

Health Information Technology Advisory Committee (HITAC)

VIRTUAL

Meeting Notes | October 13, 2022, 10 – 11:45 AM ET

EXECUTIVE SUMMARY

Steve Posnack, Deputy National Coordinator for Health IT, ONC, welcomed everyone to the October 13, 2022, virtual meeting of the HITAC and provided an overview of ONC's recent program updates. The co-chairs of the HITAC, **Denise Webb** and **Aaron Miri**, welcomed members, reviewed the meeting agenda, and presented the minutes from the September 14, 2022, HITAC meeting, which were approved by voice vote. On behalf of The Sequoia Project, the Recognized Coordinating Entity (RCE) for ONC, **Mariann Yeager**, **Zoe Barber**, and **David Pyke** presented an update on the Trusted Exchange Framework and Common Agreement (TEFCA). **Arien Malec** presented an update on behalf of the Public Health Data Systems Task Force (PHDS TF 2022). HITAC members held discussion sessions following the presentations. No public comments were submitted by phone during the meeting. There was a robust discussion in the public meeting chat via Zoom.

AGENDA

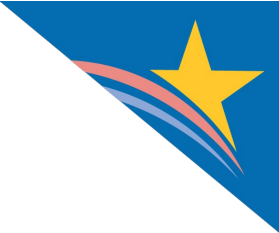
10:00 AM	Call to Order/Roll Call
10:05 AM	Welcome Remarks
10:20 AM	Opening Remarks, Review of Agenda, and Approval of September 14, 2022, Meeting Minutes
10:25 AM	TEFCA Update
11:15 AM	Public Health Data Systems Task Force 2022 Update
11:30 AM	Public Comment
11:45 AM	Final Remarks and Adjourn

CALL TO ORDER/ROLL CALL

Mike Berry, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the September 14, 2022, meeting to order at 10:01 AM.

ROLL CALL

Aaron Miri, Baptist Health, Co-Chair
Denise Webb, Individual, Co-Chair
Hans Buitendijk, Oracle Cerner
Steven (Ike) Eichner, Texas Department of State Health Services
Cynthia A. Fisher, PatientRightsAdvocate.org
Lisa Frey, St. Elizabeth Healthcare
Rajesh Godavarthi, MCG Health, part of the Hearst Health network



Steven Hester, Norton Healthcare
Jim Jirjis, HCA Healthcare
John Kansky, Indiana Health Information Exchange
Kensaku Kawamoto, University of Utah Health
Steven Lane, Health Gorilla
Hung S. Luu, Children's Health
Arien Malec, Change Healthcare
Clem McDonald, National Library of Medicine
Aaron Neinstein, UCSF Health
Eliel Oliveira, Dell Medical School, University of Texas at Austin
Brett Oliver, Baptist Health
Raj Ratwani, MedStar Health
Alexis Snyder, Individual
Fillipe Southerland, Yardi Systems, Inc.
Sheryl Turney, Caredon Digital Platforms (an Elevance Health company)

HITAC MEMBERS NOT IN ATTENDANCE

Medell Briggs-Malonson, UCLA Health
Valerie Grey, State University of New York
Leslie Lenert, Medical University of South Carolina
James Pantelas, Individual
Abby Sears, OCHIN

FEDERAL REPRESENTATIVES

Thomas Cantilina, Military Health System, Department of Defense (DoD) (*Absent*)
Sanjeev Tandon, Centers for Disease Control and Prevention (CDC) (*attending on behalf of Adi V. Gundlapalli*)
Aloka Chakravarty, Food and Drug Administration (FDA) (*attending on behalf of Ram Iyer*)
Meredith Josephs, Federal Electronic Health Record Modernization (FEHRM) Office (*Absent*)
Meg Marshall, Department of Veterans Affairs (*attending on behalf of Jonathan Nebeker*)
Michelle Schreiber, Centers for Medicare and Medicaid Services
Ram Sriram, National Institute of Standards and Technology (*Absent*)

ONC STAFF

Steve Posnack, Deputy National Coordinator for Health IT
Elise Sweeney Anthony, Executive Director, Office of Policy
Mike Berry, Designated Federal Officer

WELCOME REMARKS

Steve Posnack, Deputy National Coordinator for Health IT, welcomed everyone, thanked the presenters and task forces and workgroup for their hard work, and provided an overview of ONC's recent program updates, including:

- [2022 ONC Virtual Tech Forum](#): ONC held its Tech Forum, which featured industry perspectives on the progress made in health IT over the past year and highlighted ways to advance health technology to improve patient care, health equity, data exchange, and interoperability. The sessions occurred on September 9, 16, and 23. The Tech Forum highlighted improvements in digital health and healthcare, and



the sessions can be found on-demand on the website at <https://www.healthit.gov/news/events/2022-onc-virtual-tech-forum>.

- Applicability Date for Information Blocking: The Applicability Date for Information Blocking has been in place since April 5, 2021, but per the ONC Information Blocking Rule (45 CFR Part 171), healthcare providers must now share all electronic health information (EHI) as defined in 45 CFR 171.102 as of October 6, 2022.
 - ONC is prepared to support everyone through the change and has shared several resources on its Buzz Blog:
 - [Information Blocking: Eight Regulatory Reminders for October 6th](#) – Steve Posnack, published on September 30, 2022
 - [Top Three Themes from ONC's Electronic Health Information Sharing Workshop](#) – Amanda Woodhead, published on October 5, 2022
 - [ONC's Virtual Office Hours](#): Participants can ask questions about information sharing under ONC's information blocking regulations by joining ONC's experts for virtual office hours on October 27, 2022, from 2:00 – 3:00 pm ET.
- End of the Fiscal Year: Federal agencies end their fiscal year on September 30, so several new initiatives have been announced.
 - [Leading Edge Acceleration Projects \(LEAP\) Awardees](#): Funding opportunities have been awarded to AllianceChicago and MedStar Health Research Institute to address well-documented and fast emerging challenges that inhibit the development, use, and/or advancement of well-designed, interoperable health IT to further a new generation of health IT development and inform the innovative implementation and refinement of standards, methods, and techniques for overcoming major barriers and challenges as they are identified.
- [Food and Drug Administration \(FDA\) Webinar](#): The FDA will hold its webinar on Clinical Decision Support Software Final Guidance on October 17, 2022, from 1 – 2:25 PM.
- [ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements to Support Information Sharing Rule](#): The Notice of Proposed Rulemaking (NPRM) was accepted by the Office of Management and Budget (OMB) for review on September 1, 2022. Once it is released to the public, ONC will ask the HITAC to convene a task force to review portions of the NPRM and provide recommendations during the public comment period. The Unified Agenda has a release date anticipated for October 2022, but this date is subject to change.
 - HITAC members who are interested in serving on the task force should contact **Mike Berry**.
- Search for New HITAC Co-Chair: **Denise Webb's** term on the HITAC expires at the end of the calendar year, so ONC will begin to search for a new co-chair to serve alongside **Aaron Miri**.
 - The member selected as co-chair will serve in this role for the remainder of their appointment, not to exceed three years.
 - Interested HITAC members were invited to submit their name to **Mike Berry**. ONC will handle the process of selecting a co-chair from the submissions.

OPENING REMARKS, REVIEW OF AGENDA, AND APPROVAL OF SEPTEMBER 14, 2022, MEETING MINUTES

Aaron Miri and **Denise Webb**, HITAC co-chairs, welcomed all members and presenters. **Denise** thanked everyone for supporting her in her role as co-chair and expressed her honor. **Aaron** thanked the team from ONC for the excellent updates and expressed his appreciation to **Denise**. He also thanked the vendor community for their recent efforts to comply with the Information Blocking Provisions and shared a brief update from the Annual Report Workgroup (AR WG), which is currently developing a draft crosswalk of topics.



The AR WG will present the crosswalk and recommended activities to the HITAC at the November meeting. HITAC members were encouraged to share suggestions for the Annual Report with the AR WG.

Denise reviewed the agenda for the meeting and invited members to examine the minutes from the September 14, 2022, meeting of the HITAC. **Denise** called for a motion to approve the minutes. The motion was made by **Sheryl Turney** and was seconded by **Arien Malec**.

The HITAC approved the September 14, 2022, meeting minutes by voice vote. No members opposed or abstained.

TEFCA Update

Mariann Yeager, CEO, The Sequoia Project, ONC's Recognized Coordinating Entity (RCE) Lead, **Zoe Barber**, Director, Policy, The Sequoia Project, and **David Pyke**, Senior Technical Project Manager and Standards Architect, Audacious Inquiry presented an update on the Trusted Exchange Framework and Common Agreement (TEFCA).

Mariann introduced herself and the other presenters and explained that ONC selected The Sequoia Project as the RCE that supports the implementation and development of the TEFCA. She described how the exchange will work under TEFCA and the roles of Qualified Health Information Networks (QHINs). This was illustrated in the [TEFCA presentation slides](#). She identified the TEFCA components and shared the timeline the RCE has used to operationalize TEFCA between 2021 and 2023.

Zoe Barber explained the process for submitting applications through The Sequoia Project's website and announced that they have already received nine letters of intent from organizations who intend to apply for QHIN status through the RCE's secure portal. She described the nuances of the application, review, onboarding, and designation processes for applicants. She noted that approval does not mean that an applicant will be designated as a QHIN but does allow the applicant to begin onboarding and preproduction testing. In addition to weekly meetings with those that have submitted their letter of intent, the RCE has held regular office hours.

Zoe provided an overview of the RCE's Standard Operating Procedure (SOP) status and release schedule. She described their recently released SOPs and resources, which were detailed in the presentation slides.

David Pyke discussed the draft TEFCA Facilitated Fast Healthcare Interoperability Resources (FHIR) Implementation Guide (IG), which was released on October 7, 2022. He encouraged attendees to submit comments during the public feedback period. He described the TEFCA Facilitated FHIR IG and Pilot, highlighting processes and requirements, which were listed in the presentation slides. **Mariann** described the objective and approaches for the 2022 Pilot.

Zoe presented the payment and health care operations future use cases. She shared the charge, deliverable (Draft Payment & Health Care Operations Exchange Purpose Implementation SOP, version 1), approaches, and priorities for use case selection, which were detailed in the presentation slides. She described their guiding principles and balance points. The RCE decided to begin with the version 1 sub use case and then work to identify commonalities that could apply to various other use cases, with the goal of expanding the scope of the SOP over time. She described how stakeholders were involved in the process and how the RCE gathered nuanced feedback on stakeholder business and compliance needs, noting that they are working towards finding balance between the viewpoints. She explained that this feedback led them to focus on the use case of risk management, including activities related to both payment and healthcare operations as defined in the Common Agreement. She described the use case and the scope of definition the RCE created for it, which was defined in the presentation slides. The RCE created the SOP outline, including the use case definition, the query request, and query response.



Mariann explained that the TEFCA has brought an opportunity in relation to new and expanded use cases. She described the actors and exchange modalities (push and query) the Centers for Disease Control and Prevention highlighted for an initial Public Health use case. The RCE has reviewed several potential viable sub use cases that could be brought to the market, and she explained the feedback shared by stakeholders and the RCE's approach, which was laid out in the presentation. She directed meeting attendees to several resources. They are available on the RCE's website at <https://rce.sequoiaproject.org/tefca-and-rce-resources> and <https://www.healthit.gov/tefca>.

Discussion:

- **Arien Malec** noted his support for the RCE's cautious approach and phased roll-out, and he discussed his colleague's recent Twitter comments around patient access and policy exemptions (including **Micky Tripathi's** response). He commented on the disconnect between the Cures Act mandate to share data for all permitted purposes and the broad scale TEFCA roll-out and discussed ways to speed up the process. He discussed the net cost to the US healthcare system, the US system's cautiousness, and needs related the payer focused portions of risk management for hierarchical condition category (HCC) coding (e.g., patients easy access to records). He asked if they are making progress with the Office for Civil Rights (OCR) on policy rails for incidental disclosure of personally identifiable information (PII) pursuant to covered entities mistakenly access data through an identify mismatch. He highlighted issues around the lack of a guardrail for patients inadvertently getting access due to a patient mismatch issue and the need for related policy solutions.
 - **Mariann** responded that incremental approaches are the best way to accelerate progress, noting challenges related to tackling payment and healthcare operations. She stated that picking an area that has a high value and return on investment will accelerate future opportunities; an initial roll-out is the best way to begin getting adoption. She discussed the example of Carequality and suggested that TEFCA will be an accelerant, due to the government-endorsed approach, guardrails from ONC, and vetting of policy by stakeholder partners. Also, she suggested that TEFCA will be an accelerant due to its backing by government partners. She confirmed that Arien's comments were their top concern and that covered entities are concerned that they will run afoul of HIPAA if the wrong records are returned to the wrong patient due to challenges around patient matching; however, she could not confirm whether TEFCA could fix this issue.
 - **Arien** suggested that the ONC team partner with colleagues at OCR to create an approach to solve the individual access issue (due to the way HIPAA is currently written).
- **Steven Eichner** shared several comments, including:
 - He discussed the need for accountability back to the patient around the disclosures that have occurred related to their records and emphasized the importance of a patient-centered approach.
 - He suggested that public health should be included in all discussions, as it plays a number of roles (e.g., as a care provider). He noted that public health is involved as a participant in healthcare delivery, though it occupies a different role.
 - Due to its jurisdictional focus, public health services and exchanges occur within specific domains. He noted that public health is concerned about the entirety of the community and not solely in providers participating in HIEs. Data must be collected from all providers in the community.
- **Denise Webb** shared several questions, including:
 - How transparent and public will the process be around the QHINs? Are the letters of intent publicly available, and at what point in the process will QHINs start enrolling participants?
 - **Mariann** responded that the RCE published a set of communications protocols around the information that may be divulged. They are not sharing the letters of intent; the RCE is being



sensitive around communications during the process because they do not want to create miscommunications. Applicants may not disclose their status or progress until they have been approved, but the RCE will announce designated QHINs once the process is complete. Once a QHIN is approved, it may sign up Participants; some are already recruiting Participants in their current network to opt in to TEFCA.

- **Denise** asked if the technical implementation is constrained to the United States Core Data for Interoperability initially or if it will permit more, going toward the definition of electronic health information EHI.
- **Zoe** responded that the information is not constrained to the USCDI; rather, there is a definition for required information, which overlaps with the definition for EHI in the Information Blocking Rule but is not constrained by the designated record set (DRS). They are developing SOPs that may narrow down the floor for what information is relevant to the exchange purpose.
- **Aaron** highlighted comments from the chat that were similar to **Denise's** question. The co-chairs thanked the presenters for their participation.

PUBLIC HEALTH DATA SYSTEMS TASK FORCE 2022

Arien Malec, co-chair of the [Public Health Data Systems Task Force 2022 \(PHDS TF 2022\)](#) presented an [update on the TF's recent activities](#). **Arien** noted that **Gillian Haney**, PHDS TF 2022 co-chair, was not able to attend the HITAC meeting.

Arien explained that the PHDS TF 2022 is a collaborative effort between ONC and the Centers for Disease Control and Prevention (CDC) and shared the overarching specific charges of the TF, which included:

Overarching Charge:

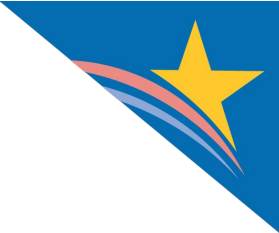
The Public Health Data Systems Task Force 2022 will build upon recommendations from previous HITAC public health-focused task forces to inform ONC's continued collaborative work with CDC on improving public health data systems, and in support of CDC's greater Data Modernization Initiative (DMI) efforts.

Specific Charge:

The Public Health Data Systems Task Force 2022 shall examine existing public health certification criterion, known as the "(f) criteria" in the ONC Health IT Certification Program, certifying the transmission of data to public health agencies to:

- 1) Identify gaps in the functionalities and standards included in existing (f) criteria, including gaps in 1) functionality, and 2) implementation by developers. Provide recommendations advancing criteria, testing guidance, and/or standards to address gaps.
- 2) Assess the specific functions (e.g., receipt of data, ingestion of data, analysis of data) supported by public health data systems that would benefit from further standardization and potential certification.
- 3) Recommend which data flows, aligned with existing (f) criteria, should be prioritized for standardized receipt of data.

Arien reviewed the PHDS TF 2022 roster and thanked all members, who represent stakeholders from across the ecosystem, for their participation. He reviewed the timeline of the PHDS TF 2022 and explained that the TF will present its recommendations to the HITAC for a vote at the November 10, 2022, HITAC meeting. He discussed the TF's approach to reviewing the (f) Criteria, determining key questions, and inviting subject matter experts (SMEs) from the industry to present to the TF. A summary of the SME presentations was included in the TF's presentation slide deck, and **Arien** described future presentations that the TF has yet to



receive. He discussed the current status of the TF's efforts and shared a list of their upcoming meetings.

PHDS TF 2022 meeting information, including materials and summaries, will be posted at <https://www.healthit.gov/hitac/committees/public-health-data-systems-task-force-2022>.

Aaron invited HITAC members to share questions and comments.

Discussion:

- **Clem McDonald** asked for more information on the query request for asking/sending.
 - **Arien** responded that there is a push-based trigger specification for electronic initial case reporting (eICR), and it allows for the reporting of case reports to public health. It is in between the pilot and national roll-out stages. He added that it is likely that the TF will recommend that ONC prioritize the public health TEFCA query-based use case. He explained that the TF has discussed the possibility of public health receiving trigger-based pushes of data from care settings that are augmented with electronic results. However, there may be situations during public health case investigations when it will be useful to open up TEFCA-based queries for public health, and he shared several specific examples. This capability is in pre-pilot testing, and he noted that the TF would likely make related recommendations to ONC at a future HITAC meeting.
 - **Clem** asked if the TF would include FHIR. **Arien** responded that it would be beneficial and shared examples where public health authorities have already deemed information necessary for case investigation. Also, in the context of information collection (e.g., from cancer registries) or case investigations, a more specific approach would be more useful.
- **Denise** thanked **Arien** for the presentation.

PUBLIC COMMENT

Mike Berry opened the meeting for public comments:

QUESTIONS AND COMMENTS RECEIVED VERBALLY

There were no public comments received verbally.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT

Mike Berry (ONC): Welcome to the October HITAC meeting! We will be starting soon. Please remember to tag "Everyone" when chatting in Zoom.

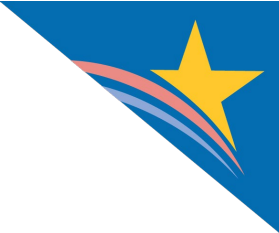
Mike Berry (ONC): Meeting materials can be found here: <https://www.healthit.gov/hitac/events/health-it-advisory-committee-50>

Alexis Snyder: Alexis Snyder is here, I was skipped on roll call

Susan Clark: FDA webinar Steve mentioned <https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-clinical-decision-support-software-final-guidance-10182022>

Steven Lane: The RCE has been doing an amazing job with their public webinars and other communications. Thanks you Mariann, Zoe, and team!

Steven Lane: Very exciting to see USCDI V2 incorporated into this initial implementation.



Deven McGraw: Is TEFCA more of an "all EHI capable of being exchanged" or is it constrained by the USCDI framework?

Aaron Miri: Any chance at a TEFCA test use case related to public health / pandemic response?

Ryan Harrison: @Aaron Clarification. TEFCA use case under the Public Health SOP or under Facilitated FHIR?

Aaron Miri: PH SOP

Jim Jirjis: Jim Jirjis joined

Steven Lane: @Deven - This would seem to suggest that the scope of TEFCA exchange should NOT be limited to USCDI, which makes sense.

Deven McGraw: Thanks, Steve - that was my assumption as well.

Steven Lane: Identifying and managing clinical risk clearly goes beyond HCC code documentation and payment adjustment. The ultimate goal is to take better care of people, so this expanded scope makes sense.

Deven McGraw: I think Denise just asked my question 😊

Deven McGraw: (thanks to her - and appreciate the responses)

Ryan Harrison: What I heard for Denise's question, "When will QHINs be public?"

- RCE has a comms plan about QHINs
- RCE is not divulging letters of intent
- Applicants cannot divulge where they are in the process
- RCE will announce once QHIN is approved
- QHIN can only sign-on a Participant once they are a designated QHIN

So QHINs can solicit Participants, but not officially sign them up (or accept money)?

John Rancourt: To build on Zoe's answer, Here's the Common Agreement definition of "Required Information": Required Information:

Electronic information maintained by any QHIN, Participant, or Subparticipant prior to or during the term of the applicable Framework Agreement:

- (i) that would be ePHI if maintained by a Covered Entity or a Business Associate; and
- (ii) regardless of whether the information is or has already been transmitted via QHIN-to-QHIN exchange.

Notwithstanding the foregoing, the following types of information are not Required Information:

(a) information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; or

(b) psychotherapy notes (as defined at 45 CFR 164.501).

Steven Lane: PHDS TF meetings have been full and engaging. The co-chairs have been doing a wonderful job bringing relevant experts forward and driving toward detailed recommendations. These will be helpful both to inform the key question of modular Public Health data system certification and PH related exchange under TEFCA.



QUESTIONS AND COMMENTS RECEIVED VIA EMAIL

There were no public comments received via email.

FINAL REMARKS

Hung Luu disclosed a potential conflict of interest: Hung has been working with the College of American Pathologists who was awarded a Food and Drug Administration (FDA) Broad Agency Announcement (BAA) grant to continue work on laboratory data interoperability. A portion of that grant will go towards his salary support.

Mike Berry reminded members that the next meeting of the HITAC will be held on November 10, 2022. All materials and testimony from today's meeting will be made available at <https://www.healthit.gov/hitac/events/health-it-advisory-committee-50>.

Denise and **Aaron** thanked everyone for their participation, presentations, and discussions. She encouraged interested new HITAC members to submit their names, as her appointment is ending shortly. **Aaron** thanked **Denise** for her efforts as a member and co-chair of the HITAC. He highlighted the promise of TEFCA and future information sharing to support continued care and treatment operations, especially in light of natural disasters and experiences like Hurricane Ian in Florida.

ADJOURN

The meeting was adjourned at 11:17 AM ET.