork system is getting more and more difficult to manage especially in the face when we have national networks set up that have to default to state laws. It is complicated and difficult.

We believe strongly in the principle of minimum necessary and data minimization in terms of sharing information. We also promote the use of de-identified data and privacy-enhancing technology practices when exchanging information that does not need to be identifiable and that there should be prohibitions put in place for organizations that received de-identified data who go against a contract, for example, and attempt to re-identify when they should not be doing that.

Individuals should have a clear and simple privacy notice. I know there has been a lot discussed about this. We completely agree and that in addition to those simple notices, folks should have the rights to include the request to access and request to correct their information.

And the HIPAA framework is something that we believe has worked relatively well and that it should be kept in place. It has engendered trust in health information exchange at least within the organizations who fall within that framework. We believe it should be upheld perhaps admitted in certain place it should be upheld.

And that any personal health information that falls outside of the HIPAA framework should be regulated and it should be regulated at the national level. And when that information is regulated, it should be done so in a manner that harmonizes with HIPAA so that we do not get bottlenecks in the flow of information.

And then as a tagalong to that issue is that when this information is regulated, we have to have meaningful penalties for violations and that when individuals report that their information has been misused that they can do so without fear of retaliation.

That is it for the slides for me. I am going to stop sharing now. I wanted to talk a little bit about an article that Deven McGraw and I co-authored fairly recently. It was in Health Affairs Frontiers, and I believe it was included as reading material for you all.

I am not going to go in depth in all of the policy recommendations that we put forward in the article. But the article basically focused on exchanges and networks. Deven did a phenomenal job describing that environment and where we are right now.

As we move towards the new way of requesting and sharing information in hopes of nationwide data interoperability in health care, there are still some privacy issues that need to be addressed that despite all the good work that the Sequoia Project has done in pulling together their governance framework, there are still some issues that are lingering out there and we wrote about it.

And without naming names of any organizations, there is a concern that, as Deven mentioned, the treatment use case, the one that is currently being used in TEFCA as a means of requesting information from these QHINs. There is a concern that some organizations or individuals may try to get on these networks and say that they are requesting the information for the treatment purpose and then perhaps

in some cases, using it for treatment but also using that information for other purposes that were not initially disclosed.

This is something that we need to figure out how to address and address in a way that does not disrupt data interoperability of health information but also holds organizations accountable for the misuse of these requests because it is not privacy protective for those individuals whose information is being shared in ways that are not allowed on these networks.

We have, I think, maybe five or six recommendations. One relates to funding, these information exchanges in a fashion so that they are able to better police to prevent conflicts.

There are two I wanted to read out loud. This is for me and Tina, not necessarily HTI but this is for Tina. I believe and Deven and I wrote about this that penalties for misuse of information are really needed. There are a lot of organizations that I think when the penalties are not strong enough, they just do not abide by the rules. We need strong penalties to make sure that everybody abides by the rules.

We write, there should be serious consequences and significant penalties for misuse of health information networks and misrepresenting the purposes for which patient data is accessed. At a minimum, the entities' participation in that network should be terminated. And the entity and its controlling officers should be banned from participating in any health network in the future. It is pretty strong, but this is what we believe.

Such misuse and misrepresentation should be treated as an unfair trade practice subject to civil mandatory penalties under the Federal Trade Commission. Networks should have a transparent and speedy process for investigating and resolving concerns. HHS should consider modifying HIPAA to establish stronger safeguards on collection of data to ensure that patients' records are not accessed on fraudulent conditions.

And since HIPAA may not apply to all exchange participants, Congress should step in to ensure that all personal health information is regulated in a manner that harmonizes with HIPAA to prevent bottlenecks and legitimate data sharing. That is one recommendation that I wanted to read out loud.

Another one that is important to organizations that are policing to make sure that we do not have bad actors coming in and trying to misuse information. We talked about a safe harbor for innocent parties when exchange participants misrepresent purposes. And this is the only other one I am going to read out loud. I want – I get it right and you hear it right. There should be a safe harbor under HIPAA and/or the information blocking rules for trusted exchange framework participants who provided patient data to an exchange participant that misrepresented the purpose of their query.

OCR and ONC should consider establishing minimum requirements for exchange network participants to qualify for the safe harbor to ensure safe harbors are not used as an excuse to deny access to information for legitimate purposes.

Some of these organizations really struggle. They in good faith have good reason to believe that there may be some sneaky business going on with some these queries. In one case, access was shut down to

one of the organizations that was requesting information. And when the access was shut down, there was an accusation of information blocking put on the organization that shut down access to the information, but that organization did have a good faith belief that the information was being used for purposes that were not representative of the exact reason why they were requesting the information.

As long as there is no ability to use a safe harbor to get out of information sharing when it should be happening, we believe that there should be a way for organizations to in a good faith effort stop sharing with someone they believe is misusing patient information that is identifiable.

And then we have recommendations. We ask for more sub-regulatory guidance to reduce fear of information blocking charges. We asked for clearer guidance on non-treatment purposes for information exchange. And then we also call for jump starting information exchange in response to patient requests.

This is the beginning process to talk about policies that we would like regulators in Congress to think about to help us keep these networks solid if there is not trust in how the information is flowing in these networks. To Deven's point, TEFCA is voluntary. People may choose not to use it. It may not succeed if trust erodes in these networks in the exchange of information.

I guess outside of Congress getting a national privacy bill passed and a law enacted, we need to think of creative ways. I think TEFCA has been pretty creative in terms of pulling in that non-HIPAA element into a HIPAA framework as long as they are inside of TEFCA. That is a great first start. And now it is time to look at the networks and close any loopholes that may exist that could erode trust in sharing and exchanging of that information.

That is all I have for introductory remarks. But I do look forward to questions after our last panelist gives her thoughts. Thank you.

Angela Alton: Now, we are going to move on to Dr. Calhoun, who is going to talk about health information and how it impacts the profession and what consumers and patients need to know about their rights to access.

Mona Calhoun: Thank you. Good afternoon, everyone. And if there are persons joining us from a different time zone, good morning to you. Thank you so much for this opportunity to share in this panel. I so appreciate the other panelists that have presented. I think you will see some commonalities in the things that we share and the concerns that we have.

I do have a presentation that I will share my slide. I wanted to start with – for those who may not be familiar with who the American Health Information Management Association is, we are a global nonprofit organization. Our primary responsibility is being the leading voice and authority for health information wherever it is and whatever it is.

We have a mission to empower people to impact health and that mission is broad but it is also very telling of who we are and what we are here to do. This is achieved through initiatives such as privacy and maintaining privacy, security, technology, and business operations, including supporting health

analytics as well.

While patients do not often see us – health information professionals. Health information professionals see our patients and we see them in a way that no other health care professional does. That is because AHIMA-certified professionals ensure that sensitive health stories remain accurate, accessible, protected, and complete at all times. And some of the examples are here on the screen. We are experts in revenue cycle management, privacy and risk management and compliance, data analytics, and it goes on. You will notice that even some of the lower-level positions, medical records clerk, which is a really critical position, medical billers are very critical when we are talking about maintaining privacy and security.

The HI professional is often the first line of data exchange through processes such as privacy, security, and compliance. Compliance officers, release of information, revenue cycle, data management, risk management, roles among some just to name a few.

Data exchange activities are guided by information blocking, HIPAA, 42CFR Part 2 and state laws. In many cases, information blocking compliance and HIPAA privacy compliance activities are undertaken by the HI professionals within a provider facility.

As has already been shown by our previous panelists and I will talk about the complexities but first before I do that, I do want to talk about the coders role. AHIMA is one of the premier standard setting organizations working with our cooperating partners such as CMS, the National Center for Health Statistics, AHA, and in implementing and sustaining ICD-10 guidance.

In addition to focusing on ICD-10, AHIMA and HI professionals work with a variety of coding standards in their daily work. AHIMA takes its charge as the preeminent source of coding education and HI professional education seriously, offering multiple options for our leaders.

As the data landscape evolves, AHIMA and HI professionals are increasingly involved in administrative data domain and growing a vital source that is being further integrated into data exchange.

As we know, it is a very complex web of agencies, state laws that dictate the current privacy and consent environment. There is no sole regulatory source for the whole privacy environment. Once data leaves the HIPAA security environment, the landscape becomes even murkier, and our previous presenters have already indicated this.

HI professionals must be knowledgeable on all of these different intersecting rules and often they can contradict themselves or if they are not perfectly aligned.

More data is exchanged more often today than it was when many of the regulatory frameworks were enacted or when many of our HI professionals began their careers. With the speed at which data travels today, many of the policies interact with the data without a human having come into contact with the data and Deven shared that with us already previously in describing TEFCA and how it works.

TEFCA will open more people to exchanging more data more often across state lines and this creates

even another layer of privacy and consent requirements that data must travel through. With information blocking now in effect, patients now have even more ability to request and hold their data through the app of their choice. This creates new chances for data moves out of HIPAA environments or into new HIPAA environments. We also know that AI even plays a role and that is even still something that is a concern when we are talking about privacy and security.

As the US looks to work through the privacy and consent process, HI professionals can be an asset. HI professionals have success in coordinating complex policy landscapes such as with information blocking. As complex as information blocking is, the policy change in AHIMA 2023 survey looked at the HI's role in achieving compliance. And some of those key findings with cross-functional groups critical for collaboration and authorization need to ensure leadership support and governance, ongoing training, communication, and the HI professional played a central role as lead collaborator. Part of how HI took the lead can do – for privacy and consent is through achieving leadership awareness and buy-in.

With the shifting landscape, there are changes that are going to be needed from HIPAA to keep up with the new environment. Part of the challenges begin with the significantly larger scope of health information that is now being used and the increased number of consumer-facing technologies and other technologies that use health data but are not HIPAA covered.

The large data sets currently gathered on patients are often outside of HIPAA scope and these concerns have already been shared and strain the current guardrails that HIPAA has put in place. As discussed previously, the state privacy landscape bearing from the federal law creates further complexity when it comes to compliance.

To solve many of these challenges, HI professionals face in our community and the partners and persons that we serve, we recommend that the National Committee on Vital Health Statistics inquire further on several issues. Those include enhancing the understanding of how HIPAA interacts with broader privacy laws under consideration, how to improve the protection of health data once it leaves a HIPAA-governed environment and simplifying the complex health data exchange oversight and enforcement process to make compliance easier.

Again, thank you for this opportunity to be part of the discussion. We welcome the opportunity to work with the committee to address these complex issues and I am happy to join the panel in answering any questions that anyone may have.

Angela Alton: Thank you.

Jamie Ferguson: That is fabulous. Thank you very much. This is Jamie Ferguson. I apologize. I had to be offline briefly due to an internet outage but I am back on and hopefully we have a stable connection now.

I am going to start off – we had some questions for the panel, and I want to start off by combining a couple of these questions to kick off the discussion. Thanks again for those presentations. I want to ask you to put yourself in the shoes of a record holder, meaning either a physician, a physician practice, a hospital or a health system or a health plan, a HIPAA-covered entity that is holding health records that is

getting a request for those records. The request could be coming from an individual, an individual representative or another HIPAA-covered entity potentially or a non-HIPAA-covered entity. What assurance does a record holder need to have about the identity of a requestor? Should there be, for example, identifying proofing standards that would apply to individual requestors? What sort of assurance levels should the record holder expect to have? Obviously, we want to release the information appropriately to people who are authorized. What sort of authorization standards and identity standards should apply so that information really is released in an appropriate manner? Any of the panelists, please kick in on this.

Mona Calhoun: I will start from an HI professional experience. Identity is verified through multiple means when a requester presents in person, a valid photo ID. When a requester contacts a provider over the phone, identity is confirmed or should be confirmed through their name and birth date. When requesting PHI to be accessed or transmitted electronically, a valid request must be completed through the means outlined by the organization whether it is electronic or wet signature, photo ID signatures do not match. That is critical. I will start there and have the other panelists weigh in.

Jamie Ferguson: Let me follow up a little more specifically. Should there be national standards as opposed to organizational policy determining what the identity standards are?

Mona Calhoun: We know national standards sets continuity, consistency across the board. So no matter where I travel as a patient or where I may go, there is consistency in what is required for me to release my information and for that entity to provide my information.

Tina Grande: Jamie, I would like to add some thoughts here. We have had organizations come in from the government to talk to us about what are their standards when it comes to issues of trust and identity and things of that nature. We have one member here from CMS. But the marketplace on healthcare.gov does have identity verification procedures that you have to go through in order to participant on the marketplace and that may be one model to look at.

And another CMS-oriented – I would not call it maybe a verification process because it is different from identity verification but oftentimes will say, CMS, you have something like blue button. How has that worked for you in terms of making sure that information is protected and maybe looking towards some of those programs that CMS has when it comes to protecting information especially in the marketplace? They have that real, solid identity verification piece that they make people go through when they are getting on the marketplace to shop.

Jamie Ferguson: Thank you, Tina. Michael, I see your hand up but I want to turn to Deven first as our panelist.

Deven McGraw: I was going to say these issues are not – yes, they are new in networked environments particularly where patients are concerned. I would definitely dive more into the policies that have already been established in TEFCO where they do actually rely on national standards that is required to meet level 2 of assurance. There is a requirement to actually use a certified identity provider so an identity provider that has been through a process of having had their opening up what they are doing

and having it assessed by a third-party assessor, not unlike third-party assessors in the security context. And then they are certified if they meet the requirements. There are a number of these identity providers that have been through that process and are certified at least for patient facing.

Identity management when you are talking about B2B exchange, one provider to another, that is up to the entity themselves to manage who is able to use their systems, launch queries, et cetera.

There are frankly also the standards that typically were adjudicated at the individual level. In networked environments, they get adjudicated through a set of common agreements, understandings, and governance systems to make sure everybody is complying with the rules. We have not seen them work exactly as we would like to as of yet but there is room for improvement.

Jamie Ferguson: Thanks very much, Deven.

Michael.

Michael Hodgkins: I want to thank the panelists. I actually had two questions if I am permitted. I understand the identity verification process but what requirements are there for disclosure if any from third-party apps that are serving as intermediaries for consumers to access health information.

Deven McGraw: There are many required by TEFCA, the Trusted Exchange Framework and Common Agreement, Sequoia Project manages. They released a brand-new SOP over the summer, which has a number of additional requirements that IAS providers need to meet in terms of their privacy policies, what needs to be in it. It calls out in particular collection of really sensitive information that is now subject to additional rules under HIPAA. Even though these are not HIPAA-covered entities, they have to be very transparent about whether they collect this type of data such as reproductive health or gender-affirming care types of data. They have to disclose. They have to have consent of the patient to make disclosure to third parties. They also cover issues around targeted marketing for data collected through passive interactions with websites as well as identifiable data that might be in the account.

I would commend you since you are just at the beginning of exploring this process to take a look at this SOP. I will drop the link in the chat and to take a look at what has already been laid out for what is required of apps that a patient might hire in terms of their disclosures to patients and then the requirement to obtain consent as well as the ID proofing and the fact that when they submit a query, they can only use identity attributes that have been validated as part of the identity process.

Jamie Ferguson: I really appreciate you calling out the TEFCA requirements. Do you feel that it would be beneficial for those to be adopted by reference in rulemaking more broadly and to actually become regulatory standards versus the TEFCA voluntary framework?

Deven McGraw: Yes. We have to think through where the authorities would be to do that. At least in the voluntary framework, there is a contractual hook. There is a member participation kind of hook to it. HHS does not have the regulatory authority to make an app that is not covered by HIPAA comply with these provisions.

On the other hand, there is a little bit of alignment around some of what the Federal Trade Commission has recently done with its Health data Breach Notification Rule in terms of expanding it – it has always been applicable to apps but now is extended into websites that are not applications necessarily. Something that people are required to abide by always has more strength than something that people contractually agree to do as a condition of being able to participate in something that is of value to the entity. But it is unclear that to me that HHS itself has the authority to impose these.

Michael Hodgkins: Just to piggy-back, I was on the Project Board of Sequoia, so I am familiar with the TEFCA SOP. But as we all know, TEFCA does not reach very far right now in terms of population that it touches. To Jamie's point, what are we going to do to plug the gaps?

A related question was I am always interested in the national comparisons. I am thinking of the GDPR that the EU has promoted. Do you think that that goes too far, not far enough? Does it plug some of the gaps that you feel exists today?

Deven McGraw: Yes. There is a lot in there. I have to commend them for doing a pretty comprehensive job at looking at the issues of transparency to patients and making sure that they fully understand what they are signed up for as well as through contractual provisions, creating some expectations around security. Lisa has her hand up. I am sure she – the AMA is doing a ton of work on what should be required here so I will defer to her on that. But Tina and I are on record for calling for a comprehensive privacy bill that incorporates this kind of stuff for anyone collecting health information. It would not be contractual in that circumstance.

Lisa Myers: Thank you and thank you for the question. Deven, it is reassuring to hear all the robust provisions and protections that are part of TEFCA now.

My question is my understanding of TEFCA is that if there is a violation of the contractual agreements, the penalty is to be barred from TEFCA participation, which would be a hard hit but still it seems to me like a more robust enforcement and penalty system would be very helpful there.

Jamie Ferguson: That is just the -- you are the perfect straight person because the next question that I was going to have was to wrap around. Sticking with the focus on consent authorization and identity, what should be auditing and enforcement provisions for violations in those areas? In the first place, should there be more auditing? We know that actually most third parties and HIPAA business associates frankly are not audited well by the covered entities but should there be more auditing requirements? Lisa, to your point, what other enforcement provisions would you envision as being helpful?

Lisa Myers: Right. I would completely agree with auditing provisions. Not to bring up this ugly subject but the change health care data breach with a lack of two-factor authentication, which may not even technically run afoul of HIPAA. There are this very not adequate standards for an entity of that size, $285 billion a year, one-third of American's data and they are not doing two-factor authentication. The breach enforcement is reactive.

We talked to the Finance Senate Committee and I never leave the house without my combined regulatory text and I showed him. This is it. It is less than a page that the technical standards. Definitely

more robust and appropriate standards given the size of the entity. I wish I had a better answer for enforcement and auditing but other than it really needs to happen. OCR is not staffed for all of health care auditing. Both of the auditing and enforcement need to be ramped up.

Tina Grande: Jamie, if I could add to that. Finance Committee was mentioned earlier when we were talking. I think that folks at NCVHS might want to register with the DeGette office on the Hill and Bucshon. They issued a recent RFI on improvements to 21st Century Cures 2.0. This is the kind of stuff that I think they would be receptive to. If we cannot get a national comprehensive privacy law over the finish line, perhaps through piecemeal as they improve cures and things like that, not saying that this is necessarily going to happen but at least they are requesting information. I think it would be good to get on record with them.

I also agree. Auditing enforcement provisions should be happening, and I think the auditing is really important. I think audit should be put on place on the organizations who are doing the verification as well.

Jamie Ferguson: Thank you very much. I am not sure if there are any other comments on this question. Angela, did you want to tee up the next question.

Angela Alton: One thing that I wanted to actually talk about or have the panel discuss is the aftermath of the Dobbs decision where there has been more access or wanting access to patient information. How do we provide information but protect our patients and protect the providers? I would love to hear what people on the panel have to say about that.

Deven McGraw: It is a big one obviously. They made some attempts to address these issues in again the TEFCA SOPs that do talk about both transparency to patients around collection and disclosure of reproductive health data as well as gender-affirming care type data, which actually goes a step further than where the most recent HIPAA rule went.

There is also again a number of state laws create some stronger provisions around protecting this data since I think it is very difficult for Congress to act on this for obvious reasons.

The other piece that is in the TEFCA SOPs as I now recall it is a required notice to the patient if the IAS provider – that is the term for a patient app in TEFCA – receives a subpoena, a court order, or an administrative request for this type of data so that the patient has an opportunity to potentially try to quash it. Those are steps that have been taken to try to create some additional safeguards in circumstances where the HIPAA rules would not apply.

Lisa Myers: If I can chime in. I thought the recent reproductive health privacy rule went as far as OCR could. It is contentious with the states and so far. Just a note because I was really looking in there for it to also cover gender-affirming care. Perhaps it is subjective but I feel it does. I thought it was pretty brilliant to craft a definition that would cover gender-firming care without using those words, which I am triggering even to some – our membership is broad and they have different points of view. But if you do a word search of the final rule, the word gender appears one time and it is in a footnote. To me it seems with the spirit of things and the intent to protect people and their medical providers from having health

information used against them. I may have loss the threat of the original question. That is a robust rule. I hope it stands to protect patients and providers but anything more than can be done to enshrine this health information.

Similar to what SAMHSA and OCR came out with before the final rule about protecting SUD records, which is originally 30 years older than HIPAA and was necessary because substance use disorder sufferers would face criminal penalties for seeking treatment. That was enacted way back when. But this is the first time in history that even the provider could be criminally penalized. The more that can be done to protect that, the better. But I thought it was extremely well crafted, the rule that just came out I think in June or July, the most recent one.

Mona Calhoun: I agree, Lisa. What you just mentioned is what came to mind for me is crafting additional securities around the request and just similar to what with 42 CFR. If it is included in this particular or if the care was in a particular private area such as gender-affirming care that there should be additional protections for accessing and giving those extra securities on getting access to those records.

Tina Grande: I would agree with that. We have had discussions at length about this within our organization. One thing that I think folks should think about are the state laws that are being passed around some of these issues of concerns about obviously patient protection and provider protection. Some of them are oriented around strict data segmentation for discrete pieces of information.

I think it is important to discover if it is possible to actually do that level of data segmentation that some of these laws are requiring. We are going to work with consumer groups to try to find a consensus spot because we all believe in the intent. We all agree that this information needs to be protected and there should be no law enforcement getting involved in providing of health care in this situation. But how do we do it in a way that is technologically feasible?

I think really maybe querying, interviewing, asking organizations who are really impacted by this on the engineering side if they can actually engineer to the point that some of these state laws are requiring would be a good idea.

Angela Alton: Thank you. Anyone else had any more comments on that topic? Val.

Valerie Watzlaf: I kind of had a new topic. If you have – but I was just going to say – maybe for Mona, I know because she did bring up about the workforce and how this whole area can really impact them. I guess what education or training or knowledge do you think the workforce needs around privacy and security of health data access? It is such a changing environment as well. If there is anything or anyone else could answer as well.

Mona Calhoun: As I am listening to my panelists and as an educator for future HI professionals, certainly understanding these laws to a depth further than what we probably currently inform our students is necessary because they are going to be the ones that will be helping to create policy for the organizations and the institution so really understanding TEFCA. I would say putting these in layman terms. It is important for our consumers to understand to the level that they would be able to take the information and be able to make appropriate decisions.

A lot of laws are written and as we have already seen, there is this interchange in circles in state law, federal law. It gets very confusing. I think from informing our consumers, our professionals, our future professionals, it is important to put these laws in a way that can be understandable so that they can help to create and shape policy around it.

Lisa Myers: Valerie, I would like to add about just back to law enforcement. I think it is really important for covered entities to train their – I am thinking particularly pharmacies and when you have someone at a pharmacy counter standing there at the cash register and if law enforcement comes in and demands a record, I think that those employees need to know when they have to handle their information and when they really do not have to handle their information. It is just like training your kids at school. What are your rights? I think that it is important for those folks behind the counter to really know when they do not have to hand over the record. We all know about Senator Wyden's concern in a letter to Secretary Becerra about that situation.

Deven McGraw: Just adding on. It is not HIPAA that would have ever required the disclosures in response to an administrative or law enforcement request. There is a whole bunch of prior to the most iteration of the rule and you all did a lot of work on this. Nobody confronted with the law enforcement request whether through some official vehicle like a subpoena or an order or just an inquiry would have been required by HIPAA to have made that response. But HIPAA also until very recently did not provide the shield for having that information go forth.

Now, under the final rule, there are some penalties that would attach to releasing information that otherwise HIPAA would have allowed to be released, and I think a lot of entities just presumed they had to because they are faced with the long arm of the law on the other side of the table. That is going to take a lot of education and frankly, it would be very helpful to educate the police forces too. That is another kettle of fish. We will just leave it at that.

Valerie Watzlaf: Just to follow up real quick. Also, what education and guidance do you think even for patients or consumers that are downloading their information on their personal device or taking something from their patient portal and downloading that? Those are other areas I know we have discussed. Do you have any advice around that for us?

Deven McGraw: Other than do not do it?

Valerie Watzlaf: But everybody is doing it though. That is the thing.

Deven McGraw: It is super convenient to be able to keep track of things that are going on or if you are searching for a medical provider outside of your state, everybody is going to go to their favorite search engine whatever it might be and that is going to leave a trail. You all know as well as anybody just the lack of protections for the data.

But you might want to look a little bit further into what the Federal Trade Commission did in terms of expanding the number of entities that are subject to its Health Data Breach Notification Rule. Questions abound about whether that was consistent with the authorities that were given to them in HITECH. But nevertheless, it is a rule and it was finalized. Somebody else can tell me if anybody has challenged it to

date. I do not believe they have. It is worth exploring where the FTC has flexed its existing muscles a bit in terms of protecting some of that digital dust as well as people using apps that is relevant to some of these types of care that is very sensitive.

Mona Calhoun: I would add that HHS might want to consider a national campaign, not only for patients but also for providers how to use, move, secure data. We would need to hold developers accountable and also involving them in educating and cautioning consumers, not just getting the app out there, but to include that as a part of their policies as well.

Lisa Myers: I agree. My mind went to public service campaign as well. I think it would be great for the federal government to do a PSA and target it in ways where you know people – I would put one on Nickelodeon too. Just get it out there. Work with the foundation or something to do a public service campaign. I think that would be a good idea.

Mona Calhoun: How many of us grew up when a bill becomes a law, the schoolhouse rock.

Maya Bernstein: If only they knew how a bill really becomes a law.

Michael Hodgkins: Go ahead, Valerie, if you had something else.

Valerie Watzlaf: I do have another one but I can wait until we are almost at the end.

Michael Hodgkins: I wish I had confidence in the new FTC rule or attempts at rules the Deven mentioned. But given the recent Supreme Court decision with regard to Chevron. I would not hold my breath.

It just seems to cry out for specific legislative action around these privacy issues. Do the panels think we have a chance of getting there?

Deven McGraw: Not this year but only because it is a presidential election year and nobody wants to give anybody credit for anything. Folks who do government affairs and lobbying more often than I do can weigh in on whether I am wrong. But I thought there was a general mantra that things become even harder to pass during this period of time where there are active campaigns going on and things of that nature.

But we got very close with a privacy bill in a prior Congress, very close, closer than we had ever gotten before. Preemption of state law and privacy right of action remain the two sticking points. If we figured out a way to get those resolved and in particular powerful members of Congress from states that have their own privacy laws that do not want them preempted can be convinced to take one for the team so that the rest of us can enjoy privacy protection across the country, then we might actually get something. Those are not small issues to resolve.

I was frankly surprised that – Dr. Calhoun can remind me of the name of the bill but it got farther than any than frankly I was surprised.

Lisa Myers: Really everything you said. I think it was this Congress even like in June because everyone calls her CMR. Cathy McMorris Rodgers had a great – it was bipartisan. I think it was just the American Privacy Rights Act, which is probably why I cannot remember it. It is generic. Our staff in congressional affairs, which is not my division, but they have seen so many come and go. They almost do not get excited. But this one looked like it could really get close and then the third rail, the privacy right of action, and the state preemption, which of course California would not go for it. I thought there was a provision that maybe address California. Do you remember?

Deven McGraw: Apparently, it was not enough at the end of the day but they did try –

Lisa Myers: Right before the pandemic hit, which was all that was talked about in privacy circles like the patchwork. We need a national law. That was the only thing and then COVID. And then it did not really pick up right where it left off. There is a ton of sentiment and I think it is very – it has good prospects as a bipartisan issue too.

Everyone loves GDPR. That is why it works. There is a private right of action. Without teeth in it, it is really hard to make an American privacy rights bill law.

Tina Grande: I am a little less skeptical that we will get there. I want us to so badly but I think the powers that are out there that do not want to be regulated have so much money and so much power that it is going to be really hard to do it.

And then what is happening in the meantime are states are passing their own bills into law and they are not harmonizing with other states that are doing their own pieces of legislation. It is just going to get much more difficult for information to flow. And then you lay on top of it the AI bills as well.

Since 2007, I have been working with Congress to try to get something passed. To Deven's point, we got really close last time. But I am a little less hopeful and that is why I am really hoping that we can find creativity in other ways to hold organizations accountable. TEFCA is a start with bringing the outside of HIPAA entities into the framework. But there are still some holes that need to be patched in TEFCA. I think we need to think of creative ways in absence of a comprehensive national privacy law. I think it is going to be hard.

Mona Calhoun: Tina, I agree with coming up with creative ways. But I am hopeful. I think with patients, consistency, and pushing, just from our own legislative agenda that AHIMA has – we have gotten there. We have gotten right at the edge. We are going to match it and some other initiatives. I am just hopeful that one year. We do not want to lose hope. We want to continue to push but yes, be creative and how we work with those entities that have greater impact and how we can influence that is going to be very important and partnering is going to be key.

Tina Grande: And I think we have to look outside of health care too and the fact that because we do not have a comprehensive national privacy law in our country, it affects our ability to in certain cases work with other countries that do have privacy laws. We should look a little broader in scope and perhaps – I am not afraid to say I am embarrassed that I live in a very developed nation that has no comprehensive privacy law for its citizens. It is just us. I guess Singapore and Australia are somewhat in that camp but

not to the extent that we are. It is a little embarrassment about the fact that we do not have a national privacy law. I am okay saying that. Embarrass ourselves into action. Embarrass members of Congress into action.

Angela Alton: Val, did you have another question or something – I think you were going to save towards the end.

Valerie Watzlaf: Yes. They answered a lot of it. But I guess I have two things. What is really keeping you up at night? How could you frame that into something that you could say directly to the secretary as far as what action should be taken or even recommendations that you could make for us? And maybe these are new areas too, maybe something different that you did not bring up yet.

Lisa Myers: I have two. One of them I touched upon earlier and not as germane to this discussion. We are in the era of consolidation in the health care market and particularly this whole – this has been so bad for our physician membership, the change health care reach. The health plan owns the clearinghouse. They have the data of a third of Americans maybe. Again, the regulations that they are subject to are less than a page – the same as applied to a rural health care provider. That is right to be addressed. If a provider has a data breach, it is bad but it does not shut down the industry. I feel like if this happens again, there are a lot of practices that struggled to make it through last time. They cannot take wave after wave. Those guys need to be held to more appropriate standards.

And the other thing that has really bothered me for a long time is the lack of regulation of health data apps. Deven got to it with the Health Breach Notification Rule. But again, to me, that is reactive. I was glad to see it but there is no floor for them. There is nothing. If FTC chooses to enforce unfair, deceptive, active practice, that just means that that company did not follow its procedures. But what is the requirements for their procedures? Anything. You could have AI generate something that sounds good and people just click through it.

And the consumers – there were some really great commercials at one point. It reflected the consumer lack of transparency of when does my health data stop being protected because Fitbit is health data but that is not covered and all the other things that have been in media. Those are my top two.

Deven McGraw: Without a doubt, there are issues in the non-HIPAA-covered environment. I sit in that environment. We actually were acquired by a HIPAA-covered entity and enjoyed that nice HIPAA umbrella for a while and then we got divested so now we are outside of that bubble and frankly cannot even ask to be regulated after HIPAA but for contractually signing up for it like it is not – I do not think the environment helps us either and I sit in the space of being an app that is helping patients gather their data so that they can pursue treatments and donate their data for research. And it hurts us when there are other bad actors out there and I have seen them. They exist. I am not suggesting that they do not.

On the other hand, we are having problems from a privacy and security standpoint with covered entities and their business associates with funny business around the permitted uses that already exist. It does not mean I am kept up at night by this. But the problem is not just about non-covered apps. Business

associates in my view are another avenue of missed opportunity around what are their standards, do we have an opportunity to strengthen the rules around how they operate and their secondary uses of data. There are business associates. There always have been hundreds of thousands of them. But our networked environments that they are hoping will help us facilitate greater interoperability are rife with them and more and more every day where they see an opportunity in that middle layer that frankly we need them to be that middle layer. Somebody needs to facilitate this. This stuff does not come for free. There is work that has to be done and often the compensation for that is fees and data monetization. Deidentified data but data monetization, nevertheless.

Mona Calhoun: And I would go back to some points as far as what keeps me up at night that I made previously. Enhancing understanding of how HIPAA interacts with broader privacy laws under consideration, determining the best path forward for protecting health data, exploring opportunities, coordinate health data exchange, oversight and enforcement, and a comprehensive national data strategy is needed to ensure that all actors that handle patient health data are playing by the same rules, are penalized under the same frameworks. And until that national data strategy can be achieved, we are going to have that patchwork. We are going to have that patchwork from the states and the patchwork in even the federal law. It needs to come together to decrease some of the complexities that we are currently seeing.

Tina Grande: One of the things that keeps me up at night is when I hear people say the horse is already out of the barn on privacy. We have nothing private anymore so why try. That really bothers me when people say that and I hear it a lot particularly from younger people. That keeps me at night.

And Deven's term – I have not heard it before, but I love it. Digital dust. That keeps me up at night. It is just this trail of information and with the stronger and stronger competing power that comes more opportunities to combine and reidentify and do all kinds of things. That keeps me up at night as well.

And then I guess the fact that we do not have a national privacy law still. That keeps me up at night and working hard to try to figure out how to get one passed.

Jamie Ferguson: Val, if I may. I know we are at time and that was going to be the final question, but I have another final question if I may. I think it will be very brief. Just for each of the panelists. I know we have talked about the lack of a national privacy law and the impossibility of getting that really broadly out of Congress. The scope of this committee is to advise the Secretary of HHS on what can be done within the department, which means within the bounds of HIPAA.

But turning that to the legislative side, if the Congress were to so-called, open up HIPAA on a targeted basis and if there was something you could change about the HIPAA law to improve privacy, security, and confidentiality, what would the one thing be within the bounds of HIPAA that you would want to change in the law?

Lisa Myers: I have one. I am a big fan of HIPAA. I really love it. I usually take offense when people level broad sides at it because often they do not understand it. But I hate to name names but Amazon with one of their health platforms – it took me a minute to figure out how they were doing this because they

were representing themselves as a business associate with their – I am trying to avoid naming the name again but with a clinic that they set up online. And they would collect a whole bunch of PHIs upfront from a potential user and give them a click through that they called a HIPAA authorization and it was extremely ended and said that they could share all that data with their affiliates and it was so loosely defined. But to be required to sign a HIPAA authorization ahead of treatment does not usually happen. If there was some way – because they were technically within the bounds of the regulation.

Getting back to Tina's point, it is like people have just given up. They want to disclose the information to be matched with the providers so they can get treatment for their allergies within 30 minutes for $30. If you decline to sign that authorization, then you could technically use their providers, but it would cost more than five times as much. Some way to rein in business associates from getting patient authorization like ahead of services. That would be one. And then the other one escapes me. That is a real weakness there that needs to be addressed.

Mona Calhoun: I would say fill in the gaps. We have identified gaps where HIPAA does not cover the exchange of information. That needs to be considered and possibly added.

Deven McGraw: You could ask HHS to actively support asking for more authority because they cannot expand their own. I like Dr. Calhoun's suggestion. I have a bee in my bonnet to use a really dated term around business associates. They are necessary. We cannot ask covered entities to perform all the functions that they do all on their own and we have to have a way of vendors being able to access data but so many of them make it quite the opportunity out of that and we are opening that door even further by relying on them so completely around this network. So many of them are creating essentially their own data links with data that they are querying in response to their customers and sometimes passing data through that did not even belong to their – Customer A – Hospital A queries uses business associate intermediary. Gets data from Hospital B, which is not even a customer of that business associate, did not agree to the terms of service of that business associate and yet the retention of the data that came from Hospital B will be held there and subject to the business associate arrangement that Hospital A got in which may be giving them a lot of rights over data that would not make Hospital B too happy.

I think the role that we are asking business associates to play was not necessarily contemplated when the privacy rule was enacted and there is a lot of room to rein that in.

Tina Grande: I do not disagree with Deven on that. I was going to mention health care operations. It is a little bit of a gray area that given the environment that we live in now of so many different players involved, I do think that is an area that could be looked at.

But two things that – this is Tina personally talking, not HTI. But I have always wanted this loophole closed on law enforcement and public health and the fact that they can redisclose information that they get. I would like for them not to be able to redisclose health information that they get.

Jamie Ferguson: Thank you all so much. I really appreciate your thoughtful presentations and discussion. It has been a real pleasure.

Maya Bernstein: Thank you to the panelists. Naomi, did you want to add something? If you have anything to add, if you have articles or documents that did not get to us already, we will leave the record open for a couple of weeks. You can send us either to myself or to Naomi or both and we will add material that you would like to appear along with the – there will be a transcript and a reporting of this meeting and the materials that you have already sent and we can add to those for a couple of weeks yet if you would like. I just want to thank you on behalf of the committee for coming and for spending this time with us.

I think I have already told you, but you are welcome to observe any of the rest of the meeting that you would like that you have time for. We welcome you to do that.

Naomi Michaelis: Thank you so much to our panelists. We are now going to take our lunch break. We will resume at 2 p.m. Committee members, please turn your cameras on when you resume so that we know that you are here and ready to go for our 2 o'clock speaker. Thank you so much.

(Lunch recess.)

Naomi Michaelis: We are waiting on our speaker. I just want to make sure he gets on without any issues. It looks like we are all here and that our speaker has joined us.

Good afternoon. I would like to introduce Dr. Micky Tripathi. Dr. Tripathi is the assistant secretary for Technology Policy and national coordinator for Health Information Technology and the acting chief artificial intelligence officer. He is going to be providing us with an update from the new ASTP/ONC. Thank you so much.

ASTP/ONC Briefing

Micky Tripathi: Okay. Hello. Thank you. I am really delighted to be here. I do have a presentation, which I will put up now and look forward to the conversation. It will be a broad sweep because I know all of you are very interested in getting overall context. I cover a number of different things that I think I understand are of interest to you and obviously very happy to dive down into anything that I have either covered or not covered as a part of the further discussion. Let me dive right now.

Just to level set. I know this is NCVHS, so you know who we are. Just to level set for everyone. The ONC, the Office of National Coordinator for Health It, that we now call ONC classic with the renaming of the organization, the elevation to assistant secretary, was founded by executive order in 2004, established in statute in 2009, which by the way is why you are will see us referred to officially as – or my title referred to officially as the assistant secretary for technology policy and National Coordinator for Health IT and chief AI officer but named National Coordinator for Health IT and Office of National Coordinator is actually in the statute in 2009 so literally it would be an act of Congress for us to change the name. We do keep that as a part of our official name although we are the Assistant Secretary for Technology Policy.

A bit set of authorities in what we do is related to certification of electronic health record products, health IT generally but electronic health record products specifically coming from the HITECH Act. That

now covers 97 percent of hospitals and over 80 percent of ambulatory providers so very big digital foundation that we are working with CMS and with the industry obviously have been able to establish over a decade now with very hard work.

And then the 21st Century Cures Act that specifically directed ONC in a number of different ways. One was related to standards, the US CDI, US Core Data for Interoperability and FHIR APIs as well as TEFCA, Trusted Exchange Framework and Common Agreement, which is network-to-network interoperability. I will get back to those topics further into the discussion. And then the information blocking provisions that came from the 21st Century Cures Act.

I was not intending in my formal comments to talk about information blocking. I am certainly happy to in the Q&A.

Another part of the authorities and the direction that we have from the department is related to health IT alignment across our HHS partners. This is also a part of the incremental work that we have been doing over the last few years that has led to the establishment of the assistant secretary for technology policy office.

In 2022, Secretary Becerra put into place a policy that we call the Health IT Alignment Policy and it is specifically related to requirements now within the department for all of the operating divisions and the staff divisions in the department and all of their applicable funding programs, contracts, policies, grants, everything that they do from a financial perspective and a regulatory perspective is required to support ONC-approved standards as it relates to clinical interoperability and implementation and also it directed us, ONC, to provide technical assistance to our agency partners to support that. That, as I said, has been in place since August 5, 2022. We have very active work that we do with all of our agency partners to help them make best use of information technology, electronic health records, USCDI data standards to be able to better support their missions.

That was already work that we were doing as we started to think more and more about accomplishing what Deputy Secretary Andrea Palm reminded us from the beginning of this administration, which is that this department needs to be more than the sum of our parts. We need to be doing everything we can for our operating divisions, NIH, FDA, CDC, HRSA, ACL, ACF, CMS. Let us not forget CMS and ONC obviously as well as all of our other HHS partners that we need to be obviously fulfilling our agency, our division, and department mission objectives. But we need to be thinking more and more about how we do that together in better ways than if each of us do it apart.

The key part of that increasingly is technology and technology strategy as we think about the great importance that technology and information technology plays from a strategic perspective. We have been giving thought over the last few years into thinking about how do we actually organize ourselves so that we are best able to leverage technology from a strategic perspective to better perform our HHS mission at large.

All of that thinking – the Health IT Alignment Policy that I described before, everything that was happening in the cybersecurity space that I do not need to remind everyone of all of the challenges that

the industry has faced there and all the work that we have done within the department as well as AI. I have not even mentioned AI yet. Now, I finally mentioned it. But all of the activity related to AI and its huge potential to be able to affect almost everything that the department does internally as well as does with the market was the calling at that point to say we really need to organize ourselves, have dedicated resources, dedicated staff, and single-point accountability for the strategic part of the uses of technology and data across the department, helping to orchestrate the work of all of the operating divisions to be able to allow them to work better and more effective in the uses of technology and data. That is really a whole bunch of work.

My main point is this has not been something that was just thought of in June and then we did it in July or that we just started thinking about when ChatGPT was released in the fall of 2022. We have been thinking about it really from the beginning, have been taking incremental steps toward it and now the culmination of that is in reorganization that happened in late July, which made us now the Assistant Secretary for Technology Policy and why I have way too many titles behind my name and hoping to get those placed into leaders that we are now in active recruitment for. Many of you are very familiar with ONC.

Just to give you a sense of what that means for the organization structure. We have the traditional ONC divisions. We have the Office of Policy, the Office of Technology, and the Office of Operations. We basically added a fourth division, which is now the Chief Technology Officer and underneath the Chief Technology Officer will be the Chief AI Officer, Chief Data Officer, and a new Digital Services Division that we are launching to be able to provide technical resources and technical assistance to our operating division partners as it relates to the uses of AI data technology to be able to better support them more directly.

And we are actively recruiting right now. The application process is closed. We have many applicants who have submitted applications for those three roles, Chief AI Officer, Chief Data Officer, and Chief Technology Officer. And we anticipate filling those before the end of the calendar year. Before then, me and my deputy, Steve Posnack, basically fill all those roles and doing everything we can.

I think all of you are familiar with – I like to always step back and say what is it we are trying to do here. I just went through a litany of acronyms and directives and executive orders and authorities and statutes. But at the end of the day, we want to keep building the digital foundation. We want to make interoperability easier through a variety of mechanisms. We want to continue to promote information sharing. As we have seen just because people have the technology, it does not mean they will use it. Things like the information blocking rules, other things to greater induce and encourage the uses of these capabilities to be able to share information in better ways to enhance patient lives.

Ensuring responsible use of digital information. Health equity by design. Everything we have been doing in health equity as well as entering the AI space for transparency rules that came into HTI-2.

And then finally, advancing health AI across the ecosystem. I will talk about the HHS AI strategy, which we are now very deep in the –

Let us start with data. The USCDI, the US Core Data for Interoperability, which is a portfolio of standards that are approved by ONC. On an annual basis, we update the USCDI and then on a regulatory cycle, we incorporate the updates to the USCDI to a particular moment in time in regulation, which is then required to be supported by certified electronic health record vendors and also is used by our agency partners for their programs like the quality measurement, public health reporting, other kinds of things. It is a growing list of things, as I will describe in a second.

At USCDI, many of you may be familiar with it but I will flash it up on the screen here. This is the USCDI Version 3. You can see there in the stars, the new elements that we added between Version 2 and Version 3. This particular snapshot version is the version that is required to be supported in electronic health records starting in 2026, I believe. It was finalized in the HTI-1 Rule, which we released in December of 2023. And then we always give the industry 18 months to 2 years to implement. That is why we have that different in timing. But this is the version that is now required in regulation. And by 2026, vendors are required to support it.

One of the things coming into my role here in January of 2021 was that we were also getting – we were a little bit of victims of the success of the USCDI in the sense that more of our agency partners as well as industry partners were asking for more data elements to be included in the USCDI, recognizing that it was starting to play a powerful role because again 97 percent of hospitals, 80 percent of ambulatory providers using certified electronic health record products is something that helps to tie together a very fragmented health care delivery system. With this being something like a minimum data set, wanting to be able to say how do we add more data elements to that to be able to support a wide variety of uses.

We, of course, cannot accommodate all requests and we also try to be very judicious and work very closely with industry on what is reasonable because you cannot be adding 150 new data elements every single year and expect that providers who ultimately are the ones responsible for supporting data elements and for doing documentation that supports that as well as the vendors who support them and creating the technologies to be able to support those data elements. We cannot expect that they can move at that pace.

We launched what we call our USCDI plus initiatives where we work with our agency partners and with industry on specific use cases where we have extensions of the USCDI to support specific use cases that will have a programmatic tie so working with an agency partner who has a strategy with respect to their mission or their programs that are going to require additional data elements to support whatever it is they are trying to do and therefore the provider organizations or whoever else, payers, others who are participating in this program, would have an interest in having more standardized data elements available to them in their technologies to help them automate more and more and reduce the burden on their users of participating in those programs.

We have launched a number of these now. They continue to spawn and they have become a little bit of a cottage industry within ONC, which is a good thing. It is a problem that we wanted to have to be able to more directly support our agency partners with their data needs and the uses of technology to support their missions.

What are these? Every one of these that you see listed there is a real live USCDI plus initiative that we have but just to call out some of those to give you a sense. I have been working very closely with the CDC and public health jurisdictions on USCDI plus for public health to get us closer to being able to have a nationwide public health data model based on standards that are supported by the health care delivery system since most public health data actually ultimately comes from the health care delivery system, being able to tie those together and reducing as much as possible the burden on the health care delivery system to reduce that information and make it available is a key aim there and the hard work that we have been doing with the CDC and with jurisdictions.

We have been working very closely with SAMHSA on behavioral health and having a USCDI plus for behavioral health initiative to recognize those data elements that are specific to public behavioral health use cases and we also with $20 million from SAMHSA are at work building resources to help behavioral health providers use technology and be able to have resources available to them. Obviously, $20 million is not going to cover EHRs in the same way that covered the meaningful use program but doing everything we can to say how can we support whatever resources are available to be able to help them move forward.

With HRSA, we actually have live UDS reporting called UDS+ that is kind of the USCDI+ for UDS reporting that has FHIR-API-based reporting to a FHIR server that is now hosted by HRSA. We worked with HRSA to put into production. It is very exciting. We actually have federally qualified health centers who are doing UDS reporting via FHIR APIs to a FHIR server in HRSA, which is the next generation and we are really excited and really just very grateful for HRSA's very strong support there.

With CMS, we are working on the data strategy with them related to their quality roadmap their eCQM, their dQM roadmap for those who are familiar with all the work that CMS is doing on the digital quality roadmap and doing everything we can to help support the USCDI+ initiative there.

And then finally with cancer, working with the White House Cancer Moonshot team, FDA, NIH, and we already on a set of cancer data elements to support research, diagnostics, therapeutics, working very closely with the mCODE dataset for those who are familiar with that. And we already have, as of September, a couple of vendors who are supporting participants in the CMMI enhancing oncology model, which started – the reporting period, I think, started in September. So early in the spring, we worked with a number of vendors on an initial set of data elements that would be a part of extensions from the USCDI that would directly support the EOM reporting that they are required to do for those participants, and we had a couple of vendors who stepped forward and voluntarily agreed to put that into the production system in September. That is now underway, and we are really delighted to be able to have that progress.

One of the things with the USCDI+ program that we have seen is a tremendous opportunity for us to work with our agency partners on being able to have that balance between a minimum data set but also being able to get greater consistency in the uses of those data standards so that whether it is a public health program or a research program from NIH or a quality program from CMS or from HRSA that they start from the same place with respect to the data that is already established in the USCDI. They do not have to figure out a different way to represent medications for allergies, for patient demographics. They

can start with what is in USCDI and then we extend from that to say what is in your program that you are going to need that is not in the USCDI and then let us build that accordingly.

Next set of things is related to TEFCA, Trusted Exchange Framework and Common Agreement. Network-to-network interoperability. Direction from the Congress for ONC to work with industry to establish a framework both policy and technical for the ability to have network-to-network interoperability.

For those who are not familiar with it, there are a wide variety of networks across the country already, clinical interoperability networks. Some of them are state and local HIEs. Some of them nationwide networks that do not give us the user experience that those of us are used to in our day-to-day lives when you think about cell phones, for example. When I purchase an AT&T cell phone, I do not worry about whether it is going to connect to a Verizon cell phone. I do not worry about whether the other user – which phone brand they are using. I never worry about that for a minute because on the back end, we have done a lot of work to make sure the user experience is a network – is as a single network even though it really is network-to-network. That was the direction that we got from Congress was do that with clinical interoperability networks. And I am very happy to report that that is now live and making tremendous progress.

A few things. The Congress did not give us additional funds nor did they give us authority to require that anyone participate in TEFCA. A very important part of that work is that we had to work very hard to say what role can the federal government play to make this something that the industry wants to do and that working together with industry we can accomplish things, building on what the tremendous work that the private sector has already done in interoperability but to get it to the next level in areas that the private sector has great difficulty doing on its own.

What are some of those areas? Public health. Public health is a very complex landscape, as we know, in the US. Very decentralized, very distributed authorities between federal and state and local jurisdictions. Too hard for the private sector on its to figure out how to attack that at scale.

We have 30 percent of providers is our estimate – less well-resource providers, particularly hospitals, who are not connected to any of these nationwide networks because they do not have the resources.

Payers. Payer-provider interoperability is right now not happening at scale anywhere across the country. And we believe very strongly that we need to have payer provider interoperability at scale both for the benefit of the patient at the end of the day but also from an efficiency perspective, a tremendous amount of improvements could be made in our ecosystem if payers and providers had more scalable ways of automating certain types of things like prior auth, for example.

And then there are other areas that we want to be able to accomplish in the future but the ones that I just named, the top bullets there, are things that we are very actively working on right now.

TEFCA went live with the Common Agreement Signing Event on December 12. It was signed in the morning. Later that day, information started flowing across seven QHINs, qualified health information networks, which are now live, exchanging information in real time. For those who are not familiar with this clinical interoperability landscape, these are kind of like the AT&Ts and the Verizons of clinical

interoperability, organizations that have networks already and they are now connecting their participants across those networks.

One of the things that we are really happy about is the diversity of networks that we have that serve different parts of the health ecosystem. What do I mean by that? Many of you may recall that we did have a large experiment from the federal government with health information exchange networks back in the 2012-2013 timeframe when ONC made available $800 million roughly in funding to states for the creation of state HIEs in every state. Each state was given a certain amount of money, as well as territories given a certain amount of money, to establish and launch HIEs at the state level where the strategy there was the thought that states are the right way of thinking about the unit of health information exchange and the idea being that each state would have its own and then you connect them up.

Well, obviously, we found after many years that that was absolutely not the right model. Most of those actually did not survive the end of the funding of that kind of funding. Certainly some did and so we certainly do not want to discount the ones that did and the ones that continue to forward but is absolutely not uniform.

What we learn from that is that networks need to emerge form the bottom-up and you need to have networks that actually have a certain degree of affinity and a certain business model's sustainability based on what the participants want to be able to do and our job at the federal level is to say how do we connect those up, not how do we dictate what they need to be.

You just see here represented – I will just give you one anecdote of the different kinds of things that we see. You look at the EPIC Network, for example. Everyone is familiar with EPIC. The EPIC Network connects up those who are using EPIC within care everywhere, which connects them up with each other. That is the affinity that they have. Tons of interoperability happens over that network EPIC-to-EPIC.

Think about Kno2, another organization. They work a lot in the behavioral health space and the LTPAC space. You have a vendor that is working very hard on the part of the care continuum that did not have the benefit of meaningful use incentive dollars to try to bring them forward to allow them to participate in nationwide network interoperability.

The KONZA HIE. It works with the state HIEs to be able to connect them up and have them connected to TEFCA. Very different angles on this question of what constitutes interoperability from our perspective. It is great to see that kind of variation coming forward in these networks.

There are six exchange purposes that are now permitted and exchange purpose number 7, as we call it, is research and we are going to start a lot of hard work on that one because there is a tremendous amount of appetite for that from the research community and from our partners at NIH and FDA.

The ones that are live now are treatment. We have done a lot of work to operationalize trust at scale based on some of the things that we have been seeing or happening in some of the nationwide networks that has been a cause for concern for participants across the health care system. We have done a lot of work to make the treatment use case, for example, something that people can trust at

scale.

We have also launched and open up the health care operations use case, which is I think a significant achievement because that really has not been a part of any of the frameworks that exist to date. In early July, we did approve a health care operations' use case so that payers can now participate in TEFCA to be able to exchange information with providers for health care operations, for example.

One of the last things I just want to talk about before we move to AI for a second is public health. Public health is very challenging, I think, as all of us know. I think there was a certain degree of caution when we started saying from the beginning of this administration that public health is going to be a priority just because of the challenges, not because people did not recognize the value and the need but because of the challenges of our very decentralized public health system, I will put that in quotes, across the country, which I think as all of you know, US Constitution gives the authority for public health responsibility to the states. That makes it very complicated to figure out how we string this together into something that would allow us to have national-level kinds of approaches to public health in areas where we need that.

I am really delighted though to report that we have tremendous success working with very closely with our CDC partners who deserve a ton of credit for the hard work that they have done on the ground with public health jurisdictions to support them. There is now $250 million that the CDC has made available for implementation support for jurisdictions that want to connect to TEFCA and to talk to them about the importance and the opportunity here for them to be able to better perform their missions with TEFCA-enabled infrastructure. There are now 50 public health jurisdictions across the country that are live doing electronic case reporting on TEFCA. And all of them are outfitted to be able to do electronic case investigation so based on an electronic case report that they may get in an automated fashion, the ability to ask follow-up questions in electronic exchange where they do not have to pick up the phone. They do not have to fax. They do not have to email. They can query a provider organization to get additional information to be able to close out that case or to decide that this case actually is active and we need to pursue it even further with more direct human interaction involved. That is something that we are really excited about, really grateful to the CDC and the jurisdictions for all of the work that they have been doing there and obviously more to come.

Every time I give this presentation, someone from the CDC is on the call and they say actually that number is now 70. I put 50 plus agencies live but they continue to do work to add more and more jurisdictions.

The last thing I will just quickly mention is that TEFCA is now FHIR enabled for those who know what that means. FHIR APIs are a very important part of the modernization of our interoperability infrastructure in the future of interoperability. We came in and made an explicit priority of having TEFCA contractual policy and technical infrastructure support FHIR API adoption because we were concerned that we would not get the kind of FHIR API adoption otherwise.

We now have FHIR-based capabilities available in TEFCA both from a policy perspective as well as some of you may have seen that EPIC announced that they are making their patient-facing FHIR APIs from a

technology perspective available in TEFCA. Obviously, it is up to the provider organization who is using the EPIC product to make the APIs available for their particular setting. But there are now provider organizations using the EPIC system who are making their FHIR APIs available.

That gives us a part of the dream, I think, of network interoperability for a patient to be able to say I can use an app of my choice as long as it meets TEFCA requirements, which are higher than the requirements that would exist outside the market because remember a number of these are not covered by HIPAA. They have certain requirements that they have to meet to essentially follow the rules of HIPAA as it relates to privacy and security protections. But if they do that, they can make that offering available to a patient. Then the patient would have the opportunity to say I can query across the TEFCA network for my records and be able to get those back.

AI. I am going to talk about AI for a second here. We are doing a ton of work in AI now, as you might expect. I like to think of it in a few big buckets. One is just the core infrastructure, which is US Government wide. That is not just HHS. That is all the things that the US Government is doing led by White House obviously to create foundational aspects, foundational components for the responsible adoption of AI across the country in every sector, not just health care.

You have everything from the voluntary commitments from the foundation model developers, the work that is being done to create the National AI Research Resource, which is basically public infrastructure for the creation of AI-based technologies, and the NIST US AI Safety Institute, which has now been launched and is live.

But diving into health care, I think of it from the product side and from the uses side. We have existing long-standing regulations from the FDA related to approval of devices and in particular, software as a medical device. They have now approved 900 software and medical device applications which are AI-enabled technologies essentially that have been approved for use through the FDA process.

The ONC rules that were the first and I think only rules that have been promulgated under the Biden Administration related to health AI, in particular, were released in December of 2023 and focused on transparency of the AI-enabled technologies that were made available in electronic health record products.

We work very closely with the FDA, as you might hope. And we think of ways that our rules work together as real complements of each other. The FDA rules are – you have to meet the definition of a device as defined by the FDA and – this is an important "and" and you have to intend to commercially market your device in the US market. And if you meet those two tests, then you are in FDA lens. You have to go through the approval process and then it depends on what type of device it is, whether you go through De Novo or 510k or whatever the PMA, whichever category you would fit in but now you are going through the FDA process.

ONC is about transparency. We are not approving devices for availability. We are also not restricting it to things that would meet the definition of a device nor are we restricting it to whether it is commercially marketed or not. We are basically saying that AI-enabled technologies that are made

available as a part of the EHR product, there should be transparency for those in hopes that the health provider organizations get transparency in the governance processes for the technologies that they use or that they are having third parties use.

We think of these as FDA is an inch wide and a mile deep and ONC is a mile wide and an inch deep. Together it gets us a lot of coverage in the market as we think about the responsible uses of AI but also allows us to proceed incrementally in a way that hopefully helps to spur innovation, starts to establish some guardrails, empowers the users of these systems to be able to be fully empowered to use the ways these technologies in ways that they think will best apply to their particular patients or members if they are payers and then finally, helps to spur innovation.

Finally, we have different regulatory initiatives underway. Section 1557. Some of you may be familiar with that from the Office for Civil Rights related to the nondiscrimination rule that OCR made available, which was about more a reminder than anything else – just a reminder more than anything else that those covered by Section 1557 provider organizations, payers, and others are not allowed to discriminate full stop. That also means that if you are using AI and using the results of AI, you are still now allowed to discriminate. You are responsible for the actions that you take based on any technology in AI as certainly being one of those.

CMS has issued certain policy guidance as related to the uses of AI and Medicare Advantage programs.

The ONC rule. I just have two more slides here and then I will stop. The ONC rule just to dive into that for a second. We focused on transparency and in particular what we have tried to do is say can we start the process as an industry of identifying what might be a model card for those who are familiar with that term or a nutrition label for those who are not familiar with term for AI products that are made available in certified electronic health record technologies.

The importance of doing that in electronic health records is that electronic health records are increasingly going to be and started to be the data that supports more refined and more specific AI-enabled technologies for uses in health care delivery and in health care in large but also and equally important if not more important are the place where AI-enabled technologies are injected into the workflow that people use in the care of patients in their day-to-day operations.

You can have AI-based technologies but if they are not really accessible, if they are not integrated into the workflow as we know, they are just not going to get used. Electronic health records are where that actually happens whether it is self-developed or a developed product by the EHR vendor or a third party or anywhere else. Everyone wants to integrate in EHRs. We think it is really important that we have a certain set of guardrails related to those AI-enabled technologies in the certified products.

These are the categories of data that are required to be made available for products that the EHR developer brings to the market. But we also required that that functionality whether it is a dashboard, and you can imagine, there are 31 data elements underlying these nine categories. The dashboard, we also said, has to be available basically for use by the customer. Oracle Health is required to make available this dashboard and populate it for the AI-based technologies that they have made available as

a part of their product. But they also need to make it available for their customer to be able to add data elements for self-developed AI-based technologies, for example, or third-party AI-based technologies that they integrate into the EHR system.

And what we are hoping, and we are getting early evidence that this is actually happening is that a provider organization, for example, will find this as a very useful tool for their own governance of AI-based technologies. How might that work? We strongly encourage that that organization set up a governance approach for how they think about the uses of AI-based technologies but this allows them a place to keep track of those to say basically, I have a dashboard now and I can have that dashboard help to monitor what are these technologies and what are the key data elements that I want to be able to use and the key information I want to be able to use about the appropriateness of them but that also allows them to say – and some provider organizations we know are already starting to do this to say I am actually going to take these data elements and put it into RFPs for other technologies that I purchase so that those other technologies are meeting the same standard as information that we think is critical before we decide as a hospital, let's say, to use this in our day-to-day operations.

The last thing I will mention is AI strategy. We are hard at work on helping to facilitate and coordinate an HHS-wide strategy as it relates to AI. This is a direction that we got from the executive order. It was already something we were thinking about within the department under this leadership and the deputy secretary already had us, starting to think about we need to be thinking about AI strategy. And then the executive order came along sort of shown a light on that and said yes, you definitely need to do that and here is a timeline for that. January 2025 is when we will release this but we are hard at work on an AI strategy.

I think, as all of you hopefully appreciate, the department covers a very wide range of activities in health care. We think about the life sciences and health care value chain that is everything from research and discovery of medical products whether it is biologics or drugs or devices, all the work that NIH does to keep pushing the scientific and medical frontier in terms of leading-edge research.

Medical product safety, efficacy, and performance, all the work that FDA and NIH do together with approval of drugs and clinical trials and approval of devices for safety, monitoring of safety events for those products.

Health care delivery. CMS, Medicare, Medicaid, HRSA, SAMHSA, ONC, all the work that is done in health care delivery.

Human services delivery. We are the Department of Health and Human Services, and human services needs to get more attention, I would argue, and we believe is a department because of the importance in thinking about the holistic view of the patient.

And then finally, public health, as we think about all of the aspects of public health. Those are all areas that we are now working hard at saying what are the strategies we ought to think about from a department perspective of having AI be something that helps to make those better but that also does so in a trustworthy manner where at the end of the day, our main policy objectives are encouraging

innovation and adoption, promoting trustworthy development and use of those technologies, democratizing those technologies so it is not the haves and the have nots but that everyone has access to those kinds of technologies and cultivating AI-empowered workforces. We live in a part of the economy where we do not have the problem of technology replacing people. We have the problem that we cannot get enough people in the sector to do the very hard work that we are doing. We want to make sure that the AI-empowered capabilities that are deployed are actually something that help empower that workforce instead of just driving more of them to lead the workforce.

Very important set of objectives. Very hard work that we are doing, and we will have more to come as we release that report in January.

I know I have taken a bunch of time. I hope that provides a good overview and I am very happy to answer any questions or get your advice and feedback. I know all of you have tremendous amount of expertise and experience here as well.

Participant: Thank you so much. I am going to send it to Lenel for questions.

Lenel James: Hi Micky. Great presentation. Thanks for trying to tie all those things together in a really short period of time. My question is a follow-up on TEFCA and AI. It may be a touchy area but minimum necessary. From a payer perspective, which has always bedeviled us in asking for something and something saying I do not think you need it. And I am thinking is that data blocking or is that you do not understand why I need the data. But now because of AI and all the research findings, it seems to me every week, every month people find new correlations. And as payers, we are keeping track of that and I worry that minimum necessary is totally irrelevant in a world where we are finding ties to information that affect patient care, coordination of care, resources. And what would it take, Micky, to get minimum necessary out of the way in a world where if there is more data and people can use it, we should be able to get it without that as a "data block"? What is your feeling or anything we can do to help minimize that disruption for information that could help a patient get better care?

Micky Tripathi: Thanks Lenel, and good to see you. The immediate answer to your question of what would it take to change that, we would have to change the HIPAA privacy rule and maybe even change the HIPAA statute. I do not know how far back that goes. Minimum necessary is a core construct in HIPAA. Certainly, ONC or ASTP does not have the authority to just wave the wand. It is not our regulation so we could not even do it but even the Office for Civil Rights does not have the ability to say we are going to wave the wand and just change that. There is obviously a lot of regulatory and statutory foundations behind that.

But that said, as you have also alluded to, minimum necessary is a judgement. Three is no hard thing that says for this, it is minimum necessary. It is always in the eyes of the parties who are exchanging the information. I think it is a great point that in a world where you have technologies that can make connections that were not otherwise obvious, it does beg the question of what is minimum necessary. There is a tremendous amount of information that actually might be valuable in that context.

There is nothing about TEFCA that really changes that equation. It is really something that TEFCA as it

relates to payer-provider interoperability, and we have just to prove the health care operations use case. The reason that you have provisions in there that say that it is option, which say that there may be fees allowed, for example, which is a whole other dimension, but I am happy to talk about but is because there are not standards related to minimum necessary. It is still up to the parties to determine between themselves what would cost to do that.

Now, we are doing a lot of work and we look forward to doing work with the payer and the provider community, for example, as we actually are doing in the work of public health because minimum necessary comes in public health as well.

CDC is actually doing a lot of active work to say can we get some common definitions of minimum necessary that will allow us across jurisdictions to scale this in TEFCA, for example, so this does not become a jurisdiction-by-jurisdiction problem.

I would really invite payers and providers to work with us in saying can we do that within TEFCA as well as a TEFCA contract. Can we all agree that within TEFCA, we will all agree that for a basic care coordination use case, here is what constitutes minimum necessary, for example, and that will allow us to have more scalability.

Valerie Watzlaf: Thank you so much, Micky. What a wonderful presentation. You covered so much information. I just wanted to ask you with your new structure, where does privacy fit into the new structure of ASTP? Does it flow like across all these areas or is there a specific area it falls under? If you could elaborate on that a little bit. Thank you.

Micky Tripathi: We do have a chief privacy officer who is in the immediate office, as we call it so in effect reports directly to me. That is Kathryn Marchesini. She supports – and we have privacy across everything that we do as well. We have a chief privacy officer as well as within the Office of Policy, for example, which is where the information blocking rules sort of live and cut across the technology areas and the other areas. It is both having a single expert and then a set of experts who are in each of those divisions who work on privacy areas. We have a number of HIPAA experts, for example, who live in those divisions as well.

I guess the answer is it is all over the place and it will continue to be all over the place. And we continue to have a chief privacy officer reporting at the highest level there.

Michael Hodgkins: Thanks for the presentation, Micky. You went through a lot of material very rapidly but I think covered it well. The AI piece – I have to say I am increasingly troubled by the fascination and the focus on promoting AI in health care as opposed to focusing on the concerns around model collapse and embedded bias and those kinds of things. I heard you talk about promoting adoption but when are we going to start promoting a little bit realism in terms of the inherent limitations in AI whether you are talking about large language models, chat box or even simple algorithms?

Micky Tripathi: It is a great question. Actually, I guess I would argue that at least from all of the discussions we have been in with the private side and thinking about it that there actually has been a ton of focus on all of the cautions and all of the areas of danger and risk and not enough discussion

about what the opportunities are. We certainly do not want to swing it to much the other way and I think that is represented in some of the regulatory approaches as well. If you look at the ONC regulations, for example, there is a ton in there that is about establishing guardrails, specific call-outs for health equity, for example, for safety risks, for example, for risk management frameworks that are required to be supported by electronic health record vendors, starting in January 1, 2025.

There is a lot there already and certainly as a part of the strategy that I showed up there. We have ethical and responsible use cutting across all of those primary domains as critical areas. We do worry about misuse but we also worry about missed use as the way we think about it.

Let me just give the example of some of the things that may not come to mind for the general public. Again, all of you are experts so you may be familiar with some of these. There are opportunities. There is an individual story of the person who had a misdiagnosed, it turns out, brain tumor, was able to get their records from the institution in part because they are part of the institution, get their records, run that through a secure version of a large language model. The large language model without any additional training came back with four or five possibilities based on the medical records that they made available to all the providers and it came back with the right diagnosis. It came back with four or five options, brought that back to the doctor. The doctor was able to say maybe it is that. It turned out to be that.

And then they were able to take their operative notes after that and that helped to energize the conversation that they were able to have with the surgeon about different things that they did in the surgery and why they might have done this, why they might have done that.

My point is that there is a tremendous opportunity here for us to think about patients being able to have better ability to interpret their information and have a much more engaged conversation with their providers, for example. But it has to be done safely. I do not want to discount that because there are all sorts of ways in the anecdote I just described. You do not want a patient uploading their records into the commercial version of ChatGPT. Full stop. We absolutely do not want that unless they know what they are doing. We need to think a lot about that as well.

But I just want to make sure that you understand that we are thinking really hard about that but we do worry that people will get too scared to use any of these technologies when ultimately we think there is a tremendous benefit that is there for the entire ecosystem and first and foremost for patients.

Naomi Michaelis: Any last questions? Tammy, go ahead.

Tammy Banks: Micky, thank you for putting amazing amount of information in an extremely short period of time. I just wanted to thank you and I can see that you are wearing a lot of different hats.

But I did want to commend your ONC staff for their collaboration with us in the past and we look forward now with the ASTP to continue that conversation alignment and look forward to appropriate collaboration as it appears. I just wanted to say thank you.

Micky Tripathi: Thank you, Tammy. We have been able to accomplish a lot over the last three and a half

years here but that is really a testament to an amazing ONC staff and an amazing leadership I would say. I personally have to have tremendous support from the bottom-up and tremendous support from the top-down and have the great fortunate of having both.

Naomi Michaelis: Thank you so much, Dr. Tripathi. We are now going to take a break. It is scheduled to go until three but we are going to give ourselves an extra couple of minutes. Let us resume at 3:05.

(Break)

Privacy and Security in Health Data Access: Public Health, Human Services, and Other Perspectives

Naomi Michaelis: Welcome back. I am now going to turn it over to Val and Cathy of our Privacy, Confidentiality, and Security Subcommittee.

Catherine Donald: I appreciate that, Naomi. Our panel this afternoon is going to be a continuation of the panel that we had this morning, which is privacy and security and health data access. But there will be a focus on public health, human services, and other perspectives that may come up.

This afternoon we have three more great panelists for our discussions and I am sure that we will continue with the informative discussions that we had this morning. What I want to do is start by introducing all three of our panelists before I turn them over to make their opening comments before we move to our open discussion.

First of all, we have Dr. Annie Fine, who is the chief science and surveillance officer and senior advisor for Data Modernization for the Council of State and Territorial Epidemiologists, which is also known as CSTE and which I will be saying in the future. Dr. Fine is a medical epidemiologist, a pediatrician, and a graduate of the CDC Epidemic Intelligence Fellowship. In her role at CSTE, she oversees the surveillance and informatics and data modernization programs. She establishes strategic direction and advocates for the needs of state, tribal, local, and territorial health departments to receive, exchange, and use data to protect the public's health. Dr. Fine previously worked at the New York City Department of Health and Hygiene where she led efforts to modernize communicable disease surveillance at the agency.

Next, we have Dr. John Loonsk, who is an adjunct associate professor at the Johns Hopkins University School of Medicine. Dr. Loonsk has been active in health informatics in several different roles and projects. In addition, he is also an adjunct professor at the Johns Hopkins Bloomberg School of Public Health and a fellow in the American College of Medical Informatics.

Our third panelist is Marko Mijic. He is managing director of Sellers Dorsey and was formerly undersecretary with the California Health and Human Services Agency. As undersecretary, Mr. Mijic's leadership focused on streamlining government operations, expanding access to safety net programs, and advancing an equitable pandemic recovery. Prior to his work in California, he served in the immediate office of the Assistant Secretary for Planning and Evaluation at HHS.

With that, I would like to turn it over to Marko Mijic to start off our discussions and he has an overview for everyone as well. Thank you.

Marko Mijic: Thanks so much, Cathy. And thank you to you and Val for both inviting us to be part of this conversation. I know we had a really exciting conversation and prep for this with Annie and John so I think that this is going to be a lively conversation around a lot of different things.

I also see other partners who I have had the pleasure to work with like Jamie with Kaiser, who has just been a phenomenal thought partner in some of the work related to what we have been doing here in California. And a huge thanks to the staff both at the CDC and ASPE for obviously pulling all of these pieces together.

My job this afternoon really is to spend a little bit of time just putting things into context in terms of the conversation and then pivoting it to Annie and John to really be able to dig a little bit deeper into some of the components that we want to talk to you all about. I am going to share my screen and please let me know if you are able to see it okay.

The goal really here – and as Cathy mentioned, I am a managing director at Sellers Dorsey. I am also an impact fellow at the UC Berkeley School of Public Health and former undersecretary at CalHHS where I spent nine years and just recently left. The important context here is I led the work around the establishment of the Center for Data Insights and Innovation at CalHHS, which looked to do a variety of different things, including think about what our workaround privacy data integration and exchange really looks like. And second, led the work in both the development and implementation of California's data exchange framework, which I will talk a little bit about in just a moment.

At a very high level, what I want to do today is just provide you a little bit of landscape of why we are having this conversation. Today, these three different sectors operate in silos and are very fragmented and each of us has our own experiences as we embark on the care journey or our family's care journey or our children's care journey around how to navigate these various systems. It is not only that poor people have to go through these journeys. All of us experience these fragmentations.

I think as a subcommittee and as a committee as you begin to think about these things, I think Annie, John, and I would urge you to think about how do we connect these dots more strategically and begin to think about the whole person or the whole family that we are looking to serve and data and technology have an important role to play.

As we look at the opportunity, we really see the place where these things begin to intersect, and I would argue these things glued together via the exchange of data and the use of technology. The way in which we bridge or connect these independent silos or fragmented parts is really by beginning to think about how we leverage data to connect these dots, and it is not just these. Behavioral health is a topic of conversation for many of us and we have to think about what does behavioral health look like. Many of us work in the child welfare space and we have to think about what are the implications on child welfare.

I have spent a great deal of time thinking about kids who have high needs, who cross multiple systems. They might be a Medicaid child, who is developmentally disabled and is child welfare dependent. I think we have to think about what is the care look like for that particular child, for example. That is going to

be an important part of the conversation.

And the IDD, intellectual and developmental disability system – in California, for example, this is an entitlement. We are the only state in the nation that provides IDD services of entitlement irrespective of your income. This is an important piece and part of the conversation related to how we think about data exchange.

You heard from Micky earlier. I have the privilege as undersecretary to author a piece in Health Affairs with Micky that really talks about the federal around TEFCA and California's work around data exchange and our ability to really focus not only on what we typically call health information exchange but what we started to reframe here in California around health and human services information exchange. And it is an important piece to really think about the human services component and we will talk a little bit more about what that really means.

We are moving in the right direction. I am not going to repeat what Micky said around TEFCA and the standards that these have looked to. It is an important differentiator between California's Data Exchange Framework and TEFCA. TEFCA is voluntary. The Data Exchange Framework in California is mandatory. It is required by law for entities to sign the agreement and abide by the agreement. And the agreement outlines in principle all of the standards as well as the legal framework on privacy that needs to be followed whether it is a HIPAA-covered entity or not. It guides organizations through the exchange of that information. As we begin to see more whole person care work, more work around value-based payments, these things become increasingly much more important.

I want to touch on three strategies. I think Annie and John will allude to these a little bit more. I think you all, as a subcommittee, and a committee as a whole need to think about. I think one is to look at the approach of how social services information is collected and shared and what those standards look like. We lack in standards on the social services side. States are beginning to look at what that looks like. I think the federal government must think about what that means here. You had Micky talk a little bit about the standards that they are looking to promulgate and are partnering with different folks. I think this is an important endeavor, so we all understand how we are looking to exchange the data. There are standards in the public health space, but I think it is also important to think about public health in this context as well.

Second, I think consent management is really important and this is a significant pain point. We have vast disparities in terms of how folks are consenting for their information to be shared. I have often thought about do we need to think about a utility here that is a public good where we create a streamlined consenting process or platform rather than have different technology vendors create their own, et cetera. But consenting is a significant pain point for a lot of providers and organizations. Consenting is going to be an important thing for you all to contemplate.

And then I think thirdly and this we talked about nationally for some time is what is our approach in terms of consistency and uniformity related to individual identification both how you identify a person and then how you use that to match data between different systems in order for us to be able to understand the holistic needs of that individual.

This becomes particularly important in the safety net but it is not excluded to the safety net. We know that individuals, for example, who I will call the forgotten middle. These are individuals who are on Medicare. They need long-term services and supports. They need a series of other benefits. How do we connect those things more holistically for them is important.

There are also a series of important considerations I want you to consider as you think about this. It is going to be really important to think about how you reconcile varying state and federal requirements that may be in conflict or not fully aligned. There is vast disparity in terms of how people interpret some of those requirements and also what those standards ultimately are. I think that ambiguity creates a lot of gray space that moves people to a space where we rather not do something instead of figure out what that ambiguity looks like and clarify that gray space.

That leads me to the idea that we really need to balance privacy here with the idea of access. Too often, a lot of entities hide behind HIPAA as a way not to actually exchange data. And I think that does a disservice in our ability to serve people holistically and provide the level of care that they need so really thinking about what that balance looks like.

And then finally, we must acknowledge that there is a lack of infrastructure on the social services side, the public health side, and I would assume the behavioral health side too to both exchange and analyze the data that is made available.

We have come a long way with regards to the health care field due to HITECH and other investments that are made at the federal level. The safety net too often lags. I want you to also think about from an equity perspective how do we ensure that when we think about infrastructure and building up infrastructure in the safety net across social services, behavioral health, and social services that we are thinking about investments in these to build up and create the economies of skill for us to be able to do it.

In the midst of the pandemic when I was an undersecretary, our public health reporting systems were able to do some of these things with regards to case reporting because we had small numbers. We duck taped and super glued our various systems. In some counties in California, we were still doing things via spreadsheet. And then you have the pandemic and everything just collapsed. And it is because we really did not invest in technological infrastructure to create the surveillance systems to be able to collect the data to think about the analysis with that. We need to just keep that in the back of our minds as we look to have this conversation.

I am really stoked to have Annie and John here. They are really leaders in their own right and I just enjoyed talked to them and I think you will learn a lot. I will pass the baton over to Annie first and then John. And then we certainly are happy to engage in further conversations with you all.

Annie Fine: Thank you so much. Marko, what a great kickoff for this conversation. And I also really enjoyed our conversation yesterday. I am going to build off of what Marko talked about. I do not have slide so I am just going to talk with you. But what we are seeing here is clearly a tension between the need for data to flow and from my perspective, this is flowing to public health and the privacy concerns

associated with that data flow.

Clearly, data are important for public health response at all the levels, local, tribal, territorial, state, and federal. We all saw it with COVID. It is clearly true. Everybody understands this during emergencies. It is also true during routine times. We have all kinds of conditions, which public health can impact as things like congenital syphilis, drug overdoses, hepatitis A, keeping our food safe, injuries, flu in a nursing home, immunization information, and very often this does require identifiable data. Often, we may have to reach out to a person. We may have interview that person and find out what foods did they eat. We want to protect the food supply. We have to know what is the food that caused the illness or detecting outbreaks. We need their address so we can detect outbreaks in space and time.

Public health reporting. It is by law in many cities, states, territories, and tribes and identifiable data is critical. And often we have to collect more information than what is available in a medical record. That is why you have to reach out to the patient.

These data are also super important for looking at issues of equity. We need to know people's race. We need to know ethnicity, their social determinants of health. The issues that Marko raised are really critical. And if we can find ways to integrate the data, then that actually reduces the work for the public health workforce of having to go out and find that information in order to address these kinds of issues. Things like how is this event impacting disabled people? How is this impacting people in different workplaces? We need linkages between data at the individual level for some cases, not all cases or at the geographic or subpopulation level. Maybe affecting a certain portion of the population or the exposures. Is it on the job? Is it due to an environment like a food desert or something like that or no access to cooling centers? All of these kinds of data are really critical for public health to take action to protect people in our jurisdictions.

I do want to remind everybody that public health does get the data on these levels to varying degrees. And public health is very accustomed to protecting confidential data. We have all kinds of procedures in place to do so and are governed by laws, often by state law, local law, and other laws to protect the data despite the fact that these types of programs are not covered by HIPAA. These are HIPAA-exempt public health activities.

We have requirements about how we can report, how we can redisclose, how we can share even within health departments. That is actually sometimes ironically a really big challenge. We cannot even share data within health departments, which is ironic and certainly trying to work on that because of all the silos.

In the past, data were reported on paper, fax, et cetera and now becoming increasingly electronic, increasingly automated. We have electronic laboratory reporting, electronic case reporting. We have syndromic surveillance. We have electronic immunization data, hospital data, and vitals and also registries, special studies, those types of things. We have seen a lot of progress in the ability for public health to do its job in a much more efficient way but as Marko alluded to, we still are working hard on catching up with health care in terms of the infrastructure both technical workforce and system level to do so.

We are increasingly beginning to use and rely upon health information exchanges. They were extremely helpful during COVID, and they continue to be helpful in all kinds of ways and we are just now starting with TEFCA. A few health departments have started to look at can they adopt TEFCA. Can they sign up with a QHIN? We are learning about TEFCA and very excited about what TEFCA can offer. But very few health departments are actually exchanging data using TEFCA now with the exception of receiving electronic health case report data, which is coming through TEFCA.

Some of the legal issues. Health departments can be HIPAA covered. Some pieces of them can be. Some of them deliver care. Those aspects are often HIPAA covered. But most health departments that do that are hybrid entities so some of the programs within the public health department are not HIPAA covered. This causes complexity and it does even when you are talk about signing up with an HIE or signing up with TEFCA. Who within a health department is subject to HIPAA and who is not?

New issues we are seeing. Integrating the data from health care. This is a really critical challenge for public health. We need to be able to get and hopefully provide data back to health care. This is relatively new and the data that we get from health care often is not as specific as what we need it to be and it often has additional data that comes with our reports that may not be parsed, filtered out. It is not illegal for health care to share the data with public health because it is under the minimum necessary concept of a case report. But there is a lot of additional data in these case reports that the health department then has to manage and filter out so that it really can be viewed by those who really need to see it. We need shared tools to help us do that with a massive volume that we are starting to see.

There are laws and regulations which can impede the flow of data. We see this with CFR 42 Part 2, the substance use data as well as there can be threats to getting data such as reproductive health data, which is very important. We do not want reproductive health data to be used in certain ways but we do need reproductive health data for public health uses, the example of congenital syphilis or now Oropouche virus. There are lots of hepatitis B, perinatal hepatitis B. This is really important for actual public health. We need to be able to transmit and exchange those data while protecting the data. That is really critical.

Marko alluded to the variability and laws that impact data sharing across public health. This is really extremely complex and there is no compendium of all the laws and regulations that exist at the state, federal, territorial, tribal, and local level. How is TEFCA going to govern the exchange of data in accordance with applicable law when there is not really one reference of what that law is. Is it just going to be based on trust or is it going to be based on something that actually has some technical component to enable the QHIN or whoever needs to know what those laws are and who is authorized to receive that information?

There is an increasing amount of data going to the federal level and increased amount of visualization that elected officials would like, that the public want. They expect it now after the pandemic. When we are showing data at very granular levels of geography, how is that impacting privacy and how can we facilitate that at the same time?

There are some risks of reidentification through data release and disclosure. It is very important that

data that gets sent around within the public health ecosystem and from health care to public health do have strong protections from redisclosure across federal agencies or to other entities to whom may be asking for the data.

There is a DUA. CDC is working on a master DUA with a lot of different appendices for different types of data but there are a lot of different kinds of DUAs out there still. This is another challenge is how do all these DUAs get worked into this framework of data exchange that we are starting to move to.

In summary, I will say we want data to flow. We need information to go where it needs to go but we need the right information to get in the right hands for the right decision making. But what are the guardrails? How do we ensure privacy within that context and how do we ensure that data do flow in accordance with existing law and regulation?

And then my last point I will just say is public health, as Marko said, has – we have been given more funding over the last few years since the pandemic. But I just saw a slide showed by Jen Layden, the leader of the Office of Public Health Data, Surveillance, and Technology at CDC. It shows this cliff of funding. We have received a bolus of funds and now in the next year, we are facing a huge cliff for managing data across the entire public health system. This is a huge challenge that how are we going to use it, given the resources we have. Do this much more complex work, not just the technical work, which is really important to the workforce, but the legal work, the policy work. We have to engage in order to have this work the way that it needs to work and to have the trust to be able to use the system.

I will stop there and turn it over to John, my colleague.

John Loonsk: Thank you, Annie. And thank you to the committee for inviting us to talk here today. I saw a lot of old friends in the video windows and a lot of people that have worked on health IT and health IT for public health for some time. Really appreciate this invitation.

What I planned on doing was just – I have a small number of slides. I understand the committees are interested in trying to sort their way through areas they would like to look. I have been heavily involved in doing public health IT for a number of actual decades now. We are progressing but there is still a lot of work to do.

Electronic health information from clinical care has been recognized as important for public health IT for several decades. The most recent public health emergency of COVID – we made further progress in moving things forward by rolling out electronic case reporting that Annie alluded to from EHRs nationally but work still remains to be done. I am going to try to tease out a few of those issues as examples for things that the committees may be interested in talking about.

Certainly, to make this connection work, the secure exchange of health information is critical. Public health right now uses health information exchanges. It uses health information networks. It is starting to use TEFCA but as Annie suggested is very early in that development. And it also uses a panoply of state laws, HIPAA business associate authorities, public health disclosures to accomplish all this. It works but it is critical to monitor and to continue to advance this because there is not a complete and consistent understanding of this infrastructure in terms of how it is implemented and what those laws and

regulations are for.

There are also new technical tools. AI was talked about earlier but there are more basic tools like being able to build in the cloud to facilitate this exchange between health care and public health. We rolled out electronic case reporting using the hub and spokes architecture. That is really important when you have as many jurisdictions and as many different health care organizations involved in the exchange as possible. That hub and spoke architecture is really facilitative of making the data flow and making them flow more consistently but it has implications in terms of how it is affected.

These legal and regulatory approaches to construct this architecture really must cross these multiple jurisdictions, must cross the multiple health care organizations and must overcome what can be very complex laws and regulations to do so.

Some examples of things that are worthy of further discussions. First, I would put one of my pet peeves on the table and say it definitely applies to security of data, which is the quality of the data. If the data are bad, they are not secure. Existing data quality efforts have been very limited due to EHR company and some extent clinical care resistance.

Public health needs high-quality data. I think Annie alluded to this as specific data. It needs to be consistent data as well. Standards and certification can be more rigorously applied to get to these quality outcomes than it has been to this point.

Another issue is how the data are distinguished between being of clinical origin, being legally extractable for clinical care purposes and being of public health or human services use and with the intent and constraints of being used for those purposes. This is sometimes alluded to purpose of use and there is a designation for purpose of usage of data in TEFCA. But there is not consistent implementation in the health information exchanges that are out there and in the health care organizations that need to feed this system and make those purposes of use marked up properly on the data and implemented properly in places where those data may come to rest.

Technically appealing as many of the modern technologies are, I am a technology person, queries for data have very different policy issues that are associated with them and querying is not reporting. A lot of the reporting infrastructure that has been put in place was put in place for a reason and public health investigation is important, but reporting is very important and needs to be supported with the technology and the policies to make sure that it can continue.

The perception of HIPAA language for disclosures as another example can be at times problematic. The privacy rule permits covered entities to disclose protected health information without authorization to public health authorities. But if you think about that and if you think about that that disclosure may align with a data transaction, can a QHIN, for example, in TEFCA or a health information exchange actually be disclosed to if it is acting to pass those data on to a public health authority? There is a confusion about that issue. There are those who think it cannot. It is example of an issue where specificity and clarity will be important in terms of moving things forward.

There are federal regulations that have similar confusion and complexity. Annie alluded to this one as

well. But SAMHSA has said to me and to others that there is substance abuse and disorder regulations, 42 CFR Part 2, should not block state required reporting. They have said that very explicitly but there are a number of public health agencies that believe that they cannot get electronic lab reports or electronic case reports even if they are required by state law if the patient is covered by such regulations. There is a lack of clarity as to how these federal regulations work with each other and this is an ongoing issue.

As a final comment, reinforce something that has also been said I think by Marko and by Annie as well is that public health agencies particularly have trailed behind clinical care in health IT adoption and health IT infrastructure and their understanding of their data rights. I will tell you that they are fastidious about trying to be as appropriate as they can be to protect the data and use them only appropriately. But they have an important mission to carry out and are sometimes confused about what they can and cannot do with the data when they get to the public health agencies in particular and their variant interpretations are spawned by the many different legal advisors in a very highly federal system.

Very much appreciate the opportunity to make these comments and look forward to the discussion as well.

Catherine Donald: Thank you very much. I think, Val, we are going to turn it over to you to lead the discussion for us.

Valerie Watzlaf: Thank you. That was wonderful. I really appreciate the wealth of information you have provided us. I just had a few – I guess one question I just – and maybe this is for John too. Could you elaborate a little bit more about how – I think you had said PHI is not always shared with public health authorities particularly under TEFCA. I think you were saying that there could be some – where they are not really understanding if they are able to do that with a public health authority. I believe that is what you said. If you could elaborate a little more, I would appreciate it.

John Loonsk: One dominant issue for public health has been it has not had the technical infrastructure to get the data. For example, electronic case reporting did not exist in a practical way that public health agencies could get it until very recently.

But there are other aspects of the infrastructure that is implemented. What I alluded to was the fact that public health disclosures specify release to a public health authority and QHIN intermediaries in the TEFCA process are not public health authorities. What has been a problem and this is really manifested itself in HIEs to this point more than in TEFCA because TEFCA is so new is that some perceive that they cannot make a disclosure, this transaction, to release these public health data if the immediate recipient is not a public health authority itself. That is what I was trying to allude to as an example of a lack of clarity and potentially something that needs to be modified moving forward.

Valerie Watzlaf: Thank you. Some other questions I had and then please feel free to others, if you have questions, just raise your hand and we will certainly get you in. How do you think the pandemic impacted the need or desire for more granular – I think you all have mentioned this such as line level or even potentially identifiable public health data to flow to the federal level.

And then I guess it is a two-part question. If that happens, what are some of the risks that you see that

would pose to privacy and what kind of roles do you think should we put around it? This could go across all of you, I guess.

Marko Mijic: I certainly can start but I think John and Annie probably have other things here. I think that COVID-19 – although an awful pandemic with certainly big impacts – pretty significant accelerant for change in terms of our thinking around what this all looks like. I do think that that was the perfect use case to exemplify the need for more granular information to be able to do the case investigation on the ground particularly in the very early stages of the pandemic when we were really looking to mitigate the case investigations and contact tracing so I think being able to have some of that granularity information.

Annie alluded to it a little bit with regards to some of the movements related to isolation of various data whether that is reproductive rights data or other. I also will tell you that in California, I think there is a pretty significant and continues to be a pretty significant chilling effect from the public charge rules that were promulgated on the prior administration. There is a significant amount of fear from individuals around what types of information they are providing and what types of information the federal government itself will have access to.

Here, we are talking about two different layers, the individual information that is provider to provider for the purposes of doing care delivery or contact tracing. But there is another layer of what is required to be reported to the federal government, which is another layer of complexity that you all have to think about and contemplate. I think there continues to be a chilling effect around what information is shared and how is that information used despite the fact that there are rules and requirements. There is this perception that it could potentially be used, for example, to deport individuals if they share certain information despite the fact that there are legal immigrants who are here legally just like I came to this country as a refugee. I think that there are some things there that you are going to have to think about and contemplate as you make recommendations to the secretary.

John and Annie, I would love for you to piggy-back on that or correct anything.

John Loonsk: I think that public health is getting more specific data than it has before in terms of electronic case reporting but the process of using identifiable data at the state level to do things like contact tracing, to do case evaluation is well established and critical. And as Annie suggested, there is a really long history of responsible and secure use of those data at that level.

I think the federal government is more interested than they used to be in getting some of that specific data. But there are a lot of technical tools like PPRL, on other words, de-identifying the data but still being able to link them that can be implemented if we have a tight infrastructure nationwide, if we can build and continue to refine the infrastructure, as I described it earlier so that it can do that de-identification but linking of data that can address some of these issues of concerns for federal agencies receiving identifiable data and potentially using them in other contexts.

Annie Fine: I totally agree with what Marko and John had said. I think the key issue is that the state, local, territorial, and tribal level needs identifiable data to do their job for some things, not for

everything. For certain kinds of diseases, they may only need to aggregate data or they may only need syndromic data, which is not actually identified. But the federal level needs data too. How do we build systems that supply timely data but allow the data to be processed and managed in a way that actually is governed by agreements that have been – there is shared governance over how this works and that the degree of identifiability is something that all parties can agree on without having health care or laboratories or whoever else have to send two different streams to two different places or three different places.

Ideally, you want a system where the data do not have to move that much. They get sent one time but they can be processed out in the ways that are most useful for the levels that need them. That is, I think, the system that CDC is envisioning and aiming to build. There needs to be a more robust discussion in my opinion around what are those guardrails and how do we bring the parties together to develop those kinds of operating rules around it. I think that has started to happen somewhat but maybe not quite as much as we would want.

Valerie Watzlaf: And also, I know you brought up too about the HIPAA Part 2 rule making and I just wondered whether the recent changes to that – has that clarified some of the complications that you are still seeing or going through? Has that improved at all?

Annie Fine: I am not in the field. I was in New York City up through 2021, the middle of the pandemic. Unfortunately, I do not think that – I think the change is better. The change that was made recently was better but it is not all the way to where we need it to be because it still requires consent from the patient for identifiable data to be transmitted. Unfortunately, the final rule did not go far enough in my opinion, and I am glad you asked t hat question. That is an important – I wish it had gone further.

I knew there were some comments to try to make it go all the way so it did not require patient consent because consent is a major issue. It is a blocker for some public health data to flow.

Jamie Ferguson: First of all, hello to the panelists. Thank you so much. It is good to see everybody and thank you so much for your presentations and for the discussion. I have a narrow question, and this is linking back to a previous panel earlier today. I do not know if you had a chance to listen in on that. But one issue that was raised is about redisclosure by public health agencies. The question was if you could wave a magic wand and change HIPAA, what one thing would you want to change?

One of the things that was highlighted there was the potential risks from redisclosure of data which is of course allowed by public health agencies. If you were trying to say what redisclosure is needed, what rules might be placed around that so that risks could be reduced in terms of redisclosure – I know, Annie, you mentioned some cases where redisclosure is absolutely critical to the public health function. But how would you change HIPAA or write rules to potentially restrict or put some guidelines or boundaries around redisclosure?

Annie Fine: One thing I would say is disclosure to whom is a really critical piece. There needs to be redisclosure in some situations. For example, tribes need data. If the state receives data that is relevant to a tribe, they have to be able to redisclose. I would presume that that would be a privilege, a

permitted redisclosure. Redisclosure to – to whom is a very important question about what those guardrails should be. But I do think we need better agreed upon rules about what does constitute actual re-identifiability within the modern context with AI and all these things out there, which is a very different world that we are living in now than what it was when we had the 18 HIPAA identifiers. I think that is a really important knowledge piece that could be incorporated into regulation.

Valerie Watzlaf: I will go to Michael and then Cathy.

Michael Hodgkins: I think Cathy had it up first.

Catherine Donald: It does not matter. It is okay. Thank you. I just want to thank you for all of this. As a public health person, I do not know if you could see but I was shaking my head and almost amen-ing everything that you guys were saying because redisclosure – that is a double edge sword, things we need to do.

The money cliff is big. There are a lot of things that we need to do in public health, but we have this big money cliff coming up. How are we going to be able to do these things and continue moving forward? We had a huge trench of money during the pandemic because they wanted all these things. But sadly, those things do not happen right away. As you can see, we are just moving forward.

I just think that these presentations have been really fantastic. Talking about the quality of data, those kinds of things. My question is – and I do not know if we want to do this one now but it is really what keeps you up at night. I think Jamie alluded to that and we did that in the other group. There are a lot of scary things. For me, it is money to be able to do what we need to do. Thank you. I will just let the others go ahead and go. I guess I am turning it over to Michael.

Michael Hodgkins: Marko, in your presentation, you talked about the fragmentation, examples like social services and what have you. I think we can all agree that there is vitally important information outside of traditional health care if you will in EHR.

But it seems like it also just raised even greater issues about privacy protection when you start to dip into areas like social services, behavioral health and so forth. I am just wondering what your thoughts are about that and how we address that.

Marko Mijic: We have contemplated this in California for a while. And part of the reason why the Data Exchange Framework, for example, in California goes beyond TEFCA – the way I think about the DEF in California is that takes TEFCA and builds on top of it and one component that it builds on top of is really the social services data. I think that you can do it. I think it is daunting to think about and just like it does – it is to think about in the public health space. But I think it is a disservice to these kids, for example.

If you think about the use case of a kid in child welfare who is also an IDD kid, is on Medicaid. And the Medicaid agency has information but is not willing to share with the child's welfare agency and that information would be helpful in terms of understanding how we support that kid. I think shame on us for not being able to figure that out and not engage in that way. I do think we need to be thoughtful about how we do this, and I think that there are templates of ways to do this. I would urge people to

think about how do you create those standards, how do you create those rules of the road?

I think we need to be technology agnostic here. We cannot be bound by any one technology. But I think that this is an issue of equity. Disproportionate number of children who are in child welfare are black and brown. And I think we cannot – these are our kids. I have two young kids, a 6-year-old and 1-year-old. And we have 50,000 kids on any given day in child welfare in the State of California. Each one of those kids we need to treat like our own kids. I work hard to try to figure out how I connect my own kids' care. But these kids do not have an advocate like me. I think we are creating purposeful friction points under the auspice of privacy or security or other things. And as a result, we are basically letting these kids fall through the crack. I am just using this as an example but there are going to be more examples in behavioral health. There are going to be more examples in other sectors.

My charge to you is not to be afraid of having the conversation and I applaud Val and Cathy and everybody else for engaging in this conversation. It is hard but we have to have this conversation and think through how we do this. If we just shy away from it, I think we are doing ourselves a disservice in a pretty big way.

Valerie Watzlaf: Thank you so much. Go ahead, Wu.

Wu Xu: Thanks. I really want to thank you, both panels, very creative and great presentation and thanks to the committee who put this together. I want to follow up on Micky and Marko and also other panelists mentioned a couple of times. The state health and human services program are really behind to adopt TEFCA, this new initiative to share the data across the federally funded programs. I think I would like to make a suggestion of how can we make this happen.

State laws are different but the federal requirements to the state program are also different. I think from the HHS level, they need a standard language to include TEFCA type of language into your funding requirements as long as that is in the contract, states will pay more attention to do it. That is the way really the state will follow up on this supporting initiative. That is my two sentences but really appreciate the panels.

Marko Mijic: You bring up such an important point and I think it is really important. In the context of California, for example, on the DXF, we actually do not have enforcement authority. But the way we look to get enforcement authority or think about enforcement is to do exactly what you just said.

When we went to re-procure our managed care plans through Medicaid, one of the requirements that we put into our contract with our managed care plans was to say you must ensure that you and the entities that you contract with signs a DXF and exchange data pursuant to the DXF that is both TEFCA and the state requirement. That enforcement then lies in the Department of Health Care Services who oversees the Medicaid program and with those managed care plans.

In public health jurisdictions, we also work with local public health jurisdictions in their funding contracts with local public health. We said you must sign the DXF in order for you to be able to get these dollars.

I think enforcement is a hard thing but I think adoption can be driven by leveraging various avenues that

you currently have just like you alluded to make this a requirement of that piece more strategically. And TEFCA should be looking at that in the same way. TEFCA is not a required right. California does have a requirement but even with the requirement, the enforcement piece lacks. Trying to think through how do you leverage that enforcement piece is going to be important.

Annie Fine: Just a dose of reality about TEFCA just for all of you is that TEFCA – the value proposition for public health has not been totally articulated yet. Though I think it is there. But there is a level of technical maturity and there is a level of participation that we are not seeing yet from the health care side that will drive that value proposition. We have a few health departments that have tried but they are not seeing the value yet. I am not saying it is not going to happen but it is going to take some time. I do not think we can do that mandatory thing at this point. It costs money to participate in TEFCA too unless you have an HIE that is participating, and they will probably pass down the cost. I think that is where we are right now.

But looking towards the future, I think incentivizing and definitely demonstrating the value is going to make a big difference. Surely, it can be encouraged by funding opportunities. Public health is largely federally funded largely. Those kinds of funding opportunities could certainly coerce to a certain extent.

The other thing I just wanted to say is that – I am sure you are all aware, but the CDC does have these implementation centers that they are just starting up right now, which are going to help show the way, which I think is what is going to happen over the course of the next few years.

And then I just wanted to answer the question about what keeps you up at night, Cathy, that you asked. Honestly, if I had to think about it, what keeps me up at night is the idea that we had this pandemic. We showed how poorly off our public health infrastructure really is. We have a lot of great people. We have a lot of great hardworking – we have some things that work. We have a lot of bright spots. But we do not have it across the whole country. It is very inequitable across the country. And the idea that we now have been given this chance and if we do not really sustain it, we made an investment but it is like building part of a house. And if you have part of a house, you are still going to get wet when the next rainstorm comes. That is what keeps me up at night.

John Loonsk: If I can just jump on top of that. It keeps me up at night that we are facing a cliff from COVID funding when we have faced a cliff from every preceding public health emergency as well. The entire paradigm of paying for this infrastructure has been episodic. It has been emergency oriented and not consistent. We are still in that boat and that is a problem going forward.

Marko Mijic: Just to piggyback off of that really quickly. Not for this committee but others to think about. We really need to rethink how we finance public health in this country more broadly. We are not going to solve that problem here but part of it is disease specific. We pay for heart disease. We pay for stroke. We pay for other things. These streams of funding that come, maternal health, et cetera. And we do not as a result build the underlying infrastructure that is needed across each one of these disease states. Everything is so disease-state isolated. I think that is going to be to John's point, going to be something that we have to really think about.

For me, the thing that keeps me up is I think we have a trust deficit. We have an unbelievable trust deficit from the public in terms of their belief in government and their belief in public health more broadly. I think we have to continue to use the model of public health to get deep in community to meet people where they are, to me culturally competent, to be linguistically competent, to engage people in a way to build that trust back in order for us to navigate into a different century. But I think with that trust deficit, I think we are setting ourselves up for failure as a country more broadly.

Jamie Ferguson: I would like to switch gears a little bit and switch to more of the human services social services side and talk about the issues of integrating social services data effectively standardizing social services data, integrating community-level data.

Micky Tripathi earlier did a great job of explaining how there are certain SDOH data elements in the USCDI for standardization and so forth. I would be remiss if I did not point out that ICD-11 has already as a WHO standard more than ten times the number and level of granularity of human services, community services and experiential data elements to drive social determinants as well as equity analysis. Obviously, we are not going to get that this year or next year or anything like that.

Today when we talk to researchers as well as both on the policy side as well as health researchers, we find that the social services and community services data are so-called messy. They are not well standardized. They are difficult to collect. Many times these are services that are provided not by government but by quasi-governmental community services, organizations, and the fact that there are a few federal standards frankly does not seem to be helping that much in terms of standardizing the level of SDOH level that could be done potentially better now in terms of integrating both the health and human services data.

What would be some next steps that you think each of the panelists – what do you think we can do now in the next year or two to better bring together to help standardize the data that could be realistically collected and integrated better?

Marko Mijic: I can start here because I think I spent a lot of time thinking about the integration of social services data, Jamie. I think you are right. There are already the federal standards or other thing that are in place. I think part of the problem is that there is a lack of connectivity between some of these entities and their capabilities to actually connect to for the exchange of this information. I think a few things.

Some of the work in terms of more concrete things – I think some of the work that ONC is doing pursuant to what Micky said around particular use cases, which I think California is also looking to embark on. I think creating a clear use case to demonstrate really how do you exchange that data. Maybe this is child welfare and managed care, for example, to be able to actually exchange and demonstrate how you actually do that and what you actually do with the data on the back end is going to be an important piece because if you do not have those particular use cases defined or those areas of practice figure out, I think the ocean is too broad to boil and people are not going to be able to really think about it.

I do worry that here we are going over inundate ourselves because we have a tendency to collect a lot

of data because it makes us feel good but then we do nothing with it. I think we need to try to figure out what is actually practically necessary for us to do the job and then go from there. I think a use case or a concept framework to be able to say here is a use case of a child welfare case that needs to be tied to Medicaid, that needs to be tied to whatever else I think will help people visualize and understand how that data flows and how it ultimately is used, which makes it to Michael's point earlier. I think it makes it more real and perhaps more concrete and creates more parameters and boundaries around what you do in this space.

Valerie Watzlaf: Annie or John, do you want to follow up to that at all before I get Maya?

John Loonsk: I would like to point out that specificity is important. Tightness of standardization and testing to that is important. And the USCDI, as much as it is a good direction to go, is still pretty high level. If we want to get good quality data, USCDI actually has US Core in the standards language that it relates to but which has a much more specific implementation in HL7 standards because that is what is needed to actually transact the data, not USCDI up here but a more specific implementation below that that is then tested and reliably implemented. I just bring that up because sometimes that is lost in the conversation, and it is really important to get quality data to be usable.

Annie Fine: I would second that. The other thing is just who should collect the data. USCDI is really mostly meant for health care. Do we really want the data that health care is going to collect and do we really trust that as being the source of truth or do we want the data to be coming from a social agency or whoever is actually working for the people or homeless services or whatever it is to come more from that source rather than from where it gets collected in health care organizations. It is just something to consider. The idea of a health data utility is something that certainly we have been thinking about but I do not know if it has been really heavily considered by some of the folks working in the data modernization space. But that could potentially integrate data from the actual sources of truth and put it together with the other data.

Valerie Watzlaf: Thank you. Go ahead, Maya.

Maya Bernstein: Thank you for recognizing me. This has been really amazing. I am really pleased with this discussion. I am sort of hearing and thinking about some of the things that Jamie, Marko, and Michael were saying about the human services side of things. In my role as the senior advisor for privacy, I do work on both health and human services kinds of issues but mostly with this committee, of course, we are on the health side.

And even in this discussion, most of what our conversation is about is when we talk about SDOH kinds of issues, we are talking about how do we get information about, for example, food insecurity or homelessness and so forth into the health system so that we can get better health outcomes as opposed to moving the information in the other direction. Can we move information from health to, for example, child welfare who needs to think about the whole child, including their medical information? Can we think about moving information from health to homelessness services who are maybe doing coordination of care that includes not just homelessness services, but perhaps behavioral health services but also housing security and other things that are more holistic on the human services side and

how can we use medical information so moving in the other direction?

We just touched on some of the complications. We do not have ICD for that. We do not have any real standards. The providers are all over the place. Human services are much more complicated.

And I think the other thing we were thinking about is vulnerability. I think about that a lot. On the one hand, I want the data to move. I am not a lawyer who just says you cannot have that. You have heard about overzealous HIPAA lawyers. I try not to be that.

Each of the data points that we need or we have, there is a person underlying those data. There are people underlying those data. I try to remember that most of the time the people that government has information about, not all the time, but most of the time, have some vulnerability or other that they need government services. I want that information to move but in what I would call a privacy appropriate environment.

I guess the question comes down to it is complicated. If we could do one thing or what is the first thing that we should be thinking about doing in order to get the data to move in both directions between health and human services? This is something that the Office of the Secretary is starting to think about. This committee is just starting to think about that kind of space between health and human services and it is very daunting. Where would you start?

Valerie Watzlaf: Would anybody like to start on that? I think that is for our panelists.

Marko Mijic: I think it is a very good question. I think just to the point that I made earlier, I do think that it is hard to talk about this in the theoretical and I think you need to make it more practical. And what I mean by that is I think you need to define the particular use cases and start defining what those look like and demonstrate how the information flows and how it is going to be used because then you build back that trust. You give people a sense of how this is actually going to be leveraged on the back end and ways in which –

I also think that from my perspective to your point, health care entities tend to think that they own the information or they want to be the bearer of that information. And I think in the examples that you shared, there are instances when really the health outcome is not driven by the health care institution. It is driven by the community-based organization that is providing the food or sheltering that person or getting them the transportation or doing those things and having access to that information is going to be important.

I think as payment – value-based payment programs change and adapt and more of them implemented. The desire and need for these things are going to be even greater. But I think you start with the use case as to clearly defined how and what and that, I think, creates clear parameters.

In your instance of child welfare, I think that is a great example to be thinking about. I think aging and long-term services and supports is another area to really be thinking about as a potential use case. Behavioral health. Again, I think another really strong opportunity to be able to connect the dots there because the study that was done in California with UCSF on homelessness really found that many of the

individuals who are homeless have behavioral health needs. They are circling in and out of care and I think being able to think about it in that way makes a lot of sense.

Annie Fine: Can I just add before Michael goes? I totally agree with Marko that you have to make it more concrete and do this incrementally. One of the things is that I think you have to be prepared to really take actions that make a difference and then you have to show that it made a difference. Whatever the use case is that gets chosen to start to integrate or move social service –combine social service with health data is you have to have something that you can do about whatever it is that you discover by linking these data. Whatever it is, getting kids into better childcare or whatever services they need or if it is getting air conditioners for home-bound elderly people who are affected heat or injury. Those are the types of actions or getting people harm reduction, reducing overdoses. Those are the types of outcomes that I think will drive the people to understand why these data integration and why having standards and why moving these kinds of data are important.

Maya Bernstein: You want to see a use case with something measurable.

Annie Fine: Yes. Something that you can actually do. Not data for data sake. Something that you do because of it.

Maya Bernstein: I am not the expert on that but my colleagues at ASPE are. That is what ASPE does, that kind of thing, pilot demonstrations and so forth. Both of you, thank you. It is very helpful.

Valerie Watzlaf: Michael, do you still have a question?

Michael Hodgkins: I guess I was thinking back to Micky's presentation and when he was talking about the USCDI+ initiative. I wonder if our panel – whether they think that might be a vehicle to start to tackle standardizing some of the things that we have been talking about here. The USCDI itself is pretty limited and does not even touch on many of the issues that the panelists have raised. But it seems like USCDI+ maybe provides a path.

Annie Fine: I would agree with that. We have been working a bit with USCDI+ in trying to get public health data elements represented there. But I do think that is an opportunity for various communities and domains to come together to start to at least put forward the data elements that are really important for them and then to have those. They need to be fed, as John said, into more specific data standards because USCDI+ by itself – it is just sort of a list of data elements. It is not really that many value sets. It is not codified into standards that actually make it actionable. But that has to feed into organizations that develop actual standards like HL7 to be more useful. But there needs to be good processes that move that what is in USCDI+ into actual standards and then implementation. There needs to be support for that. Unfortunately, that also takes resources. John, I know you will have something to say.

John Loonsk: There is not currently the specificity under USCDI+ that is under USCDI and that specificity needs to be developed. The enforcement or incentives or the regulations that require it are also not at all as clear as they are for USCDI. If it is going to be enforced by funding from different federal agencies, that is a more limited tool.

But USCDI+ as a tool for getting data out of clinical care is very limited to the extent that it is not required of clinical care organizations as things currently stand. That is a major issue that needs to be considered in USCDI+ moving forward as well.

Valerie Watzlaf: Anyone else have any questions? I wanted to ask one more. I know Jamie brought this up about ICD-11 and how it is capturing so much of the social determinants of health. I did not know if any of you have looked at that at all and what you think of it. And if you have not, that is fine because as he said, it is not something that is right around the corner, but I just wondered what you thought of it.

Marko Mijic: I think it is a good start and I think to Jamie's point, we should not just dismiss it and try to figure out how to do more. I think we also have to balance the need for providers and technology vendors to be able to adapt to these things which takes time and effort and money. I do think it is a start. And I think part of the use case conversation to John and Annie's point around granularity is perhaps that gives you a better sense of what does the current – do the current standards meet this or do you need to go even further, more granular? It helps you think that through so that we are not creating this constant churn and this amount of work that is not going to yield the outcomes that we ultimately want it to be. But I think it is a start. Again, I would layer it on top of these use cases to determine whether or not it is actually getting what you want it to get.

Valerie Watzlaf: Anyone else? We go until 4:30. Annie, go ahead.

Annie Fine: I just wanted to say – I also think that there is a role for the federal government to develop tools and this does not have to be just CDC or HHS or whoever but tools to de-identify data. How do we actually take line-level data and de-identify it or bulk data and de-identify it? Why does everybody have to be thinking about this wherever data exchange happens? There should be some shared infrastructure that can be called to de-identify to a different degree perhaps for whatever use case you need. Where do we really need the person's name? Where do we really need the person's address and where don't we? Where can we use other technology to make that data move where it needs to go but use shared tools to get it to be safe and secure?

Valerie Watzlaf: Great. Thank you all so much. If anyone does have one more question, we do have nine minutes because we do go to 4:30, I believe. Go ahead, Tammy.

Tammy Banks: I do not know if this is a question, but I found this very interesting especially with the use cases and the difference source of public health, population health. I am going to back into my question. Basically, in the health care arena, you look at population health from your value-based care lens. You go through your patient panel and figure out who needs the gaps and provide the care. And then you can back into through all the different perspectives of everybody in the chain for treating that person. I understand that population health has a lot of different reasons. We have research, which is totally different than actually connecting them with community service care or filling in a gap in a hospital.

But I love the comment of the use case because if we really think about it across everybody who touches a patient like California. I just really loved your example because all of the California population is a concern for California. If you look at that population from that whole state basis versus who is a payer,

looking at it from their population health lens, the hospital from the population health lens, and then now we are looking at it from the social determinants of health and all the networks that are occurring to connect them with the community service. How can we take all those needs and bring it to one area and one person does the population health analysis for a patient and connects them with the appropriate care? That is where you get to your use cases.

But I am just thinking that it all sounds great and I think that would be really cool to see if we can get there, but the challenge is, I think, into getting to that if you agree with that picture is how do we exchange the information with each other because hospitals use different systems. EMRs use different systems. I am sure you have different systems. We still have faxes. We still have Excel spreadsheets. We have all these different ways of passing this data.

I am just brainstorming here with the first step is connecting everybody, which we are hopeful through TEFCA but from a population health lens more from the perspective that I am coming from, value-based care and population health overall. Where do you see the first step of having that conversation of actually being able to exchange the data, assuming it is decrypted, everything the way it is supposed to be, permissions appropriately? Where would we start that type of connectivity? Is that off the wall?

Marko Mijic: No, it is not. I think it is a complicated question. I think it is quite thorny. I think it is really hard. The approach that we took in California was the belief that fundamentally we were not going to require entities to sign on to any one HIE or sign on to any one technology vendor. We were very purposeful in our conceptual framework that this should be vendor agnostic. That we had the responsibility as the state to create the rules and the parameters of how to actually do the exchange with the requirements of how the connections are the APIs actually work.

Our job was to say we will build the roads and will create the rules of the road. But getting the cars on the road and how you connect to those is going to be the responsibility of the private sector and for each individual entity to figure out on their own.

I think that that works in California because we are a ginormous state and having one HIE does not make sense. That may not be the case for Rhode Island or some other smaller state that have a more homogeneous population. I think it just will depend in terms of how you do it.

But we do have to think about what are the rules of the road, do we have the infrastructure to be able to do it, have we funded these entities to be able to actually procure and think about the technology to actually ingest the data and do something with it in a safe and secure way? Do we have the trained workforce to be able to do something with it?

I often said when I was in government that are data rich but information poor. Again, we collected a lot of information, but we did very little with it. And I think part of it is trying to figure out that last mile around how do you actually put something in the consumer's hand or the provider's hand so that they can actually do something.

Tammy, I think your question is important. I think it is just very complicated in terms of alignment of players and streams to be able to make that actually come to fruition.

Tammy Banks: And also trying to figure out a revenue model because then it becomes population needs to be supported by all entities. Why duplicate it? Because the analysis may be the same across multiple groups. Again, the use cases – step up –

If a population health soars at the local level, that is where the funding is needed. And then that could – I am getting too complicated in a short period of time. It is just so exciting and so needed and connectivity gives us so much more opportunities and yes, there has to be rules of the road and that kind of stuff. But we have to really be thinking about how can we collaborate. How do we exchange everything again with appropriate permissions and everything else to meet these needs and to fund at the appropriate level and reduce duplication? That is hard when you are talking totally different industries in my opinion. Your food bank is different than the hospital, which is different than the payer, which is different. But there are all similarities and we all need the data. There has to be a way that we can all work together and fund it appropriately and reduce duplication as we look for more workers and all that other good stuff, which obviously is a challenge today.

John Loonsk: I would concur with what was said before that specificity and incrementalism are going to be important guiding principles to get there.

Valerie Watzlaf: Thank you. Any other quick questions? We have three minutes, I think, or maybe two.

Annie Fine: I did not say this before, but it really is a privilege to speak with all of you. I just wanted to thank Valerie and Cathy for inviting me to be part of this. Public health does not always get invited to groups like this. I just feel like it has been an honor to be with you and I really enjoyed the conversation.

Valerie Watzlaf: We so appreciate you. This has been a wonderful discussion. Thank you, all, so much for being here. I am sure we will be bringing you back. Answer our call if we –

Catherine Donald: -- we will be bringing you back, our public health champions. Thank you all so very much. Great conversation.

Valerie Watzlaf: Do we have a break or do we – I think Naomi knows.

Naomi Michaelis: We are going straight into our conversation about the 75th anniversary as our last half hour of the day. We are reaching the end and this conversation will be as long as we want it to be.

Maya Bernstein: One thing I did not say before our panelists leave is that if you have something that you wanted to add to the record, you did not give us some article that is useful, we will leave the record open for a couple of weeks. Just send it to me or Naomi. You have our email addresses and welcome you to do that. Thank you so much.

75th Anniversary Celebration Discussion

Naomi Michaelis: Alright. As we started the conversation in April, it is the 75th anniversary of NCVHS. In April, we had the conversation that we wanted to make the theme Past, Present, and Future and that seems to be continued that we still like this idea. We have had conversations as individual

subcommittees. Today we are going to have it so that you can all talk to each other about it.

We have had the conversation that we want to have short videos from previous chairs of NCVHS and subcommittee co-chairs. From that, we want to also create a booklet that is highlighting the past 15 years of the committee and all the work the committee has done as well as the work we think that will happen in the future.

The first question I want to pose to all of you is we have discussed having a speaker symposium some time during our spring meeting. What I want to know is what length of time would you like someone to come in and speak for, what kind of theme or if there is a particular topic, a historical prospective. Let us just get started on what do we want out of a speaker in the spring.

Maya Bernstein: Naomi, when you say a speaker, you mean multiple speakers or –

Naomi Michaelis: It can be multiple also. That is a great question.

Maya Bernstein: And something different than what we might do in short – I am imagining – but this is springing out of my head, and I am not sure what the members think. But the video interviews that we do would be short, five minutes, something like that, eight minutes with a couple of questions for people about vignettes or anecdotes from their time. What do they remember of us about the committee? What do they think was the biggest successes or the major challenges of the time? That kind of thing.

We could do some of that in video. We could do some of that at the symposium. We could have some other way of looking at the live panelists as opposed to the video historical stuff. I am not sure how that falls out at all but just thinking out loud.

Naomi Michaelis: I am going to go with Tammy first because she had her hand raised. Although I see Lenel is very eager to go into this. Go ahead, Tammy.

Tammy Banks: Before we talk about speakers, do we want to figure out what the panel will be? Do we want a panel on the historical successes and the results of those historical successes and then have more of where do we go from here type of panel? What are the topic areas for the panels? Then we can figure out who should be in the panels.

Naomi Michaelis: We can do it that way.

Tammy Banks: More of a question, right?

Lenel James: I am thinking that whoever we have as a speaker should be the most senior person we can find in HHS that has name recognition amongst the people that typically come to the NCVHS calls because many of them over time will remember. I think that would be helpful for people that are new that may not have been around 10, 15 years ago so we have so many new entrants in the last five years because many people are getting older and retiring. We are losing some of the people that were in the infrastructure. We have new people that may not recognize some of the older folks, but they will

recognize a title.

And then the other thing is that gets back to the panels. Since we always do panels then making sure the panels include people who have that historic memory of some of the successes of NCVHS, the challenges of NCVHS, and some of the good times that we had in NCVHS would be my two cents. Thanks.

Naomi Michaelis: Thank you. Michael.

Michael Hodgkins: I would actually like to hear from the critics of NCVHS, if you will. I guess I would like to – who would challenge us to be thinking forward about how NCVHS should be working and pursuing our mission in the current context? The world has changed in 75 years. We have done a lot of good work over the past however many years since the last time that we had an event like this. But I would like to be challenged to be thinking more broadly about our role obviously within the constraints of our mission and what have you. Sometimes hearing from your critics is more important than hearing from your enthusiasts.

Valerie Watzlaf: Do we have critics? I like that. I really do like that. I just was not sure if – you are kind of like what could we do better, I guess. Is that what you are thinking, Michael.

Michael Hodgkins: Yes. It does not have to be a critic so much but somebody who would challenge us to be forward thinking about given whatever constraints we have to operate within as a FACA. Where could we expand our thinking? Where could we be pushing ourselves? Should we even be trying to expand our purview in a constructive way that would still fit within our mission? It does not have to be a critic. I am sort of saying that in a way to be provocative. If you had a suitable critic, that might be interesting. I am sure there are people that would challenge our thinking. I do not know if they will be within HHS.

Lenel James: I appreciate Michael's comment. I want to push back a little bit. This is supposed to be a celebration, so I am not sure I want people raining on our parade at our celebration but more importantly, we are just one of the FACAs the feds have. There is the Health IT Policy Advisory group that is doing a bunch of stuff that cross my radar from a health equity standpoint, which was a reminder that we are not the center of the universe for who gives the Secretary of HHS input and our mission is I think I worry that in the Secretary's mind, we have a mission and somebody can come on that stage and talk about stuff that is nowhere near our mission because they do not understand how complex the feds are and that we are defined by a role that has been given to us by the Secretary. And someone may have a bone to pick but we cannot scratch that itch because that is not in our remit no matter how much we want it. I am not sure we want to muddy the water.

I believe it would be interesting to have somebody, not provide a critique, but provide some ideas on how we could do better with what we are charged to do. I think as we do that, we have to be very careful we do not get somebody who comes in as a flame thrower throwing stuff that we cannot even begin to touch is very likely because most people barely understand what NCVHS is much less appreciate its one of many. That is my caveat is to be very careful with that.

Naomi Michaelis: Thank you, Lenel. Cathy.

Catherine Donald: Thank you. I would agree with what Lenel said. I think we can have somebody challenge us to do better, do more whatever without having someone who is a critic of us. I am not sure exactly where you find those. I also agree that we could really be tasked or whatever. I told them to do this, that, and the other and they are not even touching it. It is a celebration. Let us celebrate. Let us take time to actually celebrate and then have somebody with appropriate authority give us a challenge to go forward and try to do this. I am sorry. I am not using my words well. It has been a long day.

Steven Wagner: I think I have a compromise between what Michael is saying and what several others are saying here. On the 60th anniversary agenda, there was a topic called current and future thinking, projects for moving the strategy forward. It sounds like it fits very nicely for challenging ourselves as well as talking about what we have actually accomplished, significant things we actually accomplished and so forth. Something along those lines –

Naomi Michaelis: Michael, back to you.

Michael Hodgkins: I am sorry to be a bit of a provocateur. Somebody talking about a critic challenging us. Obviously, I do not want somebody to come in and turn a flame thrower on us. What we said that this is a celebration but also an opportunity to look forward. How can we find people that can challenge our thinking about what that looks like? I think Steve mentioned of what was on the previous anniversary agenda 15 years ago would be a suitable title and then the challenge will be how do you find the right person or persons to help us think about the future.

Tammy Banks: I will just give you an example. Linda Kloss – she would be fabulous to talk about the wealth of work that occurred with the Privacy and Security Subcommittee when she was here, what the impact was because there has been an amazing amount of impact with that area, and then also tell us where the gaps still are. There is going to be key members, past members, that can give us the insight and give us the critique, Michael, because again not everything has happened that they wanted to have happen. That is some of the stuff that we could glean out. Maybe that is a good question to add to our list of interview questions. I do not know if you want to use the word critique. And maybe we do have it. I do not remember, Naomi, what still needs to be done kind of question.

Naomi Michaelis: I believe that it was one of our questions, which just means that we keep coming back to the same idea that we do want to hear a little bit of the challenge.

Maya Bernstein: It must be a good idea.

Jamie Ferguson: I want to add a plus one on Michael's idea of being challenges to define our role in the new world. The world has changed very dramatically since the committee was chartered. The idea of personal data, the idea of even what is health data or what are health data. It is not restricted to HIPAA. It is not medical records. It is all the information about you and your life that exists in the universe can be your health data. Looking forward on that basis, how can the committee advise the department on health data policy when health data is all day about you potentially? With that kind of framing, I think we need a reframing of the challenges for the future.

Naomi Michaelis: To your goal along this thought process of the changes of the committee and the future of the committee, Maya has put in the chat something, which is also very good to be reminded of. Think about the name of the committee and think about what we do now.

Jamie Ferguson: Health statistics might be determined by commercially available data about your grocery store purchases. Those are your health statistics today. It is very different.

Michael Hodgkins: Jamie, you can be my plus one any time. I do not know quite how to capture this. Please bear with me. The process of HHS when we make recommendations just seems a little opaque to me. Obviously, our recommendations are not always adopted. I am sure there are clearly good constructive reasons for that.

I guess part of what I am thinking about is can we hear from HHS how we might be more effective in the way we bring forward recommendations so that they are more adoptable somehow. I do not know quite how to capture this. Please forgive me for not having the right words necessarily.

Maya Bernstein: This is a perennial question, I think, for members. The wheels of government move slowly. A lot of it is just resource constraints, which gets the highest priority, and which is next. Many of our recommendations are sitting there like it is not that they have been rejected, it is that we have not gotten around to them yet usually.

You saw with, for example, the reproductive health regulation. Those recommendations that they relied on in that were sort of waiting for there to be a need and they work from the aughts and from the early tens or whatever. There became a need and they looked to us.

We might see something sooner with some of the other recommendations that there is more of a timeline, a particular timeline, with standards. Standards also – the development of public consensus standards takes years and it is slow going. You have to have the long view. I think that can be a frustration for the committee because when you get the response from the secretary, it says thank you for the recommendations because there is a requirement in the correspondence office that says we have to respond to letters within 30 days or 60 days or something. That is not enough time to fully vet a new policy. You are often touching on new policy areas. They need to have a full-on policy review, and we cannot do that in 30 days or 60 days. I know that that is frustrating for the committee.

I am not sure how much someone can say more than that. It is possible and we will, I think, certainly want to invite the highest-ranking HHS person to speak that we can find to recognize and to celebrate with you this anniversary. But I like the forward-looking idea for that. What do they say? What is their vision for what is coming next? How might you help? What kinds of topics do we expect you to be thinking about or to come before the committee? Sometimes the ideas are to be sure generated from the membership. That is part of the point. You are out there in industry. You are outside of the department. What are you seeing that you are bringing to the department that the Secretary should be thinking about?

But some of it is the other way. The Secretary or someone – by that, I mean the department will sometimes recognize the expertise of the committee and say we need help with this topic. Can you

comment on it? Both of those things are true. There has to be a timeliness and an audience and so forth.

But I do think we can get somebody from the department to make an appearance and talk to us about something. I am not sure exactly what the topic would be but I think something more vision like, more forward looking is the kind of thing that somebody might welcome that opportunity in front of this body in particular, given its charge and the nature of the kind of work that it does, which could be very broad. If you look at our charter, it is really quite broad. We tend to focus on HIPAA and health IT because those are the most immediate things that are happening. In fact, the chart is quite broad.

Michael Hodgkins: I certainly do not want to overlook that we should be celebrating the accomplishments of the committee over the past 15 years. I was very taken by one of the panelists or the first panelist who acknowledged the rule making that came out that the Privacy Subcommittee had a substantial impact on with respect to reproductive health. It was not everything that was recommended but it was a lot. I think we should celebrate those kinds of victories.

Naomi Michaelis: From the sound of this conversation, I think we might somebody from the department to talk about the future for the committee and perhaps somebody who previously served on the committee or has been present for the panelists to speak about the past work of the committee. What do people think about that?

Lenel James: I would hope that the past work of the committee would be in a panel because this committee has done so much stuff over time and there are so many people like John Lumpkin and others that could be brought in that have a lot of history and could share that and there is a bunch of them. We could probably come up with six past chairs of the Standards Committee, chairs of NCVHS that could be asked and then work with who is available to figure out what would make the best panel to talk about the really breath of the history and successes here at NCVHS.

Tammy Banks: Naomi, can you tell the group what we were thinking about with the survey because I think the intent of the survey was to reach out to all the individuals that you mentioned, Lenel, past chairs, co-chairs of the subcommittees as well as the overall committee and ask them certain questions and from those responses then we would be able to narrow down what makes sense through a video presentation, what makes sense through a panel based on those topics? The question is are those questions enough to be able to do that. Because I think if we are just going to name names, we are not going to – there is just so much out there. I think those questions will help narrow down what makes sense.

Naomi Michaelis: Tammy, you have highlighted most of what we had talked about in terms of the videos. Yes, we are talking about reaching out to again the past chairs and subcommittee co-chairs with several questions for them so that we can then take that and turn those into video interviews.

The questions that we have right now are what have the impacts of your work been. What are you most proud of from your tenure? What would you do differently? Overall, what do you think the greatest impact of the committee's work has been? What do you think is the next thing? Those are the questions that we are looking at for videos.

I say all this because I want us to remember this is for the interview. This is for written and video, which is still different from what we do in person. If you say yes, all of that is great for a video. It is also great for being in person. That is also a thing we can say. We can still have those exact questions asked in person because also they will have significantly more time in person to address them because we are talking about five-minute videos versus an hour and a half or longer panel.

Maya, I see you wanting to say something.

Maya Bernstein: I was not sure whether, Tammy, you intended for those questions to be – I was going to say test. It is not the word I mean but seeing who has something interesting to say in advance and figuring out from that. We could do that too and then interview those people.

Somebody asked about Walter Suarez, Rich Landon, Judy Warren, did you mean. It turns out by complete chance and with no warning, I bumped into Walter Suarez yesterday in the lobby of the Humphrey Building. He was at a – ASTP was having a meeting in the lobby, which actually I do not what the meeting was about. Were you there, Lorraine?

Lorraine Doo: I was not, but Alex was.

Maya Bernstein: Because you are in Colorado. I keep forgetting.

Jamie Ferguson: It was an AI meeting.

Maya Bernstein: Yes. Anyway, I bumped into Walter and I said we are going to want to interview you. He said totally great. He is in the area. We do have the contact information for other past chairs and co-chairs and so forth who are still around. We have the chairs that are still with us. We can get in touch with them. They do not have to be in Washington.

I defer to Naomi, but I think we have a little bit of budget so that we could – as I understand, Naomi, correct me where I get this wrong. In December, we are going to have a virtual meeting so that we can bring more people together in the spring meeting for this celebration. That means we can bring in some people from out of town and really collect some figures from maybe Linda Kloss, maybe Bill Stead, maybe Leslie Francis, maybe other people from during that time. There are some people like Walter who are still in the area. I know John Lumpkin is still very active on another advisory committee. Although I think his chairmanship was before our 15-year cutoff, but he is still an important thinker in this area. We have lots of resources to draw on, which is great. I think an embarrassment of riches, as they say.

Michael Hodkins: At one point, we also talked about possibly involving previous DFOs in this. Are we still talking about that? Possibly interviewing previous DFOs and asking some similar questions.

Maya Bernstein: TFOs? Who are they?

Naomi Michaelis: Designated federal officers.

Maya Bernstein: DFO.

Michael Hodgkins: DFO. I am sorry.

Maya Bernstein: There is one who is still available. If you were at dinner in April, then you met her. That is Marjorie Greenberg. She was a very long-serving DFO.

Michael Hodgkins: Or our immediate past DFO was I am sure still out there. I think it might be –

Maya Bernstein: Rebecca is certainly still there too. Yes.

Michael Hodgkins: Just focusing on previous chairs and subcommittee chairs and what have you. I think the DFO perspective would be interesting.

Maya Bernstein: We talked about having some of the staff, talking to some of the staff like Marjorie and Rebecca. Unfortunately, Jim Scanlon is no longer. He died in March. We might have a little piece of the program – in memoriam sort of thing in which we have some comments about the contributions of those people. I know Lorraine put something about Justine in the chat. We remember fondly our past chairs, Justine and Simon Cohen and Jim Scanlon. I think we have a lot of resources available to us.

Naomi Michaelis: I think we are going to start with the chairs and the subcommittee co-chairs just because it is 15 years so that it is still quite a number of people. We unfortunately have an embarrassment of riches and we cannot ask everybody everything and fit it all into a 20-page booklet and 5-minute videos. We have a start – narrowing in one place. Right now, that narrowing is we are narrowing it down to chairs of the committee and subcommittee co-chairs. And then we can branch out from there because we do very much appreciate the work of DFOs but we have to narrow some places.

Michael Hodkins: And I do not mean to exclude other staff who played –

Naomi Michaelis: Also other staff.

Maya Bernstein: Are there any other thoughts?

Lorraine Doo: Maya, is Susan Burke-Bebee going to come back just like as ex-staff to celebrate.

Maya Bernstein: Maybe. Yes. I am in touch with her. For those of you who know, she was ASPE staff to the Standards Subcommittee and is a nurse informaticist who no one has been able to succeed her in that matter in ASPE because it is such a steep learning curve – so fortunate – I will be in touch with her and I will let her know what is happening.

Naomi Michaelis: You will all be receiving a poll next week to set a date for our spring meeting that will either end up being the end of March, beginning of April, depending on everybody's availability.

Since we are now approaching 5 o'clock, we are going to wrap up for the day. I want to thank all of our panelists for joining us. Thank you to all of our committee members, our NCVHS staff, our team at RLA, who has made sure that we do get muted when we need to be muted and sharing all of our screens

when we need to be sharing. They have been doing so much behind the scenes' work and we could not have made this day happen without them.

We will be resuming tomorrow at 11 a.m. Committee members, please remember to log on about ten minutes early so that we can make sure that our cameras and microphones are working. We are officially adjourned for the day. I will see you all tomorrow morning.

(Whereupon the meeting adjourned at 5:00 p.m.)