ASTP | Health IT Advisory Committee

Health Information Technology Advisory Committee (HITAC) Virtual Meeting

Transcript | February 19, 2026, 10 AM – 2:05 PM ET

Attendance

Members

Shila Blend, North Dakota Health Information Network
Hans Buitendijk, Oracle Health
Michael F. Chiang, National Institutes of Health
Steven Eichner, Texas Department of State Health Services
Hannah Galvin, Cambridge Health Alliance
Rajesh Godavarthi, MCG Health, part of the Hearst Health network
Steven Hester, Norton Healthcare
Bryant Thomas Karras, Washington State Department of Health
Hung S. Luu, Children's Health
Katrina Miller Parrish, The SSI Group
Trudi Matthews, UK HealthCare
Anna McCollister, Individual
Deven McGraw, Citizen Health
Eliel Oliveira, Connxus
Kikelomo Oshunkentan, Humana
Randa Perkins, Dartmouth Health
Rochelle Prosser, Orchid Healthcare Solutions
Dan Riskin, Verantos
Mark Sendak, Vega Health
Fillipe Southerland, Yardi Systems, Inc.
Zeynep Sumer-King, NewYork-Presbyterian
Naresh Sundar Rajan, Neantix Inc.

Members Not in Attendance

Derek De Young, Epic
Lee Fleisher, University of Pennsylvania Perelman School of Medicine

Federal Representatives

Keith E. Campbell, Food and Drug Administration
Meg Marshall, Department of Veterans Affairs, Veterans Health Administration
Ram Sriram, National Institute of Standards and Technology

ASTP Staff

Thomas Keane, Assistant Secretary for Technology Policy, National Coordinator for Health Information Technology
Mark Atalla, Deputy Assistant Secretary for Technology Policy and Deputy National Coordinator for Policy
Sam Kaardal, Deputy Assistant Secretary for Interoperability
Elise Sweeney Anthony, Associate Deputy Assistant Secretary for Technology Policy/Executive Director, Office of Policy
Seth Pazinski, Designated Federal Officer

Presenters

Michael Lipinski, Director, Regulatory and Policy Affairs Division, Office of Policy, ASTP
Kate Tipping, Deputy Director, Regulatory and Policy Affairs Division, Office of Policy, ASTP
Maggie Gaddis, Director, Interoperability Division, Office of Policy, ASTP
JaWanna Henry, Interoperability Systems Branch Chief, Interoperability Division, Office of Policy, ASTP
Sara Armson, Health IT Specialist, Terminology Content and Delivery Branch, Office of Standards, Certification and Analysis, ASTP
Talisha Searcy, Senior Advisor, Interoperability Division, Office of Policy, ASTP
Brett Andriesen, Deputy Director, Standards Division, Office of Standards, Certification and Analysis, ASTP

Call to Order/Roll Call (00:00:00)

Seth Pazinski
Good morning, everyone, and welcome to the February 2026 HITAC meeting. I am Seth Pazinski with the United States Department of Health and Human Services (HHS) Assistant Secretary for Technology Policy (ASTP). I will be serving as your designated federal officer (DFO) for today's call. As a reminder, this meeting is open to the public, and we encourage public feedback throughout the meeting via the Zoom chat feature. There will be a scheduled time at the end of our agenda for the public to make verbal comments. I would like to start with welcoming our ASTP executive leadership, who are on the meeting today. Tom Keane, our Assistant Secretary for Technology Policy and National Coordinator for Health IT, will be joining the meeting a little bit later this morning to make some welcome remarks. We also have Mark Atalla, our Deputy Assistant Secretary for Technology Policy and Deputy National Coordinator for Policy, Sam Kaardal, our Deputy Assistant Secretary for Interoperability, and Elise Sweeney Anthony, our Associate Deputy Assistant Secretary for Technology Policy and Executive Director of the Office of Policy. I will begin our call with a roll call of HITAC members.

When I call your name, if you could please indicate that you are present? Shila Blend?

Shila Blend
Present.

Seth Pazinski
Thank you. Hans Buitendijk?

Hans Buitendijk
Good morning, present.

Seth Pazinski
Good morning. Michael Chiang?

Michael F. Chiang
Good morning, present.

Seth Pazinski
Good morning. Derek De Young? Steve Eichner?

Steven Eichner
Good morning, present.

Seth Pazinski

Good morning. Lee Fleisher? Hannah Galvin?

Hannah Galvin
Good morning.

Seth Pazinski
Raj Godavarthi? Steven Hester?

Steven Hester
Good morning, present.

Seth Pazinski
Good morning. Bryant Thomas Karras?

Bryant Thomas Karras
Hello, I am still here.

Seth Pazinski
Good morning. Hung Luu?

Hung S. Luu
Good morning, present.

Seth Pazinski
Good morning. Trudi Matthews? Anna McCollister?

Anna McCollister
Good morning.

Seth Pazinski
Good morning. Deven McGraw indicated that she would be joining us late this morning. Katrina Miller Parrish?

Katrina Miller Parrish
Good morning.

Seth Pazinski
Good morning. Eliel Oliveira?

Eliel Oliveira
I am here, good morning.

Seth Pazinski
Good morning. Kikelomo Oshunkentan? Randa Perkins?

Randa Perkins
Present, good morning.

Seth Pazinski
Good morning. Rochelle Prosser?

Rochelle Prosser
Good morning, present.

Seth Pazinski
Dan Riskin?

Dan Riskin
Good morning.

Seth Pazinski
Good morning. Mark Sendak? Fil Southerland?

Fillipe Southerland
Good morning.

Seth Pazinski
Good morning. Zeynep Sumer-King?

Zeynep Sumer-King
Good morning.

Seth Pazinski
Good morning. Naresh Sundar Rajan?

Naresh Sundar Rajan
Good morning, I am here.

Seth Pazinski
Good morning. Now, our federal representatives to the HITAC. Keith Campbell?

Keith E. Campbell
Good morning.

Seth Pazinski
Good morning. Meg Marshall?

Meg Marshall
Hi, good morning.

Seth Pazinski
Good morning. Ram Sriram?

Ram Sriram
Yes, present and good morning.

Review of the Agenda (00:03:51)

Seth Pazinski
Good morning. Thank you. Is there anyone I missed or who just joined us? Thank you. That concludes the roll call. Now, I am going to just go through our agenda for today. We will begin with brief introductions of the HITAC members and federal representatives. Then, we will turn to Elise Sweeney Anthony and Tom Keane for some opening remarks. I will provide some updates on HITAC administrative items, and then we will go over the HITAC 2026 work plan. Then, we will hear from four ASTP program teams with updates, starting with the Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity (HTI-5) Proposed Rule. Then, we will take a short break. When we return, we will go through the Trusted Exchange Framework and Common Agreement (TEFCA) updates, an overview of the draft United States Core Data for Interoperability (USCDI) v7, and then updates on our Behavioral Health Information Technology (BHIT) Initiative. There will be time at the end of each presentation for HITAC discussions, the opportunity to ask questions, and make comments. We are going to start with a brief introduction from each of the members. This is our first meeting of 2026.

We have some new leadership here at ASTP, and a few HITAC members have changed organizational affiliations. It would be a great time to make some brief introductions. This is also an opportunity, if you have any voluntary disclosures or conflicts of interest, please share those as a part of your introduction as well. If we could, please just try to keep the intros to about 30 seconds or so. I will start with Shila Blend.

Shila Blend

Morning, everybody. My name is Dr. Shila Blend. I am currently the Health Information Technology Director for North Dakota Health Information Network, which is the statewide Health Information Exchange (HIE). My background by trade, I am a nurse and have gone on to get a master's and Doctor of Philosophy (PhD) focusing on health systems. I have a background with public health as well. I have no conflicts to declare. Thank you.

Seth Pazinski
Thank you, Shila. Hans?

Hans Buitendijk
Hello. My name is Hans Buitendijk. I am a Senior Director of Interoperability Strategy with Oracle Health, providing a Health Information Technology (HIT), Electronic Health Record (HER) perspective. I am active in a number of organizations that relate to this, member representative in the Electronic Health Record Association (EHRA), that is an organization of EHR vendors, Health Level Seven (HL7) to develop standards, various accelerators around that, networks active in care quality, TEFCA, Commonwealth. There are a number of different spaces to help advance and promote and drive forward interoperability. It is a pleasure to be here. I do not have any further statements to make.

Seth Pazinski
Thank you, Hans. Michael Chiang?

Michael F. Chiang
Yes, good morning again. I am Michael Chiang. I am Director of the National Eye Institute at the National Institutes of Health (NIH). My academic background was in ophthalmology and biomedical informatics. I have been in federal government for about five years and have been involved in many NIH-wide activities in areas like artificial intelligence (AI) and data science. I am really excited to be here for many reasons, particularly about the prospect of trying to foster HHS-wide collaborations. I have no conflicts of interest.

Seth Pazinski
Thank you. Steve Eichner?

Steven Eichner
Morning. My name is Steve Eichner. I am the Health IT Lead for the Texas Department of State Health Services, where I have been for just about 20 years, working largely on the implementation of data standards and interoperability. My interests are in public health information exchange and interoperability. I work across public health, including with partners like the Association of State and Territorial Health Officials (ASTHO) and the Council of State and Territorial Epidemiologists (CSTE). I also work with HL7, the standard setting organization, as a participant in several work groups. I have no conflicts of interest.

Seth Pazinski
Thank you, Steve. Hannah Galvin?

Hannah Galvin
Thank you, Seth. I am Hannah Galvin. I am the Chief Health Information Officer and Interim Chief of Pediatrics at Cambridge Health Alliance, which is a public academic health system in the Boston area. I am also on the faculty at Harvard Medical School and Tufts University School of Medicine and a practicing pediatrician. Additionally, I am the co-founder and board chair of the Shift Collaborative, which is working to advance data standards to improve patient granular data sharing and computable consent. That is my only potential conflict of interest, which I declare when we have discussions related to that. Thanks.

Seth Pazinski
Thank you, Hannah. Steve Hester?

Steven Hester
Good morning. Thank you. Steve Hester, I serve as the Senior Vice President, Chief Clinical and Strategy Officer for Norton Healthcare. We serve patients in Kentucky and Indiana and have been with the organization in an executive role for about 20 years. Prior to that, I practiced emergency medicine. I am serving on my second term with HITAC and excited to be back with everyone and excited to be here. Thank you. I have no conflicts to declare.

Seth Pazinski

Thank you. Bryant Thomas Karras?

Bryant Thomas Karras
Hello, everyone. I am Dr. Karras. I am the Chief Medical Informatics Officer, CMIO, for Washington State Department of Health. I am an internal medicine physician by training. I did a post-doc fellowship in biomedical informatics. Prior to going to medical school, I was a biomedical engineer. I wear many hats, as many of you know. I am predominantly, I think, part of this committee because of my public health informatics focus, and I bring that perspective, but I have also rolled out electronic medical record systems in three different institutions across the country. I have a lot of experience in that intersection between clinical care and public health. I do sit on unpaid board positions in both the eHealth Exchange and our state health information exchange and data utility model, Health Data Utility (HDU) One Health Port, but neither are considered a conflict of interest. Thank you very much.

Seth Pazinski
Thank you, Bryant. Hung Luu?

Hung S. Luu
Yes. Thank you. I am Hung Luu. I am a Director of Clinical Pathology at Children's Health, a pediatric healthcare system in North Texas. I am also a professor of pathology at UT Southwestern Medical Center. I am a practicing hematopathologist and clinical informaticist. I have a special interest in interoperability of health data, particularly laboratory medicine. Thank you.

Seth Pazinski
Thank you, Hung. Anna McCollister?

Anna McCollister
Hi, everyone. It is a pleasure to be here. I am Anna McCollister. I have a diverse background beginning in economic policy and foreign policy, and for personal reasons, got into healthcare. Over time, I did healthcare communications, public affairs, ran the healthcare practice for a couple of public affairs companies based in DC and got frustrated as a patient and began to work in health data and health technology. I have done two health technology startups, one in big data, one in crowdsourcing clinical research design. I was one of the early founders of We Are Not Waiting Movement, which is a white hat patient hacker movement in the Type 1 diabetes space. I run a close-up artificial pancreas system that is crowdsourced, that is now available for free and used by more than 30,000 people globally. I currently work as an independent consultant. I have been doing that for about seven years.

I have done a lot of different things, but my focus has primarily been around patient data access use and ways to engage patients in technology, technology policy and governance, particularly with an eye towards building and earning trust. I am on the board of the Sequoia Project. I am on the board of a small company called Medicarma, which is an app combining data integration and aggregation with AI, a personal navigation assistant. I do a lot of personal advocacy related to health data, interacting with patient data advocates, and I am very excited to be here.

Seth Pazinski
Thank you so much, Anna. Katrina Miller Parrish.

Katrina Miller Parrish
Good morning. I am sorry I am not able to put up my video right now, but I am Katrina Parrish, and I am a family physician and clinical informaticist. There we go. Hello. I am currently the Chief Medical and Informatics Officer for the SSI group, which is a clearinghouse representing for provider and payer from that perspective. I am also an advisor to Patient.com, where we are developing an app that is in the Centers for Medicare & Medicaid Services (CMS) Align Network, where we want to help patients be able to not only access their data, but be able to really understand it and use it better. Formerly, I have worked at Los Angeles (LA) Care Health Plan and Humana in roles of quality and informatics, also at Venice Health West. I helped with standing up Computerized Provider Order Entry (CPOE) for that organization and was a family physician before that in Los Angeles. Then, I also currently work with the Institute for Medicaid Innovation, and I do not think I have any conflicts.

Seth Pazinski
Thank you so much. Eliel Oliveira?

Eliel Oliveira

Thanks, Seth, and great to see many of you here. I am the Chief Executive Officer (CEO) of Connxus, which is a health information exchange, or HDU, based in Austin, Texas. We have been around for over 20 years now. I think since my last meeting with you all, I was initially representing Harvard Pilgrim Healthcare Institute, and before that, when I started at HITAC, the Dell Medical School, where I was the chief of informatics. My interests are focused on large data systems and data networks, that is why I was at the Sentinel Program, the United States Food and Drug Administration (FDA) Drug Surveillance Program at Harvard Pilgrim before, and before that, building the Patient-Centered Outcomes Research Network, or PCOR Net, a while back. I do not believe I have any conflicts of interest to declare here at this point, and I am glad to see all of you again.

Seth Pazinski
Thank you, Eliel. Dayo, can you go next?

Kikelomo Oshunkentan
Good morning, everyone. How are you? I am a physician executive with more than a decade of leadership experience across health plan operations, pop health, value-based care, and digital transformation. I currently serve as the Regional Vice President (RVP), Chief Medical Officer of Humana Healthy Horizons at South Carolina Medicaid Plan where I lead the enterprise-aligned strategies to improve clinical quality, manage medical cost trends, and strengthen sustainability across the care delivery in South Carolina. My experience spans Medicare, Medicaid, and commercial lines of business with prior executive role as a Chief Medical Officer of Pegasystems, which is an IT company, as well as Optimum where I served as the regional medical director. I bring a strong track record in UM, provider engagement, regulatory compliance, and designing innovative clinical and value-based models that drive measurable outcomes.

I am a board-certified internist, and I am deeply committed to digital innovation, member advocacy, patient advocacy, data-driven partnership, and improving outcomes on large scale. I have supported Epic implementations in my prior years and have operationalized clinical models for risk-bearing arrangements and advised nationally on interoperability and health data standards. This is my second tenure here at HITAC, so I am happy to see some of you guys again and meet the new members. I look forward to a fantastic three years ahead. Currently, I have no conflicts of interest to disclose this current time, but as I said earlier in my introduction, I have shifted from Pegasystems to Humana. Thank you, guys.

Seth Pazinski
Thank you much, Dayo. Rochelle Prosser?

Rochelle Prosser
Good morning. My name is Rochelle Prosser. I am the owner of Orchid Healthcare Solutions. It is the largest oncology database of pharmaceutical treatments in the United States. In my background, I am a certified legal nurse consultant, and I am also a clinical informatics and data geek, data science engineer. In this role here, I am very happy to meet all of you. I currently am serving as an advisor to the University of Illinois-Chicago for their social determinants of health as an advising board member within the past year that I have been with HITAC, and I am currently working bedside with Lee Health Systems and that is on the West Coast of Florida just to keep my nursing background, which is what I originally started for my academic endeavors. I have nothing else to declare.

Seth Pazinski
Thank you, Rochelle. Randa Perkins?

Randa Perkins
Good morning. I am joining you all from Dartmouth Health, where I have recently joined since leaving Moffitt Cancer Center in Tampa, Florida. I am now at Dartmouth in New Hampshire, supporting and overseeing clinical informatics here at Dartmouth, taking care of much of New Hampshire and part of Vermont. I am the Chief Health Information Officer working towards interoperability, integration, rural medicine, academic medicine, all of that. I am also working occasionally with the NORC on some of their efforts, but no other conflicts to declare. Thank you.

Seth Pazinski
Thank you so much. Dan Riskin?

Dan Riskin
Hello. It is a pleasure to be here. My background is CEO of Verantos and Clinical Professor of Surgery at Stanford. My experience is business, clinical, and policy. From a business perspective, I am in Silicon Valley, two decades of

health AI research with funding from NIH, National Science Foundation (NSF), and FDA over the years and have built multiple sector-leading technology companies. Clinically, I am a surgeon and clinical informaticist. From a policy perspective, I have been on the advisory committee for several presidents and have testified before Congress on 21st Century Cures and worked on other legislation. Thank you.

Seth Pazinski
Thank you, Dan. Fil Southerland?

Fillipe Southerland
Hi, good morning. Good to see everybody again. I apologize, I am on my way home from a school drop-off, but I will be on video here. Yes, Fil Southerland, I am the Director of Healthcare Solutions at Yardi Systems. We are an electronic health record servicing the senior living sector across the US worldwide. I have been in that position for about 13 years and ran a healthcare software startup prior to that. No conflicts of interest to report. Thank you.

Seth Pazinski
Thank you, Phil. Zeynep Sumer-King?

Zeynep Sumer-King
Good morning. I am Zeynep Sumer-King. I am the Senior Vice President and Chief of Staff to the CEO of NewYork Presbyterian Health System, which is a large academic health system in New York City for Cornell and Columbia Medical Schools. I have spent more than a decade working at the intersection of health IT policy and regulation, as well as health system operations, mostly hospital operations, most recently leading the regulatory affairs and enterprise policy for NewYork Presbyterian, NYP. Before that, I was at the Greater New York Hospital Association for 16 years, where I worked on HIT and exchange really closely with our state health information exchange and State Department of Health, as well as CMS and federal government, all through the introduction and implementation of meaningful use. I come to HITAC with what I would contribute as a strong appreciation of how federal policy translates to operations, or sometimes actually struggles to translate to real-world implementation.

I am really interested in advancing pragmatic approaches that can support great innovation but reduce burden on providers. I am really looking forward to this. It is my first term coming into my third year, and no conflicts.

Seth Pazinski
Thank you. Naresh?

Naresh Sundar Rajan
Good morning. This is Naresh and I currently serve as CEO for Neantix, and I am a trained medical informaticist with an extensive background in health information technology and interoperability of nearly two decades. My work has focused on advancing interoperability and effective exchange of health data. Prior to this, I have served as a Chief Technology and Data Officer for state health information exchange in the state of Nebraska and state of Iowa. I also serve as an assistant professor at the University of Nebraska Medical Center. This is my second term with HITAC, and I am excited to be here. I have no conflicts of interest at this time. Thank you.

Seth Pazinski
Thank you, Naresh. Are there any HITAC members I missed, unfortunately, or who just joined us? We will move on to our federal representatives, Keith Campbell.

Keith E. Campbell
Yes, hi, good morning. I work for the Food and Drug Administration in the Office of Clinical Evidence and Analysis. My focus is really on real-world data quality and data representation in general. I also work for the Department of Veterans Affairs under an interagency agreement. In both places, I do a fair amount of work with the Patient Information Quality Initiative, or PICI, working on that with HL7 and trying to get us to a point where we can better measure data quality.

Seth Pazinski
Thank you, Keith. Meg Marshall.

Meg Marshall
Hi, I am Meg Marshall. I am in the Veterans Health Administration at the Department of Veterans Affairs. I am Director of Informatics Policy in the Office of Clinical Informatics. I just wanted to mention that VHA is the largest

integrated healthcare system in the US. We serve over nine million veterans and almost 3 million of those access care in the community with non-VA providers. Personally, my background is I am an attorney by training, and I have been involved in health IT policy for over 25 years. Much of that has been in the private industry. I am excited to be back.

Seth Pazinski
Thank you, Meg. Ram Sriram.

Ram Sriram
Yes, I am Ram Sriram. I am with the Information Technology Lab at National Institute of Standards and Technology. We work in several areas in healthcare. My primary interest is AI in healthcare. I have been working in AI for about 40 and odd years. We are especially interested in the methodology, AI methodology, like how do you test systems which have been developed in healthcare and other places using AI techniques. Again, over the last couple of decades, we have been developing conformance testing tools so that interoperability can be tested for compliance and our tools have been used by ONC, by AIRA, the Assessment of Immunization Registries, and so on. That is where we stand at this stage.

Seth Pazinski
Thank you so much, everybody. I hope everyone enjoyed an opportunity to get a little refresher and share what the latest is with you all across the HITAC members, quite an impressive and just amazing wealth of experience and expertise. We are grateful to have your time and energy being put towards the HITAC. I am going to turn this over to Elise Sweeney, Anthony, and Tom Keane for some welcome remarks. Elise, over to you.

Welcome Remarks (00:27:09)

Elise Sweeney Anthony
Thank you. Thank you, Seth. Hopefully, everyone can hear me okay. Good morning. Thank you all for joining us today for our HITAC meeting, and welcome to the 2026 HITAC year. I want to really extend my thanks to all of the HITAC members for your commitment and your participation. Your role really helps to shape a forward-looking health information infrastructure. We are focused on creating improvements to health and care through the access exchange and use of electronic health information, all terms, all concepts that you are all familiar with. We thank you for giving your time, volunteering your time to really help us in that endeavor. On behalf of the entire ASTP team, we really appreciate the service, the expertise, and the thoughtful engagement that all of the HITAC members provide in advancing this work. Thank you. I do have a couple of things I wanted to share. I wanted to let folks know about a few reappointments since we last convened.

I am pleased to announce that the GAO, or the Government Accountability Office, has confirmed the reappointment of seven HITAC members. Shila Blend, Hannah Galvin, Bryant Thomas Karras, Anna McCollister, Deven McGraw, Kikelomo Oshunkentan, and Naresh Sundar Rajan. Thank you and welcome. Congratulations. We appreciate all of your excellent contributions today and we look forward to your ongoing commitment to HITAC. Welcome back and welcome back to all the HITAC members. Now, before I turn it over to our wonderful Assistant Secretary for Technology Policy, I did want to take some time to introduce him. Many folks know Dr. Keane and all the work that he has done throughout his career, as well as being a previous ASTP alumni who has now returned. Dr. Tom Keane is the Assistant Secretary for Technology Policy and the National Coordinator for Health Information Technology. It has been a pleasure to have Dr. Keane return to ASTP/ONC. His leadership and the breadth of expertise is greatly appreciated here amongst ASTP.

In fact, he is the second Assistant Secretary for Technology Policy and the ninth National Coordinator for Health Information Technology. He is an engineer and a physician. He previously served within ASTP and as a Senior Advisor to the Deputy Secretary of HHS. He brings a unique blend of technical, clinical, and policy expertise to his role. Among his many contributions, he served as an administrator of the COVID-19 Provider Relief Fund and led the development of the Agency for Healthcare Research and Quality (AHRQ) National Nursing Home COVID Action Network. Prior to his federal service, Dr. Keane worked as a finite element software developer and an enterprise software engineer before completing his medical training as an interventional radiologist. Surely, the amount of expertise just in that sentence alone is really appreciated across all that we have going on and engaging in ASTP. We are truly excited to have him with us today to offer a few opening remarks. Let me welcome our Assistant Secretary, Dr. Thomas Keane.

Thomas Keane
Thank you, Elise, for that too kind introduction and good morning, and welcome to our HITAC members. As Elise noted, this is my second stint at ASTP, and what drew me back to this organization is the exceptional dedication, integrity, and sense of public service demonstrated by everybody here. I have long admired the thoughtfulness, professionalism, and commitment with which this team approaches its mission. It is a privilege to work alongside colleagues who bring such care and rigor to advancing health technology policy and service of the public good. It is truly my sincere pleasure to be back at ASTP. I would like to take a few moments to recognize some shifts in HITAC membership. Elise mentioned the reappointments of several of you, and I would like to extend my congratulations as well.

I look forward to your continued contributions to the committee. We have also had a few members who have moved on from HITAC, and I would like to take this opportunity to acknowledge their service. First, I would like to start by thanking Dr. Medell Briggs-Malonson. Medell offered her leadership and dedicated service as a member and co-chair of HITAC since 2022. Her contributions as HITAC co-chair as well as her leadership on the Annual Report Workgroup and participation in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule Task Force were instrumental in strengthening HITAC's collective work. I would also like to thank Dr. Sarah DeSilvey. Sarah was a member of HITAC since 2023 and offered leadership as co-chair of the HITAC and the Interoperability Standards Workgroup. Sarah was also a member of the Annual Report Workgroup.

Both Medell and Sarah consistently brought insightful, thoughtful analysis and a collaborative spirit to HITAC discussions. I am thankful for the time, expertise, and devotion of both Medell and Sarah, and for their work with HITAC. Medell was kind enough last week to allow me to read a letter that she sent me at the national meeting. I want to let you know that we will continue to be engaging with them regularly, as both have agreed to continue to offer their expertise to ASTP. I personally connected with each of them and will share sentiment back to all of you of gratitude on behalf of the entire ASTP and HITAC team.

I would like to talk a little bit about priorities. As we kick off 2026, ASTP continues to advance our vision of better health enabled by data. This HHS administration is laser-focused on bringing a person-centered healthcare system to the American people. This means giving patients and caregivers the power to access and share their health data, whether it is with a doctor, a family member, or even a nutrition app.

Many individuals have multiple conditions that they are actively monitoring and managing. We seek to shape a health system where these folks can have all of their information electronically in one place. Secretary Kennedy has many goals. One of them is to address the sources of chronic disease, and another is to empower patients. Both of these goals require the access, use, and exchange of health information. In addition to patient access to health information, we are working on efforts to increase data liquidity across the entire healthcare system. We remain committed to advancing interoperability nationwide and delivering on a vision where data flows seamlessly, including for patients, between providers and payers, and hopefully, resulting in lower costs and improved care. Of course, one of the biggest obstacles to data liquidity is information blocking. Let us be clear, no one, whether it is a doctor, a hospital, or an EHR company, should be able to hoard health information for their own gain.

It is bad for patients, bad for innovation, and quite frankly, bad for business. That is why addressing information blocking is a top priority for this administration. As many of us with the HTI-5 Proposed Rule, we propose changes to certification criteria and modifications to the information blocking exceptions to allow for greater exchange of data. The Proposed Rule includes deregulatory actions that update the ONC certification program to reduce burden on health IT developers by streamlining certification program requirements and removing redundant requirements. It also revises definitions to better promote electronic health information access, exchange, and use that patients' access to their data is not blocked. It also advances a new foundation of AI-enabled interoperability solutions through modernized standards and certification. I will remind you all that the public comment period for the Proposed Rule closes on February 27. If you and your organizations have not commented, now is the time. We are making significant strides with TEFCA.

We have nearly 500 million health records that have been exchanged across more than 70,000 organizations, up from roughly 10 million in January 2025. Under this administration, we have accelerated efforts to use TEFCA to access more and better health data. I want to say that I appreciate the continued dedication of the HITAC members to the public and public good as we work together to advance the nation's health IT ecosystem. The HITAC's work is grounded in its statutory charges, including advising the National Coordinator on policies and standards to promote interoperability and to improve the secure access, exchange, and use of electronic health

information. Given this administration's priorities, which include empowering patients with access to their data, increasing data liquidity, combating information blocking, and modernizing interoperability, ASTP is sharpening its focus to ensure that HITAC members' time and expertise are leveraged where Congress directed. This year, HITAC's work will concentrate on activities that are statutorily required, allowing us to align directly with legislative mandates, while supporting the department's highest priority interoperability goals.

Routing HITAC scope to statutorily required responsibilities reflects the sentiment of the administration and department to ensure that resources are efficiently aligned to congressional intent and that work directly supports the administration's highest impact health data priorities. In that spirit, the 2026 HITAC work plan addressed on today's agenda reflects our continued commitment to ensuring that the committee's recommendations are clear, actionable, and aligned with federal requirements under the Cures Act. I would like to, again, thank you all for your continued commitment and the significant time you have dedicated to these complex issues, and I am looking forward to this year's HITAC contributions. I will now turn it over to Seth Pazinski, our HITAC designated federal officer, to continue with the meeting.

HITAC Updates and 2026 Work Plan (00:37:53)

Seth Pazinski
Thank you, Tom. I am going to go over just a couple of quick HITAC updates, and then, we will walk through the 2026 HITAC work plan. I am going to thank Elise and Tom for your welcoming remarks. Just one reminder for panelists and HITAC members, if you want your chat comments to be included in the public record with the meeting minutes, just please select “everyone” when making your comment, and then that will be a part of the public record for today's meeting. Can we go to the next slide, please? We are going to get into the HITAC schedule. We are expected to meet roughly quarterly in 2026, with the next meeting coming on May 7. This will be a hybrid meeting. There will be an option for HITAC members to participate in person, and our team will be following up with HITAC members with information and instructions for those of you for travel for that meeting, if you do want to attend in person. Also, just one update, there were some updates to the Federal Advisory Committee Act rules, which are rules that also govern our HITAC meetings.

The one change that does impact HITAC operations is that notices in the Federal Register require at least seven days prior to the meeting date. This was previously 15 days prior to the meeting date. We can go to the next slide. Within ASTP, we are going to be transitioning the HITAC designated federal officer role, so that would be transitioning from myself to Tara Porter on the ASTP team. This will take effect after this meeting today. I wanted to take a moment to welcome Tara to the HITAC family. While I certainly will miss working with all of you in the role of HITAC DFO, I certainly look forward to continuing to engage with you all in my role as Deputy Director of the Office of Policy at ASTP. I will be working with Tara to ensure a smooth transition, so if you have any questions, please, as always, feel free to reach out. We can go to the next slide. HITAC co-chairs, we are calling for volunteers to serve as the two co-chairs of HITAC.

Co-chairs play an important role in that they manage HITAC conversations in guiding towards inclusive, forward-looking discussions, building consensus across the diverse perspectives shared amongst HITAC members, and shaping strategic recommendations that inform federal decision-making. The leadership provided by the co-chairs helps to make sure the committee remains strategic and balanced and forward-looking in your health IT recommendations. Members selected as co-chairs can serve in the role for the remainder of their term appointment, not to exceed three years. Any HITAC member interested in serving as a co-chair, if you could please let us know by emailing Tara Porter by February 27. Her email address is on the slide for today's meeting. The ASTP National Coordinator will select the co-chairs and will begin working with you in preparation for the May HITAC meeting. We can go to the next slide.

Looking at the year ahead, we have planned activities which are aligned to our baseline HITAC statutory requirements established in the Cures Act. We can go to the next slide. For 2026, we are going to have roughly quarterly meetings, and we anticipate two subcommittees and two sets of recommendations coming from HITAC. One will be the HITAC Annual Report Worker, which will start next month. That work group will provide a draft report to HITAC at the September HITAC meeting and then, that final report will come for a vote for approval at the November HITAC meeting. HITAC will also have its second iteration of the HITAC Adopted Standards Task Force. This is a task force that will review all the existing ASTP standards and implementation specifications adopted in regulation and make recommendations with respect to whether to maintain those standards and implementation specifications or phase out or update those standards or implementation specs. The HITAC had previously executed the Adopted Standards Task Force back in 2022. It is now time to reconvene that task force.

We can go to the next slide. Just to go over the charge for the Annual Report Workgroup, which will kick off next month, this work group will form, contribute to, and review draft and final versions of the HITAC Annual Report. That report gets submitted to the Secretary of Health and Human Services as well as Congress following each fiscal year. As a part of the report, the work group and HITAC also report on ongoing HITAC progress. We can go to the next slide. For the Annual Report Workgroup, this is expected to run March through November with twice monthly meetings. Any HITAC member who is interested in participating is encouraged to email Tara Porter by March 6 to let us know. There is also one co-chair opening for this work group. If you are interested in planning to participate in the work group and have an interest in serving in a co-chair role, if you could please let us know that as well. Again, Tara's email is listed on the slide here. We can go to the next slide.

The Annual Report Workgroup focuses on three priority target areas that are specified and required in the Cures Act, that is interoperability, privacy and security, and patient access to their information. Do recognize that in previous annual reports from HITAC, some additional recommended target areas were included beyond these three. For 2026 HITAC report, we are focusing on the three required target areas from Cures. I believe we are at a point where we will open it up for any questions or comments that HITAC members have. If you could please use the raise hand feature in Zoom, and if you are participating by phone only, if you could just unmute yourself and let us know if you have a question or comment. Bryant, go ahead.

Bryant Thomas Karras
Hello there and thank you for having me back on the committee. I know there is a leadership change and the process takes time, but I wanted to put on the record that I think that we, for the function of HITAC, need to have an ex officio member from both Centers for Disease Control and Prevention (CDC) and CMS to interact with in our deliberations. I am hoping that those appointments are in the works. Thank you very much.

Seth Pazinski
Yes, thank you, Bryant. Hannah?

Hannah Galvin
Thank you. Yes, I am also very excited to be back for a second term. I had put my question in the chat, but I was just wondering about the decision to move the larger HITAC meetings to quarterly and the thoughts behind that, and if that is a plan to continue on in the long term or just for this year?

Seth Pazinski
Yes, we do anticipate moving to more of a quarterly cycle for the HITAC. There is always the potential for that to be adjusted based on the needs and charges to the committee. For this year, one of the statutory requirements for HITAC is to annually look at health IT priorities and related standards and implementation specifications. For 2026, the focus is going to be on the Adopted Standards Task Force. That is a requirement that we repeat every three years. We are due to do the Adopted Standards Task Force and have those recommendations from the committee on taking a look at the full set of adopted standards that are in ASTP regulations at this point and making recommendations for maintaining or phasing out or updating those standards. That is going to be the focus for the Health IT Standards Recommendation for the work plan for this year. We do anticipate that next year, the IS work group will resume and take a look at the draft USCDI Version 8 for next year. Dan, did you have your hand raised?

Dan Riskin
Yes, I did. Just an addition of a comment for discussion. I think that we have a number of years of focusing heavily on EHRs, and it would be great as we enter this new year if we consider a little bit of an increased focus in additional uses of data, with AI becoming prominent, to think through what can be done in terms of learning a new standard of care in terms of improving overall quality. I think it is in line with messaging I am hearing across parties, and it would be wonderful to see some focus on that from the HITAC.

Seth Pazinski
Thank you, Dan. I think one of the things I will highlight is with the Annual Report Workgroup, that is an opportunity for the HITAC to make recommendations related to various policy areas. It is a great place to identify potential areas of focus for the HITAC in the future, too. Eliel?

Eliel Oliveira
Yes, thank you, Seth. I think very much related to what we do here is what I am working with at CMS, right? We are one of the aligned networks and also a Kill the Clipboard members on that CMS ecosystem, which I think is the

pathway forward to finally transform how healthcare and technology enable advancements in the country. I am very excited about that work. As you know, we have helped build the standards with ONC in the past and implemented some innovative technologies for patient access. Now, we are engaging in a lot of AI development as well. In short, what I am trying to ask is, given the alignment between what CMS is doing and what we have here at HITAC and ONC, how do you see those interactions going forward, and how can we support that work on the CMS side of things? That includes AI, like was just mentioned here by Dan. Is there anything that can be shared at this point?

Seth Pazinski
Yes. I welcome thoughts from the committee. We will have an opportunity today to get some program updates from ASTP, but always happy to, as we have in the past, coordinate with our CMS colleagues to bring folks in and give presentations that can help inform the deliberations of HITAC in areas that you all feel are relevant and pertinent to understand, and the latest thinking from the HHS side of things. I am happy to take that back. Anna?

Anna McCollister
I am a little confused by what we are doing with the video policy at this meeting. One of the things I am trying to really understand is the mention that we are going to be focusing our efforts on the statutorily required activities because much of what is happening within HHS, particularly CMS, but also including some of the specific Request for Information (RFI), which I think are excellent, but have been issued, are not necessarily directly linked to statutory requirements because the statutes do not anticipate everything. It gives HHS and ASTP significant latitude in figuring that stuff out. How will the specific areas that ASTP deems statutorily required and appropriate for HITAC deliberations be developed and considered, particularly, historically, when there have been big HTI-1, 2, etc., all the USCDI recommendations, and there have been different RFIs that have been put out in different ways, or at least policy proposals? There have been specific work groups for the HITAC.

While that certainly created a lot of work burden for advisory committee members, it was a helpful way to engage everybody, consolidate input, and create a process through which we can provide input to ASTP and focus our energy. It feels like maybe that is not going to be happening this time. I would just love to understand. You have got all of us here. How are you planning on tapping into the expertise of the committee for things that happen that are not specifically articulated within the statutes?

Seth Pazinski
Yes, thank you, Anna, for the question. A couple of thoughts on that. Overall, we are aligning with the administration direction to make sure we are tying our work to the statutory requirements. You will see that reflected in the work plan, where we are focusing on a set of standard activities and getting recommendations on those in the Annual Report Workgroup. I will highlight that the Annual Report Workgroup is a space for HITAC members to raise issues and make recommendations. The target areas for those are relatively broad in the concept of interoperability, privacy and security, and patient access to information. That is really an opportunity for HITAC to have deliberations and make recommendations to the national coordinator in areas that could be a future focus for HITAC. In addition to that, there is also the opportunity, in addition to task forces or other subcommittees we have done in the past, we can have presentations and discussions through these full HITAC meetings. In the past, if you recall, we have done things like hearings where we have brought in both a mix of HITAC members and other experts to talk through and get HITAC feedback as a part of the full committee meetings.

That is another opportunity to think about the agenda for the quarterly meetings over the rest of this year. How do we fill those out with agenda topics that may be of broader interest? That could also be coming from the Annual Report Workgroup's conversations throughout the year. Are there any other comments or questions before we move on to our next topic? Thank you so much. Oh, sorry, go ahead, Rochelle.

Rochelle Prosser
Hi, good morning. I was reading something in the chat that I would like to address something from Mark. He was asking why the Interoperability Standards Workgroup is now listed as inactive. I also was part of that, so I do have a stake in this question. Will we be ramping that back up? Since we are looking at USCDI 7, we were wondering if this would be something to reconsider? Mark can speak to that later.

Seth Pazinski
Thank you. Yes, I am happy to take that question. For 2026, the work on health IT priorities and related standards is going to be focused on the Adopted Standards Task Force. We do anticipate the Interoperability Standards Workgroup to continue its work, picking up with USCDI Version 8 draft next year. I think that is something we can

correct on our end and update the website to indicate that that group is still active. At this point, we are not anticipating a charge for IS WG this year because we will be doing the HITAC Adopted Standards Task Force. Thank you, Rochelle. Certainly, feel free to reach out if folks have other questions, but we are going to transition to our next agenda item. I would like to welcome my colleagues, Kate Tipping and Mike Lipinski, who are the leadership for our Division of Regulatory and Policy Affairs here in the office of policy at ASTP, and they are going to give an overview of the HTI-5 Proposed Rule. I am going to turn it over to Kate and Mike.

HTI-5 Proposed Rule Overview (00:57:25)

Kate Tipping

Thank you, Seth. I will go ahead and start us off, and then I will send it to Mike to go over the information blocking proposals. We are going to give you a brief overview of the HTI-5 Proposed Rule. Next slide. A couple of disclaimers before we get started. The materials contained in this presentation are based on the proposals in the Proposed Rule as it is published in the Federal Register. This presentation is not a legal document. The Federal Register is. In order to protect the rulemaking process and to comply with the Administrative Procedure Act, we can only present the information as it is presented in the Proposed Rule, and we cannot interpret that information or clarify or provide any further guidance. Comments must be submitted through the formal rulemaking submission process through Regulations.gov, which is highlighted in the Proposed Rule in the Federal Register. We can take comments today, but nothing will be a part of the official record for this rulemaking. They need to be submitted through Regulations.gov. This communication is produced and disseminated at the US taxpayer expense. Next slide.

This is the agenda of how we are going to go through the proposals. I will start with the certification program and turn it over to Mike for information blocking proposals. But before we get started, I just wanted to mention a few things. As you are aware, regulations can spur progress and innovation, but they can also have the opposite effect and slow down progress and inhibit innovation. When preparing for this rulemaking, we took all of that into consideration. Since the inception of the certification program, we have always aimed to implement and administer the program in the least burdensome manner. We are constantly reviewing the certification program and the requirements to ensure that it supports interoperability progress and innovation, as well as balance the burdens and costs associated with our priorities and our goals.

As you are aware, through the Cures rulemaking, we have in the past deregulated various parts of the certification program, including removing some of the certification criteria and requirements, but also moving interoperability forward, such as moving from Continuity of Care Document (CCD), Continuity of Care Record (CCR) to Consolidated Clinical Document Architecture (C-CDA) and Application Programming Interface (API) to Fast Healthcare Interoperability Resources (FHIR)-based access and exchange. I just wanted to mention that we also considered a lot of the feedback we received from both the deregulatory RFIs that the government put out, but also the CMS/ASTP/ONC RFI. We considered some of those comments when we put together this HTI-5 Proposed Rule. Next slide. The purpose of the Proposed Rule, as I mentioned, we took a lot of items under consideration, but, ultimately, further implementing the 21st Century Cures Act through APIs and information blocking exceptions, those reasonable and necessary activities that do not constitute information blocking.

As well, the Proposed Rule is set out to support the Trump administration executive orders. This is a deregulatory rule, so it mainly supports Executive Order 14192, unleashing prosperity through deregulation. It also reduces anti-competitive regulatory barriers and removes some of the artificial intelligence barriers through Executive Order 14179. We also leverage health IT and advanced interoperability through authorities that we have in the HITAC Act, as I mentioned, transitioning to FHIR-based APIs and making revisions and removals to the certification program. Next slide. The Proposed Rule set out to reduce any outdated and redundant certification requirements, basically, reset our regulatory foundation for future FHIR-based interoperability. We do that by refining the certification program and the information blocking regulations all in an effort to improve electronic health information, access, exchange, and use. Next.

As I just mentioned, the goals of the Proposed Rule are the three listed here. To go over again, it is to reduce the burden on health IT developers by streamlining the program requirements and removing any redundancies. Updating the information blocking regulations to better promote access, exchange, and use so that patients have access to their data, and it is not blocked. Advancing the new foundation of FHIR-based APIs that promote AI-enabled interoperability solutions through modernized standards and certification. In the Proposed Rule and the regulatory impact analysis, we estimate the cost savings to be $1.53 billion, which includes $650 million over the

next five years for health IT developers, providers, and other stakeholders. We also estimate that it would save health IT developers an estimated 1.4 million compliance hours in their first year, giving them the new capacity to develop innovative solutions for their customers. Next slide.

This table set up here is included in the Proposed Rule as it is published in the Federal Register. This is Table 1. This sets out and shows all of the certification criteria that we propose for removal or revision. Of the 60 certification criteria currently in effect, we propose to remove 34 of those and revise 7. That includes removing the model card requirements in the DSI, the Decision Support Intervention Certification criteria. Of the 60, there are 19 that we do not propose to make any changes too. Next slide. This is just a continuation of Table 1, which is included in the Proposed Rule. Next. This is just another visual that you can see how we are revising the certification program requirements. This includes, basically, the same information on the two earlier slides, but it shows the mandatory and conditional certification criteria and the certification criteria associated and here not associated with the CMS programs.

Next slide. This is a continuation of that, but we highlight it in different colors. It might be a little difficult to see, but you can see the blue font shows that it is certification criteria that are included in the base EHR definition and the cert definition and then, in the green is the cert definition only. It is just another visual to see how the relation of our certification program fits into the CMS programs. Next slide. I wanted to highlight the privacy and security certification criteria and our proposals included in the HTI-5 Proposed Rule. If you have already reviewed it, I just wanted to note that we still do prioritize privacy and security. We intend to prioritize the adoption of those capabilities that are fit for purpose, use case specific, and deliver much needed technical consistency in the market when paired with specific conformance requirements. For example, as we pursue different API focused certification criteria, if those standards and the implementation guides do not specify or have optional security requirements, we may look to add further constraints, for instance, multi-factor authentication support.

In all of these cases, we do intend to make security capability a built-in part of the certification criterion's conformance and not a separate standalone conformance assessment that we currently have today. Our proposals in the HTI-5 Proposed Rule, we do propose to remove all of the privacy and security certification criteria in Section 170.315D and the associated privacy and security certification framework. An alternative proposal that we did include was to remove the majority but retain certain certification criteria related to audits that may serve to help identify fraud and abuse. Next. For the standards and implementation specifications, for instances where we propose to remove or revise any of the certification criteria, we also propose to remove the standards that are referenced in that certification criterion. In some instances where we include a transition date for the certification criterion, we also do include a transition date for the standards for removal.

In very limited circumstances, we do retain a standard that is referenced by a criterion proposed for removal. We do this in order to support the HHS Health IT Alignment Program. For example, we do not propose to remove the direct project transport standard. The direct project standards are widely utilized in other various use cases and maintaining that standard we feel would help support interoperability. We also propose to remove any standards from the Code of Federal Regulations that are outdated and that are no longer referenced within the certification program. Next slide. Along with the terms and definitions, we also make some conforming changes. For instance, we revised the base EHR definition to remove any references to certification criteria that we have proposed to remove. We also propose to remove terms that are no longer referenced in 45 Code of Federal Regulations (CFR) Part 170, which include the Common Clinical Dataset, Global Unique Device Identification Database and Production Identifier. Next slide.

We make proposals to revise the conditions of maintenance of certification requirements. For a number of the conditions, we propose making conforming edits. We make conforming edits to the assurances, the APIs condition and attestations. For real-world testing and insights, we propose removals and to de-scope those conditions and maintenance of certification requirements. For real-world testing, we propose to remove the requirement to submit real-world testing plans. We limit full real-world testing results reporting to only health IT modules that are certified to API certification criteria. We permit the use of the standards version advancement process for the remaining non-API real-world testing certification criteria. For insights, we propose to remove and de-scope the measures associated with the condition. We limit the reporting requirements only to the use of FHIR and apps through certified health IT measures. Next slide.

We propose to make conforming edits to some of the certification program administrative requirements, specifically the section set out here. As an example, we propose to make some conforming revisions to the principles of proper conduct for ONC-Authorized Certification Bodies (ONC-ACBs) in Section 175.23 by removing the cross-

references to certain certification that we had proposed to remove. More specifically, this is the section in 523 F1 where we reference privacy and security certification criteria, quality management system certification criterion, and accessibility center design certification criterion. We propose to remove those from the principles of proper conduct. Next slide. I will turn it over to Mike Lipinski to go through the information blocking proposals.

Michael Lipinski
Thank you, Kate. Just a quick check. Make sure, before I get on a diatribe, everybody can hear me well. Kate, are we good?

Kate Tipping
Yes, all is good.

Michael Lipinski
Great, thank you. Good morning, everyone. I appreciate you joining, getting back together, and going today to hear a little bit about the second part of the HTI-5 Proposed Rule. I am going to just give a little context before I get into the actual proposal. From an information blocking perspective, ASTP/ONC administers the regulations for information blocking. What does that mean? We interpret the terms using the statutory text. Looking at plain language and context of the definition and Congress gave us the definition of information blocking. The other key thing that we do on behalf of the secretary, per the statute, is identify reasonable and necessary activities that do not constitute information blocking. We call those exceptions in regulations. The other question you might be asking yourself is, "How is the information blocking part of this deregulatory rule?" That is because, from a regulatory perspective of costs and benefits, it is budget neutral in that they do not create costs or, essentially, benefits.

The law itself creates benefits, but in our implementation of the law, the definition does, but the exceptions, which are voluntary and really are to give certainty to actors covered by the regulations and information blocking, that they are not committing information blocking, do not create costs because they are voluntary. That is how it became part of what is a deregulatory rule primarily focused on proposals related to our ONC health IT certification. The last piece I want to mention to set context, and this will come up again as I go through the proposals, is what Kate alluded to, which was feedback from the public. We had some feedback, obviously, on the HTI-2 Proposed Rule. There were some information blocking proposals in that role as well. There was a multitude of what Kate alluded to RFIs, requests for information, including, as she mentioned, the ASTP, CMS, RFI. We had an RFI from the department, HHS RFI, last summer, as well, and then there was an RFI from the Office of Management and Budget, OMB.

There was a separate RFI, and these were focused on deregulatory initiatives from the Department of Government Efficiency, DOGE. There was another RFI focused on competition, which information blocking is also focused on. That was from U.S. Department of Justice (DOJ) Federal Trade Commission (FTC) in regard to an executive order. It looked at two things, improving competition in markets, but also looking at reducing barriers to entry, which is important related to the certification program. In that context, we will jump into each of the proposals that were in HTI-5. Next slide, please. The first proposal is really a codification of, from our position, a clear interpretation of the definition and our regulations. We received comments and feedback on those RFIs and through other stakeholder engagement, there was concern, particularly with the proliferation of use of AI tools. There have actually been court cases that arguably involve automated means of access that implicate information blocking that we should clarify. I should not say clarify. We should emphasize the definition by codifying a particular addition to the definition of access and use.

Alternatively, we are saying we would incorporate that into the definition of exchange as well. This is getting at, again, automated means of access exchange and use, as well as agentic AI and autonomous, which is autonomous artificial intelligence. We have crafted a definition along those lines, additions to the access and use definition to make it utmost apparent that these were always included. We issued Frequently Asked Questions (FAQ), actually, in December, pointing out that it was always our interpretation and, in doing so, pointing to discussions in the HTI-1 final rule, as well as discussions in the HTI-2 proposal, and even going back to the Cures Act rulemaking. Next slide. Now, we are going to shift to those exceptions. It is always an assessment of whether they are reasonable and necessary; what are the exceptions?

This entire Proposed Rule is proposing either removal or modification to current exceptions based on stakeholder feedback and changes in the market. These may seem very new in terms of being conditions and exceptions. The first one we are revisiting them is the third-party seeking modification use. To go back to that point, the entire

rulemaking is fairly new. It was not finalized until 2020, the first information blocking regulations. It has been a constant iteration over the years up until now since. There was a lot of confusion along this condition that we added, and it applied to all actors, but it was geared towards EHR developers, which would be a developer of certified health IT and, generally, acting as a business associate for a covered entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) rules. It was saying that if you got a request to modify the record, and that request was not coming from the covered entity that is your business associate, then you could deny the request to modify.

To modify is to, for example, delete, add to the record, or change the record. We are talking about the healthcare record, essentially, designated records, when we are talking about Electronic Health Information (EHI). This was a way we saw to simplify certain specific situations for actors, versus using one of the other exceptions, or not even meeting information blocking if you denied such a request. We received a lot of feedback, a lot of confusion around this exception that is discussed in the rule, and it is discussed in prior rules. We have also received things in the market have changed as well. We think that between, for example, use of AI tools, but also other forms of two-way bilateral exchange from an interoperability perspective that one of our goals here, in terms of the market moving, may no longer be aligned in that there are better ways to now do bilateral exchange and take in some information from another healthcare provider that would not be a business associate and inevitably and eventually patients, the data back from them.

Second and most importantly, a lot of feedback about misapplying and abusing this, which we were concerned with when we even finalized this exception, in that we provided flexibility for that business associate, the EHR developer, in confirming whether the third-party modification use was on behalf of the covered entity. What we found is that a lot of third parties that could be actual or potential business associates, so they are not a business associate yet, using a use case where the cover entity is like, “We like your product. We think it might be a best-in-breed product for data analytics, but you need to be able to integrate with our EHR company before we sign a contract agreement and license with you.” We have heard that that has been used in terms of, “Well, we do not have to give you access. We can use this condition to deny you access because you are not acting on behalf of the covered entity yet.” That was never our intent. We have expressed even some of that concern in the prior rulemaking.

At this point, we are proposing to remove this condition, welcoming comment on that, and that pointing out that before this was proposed and finalized, there were still all the other exceptions available to actors if they chose to address circumstances where they did not want to permit modification of the record. Now, I will move on to the second condition that we are proposing, in this case, to modify under the infeasibility exception. This is the manner exception exhausted also new through the HTI-1 finalized rulemaking. I think we even expressed reservations then based on our proposals about the potential for it to be manipulated as well, of which we got feedback through those RFIs. We cite that in the HTI-5 rulemaking. To point out the distinction between the manner exception because there was confusion with that as well that was reported and we have issued some FAQs on the manner exception, importantly, you have to meet all the parts of the condition to be able to take advantage of the condition at all relevant times.

You only had to offer the alternative manners. Under the manner exception, the requester must identify the manner in which they are willing to accept the EHI requested or have to agree to it if it is the third manner under the alternate manner condition of that exception, which is a machine-readable format. Here, we had finalized that you had to only, as the actor, offer two other ways, whether or not they identified those means, that being the requester or agreed to it if it was a machine-readable format. We had proposed originally all three. Now, based on feedback, we are going back to proposing to require all three again, which was in the first HTI-1 rulemaking, we landed on only having to offer two, but we are going back to proposing three, which was originally what we did in the HTI-1 rulemaking.

We are changing the other key part of this condition, which, on the screen, you see how it is now. We talked about all these different terms through that rulemaking, the same access, what same meant, that it had to be a substantial number, and that they had to be similarly situated for the requester. If any of those things were not true from the requester, they could use this condition to deny access to that particular means of access, exchange, or use. We have already got feedback, and it was never our intent about same being interpreted to be identical and that that was not our intent and that it was manipulated in that way that every single part of the request had to be identical for the requester themselves. We are proposing a basis that is, we think, less subject to manipulation, which is analogous access, exchange, or use. We are really looking forward to the feedback we get on that. We are also removing the substantial number because, again, it was a terminology open to interpretation.

That is being replaced with, essentially, if you are offering this to anyone else, we are also removing similarly situated, then you are not going to be able to use this condition. If you are offering analogous access to any other individual entity, you as an actor are not going to be able to use this condition if we finalize our proposal. We think that it aligns with the definition and intent of the information blocking regulations and definition provided to us by Congress, but also still achieves our initial goal. If you go back to when we proposed this new condition in the HTI-1 rule, which was that we said we had got a lot of feedback from actors and were receptive to the fact that from an interoperability perspective and a cost and access, exchange, and use perspective, they should not have to create one-off interfaces for anyone who came or be worried that they could be subject to information blocking because for them to prove infeasibility, there was only the condition infeasibility under the circumstances, which was the weighing of a multitude of factors, including resources, financial obligations.

It does look at who else you provide that access to. In this case, we still think we are meeting that goal and objective of certainty for actors that they do not have to necessarily create one-off interfaces. If they do provide that same access, say it is a payer API, to others, and they are not providing it to a particular requester, they would not be able to use this condition. It does not mean other exceptions apply. It does not mean it is information blocking. The point being, based on our proposals, they would no longer have the benefit of this potential condition under the infeasibility exceptions. Based on comments we get back, we may just remove the entire condition if, for example, we receive comments and there is concern about, again, interpretation or manipulation of the condition, even with revisions. Next slide, please.

We are going to shift now to the manner exception. I had referenced earlier, we had issued a couple of FAQs about the manner exception in late December, again, clarifying points about how it applies to data requested, that if the data requested is more than you can provide, for example, under the manner exception, does not alleviate you of still having to provide that other data or meeting another exception for why you would not provide that data. Another point in that FAQ was what I had emphasized earlier, that it was the requester would have to identify those alternative manners and/or agree to receiving it in a machine-readable format. Again, that was reported back a lot of confusion about that or misapplying the exception. For example, saying that if they provided you USCDI through the FHIR API, that was sufficient and they had met the exception, even though you may have asked for, you as a requester, data beyond the USCDI Version 3.

What I want to emphasize first on this slide and for this exception is what you see at the bottom, which is whether or not we adopt this proposal. There are key points that are clear through the proposal and finalization and then updating of this exception through rulemaking, which is it only covers technical manner exchange of the requested EHI. You may think there are related or ancillary issues to the request. This exception covers the technical manner of the request. We have given plenty of interpretation of what could be an interference in the preambles of our rules, including that particular types of agreements could implicate the information blocking definition and regulations and those that include ones that have unconscionable terms.

We have pointed out now through this rulemaking that contracts of adhesion could fall into that category. The other point that I want to emphasize before I talk about the proposals, we said, “If you are going to use the condition that we are talking about for proposal here, that is the first part of the manner exception comparative to the alternative manner part of the exception, is that we expected there would be a negotiation on market terms in terms of reaching agreement under this first part and not applying the fees exception or the interoperability exception to any circumstances in that agreement.” What we have heard is all that has been manipulated in various ways, including offering take it or leave it terms, which can include stuff that actually violate the fees exception. For example, that we get a percentage of your revenue, the EHR developer that is, to give you access. We talk about the fee’s exception, again, we issued an FAQ about this, that that is prohibited to even meet the fees exception.

They were saying, “Well, you have to take this and then we are going to say it meets the manner exception.” That also is not market rate as well. You would not even be able to meet the manner exception under current status. We have heard about these various types of ways of misapplying or abusing the exception through the RFIs and other stakeholder engagements. Therefore, we have two proposals through the HTI-5 rule. One is specifically saying that certain contracts and agreements that do not meet specified requirements will not get the benefit of the exception. For example, they have to be, as you see on the screen here, at market rate, cannot contain unconscionable terms, and cannot be a contract of adhesion. We understand. We pointed out in the preamble that that may not provide the same certainty or even clarity that the market would want. We are looking for comments on that, and we put forth an alternative proposal.

That alternative proposal, as you see on your screen, would keep the manner requesting addition as is in terms of reaching agreement, but it would apply the fees and licensing exception back to all agreements then. It is not just agreements reached under the alternative manner of this exception, but also under where the parties reach an agreement, the agreement would have to meet the fees and licensing exception to get the benefits of the manner exception. Again, I am looking forward to feedback on both those proposals. We can move to the next slide, please. The last proposal is removing the TEFCA manner exception. This gets back to the contextual point I made at the beginning and that I have emphasized in some of the other proposals, which is we are always looking at whether or not these are reasonable and necessary activities that do not constitute information blocking.

I will start with this exception was finalized through the HTI-1 rule. Through the HTI-2 rule, we took additional comment on that exception and did not change it based on comment. Our going rationale behind this was to incentivize participation in TEFCA and that it would support interoperability and would support access exchange and use of EHI. As we discussed in the rule, this exception is already unnecessary based on the robust TEFCA participation to date. This was talked a lot about it at our annual meeting. We have put out through press releases in terms of both the participants in TEFCA, the amount of Qualified Health Information Network (QHIN) we have, but also importantly, the amount of exchange that is happening already on TEFCA. I think other concerns that we point out in the rulemaking that we have is it could possibly disincentivize participation.

What this exception allows is if both parties are in TEFCA, the requester would have to accept the data through TEFCA means. Whatever that is available at that time, whether it is just through document-based exchange, or if there is API in FHIR-based exchange, then that would be a potential option, but they have to accept it through that exchange. That can be limiting, as we heard through the rulemakings, particularly if FHIR-based exchange was not prevalent yet, and that is the way you wanted to receive it. As I talked about earlier, what if you wanted to use automated tools in some way or form, such as artificial intelligence, to improve your access, exchange, or use under TEFCA? Arguably, if that is not part of TEFCA yet, that would not be permitted, but they could use this exception to give you the requested EHI in the TEFCA means way. We are worried about some unintended consequences in de-incentivizing TEFCA, and we think TEFCA can stand on its own.

We also got feedback about some misunderstandings of Individual Access Services (IAS), and that those that are not participating in TEFCA can still get data from those actors without being forced into TEFCA. I think we tried to make that clear through rulemakings but still receiving feedback that that is either being misunderstood by TEFCA participants and misapplied sometimes in individual access requests. We have proposed for those reasons and discussed in more detail in the rule to remove the TEFCA manner exception. I believe at that point, if we go to the next slide, it would take us to the end of this presentation. As noted, a few times today, comment period is closing shortly. There are two other comment periods open just for awareness that the AI RFI is closing actually even sooner on the 23rd of this month and then, we have the diagnostic imaging RFI, which we are really looking to get feedback on that as well. That runs into March. I do not have the date in front of me. I just thought I would mention those as well.

Seth Pazinski
Thank you, Mike. We appreciate it. We are going to transition to open it up to the HITAC members for any comment, questions, or other discussions. If you do want to make a comment or have a question, please use the raise hand feature if you are on Zoom and just come off mute and let us know if you are just on the phone. Eliel?

Eliel Oliveira
Yes, thank you, Seth. Thank you to the team for presenting these details. I wanted to first commend ONC and the federal administration for these deregulation activities. This is terrific news, I believe, for the improvement of technology in healthcare. I wanted to note that likely I will provide my comments through Civitas for Health, which is the national association of different types of data networks and collaboratives nationally, as you know. But I wanted to point out a couple of things here that I thought, initially, I was a bit concerned about, but I think the comments today are quite helpful and one specifically was related to security and privacy. I think the elimination possibly of audit logs, but I think I was happy to hear the alternative proposal here that audits may serve to identify fraud and abuse. I think that is great, especially related as we track down where there is fraud in healthcare. I think from a patient perspective as well, one of the key challenges we have had in the past is the counting of disclosures.

Without a national strategy on how all types of electronic systems that manage healthcare data, it is going to be virtually impossible to track down when data is shared and for what purpose and what it was used for specifically. I think I want to highlight that as it relates to Senator Cassidy's new bill related to expanding the reach of HIPAA.

That also, basically, highlights what I am trying to say. That is going to be beyond electronic health record systems to be able to keep that capability to audit events. I like to think in terms of auditing as we have with Transmission Control Protocol/Internet Protocol (TCP/IP) and network connectivity between computers where the Federal Bureau of Investigation (FBI) and other agencies are able to track down, in some capacity, when a hack attempt has taken place and where it came from. I think if we do not keep some sort of logging, it would become almost impossible to see what happened to someone's data. I applaud the alternative proposal that is under that deregulatory aspect, as I think that is going to be quite powerful to maintain.

I think the other point that I had highlighted to the staff of Senator Cassidy was related to, and which does not necessarily affect all these comments here, but it was on the ability of patients to make changes to their records. In some ways, it does affect how logging takes place, but we have several examples. I know personally individuals that are harmed by the fact that they cannot make changes to their records or ask a health system or another provider of care to make changes to their record. The result of that is that they have to be with their families and relatives at the point of care, during a hospital visit or any other type of visit to make sure that folks know that what their records say is wrong, and they cannot fix it that manually they have to be there in person. Again, from a logging perspective and auditing perspective, that is also a very important aspect of maintaining some level of regulation to guarantee that the individuals can make edits to their records.

As far as I know, there is no pathway today for someone to identify themselves as a provider of care and enforce the changes to their records that are reflected appropriately during care activities. Thanks for the opportunity to give some comments here.

Seth Pazinski
Thank you, Eliel. Any other comments or questions from HITAC members? Anna, go ahead.

Anna McCollister
One of the things that I am trying to get my head around is the proposal to remove the requirements around what was colloquially called the nutrition label for AI. That was one of the things that we discussed quite a bit as HITAC, particularly within the work groups, around the need to really have a basis of understanding like what is the training data? What is the direction for which this AI is maximizing? What is the outcome? I feel like that is an incredibly important part of any situation or any clinical setting or would need to be an incredibly important part of any clinical decision-making based on outputs from AI. While I certainly appreciate and applaud the desire to get rid of onerous regulations, I think that is important, I am really trying to understand how that facilitates comfort on behalf of both patients and clinicians and the use of AI.

Michael Lipinski
I can go first, and any of my colleagues are on, and I invite them to also respond. Obviously, I am going to adhere a lot to what we said in the rule about this. I think with all rulemakings, there are sometimes assumptions and presumptions about proposals and what the impact of those proposals would be. Generally, you want proposals to be evidence-based proposals. The underlying assumption with that proposal was that you would provide transparency and that the information would then be used to make decision-making and particularly clinicians in terms of what AI tools they would use and would align more with picking the best tool based on the source attributes. We had no specific information that that is how those determinations would be made in the first place in terms of by providing that information. We heard back from the EHR developers the amount of burden that it was creating for them in terms of cost to do this without definitive evidence that it would create the benefits that we estimated, which were in the billions of dollars, by making all this transparent.

To that point, we have talked publicly about how FDA has approved 1,300 tools that fall within the AI category, but very minimal of them are being used. We want to learn more about why or what would incentivize clinicians and healthcare providers to use these tools. Are there concerns about cost, liability? Does it improve care? Does it improve either revenue, payment, or profit? What is holding back the use of these tools that already exist in the market? I think as we talked about in the rule, there is a concern about an unequal approach to this, too, and that this was where we were putting a burden on particular entities and those are the entities that participate in the certification program while other entities that also produce AI tools and offer them to healthcare providers are not encumbered by the same requirements of our regulation. There was a concern about, “Are you hindering them in their attempts at innovation at the benefit of a different set of entities?”

We want to take a holistic approach from the department you have heard about. That is why you have an RFI that our agency participated in with the department to issue to get that feedback and make decisions based on both

stakeholder feedback and whatever evidence we can gather to take a holistic and what we would feel would be a better approach to any type of regulation. Dr. Keane has in interviews indicated that he knows that at some point that, or the department knows at some point, some type of efforts and oversight would have to be provided to improve trust and safety. I think you want to make sure you are not ahead of the game and you are stifling innovation or not equally applying your requirements to everyone who would be within the market that your regulations cover or the department. That is the rationale behind it. Again, there is an RFI out as well as this rule in which we are taking feedback and, obviously, want to hear more from stakeholders before we are making a decision in this space so we can get the closest we can to the right decision.

Seth Pazinski
Thank you, Mike. Hannah?

Hannah Galvin
Yes, thank you. I have submitted comments to the RFI specifically on this, but I will use this opportunity to just share as someone who does this day-to-day, evaluating AI tools for a health system. I am not sure that the model cards themselves are the problem but the content of the model cards. I know that myself and many of my colleagues who do this day-to-day on the ground and evaluating these tools have, basically, come up with our own requirements and request that the vendors fill out our version of our model card, the information that we want because the model card itself does not give us enough information. I do not know that shifting away from having a model card is what we need as much as changing the information that is provided. To your point, only certified EHR technology is required to do this. Just to get my comments in there, but you will receive them in writing as well. I know that others are finding the same issue. Thank you for that opportunity.

Seth Pazinski
Any additional comments or questions from HITAC members? Thank you, Mike. Thank you, Kate. Thank you for the comments. We are about right on schedule agenda-wise, and we will be taking a short break and reconvening at 12:05. Before we break, Mark Sendak, one of our HITAC members, has joined the call. I wanted to give him a chance to give a brief introduction. I will turn it over to Mark. Mark, you are on mute if you are talking. Maybe we will try that when we come back from the break. Again, we are going to take a short break now until 12:05 and we will resume. We will be pausing the recording. Just a reminder, the webinar is still live. Please, if you can mute your mics and turn off your video while we are on break and we will be reconvening at 12:05. Thank you, everyone. Thank you.

TEFCA Updates (01:50:34)

Seth Pazinski
We are going to continue with our agenda. I want to welcome everyone back from our short break. We are going to move into the TEFCA update. I am going to move to our presenters, Maggie Gaddis, who is our Director of the Interoperability Division within the Office of Policy at ASTP and JaWanna Henry, who is the Interoperability Systems Branch Chief in our Office of Policy at ASTP. Maggie and JaWanna, over to you.

JaWanna Henry
Great, thank you. Today, we will be giving you all an update on where we are with TEFCA. We will be starting with giving folks a little background because I know sometimes it is hard to understand actually what TEFCA is. We will be starting with that and then giving you more details in how we have progressed with TEFCA since implementation. Next slide. To give you insight, a quick snapshot of what TEFCA is. It really is just one connection to access all trading partners, and that is those who have agreed to participate in TEFCA at nationwide scale. What does that mean? It means there is one set of network participation policies. We have the common agreement, which is signed by all of our qualified health information networks. We have the terms of participation, which is essentially a flow down of some of those agreements that are signed by our participants and sub-participants.

Then, we also have policies around cybersecurity, and then we have policies related to our different exchange purposes. In addition to the network participation policies, we also have the one interface to nationwide connectivity services. Under that, we have what we call our QHIN technical framework or our QHIN Technical Framework (QTF), which really lays out all the technical requirements for supporting connectivity services in TEFCA. We have our TEFCA directory service, which includes the different nodes that are supported by those who sign on to TEFCA, which is also supported by record location, which helps with those connectivity services

nationwide. In addition to our participation policies, our connectivity services, we also have the network oversight approach. What that means is we have processes for dispute resolution, conflicts of interest that all of our QHINs and participants must follow. Under that, there are also the same expectations of cooperation, and all of this is governed by the one set of governing bodies that we have for TEFCA.

To reiterate what TEFCA is, it is really that one connection that gives you that one set of network participation policies, that one interface for nationwide connectivity services, and one network oversight approach as we function as a network of networks for TEFCA. If we go to the next slide, then you may ask, “How is this actually implemented?” We start with ASTP who defines the overall policy and the certain governance requirements to support TEFCA and then, we have the recognized coordinating entity, which is the RCE. This is a contractor, the Sequoia Project, who actually provides oversight and a governing approach for our QHINs based on those policy and governance requirements that were set. For those QHINs, our Qualified Health Information Networks, those are the health information networks, usually national networks that connect directly to each other to facilitate the nationwide interoperability that we see across TEFCA today. Each one of those QHINs then has opportunity to connect with our participants or sub-participants.

These sub-participants can be EHR vendors, they can be health systems, different hospitals, and public health authorities that are all able to connect to TEFCA. In addition to connecting to a QHIN, participants and sub-participants can also connect with each other. All of these connections really supports, again, that network of network connection through TEFCA. One thing, again, just to highlight, I mentioned all of our QHINs do sign a common agreement with those specific policies that they are governed by. Then, we have our participants and sub-participants who agree to the terms of participation, which is, again, some of those same terms that are included in a common agreement, which really supports them being able to do TEFCA exchanges, essentially in the same manner as our QHINs. If we go to the next slide, I am glad to say as an update that in 2023, we started off the implementation of TEFCA with just five QHINs.

To date, we have 11 QHINs that have signed the common agreement. In 2025, we were able to welcome three new QHINs to the network of networks, and that includes Netsmart, Oracle, and Surescripts. We can go to the next slide. Now, these 11 QHINs have definitely helped support our TEFCA network participation. Currently today, we have over 70,000 sites, and those sites have been exchanging more than 474 million documents since December of 2023. We wanted to be able to show you all this map, you can see where those different sites are located across the nation. Next slide. If we look at this more than 474 million documents that have been shared since going live in December of 2023 is something that we are very, very proud of because if you take a look at this graphic, you will see that TEFCA documents exchanged in 2024 were just 10 million. We are very excited that alone in 2025, we have already reached nearly 500 million documents that have been exchanged.

You can go to the next slide. Now, there is a lot of exchange that has been happening since TEFCA, and you can tell by the number of documents that have been exchanged. This is all supported by the six exchange purposes that are authorized under TEFCA. You will see those six exchange purposes that are bolded in this table, include treatment, payment, healthcare operations, public health, individual access services, and government benefits determination. We have a specific exchange purpose, SOP or standard operating procedure, that defines these authorized exchange purposes and the specific exchange purpose codes. Now, with this table, there are a lot of things going on here if you are not used to TEFCA, it may seem, and that is because we wanted to show you that we have six exchange purposes that are authorized, but under those six exchange purposes, we also have different use cases under those exchange purposes as well. Along with these use cases under the exchange purposes, it offers the opportunity for us to put further specifications around the different use cases that are listed under those specific exchange purposes. That is not to say that if you take healthcare operations, for example, or public health, that you can only use these exchange purposes for the specific use cases.

You can use them for other healthcare operation use cases that are not listed here, but with exchange purpose SOPs and the specific implementation SOPs, they are just more specification and policies around how those exchange purposes are to be implemented. If we go to the next slide, as you can see from the previous slide that we have been doing some work to increase the different use cases that are supported under TEFCA to help with the exchange of data and how TEFCA is used. I think it highlights our flexibility and some of the work that some of you may or may not have seen within the past years that we have been doing a lot of work to really support the implementation of TEFCA and under the different exchange purposes. We released at least eight documents in 2025, some that were new documents and some that were updated. Now, I am just going to take a little bit of time to just go through the different documents with you to give you insight into what we were doing in 2025 and some of those specific updates that were made.

If you were all at the annual meeting, you all saw that there was an announcement of the Social Security Administration (SSA) signing up with their QHIN and really signing on that they could support the government benefits determination exchange purpose. In addition to coordinating with our federal partner, there was work that we did behind the scenes and updating our QHIN technical framework, again, which provides the technical requirements that are needed to support TEFCA. For Version 2.1, what we did with that was updated really to add the ability for direct query. This helps support the government benefits determination exchange purpose and helps the exchange of data for SSA. Specifically, for SSA, we added a use case for their organization. You will see this in the next document, which is the government benefits determination implementation SOP. We added a specific use case for SSA, the Social Security determination sub-exchange purpose to support their exchange needs across TEFCA.

I do want to go back to the QTF because I do not want to skip over this. One of the other things that was added to that previous version, aside from the direct query to support a government benefits determination is we did also add the requirement for QHINs to report on transaction volume that is based on exchange purpose. That was something that was new to that QTF that we hope to see being shared in the near future. For the third item that we updated in 2025 was the exchange purpose SOP. You saw we have six exchange purposes with several different use cases. Along with updates to the different exchange purposes, there also comes updates that we need to make to the exchange purpose SOP as well. For this specific update, we did add more detail on exchange for non-acquired exchange purposes and updated the table. That is a little clearer for folks to be able to see as they go through that SOP.

For healthcare operations, we are on Version 2 for that. This one was something that took a little bit of work, but with the update, we updated the exchange purpose codes in hopes that it enhances the flexibility and use of healthcare operations in the specific use cases with the specific use cases that are there. We are hoping that this also adds a layer of protection for individual privacy as well. If you did not get a chance to really capture it on the previous slide with the healthcare operations SOP, you will see that there are six use cases that have certain level of specificity, which includes care coordination and management, the Healthcare Effectiveness Data and Information Set (HEDIS) reporting, quality and assessment improvement, population-based activities, patient safety and performance review. In addition to healthcare operations, we have also been doing some work in the space of treatment, and Maggie will give you more details about that. For the current version that is published, that was updated to clarify the responding nodes that must respond to the TEFCA required treatment.

It also adds more details for what types of treatment related purposes and activities. Our hope is that by updating this SOP and adding that content that it further builds trust between those who are participating in TEFCA. We also updated the facilitated FHIR implementation SOP. Again, this is Version w of that SOP, and this was another update to further clarify specifically the procedure requirements for implementing FHIR. Along with that update there, this also gives users the opportunity until early 2027 to support dynamic registration, authentication, and authorization. Just to clarify that a little bit further, it gives users until 2027 to start using, to use the HL7 FHIR Implementation Guide (IG) and that is 1.1. Just as a reminder for the facilitated FHIR SOP, if you are not aware, this SOP was developed to encourage consistent adoption of scalable network approach to facilitated FHIR across TEFCA.

Lastly, we also updated the individual access services provider SOP. This is Version 2.2. Along with the updates in that SOP, it gives the individuals really more transparency into the choices that they may have for sharing their data. It also requires the IAS provider to make sure that they implement the choices that the individual indicates and make sure that they adhere to processes to ensure that that choice is honored. Again, just within 2025, there is a lot of work that is been happening. I know some of you may just feel like you consistently see documents coming out of ASTP. I think we like it that way because that means that we are really listening to and understanding the needs for implementing TEFCA and what we need to do in order to advance TEFCA and increase the use of the different exchange purposes across TEFCA. I am going to pass it over to Maggie to talk a little bit more about some of the work that we have been doing within TEFCA behind the scenes.

Maggie Gaddis
Thank you, JaWanna. Can you all hear me? Can someone give me a check?

Seth Pazinski
Yes, we can hear you.

Maggie Gaddis
Great, thank you, Seth. Good afternoon, everyone. We are excited to be here with you to provide updates on TEFCA. As JaWanna mentioned, as TEFCA participation has been scaling and exchange has been increasing drastically, the natural outgrowth has been for us to focus on transparency and trust in the network. The next couple of slides go over our efforts with the RCE in increasing transparency and trust. This past summer alongside the RCE, we developed a map. You saw a glimpse of it when JaWanna was showing the numbers that provides insight into participation across TEFCA. The map shows the TEFCA sites that are currently exchanging data and allows for search functionality by organization name, address, or zip code. As JaWanna mentioned, the map currently captures over 72 sites that are currently participating in TEFCA. Also, this past summer, the RCE launched a call for volunteer experts to help advance TEFCA implementation by participating in two time-limited work streams on specific issues.

I will be sharing more information on these work streams in the coming slides. Lastly, there is always opportunities for interested stakeholders to participate, whether it be through the RCE's monthly informational calls or to provide feedback on the draft versions of new or revised SOPs as JaWanna shared. Next slide. As we have been focusing on trust for the past few months, we have been working with the RCE on two important work streams alongside the TEFCA community. One has been on individual access service and the other on treatment. These work streams included members from both the QHIN and the participant and sub-participant caucus, as well as external expert volunteers. The goal of the IAS work stream was to increase trusted response to IAS queries in TEFCA. Although responding to an IAS query is designated as a required response, response in the network has been suboptimal due to some technical and policy variations in getting a patient match.

The work stream identified consistent IAL-2 and other self-asserted demographic data to include in an IAS query to ensure that this data can then be used to match the individual in the responder's system with enough accuracy to compel a response. This led to the following things that are now up for consideration. One being requiring CSP or credential service providers that support TEFCA to increase the amount of demographics data that they must be able to IAL-2 verify. Secondly, increase the required IAL-2 data elements that must be included within an IAS query for it to be considered valid. Then thirdly, allow individuals to self-assert demographics data and also for IAS providers to include self-asserted demographics in their queries along with the IAL-2 verified data so that responders can use them to increase patient matching. Also, as part of the work streams, we led a breach mitigation subgroup to develop risk mitigation approaches that align with the HIPAA breach notification rule of low probability of compromise related to breach notifications.

Next slide. As for the treatment work stream, the goal was working towards ensuring that all HIPAA-covered entity healthcare providers can compel a response for treatment. This has been an important part of our work this past year as currently certain HIPAA-covered entity healthcare providers are excluded from being able to use the treatment exchange purpose code that has a required response for queries that are related to treatment. This has led to the following changes that are being considered. Expanding the definition of TEFCA required response for treatment to include all covered entity healthcare providers, optimize the vetting process for healthcare providers that are currently HIPAA-covered entity healthcare providers, and then thirdly, updating the onboarding and designation SOP to require upfront and ongoing review of HIPAA-covered entity healthcare providers. Next slide.

I also want to highlight, as JaWanna mentioned earlier, the exciting news about federal government participation in TEFCA to advance secure health information exchange. IHS or Indian Health Services was the first federal agency to select a QHIN for TEFCA participation. More recently, the Consumer Protection Safety Commission signed with a QHIN to support data exchange using the public health exchange purpose to collect data from hospitals. Even more recently, as JaWanna mentioned, the Social Security Administration also selected a QHIN and has been involved with us and the RCE in developing their own sub-exchange purpose within the government benefits determination exchange purpose. This is significant as obtaining medical records through TEFCA accelerates the process for benefits determinations and also reduces the burden on patients and providers who are providing the medical records for benefits determination. Next slide.

Lastly, on this slide, we are highlighting a new fact sheet that was released last week during the annual meeting on the history and growth of TEFCA and it goes through how the network has made health information exchange easier, faster, and more secure, supporting better healthcare and outcomes. It also provides a visual timeline of the stages and growth of TEFCA as well as instructions for individuals, participants, and sub-participants, or QHINs who are interested in joining TEFCA. Next slide. That is it. I will hand it off to Seth for questions.

Seth Pazinski

Thank you, Maggie. Thank you, JaWanna. We are going to open it up to HITAC members. If you have any comments or questions, again, please just use your raised hand feature. If you are on Zoom, if you are just calling in, just unmute yourself and let us know you have a question or comment. Katrina, go ahead.

Katrina Miller Parrish
Thank you much for that information. I do work with the TEFCA subcommittees and committees but happy to get the summaries and I also have a quick question that I have asked before but just want to see if I can get a different answer. Thanks much for the map, and it will be great when we start having a better provider directory, so we really get a better understanding of who is on TEFCA and how they are exchanging all of that. I am still looking for if it is ever possible to get some understanding of what the potential goal is for all providers. If we are saying TEFCA now has 60% of all providers in the country connected, if there is ever a way that we could say something like that and track that to a completion, that would be terrific.

Maggie Gaddis
I can go ahead and begin to answer that question and will also offer an opportunity for my colleagues. We are currently working through and thinking through an evaluation, a broader evaluation plan for TEFCA. That type of metric would be one thing that we would be looking at. Yes.

Seth Pazinski
Thank you. Michael?

Michael F. Chiang
Yes, thank you, Seth. JaWanna, great to see you. Thank you to you and Maggie for your presentation. I have a question. I want to just to verbalize something that we have talked about a little bit individually, which is the six TEFCA exchange purposes. My question is that there is, obviously, an aggressive push toward real-world data at HHS. We want to use it for things like research and post-market surveillance, which I think is great. However, I know research is not explicitly listed as one of the TEFCA exchanges. Do you see any movement toward adding that or do you feel like we are better off fitting it under things like public health exchange or operations?

JaWanna Henry
Yes, thank you, Michael. Good to see you again as well. It is definitely something we are still considering. We are definitely having discussions of what that could look like under TEFCA. As far as having some timeline or a final decision on what that will look like in TEFCA, we have not reached that yet, but we are definitely taking comments. Again, we are always open to how TEFCA can be used definitely for our federal partners and for different use cases and exchange purposes. Thank you.

Seth Pazinski
Anna?

Anna McCollister
Thank you for the presentation and the updates. I have a couple of questions on my list, but one of which is similar to what Michael just asked. One of the issues that keeps emerging within the context of TEFCA is use of data that is not necessarily for treatment, but that is being exchanged under the treatment exchange purpose. To Michael's point, part of the cool things about the health data exchange is that we will be able to do robust, rich, and much needed analysis, secondary analysis of clinical data. There are a lot of different entities that are interested in this. Some are academic researchers, some are insurance companies, I do not know, trial lawyers, whatever. I will let the market figure out who exactly is interested in getting it. We have known from the beginning that that kind of access was going to be baked into the system, but it feels like none of the treatment exchange purposes really take that into consideration.

I feel like it is important for us to state that outright and say, “We know that people are going to want to use this data for secondary research. In many cases, we want to encourage the use of this data for secondary research, but here are some guidelines around what that looks like so that treatment exchange purposes moving forward will only truly be for treatment purposes, as opposed to treatment being twisted to mean lots of different things, ultimately, defeating secondary research.” That is one. I feel like we have talked about this before. I know I have raised this issue before in prior HITAC meetings, but I feel like it is absolutely essential if we are thinking about how to really build trust within the trusted exchange framework because the way that it is set up now, it makes some assumptions that people are not going to try to get access to this data. It encourages people to do it in ways

that maybe are not as straightforward as they should be and perhaps encourages dishonesty. That is a very broad statement.

I do not mean to disparage anybody, but people will bend the rules as much as possible to get access to the data because it is incredibly valuable. I feel like that is a really important thing that needs to be addressed by ASTP because it is happening. The question is do we want to keep the integrity of the treatment exchange purposes intact and acknowledge the fact that this data is going to be used for secondary research and create some parameters around what types of secondary research is allowed. Secondly, from the IAS perspective, I love the map around exchange. I think that is super helpful to visualize. I would love to see if you have any data, and if so, how that might be displayed or collected around IAS exchange and how much IAS exchange is happening. We keep hearing reports anecdotally. Again, the voice that I bring to the table is very much informed by my perspective as a patient, but interacting with other patients, interacting to try to use Personal Health Record (PHR), there is still lots of data that is not coming through when done under the IAS exchange.

I know that you referenced that and you referenced that you are working with the RCE on addressing some of these issues. A). I would love to have more detail on that. B). It would be really helpful to see the data around, if there is any way to collect those, and maybe there is not, but to see any data around where IAS is getting stopped. Again, I am not completely sure how this works so if there are any kinds of codes that are entered to suggest why the data is being stopped. Is it all an issue of patient matching? Is there any kind of documentation and data collection related to this that could be shared because I think just sharing that data could be helpful in creating momentum for changing?

JaWanna Henry
Anna, to answer your first question, and it made me realize as soon as you started talking, one thing that I forgot to mention that Michael was speaking to, you definitely should not just make an assumption or try to use other exchange purposes to get data for other reasons. I will say, again, we have the six exchange purposes that are authorized through TEFCA. That is why we have the SOPs so that it gives details into why that exchange purpose can be used and some specificity on how that data should be exchanged and by who. If you have been tracking, again, our work in the treatment space, I think that is why we have given much focus to treatment that it is clear on who actually can access that data and for what purposes, again, just bringing it back to thinking through the fact that, yes, this data exchange is happening. There are other people that are interested in this data for secondary purposes and uses.

You are heard and we are thinking through that at ASTP and figuring out what our next steps are for that. Then, I think for your comment on IAS, again, as we continue to advance in our implementation within the work group, I know we have been doing some work to try to figure out where those stops are and getting some type of data and making connections. We are having conversations and figuring out ways where we may be able to assess that. We will see if there is something we can share or how we can communicate that as we continue to do the work within the work streams, again, especially for IAS. We are figuring out the solutions to some of the things that need to be addressed. We are also figuring out ways and how we communicate about IAS as well. I really just appreciate your comments and thoughts on what we need to consider in those communications.

Anna McCollister
Thank you.

JaWanna Henry
You are welcome.

Seth Pazinski
Thank you. Hung?

Hung S. Luu
Thank you. Along the lines of research, I am thinking that our research infrastructure may not be adequate or has not kept up with the pace of technology because, obviously, when people do research, there is informed consent and there is Institutional Review Board (IRB) oversight. But usually that is local and that is dependent on using the data that is local to the institutions that are covered by that IRB. Now that we have the capacity to integrate data from other institutions, when we consent patients for research, I do not know how many of us really explain that not only might we use the data that is occurring in this encounter, but we could also be accessing data from their prior history that is coming over from institutions. I do not know whether or not patients will make the connection that by

signing this consent, they might be consenting for availability of all data that they have ever created in their encounters. I really think that there are issues where our existing research infrastructure may not be prepared for the capabilities we have now with technology.

Maggie Gaddis
Yes, I will go ahead and address this. Thank you for the comment/question. That is something that we are definitely considering and very aware of in our exploration of whether research could be an exchange purpose or used across the TEFCA network. Yes, we agree with your concerns, and it is something that we are examining and looking at as we are considering next steps.

Seth Pazinski
Are there any additional comments or questions from HITAC?

Michael F. Chiang
Seth, may I make one point? I know we do not have a lot of time, but I thought that Hung and Anna made really important points. To restate the obvious, I think that there is a huge amount of variability in what is happening out in the real world as far as research. A lot of research is being done retrospectively, and some is consented, but a lot is not because it is legally de-identified. I think that raises a lot of questions. 1.) What does it really mean to be de-identified in 2026? 2.) What is the role of informed consent in research if it is A). de-identified, B). not legally de-identified? Should there be some upfront step built in to address exactly what Hung is talking about? As you can imagine, we have had a lot of those conversations within NIH because our wheelhouse is research, but I think this is an issue that affects everybody and just would love to talk more and to try to chip away at solving this if that is of interest, but thank you.

Seth Pazinski
Thank you for the comment. Are there any additional comments or questions? We are going to transition to our next agenda topic, but I did see we had a few HITAC members who were able to join us and I want to give them a chance to do a quick introduction. I am going to open it up for Deven McGraw if you could just do a quick intro.

Deven McGraw
Great, thanks, Seth. Apologies that I could not make the first part of the meeting. I am Deven McGraw. I am the Chief Regulatory and Privacy Officer of Citizen Health, which helps patients, in particular patients with rare disorders, gather all their health information from all the places where they have been seen that they have it under their control and can use it and share it as they wish. I was previously the Deputy Director of the HIPAA Office at HHS and also served as the Acting Chief Privacy Officer of the organization that used to be known as ONC and is now ASTP. I am the chair of the Steering Committee for the Care Quality National Network, and I serve on the participant and sub-participant caucus for TEFCA. I am very glad that we are meeting again. I am glad to see all of you, even if It is virtually, and look forward to working together for another three years. Thank you.

Seth Pazinski
Thank you, Deven. Trudi?

Trudi Matthews
Hi, everyone. My apologies for being a little late. I am Trudi Matthews. I work for the University of Kentucky Healthcare System as the Chief of Value-Based Programs. I want to echo Deven's comments that we are delighted to be meeting again and that we are right in this meeting dealing with some weighty topics. Thank you all.

Seth Pazinski
Thank you. Then Mark Sendak? We will then transition into our next agenda topic; I will introduce Sara Armson from ASTP. She is a health IT specialist in the Terminology, Content, and Delivery Branch within the Office of Standard Certification and Analysis. She is going to give us an overview of the craft USCDI v7. Sara, I will turn it over to you.

Draft USCDI v7 Overview (02:28:53)

Sara Armson

Thank you so much, Seth. I am happy to be here today and getting to share with you draft USCDI Version 7. Next slide, please. The US Core Data for Interoperability is the standard set of data elements that serves as the baseline for data exchange in the US. Stewardship of USCDI is guided by these three core principles. This comprises the data that is needed to support patient care and facilitate patient access using health IT. It establishes a consistent baseline across use cases. USCDI expands over time via a predictable and transparent and collaborative public process. I want to take a moment to thank the HITAC members who have helped shape USCDI over the years through this collaborative process. Some of you have been supporting USCDI since Version 1 and now here we are looking at draft Version 7. Next slide, please.

The Cures Final Rule established USCDI Version 1 in 2020. USCDI now serves as the baseline set for the ONC certification program. This means that certified health IT must have the capability to exchange the USCDI data elements. At the end of this month, certified health IT will need to be compliant with USCDI Version 3.1. We are here to talk about draft USCDI Version 7. There is an interval between the final version of USCDI and the compliance deadlines in regulation. However, health IT developers can opt to update their products to newer versions of USCDI through the standard version advancement process, SVAP. Last year, USCDI Version 5 was included in SVAP. Next slide, please. Fitting USCDI into the ecosystem of interoperability. In addition to being the requirement for certified health IT, where does this fit into the picture? The data elements in USCDI inform the development of the exchange specifications, the implementation guidance, specifically for the US realm specifications, which include FHIR, US Core, and C-CDA.

You may think of USCDI as what to send. The exchange specification is the structure and how to send it. Then, the data exchange is given semantic meaning through standard terminologies. Next slide, please. In our predictable process, ASTP releases a new version of USCDI every year, starting with a draft version, just like the recently released draft Version 7 and then a final version that is published in the summer after a public feedback period. Since we last talked with HITAC, USCDI Version 6 was finalized in July of 2025. It included six new data elements. Those data elements are facility address, family health history, unique device identifier, care plan, portable medical order, and date of onset. Draft USCDI v7, that we will talk about more in depth today, includes 156 data elements. Next slide, please.

This gives you a big picture view of the yearly USCDI activities. When we released draft Version 7, we kicked off the public feedback period that will last until mid-April. The feedback that we received during this time will help shape final USCDI Version 7. Next slide, please. Today, we will get into what is new in draft Version 7. To find the full standard document and standard bulletin on USCDI, you can visit HealthIT.gov and navigate to the USCDI page. Those are both available for download there. Draft Version 7 includes two new data classes and twenty-nine proposed data elements, and one that is so significantly revised that we are including it in that total of proposed additions to get us to 30, and we will talk about those in detail. Next slide, please. We will do a high-level walkthrough of the 30 data elements and some deeper dives into a few of them. We will walk through these by broad theme, and because we cannot do deep dives into all 30 in the discussion time at the end, we can revisit any data elements that you would like.

We will start with proposed data elements supporting patient safety and adverse events. These include allergy intolerance criticality, the potential harm or seriousness of an allergy, reason not performed, or the explanation of why a care activity was not performed and then the new data class, adverse events. Next slide, please. These new safety-oriented data elements, adverse events, and adverse event outcomes support a more complete tracking of the unintended effects of clinical intervention. These may include things like medication reactions or vaccination reactions, and these data elements improve patient safety monitoring. Next slide, please. Some of our data elements supporting care coordination in patient context include appointment or a future healthcare event, healthcare agent, the person designated to make decisions on behalf of a patient who cannot make decisions, accommodation, which is the supports a person needs to access care, deceased indicator.

In addition to the existing USCDI data element, date of death, this data element indicates deceased or not, which is helpful in cases where the patient is deceased, but the date of death is unknown. Next slide, please. Some additional data elements supporting care coordination include referral order and referral note, supporting the referral workflow across use cases. This helps reduce redundant communication and improves coordination across specialties. I will note that like our other clinical note, data elements, referral note is a narrative summary, and it is exchange specification agnostic, though some of you who may have been implementing things like our clinical notes data elements have noticed that sometimes they inadvertently share names with document names in CDA because that is what we call them, but they are not necessarily tied to the CDA document names. Next slide, please.

New data elements supporting clinical care include medical device order, specimen collection method, medication administration, and two new nutrition data elements, nutrition assessment and nutrition order. Next slide, please. An additional data element that is new supporting clinical care includes diagnostic imaging reference. In this simple drawing of the complex workflow of imaging data, the image lives in the post-acute care (PAC) system, the picture archiving and communication system, which can be accessed by providers and patients. This data element is the information that is needed to access that information in the PAC system. Oftentimes, that is the end point along with the unique identifier for that particular image or imaging series concatenated together. Next slide, please. Still along the lines of clinical care, our data element of smoking status has evolved into the data element of tobacco use. This expanded definition includes the use of tobacco nicotine products, and it aligns with the FDA definition, and it still includes the smoking status data that has existed in USCDI previously.

We welcome feedback on all things USCDI, and I will get to that in the future, but we are asking for specific feedback on the evolution of this data element and how to evolve this in USCDI in a way that best suits all use cases. Next slide, please. A new data class that cuts across many domains is the new healthcare information attributes data class. This includes indication, which was moved from medications data class and performance time, which was moved from the procedures data class. This also includes two new proposed data elements, reason not performed and diagnostic report date. Next slide, please. Thirteen of our proposed new data elements already must support in US Core and, therefore, the capability to exchange these data elements is already required of certified health IT. Therefore, there would be little or minimal additional implementation burden for these data elements.

There are many must support data elements in US Core, so some background on how these 13 became the data elements included in draft v7. Either these particular data elements were being requested through USCDI public feedback to be added to USCDI, even though they were already must support there, there was still a drive to add these as requested data elements or the data element was added to align with the USCDI+ initiatives. Briefly, the USCDI+ program is the program that goes beyond USCDI for use cases that do not necessarily fit in the baseline set but could still benefit from a data set standardization. Next slide, please. In addition to the new proposed data elements and data classes, we did revise data element and data class names and definitions. We also added some applicable standards to data elements. Next slide, please. We do have an open public feedback period and that closes on April 13.

We are asking the public, and I am hoping discussion today hits on a few questions, are the data elements being exchanged today in health systems? Then, tell us more about that. Are the data elements broadly usable across health use cases and specialties? Should any data elements, new or existing, have their names revised or definitions revised? Are there any widely exchanged data elements missing from our USCDI floor? As always, our online submission system called On Deck is open and submitting data element recommendations. Comments on existing data elements can be made on the data element page. All that is accessible through HealthIT.gov navigating to the USCDI page. I will pause there, handing it to Seth and opening it for discussion.

Seth Pazinski
Thank you, Sara. Yes, we will open it up for HITAC members, comments and questions. Again, please raise your hand if you are on Zoom and if you are on the phone, just unmute yourself and let us know you have a comment or question. Go ahead, Katrina.

Katrina Miller Parrish
Hello, and thank you, Sara, again for walking through all of that and for taking my pre-question. I appreciate you addressing that. I was also wondering, can you remind me how we take Level 1 and Level 0 elements and bring them forward? Yes, thank you so much.

Sara Armson
Absolutely. For the broader audience, if you have not looked at the USCDI page recently, which not everyone looks at it every day, data elements are categorized in Levels 0, 1, or 2. Level 2 is the most technically mature data elements and the data elements that apply across use cases and domains. Those are the ones that are considered for the upcoming draft USCDI. To meet the threshold for Level 2 data elements, those are data elements that have standards for exchange of that data element. Those data elements are being exchanged in two or more production systems. Then, Level 1 data elements may have slightly less technical maturity, as we call it. The standards for exchange maybe are not as mature and are not yet being exchanged in two or more production systems, but there may be ongoing or developing of exchange of that data element at the production level so

things like pilots of exchange of that data element. Level 0 data elements are in Level 0 because they are very specific for a use case or a specialty.

They may be a mature data element, and they are exchanged between production level systems, but they do not apply to all use cases and specialties, so they are in Level 0, or they are a data element where standard exchange is still developing. The standards are not mature, and they are not being exchanged in production level systems. That is evolving so quickly, and because of that data elements move up and the feedback from the public feedback period is one of the ways that we assess the movement of data elements. If you have information about the evolving maturity of a data element, the standards and the use of production level systems, that helps us re-level a data element to the most appropriate level at that time. The other source of leveling information is the USCDI+ work is doing lots of deep dives and lots of these data elements. That also provides us with excellent feedback on the data elements.

Seth Pazinski
Thank you, Sara. Thank you, Katrina. Michael?

Michael F. Chiang
Thank you, Seth. Sara, I have a question about diagnostic imaging. I love that you are including this in Version 7. My comment is that the diagram was labeled PACs for the imaging archive. PACs is generally thought of as the radiology archive. My concern is that diagnostic images outside radiology are often stored in other domain specific image management systems. The question is does Version 7 apply only to radiology PACs or to image management systems broadly?

Sara Armson
Great question. That is why I did try and caveat that this was a very simple picture of a very complex workflow because I was trying to capture something that gave an example for the presentation. The data element is not written to be specific to the radiology workflow and with your expertise, with knowing the eye imaging workflow, your feedback on that data element and maybe to coincide with the recently released imaging RFI, and I will grab that and put that in the chat if anyone is interested giving feedback on those that give us a picture of both how we should develop this data element and then other related activities that would be very valuable.

Seth Pazinski
Thank you. Eliel?

Eliel Oliveira
Thank you, Seth and Sara. I think like I was saying earlier, I represent a health information exchange, health data utility. I just want to provide my perspective on the ground of adopting USCDI. It is great the advancements that I have seen with additional data elements over the years. I think the reality that we see is that I tried to implement Version 3 probably about two or three years ago. We are still working on it. It takes a lot of work to get all the interfaces from EHRs and different organizations to be able to get to that level. If I were to open my mouth today and say, “We are going to move to Version 5,” it will be catastrophic for the network because it remains a lot of work to make adjustments again. My point here is to say that implementation on the ground takes quite a bit of work. I kept wondering myself, “What is the reality out there? Are there others that are much more advanced than we are? What is their stage?”

I think likely where we had TEFCA discussions a bit ago in a map, it will be helpful in some way to understand what is the level of adoption of USCDI across the country by vendors, by health systems, by data networks. Since the CMS aligned networks and ecosystems in place that could be a good hook as well to understand what is the completeness of data that is flowing around because I think that many of the clinical questions or research questions are going to depend on that. Folks are not up to the standards that we have established. We just cannot address certain things. When we are thinking about AI and research capabilities that we were talking about earlier, data completeness and high quality there are very important, otherwise, we cannot do much. That completeness may come with compliance with some of the version of USCDI. Thank you for your work there very much.

Sara Armson
Thank you much for that comment. It does highlight how USCDI is one piece, a very important and dynamic piece, but just one piece of a very big picture for interoperability. USCDI data elements can drive what certified health IT has to be capable of exchanging, but having the capability of exchange and the certified health IT, like you said,

there is a lot to getting that data to then flow and is it complete and the capability is not the whole picture. Absolutely. Thanks for pointing that out.

Seth Pazinski
Thank you. Bryant?

Bryant Thomas Karras
Sara, fabulous presentation of complex set of data elements rolling out and I applaud the advancement. I am excited to see some important public health data elements advancing. I do want to raise a point to put a spotlight on that we may need to see some advancement of the vocabularies that populate some of those elements that may not be as robust as we need or as consistent as we need across the country. Immunization status, for example, or reason not performed as another are things that we may not see consistently used in electronic health record systems. I also wanted to point out that source and the gold record source of where the immunization registry data is housed, as TEFCA and the QHINs advancement have improved and we have the immunization (IZ) gateway allowing state registries to share data across state lines and to other jurisdictions, the source of truth of where that immunization record resides is going to quickly become complicated due to our own success of data exchange.

I think that there are some guidelines that are going to be needed and I hope that CDC has been alerted and brought into this situation they can appropriately resource the state immunization registries to be a part of this solution going forward. I am looking forward to that discussion and, unfortunately, we are not going to convene again before the final comments are due. I will be submitting comments in writing, of course. Thank you, Sara.

Sara Armson
Thank you much for spotlighting the applicable vocabulary standards and for adding your comments to our public feedback process. We are always pleased to get information about which applicable vocabulary standards are being used in production systems right now. That helps us know which applicable vocabulary standards to add to a data element. Yes, the timing is such that we will not convene again before April 13, but I will put a plug in for putting your comments on the data element pages because they are public, which does allow for then other people to read your comment, respond to it, give more supporting information or discuss the comments that you make on those public pages.

Seth Pazinski
Thank you. Hans?

Hans Buitendijk
Thank you. I very much appreciate the update and one slide that really stood out that is very helpful to understand the scope of what the USCDI is encompassing from 52 to now 156. By the time it is done, give or take data elements that are now in there and more expected as we progress. Comments will be certainly forthcoming from me, others, on this. There is one comment that probably is not a surprise for other HITAC members in this regard. As it is growing and we talk about certified HIT, there is quite a variety of HIT out there. I think it is a great scoping mechanism, continues to be. I would love to see more data over time in there that we have alignment on standards on that can focus on that. It makes the question bigger and bigger every year. Every year that we add more and we maintain the current certification approach of implementing USCDI more challenging, does every HIT really need to support everything? There are a number of examples that you will see in the commentary that are going to come up where not every EHR is going to have a need to support that.

Other HIT that we are interested in to be able to align with the capabilities would have to support that. if We are looking at interoperability in general, as we are with HTI-5 focusing increasingly more and then HTI-6 and otherwise on interoperability, makes a lot of sense. That is really where we need to align across the board and make sure it works. I think It is going to be important that we address the question sooner rather than later on how do we manage that so that we do not get a shrinking number of HIT that actually can be certified to this, that we can actually have a larger group of HIT that can certify to this and as a result, we have more predictable, less friction, more transparent access for the data that somebody needs to share. Hopefully, we will be able to take that step as well because we would rather not push back on shrinking the scope of your USCDI. We would rather expand the scope, get more standards, get ultimately to EHI, EPHI, where we can say, “Yes, we got standards for all the data,” but not everybody needs to do everything. That is not needed.

It is just when you do it, when you manage the data, that is when you need to adhere to the standards and share it with everybody. Again, I really understand and appreciate the role of USCDI can play there, but the numbers are pointing out that our challenge is becoming bigger by the year to get more HIT involved.

Sara Armson
Thank you, Hans.

Seth Pazinski
Thank you to the HITAC and Sara. Any additional comments or questions? We are going to move into our final agenda topic for today, which is going to be an overview of the Behavioral Health IT Initiative at HHS. That is going to be by Talisha Searcy, who is a Senior Advisor in the Interoperability Division in the Office of Policy at ASTP, and Brett Andriesen, who is the Deputy Director of the Standards Division in ASTP as well. I am going to turn it over to Talisha and Brett.

Behavioral Health Information Technology (BHIT) Initiative Updates (03:01:48)

Talisha Searcy
Wonderful. Thank you so much. Can everyone hear me okay? Thumbs up that we are good. Excellent. Next slide, please. We are excited to present to you all today with an update on our Behavioral Health IT Initiative where we have just announced on February 4, the start of our pilot project. We are excited to be entering into this next phase of the project or the initiative. The purpose of today's update is to provide a little bit of detail regarding how we got here, and then to do a little bit of a deeper dive into the pilots, what they are, what we are hoping to achieve, and, ultimately, be able to communicate who was awarded resources. Next slide. Why are we doing this? Recently, ASTP in partnership with the Substance Abuse and Mental Health Services Administration (SAMHSA) was able to obtain data through the 2024 National Survey of Substance Abuse Treatment Services, or the NSUMS, where we wanted to get a better understanding of what is the current landscape of health IT adoption and use amongst behavioral health providers.

What we found was that most behavioral health facilities reported exclusively using an EHR system at about 68%, but interoperability is lacking. Only 44% of those facilities, and it was about 21,000 facilities that responded to the inquiry, integrated external clinical data without manual entry, only 29% electronically query external data almost daily, 31% lack the capability to search and query external records and then also as it pertains to patient access, 39% allow their clients to view medical information online. This is not the technical infrastructure that exists today. It is not the only barrier that behavioral health providers have faced in terms of moving forward and advancing in interoperability. We know that through the 2009 HITAC Act, behavioral health providers were excluded from financial incentives. We also understand that there are serious workforce shortages in the behavioral health space, not just as it relates to providers, but also as it relates to staff that would have the technical knowledge to be able to help with installation and communication regarding the technology needs that the providers have.

We also know that there are reporting burdens that these providers experience, primarily because they are having to juggle different funding resources to provide treatment. Many of their clients are eligible for things like Medicaid, but they are also using grant funds like SAMHSA grants to cover treatment services. There are typically a lot of reporting requirements that they have to experience that may be a little different from other provider types. Of course, there are some policy issues that are at play and making sure that there are clarity and education around 42 CFR Part 2 in terms of how they share. This pair setting is a bit unique in terms of some of the challenges that they are experiencing with adopting and using an, ultimately, interoperable exchange of health information. Next slide. The goal of the Behavioral Health Information Technology Initiative is really threefold. SAMHSA and ASTP entered into a partnership where SAMHSA provided $20 plus million to ASTP and began in 2024 to really try to move the needle forward in terms of improving data exchange in behavioral healthcare settings. There were three work streams tied to this effort.

The first is the USCDI+ BH data elements. Sara just did a fantastic job of walking through the USCDI Version 7. The USCDI+ is an extension on the USCDI core, but it allows us to really work to identify data elements, terminologies, and standards for specific use cases and settings that have some unique needs that are different from the USCDI core. Part of this effort is to establish data content and standards for EHRs and health IT that really help to provide a bit of a floor for data elements that behavioral health providers really need, but we are doing it in a streamlined way that will help to make it a little easier when it comes to adoption. We have worked on the USCDI+, and now we are entering into the pilot space, and you will hear a little bit more.

The goal is to really pilot those standards, pilot the USCDI+ that is a part of the USCDI+ so that we will be able to, again, really move the needle forward and identify what are some of those challenges and barriers to implementation, and then, ultimately, use that information for our behavioral health informational resources, which is the third phase where we are trying to compile all of the lessons learned from the USCDI+ data elements and the deliberations that happen to develop those elements to what we learned through the pilots and how we may be able to, ultimately, put together resource guides that can help behavioral health providers to adopt health IT in a way that works better for them, but it is more efficient and a little easier for them at the start. Next slide. As I mentioned, we have been working on this project since 2024. It began with the first draft of the USCDI+ and was open for feedback and received hundreds of comments on the initial version.

We have also gotten to the point where we have developed a FHIR IG, which began in June. We have done some recent updates to that IG. We have also done some sandbox testing of the USCDI+ BH through the HL7Connectathon. We have done two Connectathons to really help us with trying to understand how the USCDI+ BH will work from a technical perspective. Now, we are at the phase where we are instituting the real-world pilots as a way to really just continue to move forward with iterating on the USCDI+ BH but also see how our IG is working and to really, again, build information for future users and future adopters of the USCDI+ BH. Our hope is that the pilots will end by the end of the year, 2026. Then, our informational resources will be completed in 2027. I am going to turn things over to Brett Andriesen, who will walk through the pilots in a little bit more detail and share more information about who we, ultimately, selected for inclusion in the pilots. Brett?

Brett Andriesen
Thank you, Talisha. Hi, everyone. I am Brett Andriesen. Going into more detail on the pilots, we really structured these around giving sites, as they were putting their applications and proposals together, a structured set of required attributes and optional ones that they could propose to enhance their applications. As part of those, each pilot is going to be conducting real-world testing of USCDI+ behavioral health data elements, as well as the associated FHIR Behavioral Health Implementation Guide. This will include live implementation across behavioral health providers, HIEs, state agencies, vendors, community-based organizations, not just simulated exchange, most importantly. That implementation must occur within clinical and operational workflows. That could be intake, care coordination, referrals, reporting, consent so we really understand how the standards function in practice, and that includes the environment subject to 42 CFR Part 2.

Pilots are also required as part of their work to identify and document their behavioral health information exchange priorities, current exchange capabilities, workflow, privacy, consent, and confidentiality constraints that they are experiencing, as well as any technical, operational, or policy barriers to adoption and implementation of USCDI+ behavioral health data set. These findings will really directly inform the refinement of the USCDI+ data set, updates to the FHIR Implementation Guide, and further development of the behavioral health information resource. Another important aspect, pilots must demonstrate meaningful behavioral health impact. That could be improved coordination, reduced fragmentation, strengthened reporting, or enhanced patient access. Again, seeing real world impacts there, not just interoperability exercises and isolation.

In addition to the required elements, applicants can propose community-specific priorities that would work best in their areas, such as advanced or granular consent management, integration of quality measurement or value-based programs, reporting to state or federal agencies, looking at leveraging HIE infrastructure for bigger scalability, patient access, cross-sector exchange, other innovative approaches, including potentially looking at AI workflows. Then, with the help from our contractors, we did evaluation based on the combined strength, feasibility, and potential impact of both the required proposed elements and the selected pilots that we will go into in just a moment, represent the highest scoring proposals across all those aspects. Bringing us to the next slide, we have nine selected pilots. As you can see on the map, we were pretty pleased with the level of geographic diversity and the varying levels of interoperability maturity and implementation models here across the different states.

Just to briefly go into them, we have Delaware, which will be testing statewide behavioral health information exchange to improve referral and care coordination across substance use and mental health providers. In Florida, they are establishing a multi-organization behavioral health exchange framework, really leveraging that behavioral health USCDI+ data set to improve cross-provider coordination. In Colorado, they are expanding behavioral health data exchange infrastructure by looking at standardizing behavioral health data elements across the state. In North Carolina, they are doing some modernization work for reporting aligned with USCDI+ behavioral health data set across managed care and provider systems. In Oregon, they are looking at using the USCDI+ data set and integrating that into person-centered care planning workflows to support longitudinal coordination. In Rhode Island,

they are working with Certified Community Behavioral Health Clinics (CCBHCs) quality measurement and reporting using standardized data elements.

In Massachusetts, they are connecting substance use disorder treatment across providers and public health systems. In DC, they are enhancing Medicaid and community behavioral health data exchange, supporting integrated physical and behavioral healthcare. Then in Connecticut, they are developing scalable consent management solutions within the state HIE aligned with 42 CFR Part 2 requirements. Collectively here, these nine pilot sites represent forty-five or more exchange partners across all of them and a wide range of implementation environments. The goal of that was really to increase likelihood that the lessons we learned here are scalable and generalizable as we bring lessons learned into the behavioral health information resource. I think that brings us to the next slide, which really just closes us out and brings us here for questions. Our pilots are really just getting going and we will continue, as Talisha mentioned, through the end of 2026. We will use those lessons to inform the enhancements and refinements to the behavioral health dataset on the USCDI+, the implementation guide, as well as the information resource.

There is a link here on the slide at the very bottom where there are some additional details about each of the pilot sites and we will likely have more information on the way as more details become available. Now, we can take any questions folks have.

Seth Pazinski
Thank you, Talisha. Thank you, Brett. We will open it up to the HITAC members. If you could please, again, raise your hand if you are on the Zoom or just unmute yourself if you are on the phone and let us know you have a question or comment. Go ahead, Eliel.

Eliel Oliveira
Thank you, Seth and thank you both for the great presentation. It is great to see updates on this front on behavioral health and I could not help to notice as well earlier that Netsmart had become a QHIN, and I know JaWanna may not be on the call anymore, but that to me raised the question of how a QHIN behavioral health data provider can effectively do that within the confines of TEFCA. I am asking that because as a data network as well, it has been quite difficult to implement Part 2 data sharing for many use cases. I think we feel like this year, we are going to be able to achieve that and be able to control that based on consent and provider that have rights to access. I think on the wave of deregulation, I think that is a point to consider that for the administration and validating the true need for to Part 2 requirements because it creates quite a challenge for data access and support for individuals. We have quite a bit of coordination that goes on between our behavioral health providers and the court and jail systems that are managing individuals that have lots of behavioral challenges.

It is quite a lift of work that we have to handle in the community. On that note, we have the incarceration data aspects that follow under a completely different jurisdiction. There is a need there for making advancements. I think we are going to be working on that here at least in Travis County in Austin to be able to solve that and implement. Based on the collaborations that I have had with colleagues on this front, there is a very minimal set of examples nationally of that level of interaction between the judicial system and behavioral health systems. There is probably an opportunity there to advance that work and build some standards. In summary, I am making some comments, but some questions as well that you might not be able to answer related to TEFCA in Part 2 management at scale because it is challenging from a data sharing perspective.

Talisha Searcy
Yes, I can speak to that and I totally agree. I know that from the SAMHSA perspective, the intersection between service provision because they provide funding for entities that are providing substance use treatment, mental health services in correctional facilities and so, trying to make sure that we are able to think through all of the, dare I say, full spectrum of the care continuum as we are talking about behavioral health, which involves different entities like correctional facilities, schools, other entities that go beyond the behavioral health and the primary healthcare settings. It is going to be important. I think that what we are trying to do with this project to start is to start to really try to think through what are some places where there are clear data needs from the behavioral health perspective that aligns with SAMHSA's goals that we think as ASTP we might be able to move the needle forward in terms of terminology and standardization. I will be the first to say that our initial list was very long. My expectation is that as we continue to move forward with iterating on the USCDI+ BH, there is going to be subsets of data needs that we are going to have to work on beyond this particular project's end, but the goal is to give us a bit of a foot in the door. I will say in terms of 42 CFR Part 2, we are not planning in any way, from a policy perspective right now, to modify that.

What we are hoping for through this project is that we can help with provider education, that we can look through what some of the technical solutions could be to make the execution of what exists in the regulatory space today easier. I think that those are some of the things that we are trying to do now as a way to, again, just continue to press to move the needle forward to address some of these well-known challenges. Unfortunately, we did not necessarily have the resources to be able to really provide some scalable solutions for folks. I think that is what we are trying to do here.

Eliel Oliveira
Thank you so much.

Brett Andriesen
Yes, and just to add on the Part 2 piece, finding where there might be some of that friction that exists for providers and their exchange partners and seeing what additional guidance, whether it is implementation guidance or policy guidance that we can bring forward through the informational resource or pass on to SAMHSA can be helpful, too, really seeing this as a way to start to dig into those issues or dig into them further. I know we have heard about it for four years now.

Eliel Oliveira
Yes, thank you both. It is deregulation on something so sensitive would be very difficult, but I think the two paths would be that or actually addressing the data challenges. I think that is what you are saying, Talisha, with the pilots and the projects, which is great. I see John Fitzpatrick's note on the chat that really highlights the challenge here. Not every behavioral health, mental health challenge is the same. Some of them for mothers, it is quite critical that data gets shared that we can support, but sometimes we just feel that is locked up. In other cases, maybe not so much. That should be between critical mental health providers and the incarceration systems and whatnot because of the types of challenges that certain individuals have. That year's approach and pilots of different use cases really are going to help us advance things. I am glad to hear all that because this space has been very difficult from a data exchange perspective to handle in the past. Thank you so much.

Talisha Searcy
Yes, sure. You will see in the master list of the USCDI+ BH where we try to push the needle. There are some data elements that were proposed that may not necessarily see the light of day but are really critical. For example, number of children under the age of 18 that were removed from client's care by court order. Those are the types of data that are really important for SAMHSA, again, that nexus between the criminal justice system and the behavioral health system and trying to make sure that we are keeping those points in mind. Then John's question around how does it relate to maternal health overlaps quite a bit, quite frankly. We do include as part of the USCDI+ BH pregnancy status, postpartum depression. We have been working with the USCDI+ maternal health data element folks to try to make sure that there is a clean connection between that USCDI+ project and what we are trying to iterate on as part of the behavioral health space because the target population for a lot of these programs that are critically important to SAMHSA are pregnant and postpartum women.

That was something that we set out at the start to really try to keep that in mind as we were iterating with SAMHSA on the starting point for the USCDI+ BH.

Eliel Oliveira
Yes, if I add to that, early psychosis would be another one that comes to mind. We need a lot of progress to help kids that are transitioning from being a kid to adulthood, but in that 16 to 18 years old that have a lot of challenges taking place at the same times that they do not have clear guidance, regulatory because they do not fall in being an adult or a kid anymore. That is another area of focus that I will completely highlight being important to address.

Thank you much for the work you are doing on this one. I am very excited to see this advancing.

Talisha Searcy
Great, thank you.

Public Comment (03:25:19)

Seth Pazinski

Do we have any other comments or questions from the HITAC? Thank you so much, Talisha and Brett. Thank you to the HITAC members for your feedback. We are going to pivot into public comment now. Our meeting today was really mostly focused on ASTP program updates. The aim was really to provide an overview of some of the significant ASTP efforts over the recent months and certainly looking forward to our HITAC meeting on May 7. The presentations today were just a current look at a number of areas that are underway and hopefully can inform the HITAC and your upcoming deliberations, including through the Annual Report Workgroup. A few things now between today and our next meeting in May, just the reminders to the HITAC members, if you are interested in serving as a HITAC co-chair, if you could please let us know, we would welcome that feedback. Separately, if you are interested in serving as an Annual Report Workgroup co-chair, there is opportunity there as well so please let us know.

We do anticipate that the Annual Report Workgroup is going to kick off next month in March with two times per month meetings. We are going to open it up to public comment. If you are on the Zoom and you would like to make a comment, please use the hand raise function, which is located in the Zoom toolbar at the bottom of your screen. If you are on the phone only, you can press star nine to raise your hand and then once called upon, you can press star six to mute and unmute your line. As we wait for the hands to raise, again, just a reminder, our next meeting is going to be on May 7 of the HITAC from 10:00 a.m. to 3:00 p.m. Eastern Time with the opportunity to meet in person for folks who can come to the DC area. A reminder that all the meeting materials from today's HITAC meeting can be found on HealthIT.gov. Checking, it looks like we have Mark Savage, if you can go ahead and make your public comment.

Mark Savage
Thank you, can you hear me well?

Seth Pazinski
Yes, we can hear you.

Mark Savage
Great. I had asked in the chat during the opening discussion if someone could please let us know why HITAC's Interoperability Standards Workgroup is now listed on the website as an active and I appreciate Rochelle's lifting up that question and appreciate your response, Seth, that work in 2026 is focusing on statutory requirements, but that the Interoperability Standards Workgroup will resume activity next year with USCDI v8. It sounds to me like the decisions and priorities have already been set, but because I think the expertise and work of the work group has been helpful and important to HITAC and ASTP, I will just add that USCDI is likewise grounded in statutory requirements. As ONC originally explained back, I believe, it was 2020, USCDI implements the Cures Act's requirement in Section 4002 that interoperability provides access to all data elements of a patient's electronic health record by APIs or successor standards and certification criteria. It is not going to happen this year. It will be especially important for, even to the statutory standards, it to happen next year. Thanks so much.

Seth Pazinski
Thank you, Mark. I do not see any additional public comments in the Zoom chat. Do we have anyone on the line?

Operator
No additional comments.

Final Remarks and Adjourn (03:29:28)

Seth Pazinski
Thank you. We did receive one written public comment. I will read that off now for HITAC members' awareness and for inclusion in the public record. We will also include this in the meeting minutes as well, along with the other public comments made today. This comment is from Rohan Sharma, who is the CEO of Zenolabs.AI. His comment was, “Validation standards for AI and health IT as the FDA and ASTP continue evaluating interoperability standards, the integration of generative AI into EHR systems introduces validation challenges that extend beyond 21 CFR Part 11 controls. In particular, the concept of validation for non-deterministic AI models requires further clarification to support auditable deployment and clinical workflows. Recommendation: HITAC should prioritize defining specific validation standards for non-deterministic AI models in health data exchanges.

We will conclude our public comments and move to adjourn today's meeting. I want to thank everyone for your time and expertise shared on the call today. I look forward to the May meeting and look forward to hearing from folks on interest in both the Annual Report Workgroup and HITAC co-chair opportunities in getting the Annual Report Workgroup going next month. We will adjourn today's meeting. Thank you, everyone.

Questions and Comments Received Via Zoom Webinar Chat

Gail Keenan: cant hear this board member

Randa Perkins: I can hear her.

Gail Keenan: volume very low

Michael Chiang: My apologies for needing to drop off for 90 mins.

Maggie Zeng: TEFCA: https://healthit.gov/policy/tefca/

Maggie Zeng: HTI-5 Proposed Rule: https://healthit.gov/regulations/hti-rules/hti-5-proposed-rule/

Hannah K. Galvin: ASTP, could you please speak to the decision to move from monthly to quarterly meetings this year?

Mark Savage: I may have missed this, but could someone please let us know why HITAC's Interoperability Standards Workgroup is now listed on the website as "inactive"? Was this perhaps an accident? With the recent release of draft USCDI v 7, there is great benefit to HITAC and ASTP in getting the Workgroup's review and expertise, and the important recommendations that the Workgroup's review and discussion have historically produced for every draft. Thank you.

Ben Rosen: I agree with Eliel, but I would say we broaden out that question to all exchange networks that ASTP has stake in. I know that is something that was a topic last week at the ASTP meetings as well.

Kendra Wyatt: Understood on 2026 ASTP priority to focus on ASTP specific statutory legislation and appropriations (eg, data blocking, Behavioral Health). Let's acknowledge previous and concurrent statutory requirements. A high value use case is enforcing information blocking between EHR vendors affecting maternity care between FQHCs and Hospitals covered by CMS Conditions of OB Services, VA,Tricare, & IHS Interoperability to private providers. CMS/CMMI/TMAH APM models depend on data liquidity and CMS Rural Health Transformation funding is pouring into AI/EHR/Interoperability/Pop Health for maternal health right now. Eg, real time AI enabled risk assessment, reflexive rural Lev 1 to Lev 2 US Readings, telemedicine, etc. Or, do you need Congress and HELP committee to pass maternal HIT appropriations to facilitate this critical maternal health work. If I had to pick one thing, start with ASTP enforcing basic data blocking to support the rural perinatal transformation work. Thank you.

John Fitzpatrick, KC Digital Drive: Leveraging the prospect of alignment in information blocking for RHTP and TMaH provides one of the most compelling use cases.

John Fitzpatrick, KC Digital Drive: Following from the earlier maternal health comment, (also noting highest mortality in developed world, foundational for youth health in MAHA) behavioral health challenges are the greatest single contributor to postpartum mortality. Where does this show up in BHIT? Is it implicit in some of the pilots?

John Fitzpatrick, KC Digital Drive: Thanks!

Rochelle Prosser: If we want to find out about these and other USCDI + programs, who do we contact?

Questions and Comments Received Via Email

This comment is from Rohan Sharma, who is the CEO of Zenolabs.AI. His comment was, “Validation standards for AI and health IT as the FDA and ASTP continue evaluating interoperability standards, the integration of generative AI into EHR systems introduces validation challenges that extend beyond 21 CFR Part 11 controls. In particular, the concept of validation for non-deterministic AI models requires further clarification to support auditable deployment and clinical workflows. Recommendation: HITAC should prioritize defining specific validation standards for non-deterministic AI models in health data exchanges.

Resources

HITAC Webpage
HITAC - February 19, 2026, Meeting Webpage

Transcript approved by Tara Porter, HITAC DFO, on 3/31/26.