

Meeting Notes

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC)

February 17, 2022, 10:00 a.m. – 12:30 p.m. ET

VIRTUAL



EXECUTIVE SUMMARY

Micky Tripathi, the National Coordinator for Health IT, welcomed everyone to the February 17, 2022, virtual meeting of the HITAC and welcomed the HITAC members. He provided an update on ONC's recent achievements. The co-chairs of the HITAC, **Denise Webb** and **Aaron Miri**, welcomed members, reviewed the meeting agenda, and presented the minutes from the January 19, 2022, HITAC meeting, which were approved by voice vote. On behalf of the Annual Report Workgroup, **Aaron Miri** presented the Revised Final HITAC Annual Report for FY21. HITAC members submitted feedback and approved the annual report by a voice vote. **Steven Lane** and **Arien Malec** presented an update from the new Interoperability Standards Workgroup (IS WG) and responded to questions from HITAC members. **Sheryl Turney** and **Tammy Banks** presented an update from the e-Prior Authorization Request for Information Task Force 2022 (ePA RFI TF) and responded to questions. On behalf of ONC, **Elise Sweeney Anthony** and **Mike Lipinski** presented on the topic of information sharing under the ONC Cures Act Final Rule and the transition from the USCDI to the full scope of the electronic health information (EHI) definition. HITAC members discussed each presentation and submitted feedback and questions to the presenters. No public comments were submitted by phone during the meeting, but there was a robust discussion in the public meeting chat via Zoom.

AGENDA

10:00 a.m.	Call to Order/Roll Call
10:05 a.m.	Welcome Remarks
10:15 a.m.	Opening Remarks, Review of Agenda and Approval of January 19, 2022 Meeting Minutes
10:20 a.m.	Revised Draft HITAC Annual Report for FY21: HITAC Discussion and Vote
10:50 a.m.	Interoperability Standards Workgroup Update
11:05 a.m.	e-Prior Authorization Request for Information Task Force Update
11:25 a.m.	Break
11:30 p.m.	Information Sharing Under the ONC Cures Act Final Rule: Transition from USCDI to Full Scope of EHI Definition
12:15 p.m.	Public Comment
12:30 p.m.	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 February 17, 2022, meeting to order at 10:00 a.m.

ROLL CALL

Aaron Miri, Baptist Health, Co-Chair

Denise Webb, Individual, Co-Chair

Medell Briggs-Malonson, UCLA Health

Hans Buitendijk, Cerner

Steven (Ike) Eichner, Texas Department of State Health Services

Cynthia A. Fisher, PatientRightsAdvocate.org

Rajesh Godavarthi, MCG Health, part of the Hearst Health network

Valerie Grey, New York eHealth Collaborative

Jim Jirjis, HCA Healthcare

John Kansky, Indiana Health Information Exchange

Kensaku Kawamoto, University of Utah Health

Steven Lane, Sutter Health

Leslie Lenert, Medical University of South Carolina

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
Abby Sears, OCHIN
Alexis Snyder, Individual
Fillipe Southerland, Yardi Systems, Inc.
Sheryl Turney, Anthem, Inc.

HITAC MEMBERS NOT IN ATTENDANCE

Lisa Frey, St. Elizabeth Healthcare
Steven Hester, Norton Healthcare
James Pantelas, Individual

FEDERAL REPRESENTATIVES

Thomas Cantilina, Military Health System, Department of Defense (DoD) (*Absent*)
Sanjeev Tandon, Centers for Disease Control and Prevention (CDC) (*standing in for Adi V. Gundlapalli*)
Ram Iyer, Food and Drug Administration (FDA) (*Absent*)
Jonathan Nebeker, Department of Veterans Health Affairs
Michelle Schreiber, Centers for Medicare and Medicaid Services
Ram Sriram, National Institute of Standards and Technology (*Absent*)

ONC STAFF

Micky Tripathi, National Coordinator for Health Information Technology
Steve Posnack, Deputy National Coordinator for Health Information Technology
Elise Sweeney Anthony, Executive Director, Office of Policy
Avinash Shanbhag, Executive Director, Office of Technology
Kathryn Marchesini, Chief Privacy Officer
Mike Berry, Designated Federal Officer

PRESENTERS

Tammy Banks, Co-Chair of the ePA RFI TF 2022

WELCOME REMARKS

Micky Tripathi, the National Coordinator for Health IT, welcomed everyone and provided an overview of ONC's recent program updates, including:

- The first part of the ONC Annual Meeting was held February 2 and 3, 2022, and featured education sessions and office hours. The second part will feature a variety of dynamic and engaging panel sessions and exhibits and will be held on April 13 and 14, 2022. Related information will be released on the [healthit.gov website](https://healthit.gov).
- ONC received and published the [Electronic Health Record \(EHR\) Reporting Program: Developer-Reported Measures Final Report](#), which was delivered by the Urban Institute and HealthTech Solutions team. He thanked HITAC and EHR Reporting Program Task Force members for their input and support.
- **Micky** thanked everyone who has contributed feedback and engagement to ONC through many channels and explained that this shapes the form and content of ONC's reports, blog posts, FAQs, and other work products. He described the iterative process that is behind ONC's recent work and highlighted recent blog posts on ONC's [healthit.gov website](https://healthit.gov), which included:





- [DYK: There's a Conformance Review Process for Certified Health IT](#): This blog post described the ONC Health IT Certification Program (Certification Program), which compels participating developers to ensure that their certified health IT conforms to the full range of requirements during and after lab-based testing. When suspected issues arise with certified health IT – sometimes called “non-conformities” – the Certification Program’s conformance review process helps provide a path to resolve them.
- [Shining a Light on FHIR Implementation: Progress Toward Publishing FHIR Endpoints](#): This blog post described the [Lantern tool ONC developed](#) to monitor the nationwide implementation of Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®) application programming interface (API). The Lantern tool consumes public endpoint information (published by EHR developers), tests the accessibility of these endpoints, and reports capability information to its public-facing dashboard.
- [Calling all Beta Testers: New Opportunity to help ONC Update the Inferno Test Tool](#): This blog post highlighted Inferno, ONC’s test tool for the “standardized API for patient and population services” certification criterion, will support beta testing for the HL7 FHIR US Core Implementation Guide (IG) 4.0.0. He described the importance of Inferno and invited HITAC members to submit feedback.
- [Four New Information Blocking FAQs](#) : These FAQ address concerns related to the Information Blocking Provision of the 21st Century Cures Act (the Cures Act) and include information on [how any claim or report of information blocking would be evaluated](#), [how information blocking regulations \(45 CFR Part 171\) require actors to make patients aware of newly available electronic health information \(EHI\), if an actor can grant a patient's request to delay the release of a patient's test result\(s\) to the patient without implicating the information blocking regulations](#), and [describe how not complying with another law would implicate the information blocking regulations](#).
- [The Guide to Getting & Using Your Health Records](#): This guide is for patients who want to get their health records. This guide is also for people who need the record of someone they represent or care for.

Micky thanked all HITAC members serving on the various task forces and workgroups for their input and dedication.

OPENING REMARKS, REVIEW OF AGENDA, AND APPROVAL OF JANUARY 19, 2022, MEETING MINUTES

Aaron Miri and **Denise Webb**, HITAC co-chairs, welcomed all members and presenters. **Denise** and **Aaron** thanked ONC for the release of the FAQs and blog posts and emphasized their usefulness. **Aaron** reviewed the agenda for the meeting and the list of planned presentations.

Denise invited members to examine the minutes from the January 19, 2022, meeting of the HITAC and called for a motion to approve the minutes. The motion was made by **Aaron Miri** and was seconded by **Jim Jirjis**.

The HITAC approved the January 19, 2022, meeting minutes by voice vote. No members opposed or abstained.





REVISED DRAFT HITAC ANNUAL REPORT FOR FY21: HITAC DISCUSSION AND VOTE

Aaron Miri, Annual Report Workgroup (AR WG) Chair, presented an update on the revised draft HITAC Annual Report for FY21, and the information was detailed in the [AR WG presentation slides](#). He thanked **Carolyn Petersen**, the previous co-chair of the AR WG, who recently completed her term on the HITAC and AR WG. He invited HITAC members to serve on the AR WG and briefly reviewed the AR WG scope, membership, meeting schedule, and next steps of developing the Annual Report. He thanked all who submitted comments on the draft report document and expressed his gratitude to the other WG members and **Michelle Murray**, and the ONC team for their work.

Aaron guided members through the [revised draft HITAC Annual Report for FY21 document](#) and focused on the crosswalk of topics, key gaps, key opportunities, and recommended HITAC activities, which were detailed in the draft document. The crosswalk was divided by the HITAC Target Areas of Use of Technologies that Support Public Health, Interoperability, Privacy and Security, Patient Access to Information, and Federal Activities Across Target Areas. He highlighted some immediate opportunities and elaborated on several topics with real-world examples. He thanked HITAC members for the in-depth and valuable feedback they contributed and invited them to submit any final comments.

Aaron thanked HITAC members for their input following the discussion period, reviewed the next steps, and invited everyone to contribute additional feedback to him via email.

Discussion:

- **Steven Lane** thanked **Aaron** and the members of the AR WG and highlighted the importance of the Annual Report in guiding the activities of the HITAC. He encouraged HITAC members to join the AR WG and consider serving as a co-chair.
- **Sheryl Turney** congratulated the AR WG on the report and highlighted the area of Patient Matching. She stated that having a standard for a digital ID card that is part of the certification process would help providers and other stakeholders improve the quality of the data at its capture point.
 - **Aaron** voiced his agreement and shared relevant experiences in Florida.
- **Steven (Ike) Eichner** commented that using a different use case/user story for the Public Health Reporting topic would be more easily understood than the example listed. He suggested the use cases of leveraging health information exchanges (HIEs) to populate missing race and ethnicity data in reports to public health or rerouting laboratory orders through HIEs to and from the lab to the provider and public health (for notifiable conditions). He shared more information in the public Zoom chat.
 - **Aaron** explained that the AR WG chose the included example to illuminate how public health reporting could look in an environment of seamless data access. He offered to amend the example next year to be more specific and invited Ike to join the WG.
- **Abby Sears** commented that the document and the illustrative stories were easy to read and nicely laid out the priorities of the HITAC. She made several suggestions for use in the next version of the HITAC Annual Report:
 - Add a Target Area of Health Equity that focuses on closing the digital divide supports and encourages more culturally competent technology to support different patient demographics and needs.
 - Ensure policies suggest incremental changes, including strategies that push them across the “last mile,” and address the needs of the 20% of patients that have the greatest challenges.





- Consider adding the topic of the closed loop referral. She described patient population challenges around accessing referrals and then getting that referral-related data back. She stated that if that data does not come back, the part of the infrastructure related to value-based pay that serves some of the most fragile patients will continue to be at a disadvantage. Other than faxes, information for these patient's closed loop referrals is not making it back. The smaller practices and the safety net clinics are at a disadvantage.
- **Aaron** thanked her for her comments and explained that the HITAC's charges are related to the Target Areas called out in the Cures Act. He suggested adding callouts under each area in the next report that would highlight and expand on health equity topics.

Denise explained that HITAC members would be voting on the version of the revised draft presented at the meeting, and all comments and feedback submitted at the current meeting would be added to next year's report. She called for a motion to approve the Revised Draft HITAC Annual Report for FY21 for advancement to the National Coordinator for Health IT. The motion was made by **Aaron Miri** and was seconded by **Steven Lane**.

The HITAC approved the Revised HITAC Annual Report for FY21 by voice vote. No members opposed or abstained.

INTEROPERABILITY STANDARDS WORKGROUP UPDATE

Steven Lane and **Arien Malec**, co-chairs of the new Interoperability Standards Workgroup (IS WG), explained that the IS WG was chartered to replace the work of the prior United States Core Data for Interoperability Task Force (USCDI TF) and the Interoperability Standards Priorities Task Force (ISP TF). **Steven** presented an overview of the IS WG's overarching and specific charges, membership, meeting schedule, and deliverable due dates, [detailed in the IS WG Update presentation slides](#).

Steven described the areas of focus for this iteration of the WG, which runs through June 2022 but could potentially extend its work through the summer into the fall (if requested by ONC). The charges included:

- Overarching charge: Review and provide recommendations on the Draft USCDI Version 3 and other interoperability standards
- Specific charges:
 - Due to the HITAC by April 13, 2022:
 - Evaluate Draft USCDI v3 and provide HITAC with recommendations for:
 - 1a - New data classes and elements from Draft USCDI v3
 - 1b - Level 2 data classes and elements not included in Draft USCDI v3
 - Due June 16, 2022:
 - Identify opportunities to update the ONC Interoperability Standards Advisory (ISA) to address the HITAC priority uses of health IT, including related standards and implementation specifications.

Steven shared a list of specific questions on which ONC requested feedback, which was detailed in the presentation slides, and included general feedback on Draft Version 3 of the USCDI (draft USCDI v3) and specific feedback on several existing data elements.

Arien described the work completed by the IS WG since its kick-off meeting on January 25, 2022, and he highlighted the subject matter expert (SME) presentations from the Gender Harmony Project and Project





US@, which will inform the WG's work going forward. He encouraged HITAC members to review the transcripts from those meetings or to review the presentation materials linked on the [IS WG's webpage](#). The IS WG plans to discuss the Health Status Data Class at its March 1, 2022, meeting. He summarized the IS WG's remaining work, which includes general feedback on draft USCDI v3, and noted that the WG already created a matrix to review these items. He provided a schedule of upcoming meetings and explained that the IS WG would bring its first round of recommendations forward for a vote at the April 13, 2022, HITAC meeting.

Discussion:

- **Steven Lane** explained that the IS WG will focus on the Disability Status data element following the interest expressed at the previous ISP TF and USCDI TF meetings.
- **Denise Webb** thanked the co-chairs for their presentation and noted no pending questions from HITAC members.

E-PRIOR AUTHORIZATION REQUEST FOR INFORMATION TASK FORCE UPDATE

Sheryl Turney and **Tammy Banks**, co-chairs of the e-Prior Authorization Request for Information Task Force 2022 (ePA RFI TF), presented an update. **Sheryl** welcomed her co-chair, who is not a member of the HITAC. **Sheryl** presented an overview of the ePA RFI TF 2022's charge and timeframe, membership (including changes/additions), approach to its work, and meeting schedule, which were detailed in the [ePA RFI TF presentation slides and materials](#). She described the presentations the TF received (and will receive) from SMEs.

Sheryl explained that ONC issued a request for information (RFI), published in January 2022, that seeks input from the public regarding support for electronic prior authorization (ePA) processes. ONC is requesting comments on how the ONC Health IT Certification Program could incorporate standards and certification criteria related to electronic prior authorization.

- Task Force Charge: Provide input and recommendations in response to the RFI on Electronic Prior Authorization to inform future rulemaking and other actions in this area.
- Timeframe: Provide recommendations by March 10, 2022.

Sheryl described hindrances in ePA and related implementation guides (IGs), which have prevented the processes from maturing. An additional TF meeting will be held on March 7, 2022.

Tammy presented a summary of the topics the ePA RFI TF 2022 has discussed, which included: prerequisites and functional capabilities, the PA workflow, standards, health IT criteria, adoption at scale, and additional considerations. These topics and the key discussion points that TF members raised during meetings were detailed in the presentation materials.

The co-chairs thanked HITAC members for their feedback and ONC for their support.

Discussion:

- **Cynthia Fisher** thanked the presenters and submitted several comments based on her work as a patient rights advocate. They included:
 - Patients are looking for a binding, complete, and actual price upfront, not an estimate.
 - Patients' bills should be complete and include the full price for planned healthcare services.
 - Prior Authorization should include all providers/practitioners in hospitals, even if they are contractors and/or are supposedly out of network.





- Patients should have the ability to compare prices within the same hospital system and at various stand-alone care locations.
- Design future systems that can move to a world that allows choice while providing full price transparency to patients.
- **Sheryl** agreed with **Cynthia's** comments and explained that the TF has already discussed similar topics and planned to provide a recommendation that reflects her comments. **Tammy** added that the TF discussed designing the PA process to include bundles to provide treatment plans to patients.
- **Arien Malec** thanked the presenters and previous commenters and made the following suggestions to the TF:
 - Prepare for an advanced explanation of benefits (EOB) ruling and have payors and providers who can meet the advanced EOB rule set.
 - Look at additional specification around eligibility information and connect between eligibility and ePA to create a more holistic administrative process that better serves patients. He described parts of the eligibility transaction that could be pulled out to serve as better triggers for ePA transactions.
 - Reconcile the care delivery process and services with all financial information (pre-service) so that patients are not surprised by costs (post-service). Prioritize collecting as much data before the service so that patients and providers can concentrate on care, not billing.
 - **Cynthia** commented that systems should be streamlined so that the patient is well-informed in advance and described the use case of a patient who encountered issues with the billing and insurance process around a medically necessary breast reduction procedure. She suggested that anyone who can pay a cash price through their business to a hospital/provider for care should have the option to do so instead of paying through an insurance premium. She explained how small businesses can save money through this proposed process.
- **Clem McDonald** asked if the TF was also working on attachments/attachment standards, in addition to the work they described.
 - **Sheryl** responded that much of the certification process and ePA work requires a certain level of attachments or supplemental documents (structured and/or unstructured). The goal the TF ultimately would like to reach is the sending and receiving of data digitally, without the need for an attachment. Because this will not be achievable for the next several years, this topic needs to be addressed in the RFI (especially in the case of many providers of value-based care services that are not connected to mature EHR systems). **Clem** agreed and explained that many of the items needed are documents (e.g., x-rays).
 - **Tammy** responded that the TF would release a recommendation on attachments and explained that the ideal future state would be a more data-driven digital system via APIs, though there will be an interim process. **Clem** urged the TF to make a recommendation to use digital documents, and **Tammy** agreed, noting that ONC has created the USCDI as a baseline of functionality for certification of health IT vendors. **Aaron** added that the full definition of electronic health information would become effective in October 2022.
- **Hung Luu** stated that ONC has authority as far as regulating EHR systems, but it does not have purview over the full PA process (e.g., standardizing the fragmented processes that insurance companies use to complete a PA request for authorization).





- **Aaron** suggested that, in this case, ONC could coordinate with other federal agencies to get the desired results.

BREAK

The HITAC took a short break. **Mike Berry** reconvened the meeting at 11:30 a.m., and **Aaron** and **Denise** welcomed HITAC members, presenters, and the public back to the meeting.

INFORMATION SHARING UNDER THE ONC CURES ACT FINAL RULE: TRANSITION FROM USCDI TO FULL SCOPE OF EHI DEFINITION

Elise Sweeney Anthony, Executive Director, Office of Policy, ONC, and **Mike Lipinski**, Director, Regulatory and Policy Affairs Division, ONC, presented on the topic of information sharing under the ONC Cures Act Final Rule and the transition from the USCDI to the full scope of the EHI definition.

Elise shared a disclaimer with the HITAC before she began the presentation, and it was included in the beginning of [ONC's presentation slide deck](#). She provided an overview of the Information Blocking provisions of the 21st Century Cures Act (Section 4004) Final Rules and summarized several of the exceptions that do not constitute information blocking. She described how the HHS Office of Inspector General (OIG) investigates claims of information blocking and explained how Section 4004 of the 21st Century Cures Act affects information sharing between patients, clinicians/other health care providers, and health IT developers. She highlighted the information sharing opportunities to all stakeholders in the landscape, which were detailed in the presentation slides. She presented a timeline of key dates related to Information Blocking between 2020 and 2023 and noted that the EHI definition now is limited to the EHI identified by the data elements represented in the USCDI. On and after October 6 2022, the definition of EHI is no longer limited to the EHI identified by the data elements represented in the USCDI. She discussed the definition of Information as defined in 45 CFR 171.103 and shared elements of information blocking, all of which were defined in the presentation slides.

Elise described how “actors” are defined under the Information Blocking provisions and shared the proposed and final definitions for EHI, which were detailed in the presentation. She explained that the definition of EHI means electronic protected health information (ePHI) to the extent that the ePHI would be included in a designated record set as the terms are defined for HIPAA (moving toward alignment). She highlighted the shared decision-making process between a patient and care provider and how it would be supported.

Mike thanked HITAC members for their robust discussion and debate in the public Zoom chat. He referenced the blog post that ONC published on its [healthit.gov Buzz Blog](#), which was titled “[Say Hi to EHI](#),” and it included fact sheets and infographics on the scope of EHI for the Information Blocking definition. He explained that EHI is not limited by when the information was generated and referenced the four new FAQs recently released by ONC and were highlighted earlier in the meeting by **Micky**. He discussed the reasonable and necessary activities that were exceptions to information, which were listed in the presentation slides, and listed the actors that are covered. **Mike** described some of the most regularly referenced exceptions, like the Content and Manner exception and the Infeasibility exception; he shared detailed descriptions of these exceptions, noting how they were defined in the final rule, and described the conditions the actors must meet. He described the Factor Test that is used to evaluate the infeasibility under a specific list of circumstances, which were detailed in the presentation materials. He noted that there are contexts in which exceptions “don’t work” and shared a list of resources and a link for reporting instances of information blocking.





Discussion:

- **Denise Webb** stated, since the publication of TEFCA, the landscape for HIEs is evolving, and patients may want to avail themselves of an HIE that provides individual access services by asking their provider to send EHI to their HIE. She stated that connecting to an HIE involves financial and technical investments, particularly for small providers and clinics. Could they look at the circumstances around their request and do the Factor Test with the Infeasibility Exception?
 - **Mike** responded ONC is unable to give an advisory opinion that can be applied to the exception. However, they can focus on explaining the terms in the definition and what is likely to be considered interference. The circumstances would have to be taken into account, including the knowledge and intent behind the particular action. He stated that, in terms of HIEs, the President and Congress (via the Cures Act) weighed in on their value, and he suggested reviewing the Cures Act, including Section 4006 and the amendments. ONC has tried to address some of these questions in the FAQs.
 - **Denise** commented that, though the ONC FAQs are helpful, provider organizations prefer to train staff using scenario-based training, and the FAQs are lacking these scenarios/use cases. She stated that she understands the balancing act around providing regulatory guidance around specific use cases.
 - **Elise** commented that there are some examples of general scenarios/use cases in ONC's FAQs that are factor specific. ONC gave some general examples, but a differentiating factor could be whether information blocking did/did not occur. She suggested that HITAC members review examples in the final rule and the FAQs, and **Mike** commented that OIG will do investigations to determine if an exception was applicable in that circumstance. ONC does not give scenarios where exceptions would apply because it could be inconsistent with OIG's final determination, which would be problematic in terms of implementing the regulation.
- **Steven Lane** asked for clarification around the term "factor test." Does ONC mean various factors that could constitute Information Blocking under the use of the term?
 - **Mike** responded that the term came directly from the regulation text and noted that it also includes certain factors that are not to be assessed. He listed some examples.
- **Clem McDonald** highlighted two key issues: do they anticipate that care providers/systems will hold back information? Can they start to promote the use of email through medical record systems, despite some security concerns?
 - **Elise** responded that ONC hopes that providers participate in supporting their patients under the aspects of the Cures Act. If an entity does sidestep the provisions, there could be an investigation to see if their actions constitute Information Blocking. She added that email is a way that information can move, noting that OCR has discussed this topic, and she invited ONC's Chief Privacy Officer to comment. Also, there are ways to be flexible to support patients' requests under the Content and Manner exception.
 - **Kathryn Marchesini** stated that there is guidance in the HIPAA Privacy Rule on Patient Right of Access that specifically speaks to any liabilities and/or security risks that a patient might accept when requesting their information be shared via email. She stated that there are nuances around third-party interactions with this data.





- **Mike** discussed his and other ONC staff members' recent work on Information Blocking, noting that it seems like everyone is trying to do the right thing. He described how potential instances of Information Blocking are investigated. In response to a comment made in the public chat about the lack of disincentives for Information Blocking, he explained that OIG has not issued their rules yet, but, once they are effective, they may choose to make them applicable to all actors as of April 5, 2021.
- **Clem** emphasized the need to focus on email in the future, as many patients share their email information, and it could prove useful, despite potential issues.
- **Denise** mentioned that the AMA had published a playbook focused on patient records electronic access, including using email. She shared a link to the playbook in the public chat in Zoom.
- **Alexis Snyder** commented that a provider must comply with a request from a patient that information be sent to them outside/in the absence of a portal (via email). If the email is not sent, would this be Information Blocking? She stated that this conversation emphasizes the need for a standard way of responding to the electronic process around sharing health data with patients.
- **Elise** responded that ONC is supportive of allowing all actors (patients, providers, developers, etc.) to access data. This support is expressed not only on work on information blocking but also through supporting the certification process. She described a variety of scenarios in which having the flexibility and technology to support data sharing is needed.
- **Steven (Ike) Eichner** described several situations in which public health collects information for its own activities. He noted that many public health systems that were designed for their data collection efforts were not created to be used for coordinating health care and that many have specific requirements about with whom and under what circumstances data may be shared. How can they resolve these issues (e.g., no support for querying of data by providers)?
 - **Elise** responded that Information Blocking does not just refer to data in an EHR; it can support data in other record systems that would also be subject to HIPAA regulations. Also, if a system cannot/does not move information according to a state law or federal law, then that is considered in the information blocking analysis by ONC.
 - **Mike** described how immunization registries may/may not meet the functional definition of a health information network (HIN). Through the regulation, ONC interpreted those situations according to state and federal laws but also included court and federal administrative body decisions. He described how exceptions would or would not be needed in different states and described how this is handled by California state law.

PUBLIC COMMENT

Mike Berry opened the meeting for public comment and reminded attendees that written comments could be submitted at ONC-HITAC@accelsolutionsllc.com.

Questions and Comments Received via Telephone

There were no public comments received via telephone.

Questions and Comments Received via Zoom Webinar Chat

Michael Berry: Good morning, and welcome to the HITAC meeting!





Michael Berry: Please remember to change your chat setting to "Everyone" if you would like everyone to see your comment. Thanks!

Steven Lane: <https://www.urban.org/research/publication/electronic-health-record-ehr-reporting-program-developer-reported-measures>

Steven Lane: <https://www.healthit.gov/buzz-blog/healthit-certification/dyk-theres-a-conformance-review-process-for-certified-health-it>

Aaron Miri: Lantern is amazing: https://lantern.healthit.gov/?tab=capability_tab

Steven Lane: <https://www.healthit.gov/buzz-blog/healthit-certification/shining-a-light-on-fhir-implementation-progress-toward-publishing-fhir-endpoints>

Steven Lane: <https://www.healthit.gov/buzz-blog/healthit-certification/calling-all-beta-testers-new-opportunity-to-help-onc-update-the-inferno-test-tool>

Steven Lane: <https://www.healthit.gov/curesrule/resources/information-blocking-faqs>

Steven Lane: https://twitter.com/ONC_HealthIT/status/1493993204273844226

Steven Lane: Suggest that we differentiate Health Equity, Healthcare Equity, and Health Data Equity and consider specific recommendations in each area.

Steven (Ike) Eichner: One potential user story for public health reporting would be to leverage HIEs to populate missing race/ethnicity data in reports to public health. A report could be routed through an HIE which has the missing data.

A second potential example is rerouting laboratory orders and results reporting through HIEs. both on the way TOO the lab and results FROM the lab to the provider community AND public health (for notifiable conditions)

Steven (Ike) Eichner: This has the advantage of limiting the need for labs to modify their systems to store demographic and other information needed by public health but unreleased to processing the same. It also supports routing test results to the patients' regular care providers (with consent)

Steven (Ike) Eichner: This approach would help route things like drive-through COVID-18 test results to the patient's PCP, if the patient has opted into the HIE, something that may be challenging today.

Eliel Oliveira: @stevenEichner, great points on public health reporting. Thank you.

Mark Savage: Yes @Steven Lane about differentiating health equity, health care equity, and health data equity and paying attention to each. The distinction parallels, for example, differentiating health literacy, health care literacy, and health IT literacy.

Steven Lane: <https://www.hhs.gov/about/news/2022/01/21/onc-seeks-public-comment-electronic-prior-authorization-standards-implementation-specifications-and-certification-criteria.html>

Steven Lane: Bravo/a to those HITAC members who have chosen to step up and volunteer for BOTH of the workgroups/taskforces presenting today!

Eliel Oliveira: Completely agree @aaronN. We are all in the dark and I am not sure any other business/industry is that way.





Samantha Burch: There are patients in the safety net that are walking away from primary care because of GFEs. Is this focusing on the right problem.

Eliel Oliveira: Agree Samantha. We need to keep the Health Equity lens in the PA work as it does impact disproportionately *[sic]* the most in need.

Arien Malec: You need attachments or the moral equivalent to adjudicate ePA.

Arien Malec: The 275 spec already allows for this; CMS just needs to finally make it happen.

Arien Malec: My usual reminder that ONC authority over health IT is not limited to EHRs.

Hans Buitendijk: @Arien: Agreed. ePA spans multiple HIT, not limited to EHRs on the provider side, nor the intermediate area between provider and payer to help tie providers to their multiple payer relationships.

Aaron Miri: I ***STRONGLY*** suggest every single provider look at every element of the EHI and map out in your systems where those data elements are, and how you will be able to provide that data to a patient. Note - do not rely on your EHR vendor. This is all information both within the EHR and outside.

Steven Lane: This difference in the knowledge standard for providers and other actors adds a layer of confusion as we endeavor to educate regarding these requirements.

Jim Jirjis: Yes Aaron, and one issue is what is actually feasible and what is not right now

Aaron Miri: Precisely correct Dr. Jirjis. Frustratingly so.

Jim Jirjis: Yes and how much expectation is there that hospitals dedicate a lot of resources to this in advance of the EHR requirements which come later and will make it easier

Abby Sears: +1 Jim

Steven Lane: The current requirement would seem to allow any provider to simply claim ignorance of the law, which will delay our eventually ability to enjoy the benefits of consistent Information Sharing.

Jim Jirjis: And in the meantime there is not yet an enforcement system for providers

Brett Oliver: Great point, Jim

Steven Lane: Providers are incentivized to ignore the law altogether so that they can claim that they did not know that their practice constituted InfoBlocking.

Abby Sears: This starts with the EHR products enabling the movement.

Aaron Miri: Abby - interestingly most modern health IT vendors have the technical capability to share info but "other" reasons seemingly pop up.

Steven Lane: And to be clear, all these references to USCDI are exclusively to USCDI Version 1.

Abby Sears: I understand the use of the word enable but not to the level of the USCDI

Jim Jirjis: Well, I mean that often the data may be found in other systems than the EMR, and those systems do not have a way to externalize *[sic]* the data without effort and cost. Think provider to provider messaging apps





Jim Jirjis: For exam ple [sic]

Abby Sears: So we are only uniformly required to move to the USCDI Level 1

Aaron Miri: +1 jim. Agreed

Steve Posnack: To piggy back on Aaron's point and echo what Elise just covered, it is not just data to be provided to patient -- that may be one context. There are many other contexts under information blocking where sharing data does not direct patient interactions. It may be a provider to provider data sharing context. Or a provider seeking to use the data it stewards itself and making it available certain EHI to business partner(s) under contract, where an interference could occur by a developer of certified health IT.

Jim Jirjis: Agree

Aaron Miri: +1 Steve

Steven Lane: <https://www.healthit.gov/buzz-blog/information-blocking/say-hi-to-ehi>

Steven Lane: Realistically, requests for All EHI will be fraught for quite some time. Hopefully the continued advancement of USCDI, year by year, will establish technical standards and operational processes that allow actors to readily and timely respond to requests for access, exchange, and use of an increasing proportion of EHI.

Aaron Miri: @Steven - technically and practically, I agree. But as we don't know the enforcement process yet, I want to show we tried every single avenue to meet the letter of the law and demonstrate just how difficult and "impossible" some of it is to achieve.

Steven Lane: Hoping to see USCDI V2 added to SVAP later this year to initiate what should be an annual cycle of advancing technology on the part of HIT vendors, while we await additional rulemaking to eventually require more advanced versions of USCDI.

Brett Oliver: Agree, Steven - not sure how useful all EHI will be without said technical standards and operational processes

Steven Lane: First time I have heard/seen the term "Factor Test". Can we get more background on this??

Deven McGraw: Info blocking rules are not tied to use of a particular technology - so while yes, helpful to have USCDI and EHI aligned, because that facilitates responding to data exchange needs much more easily, the requirement to produce information (where lawfully permitted) under the Info blocking extends to EHI wherever its kept. Just like the HIPAA designated record set is not limited to just the "medical record" .

Hans Buitendijk: Both ePHI and EHI includes data that are not limited to EHRs, but spread across HIT. In addition, there is a challenge with EHI that DRS is well defined, but can be scoped differently by provider. EHRA, AHIMA, and AMIA published this report <https://www.ahima.org/media/ztqh1h2q/final-ehi-task-force-report.pdf> with considerations around the scope of EHI/DRS. At the same time we need to consider whether ePHI can become a more stable target as perhaps indicated by TEF that considers ePHI part of "required information".

Hans Buitendijk: <https://www.ahima.org/media/ztqh1h2q/final-ehi-task-force-report.pdf>

Aaron Miri: The AHIMA link provided by Hans is an excellent document that's easy to follow





Hans Buitendijk: At that same time, if the scope of EHI varies across data holders, requests for EHI may yield expectation mismatches and friction.

Steven (Ike) Eichner: What [sic] is the interplay between information blocking, HIPAA, and non-HIPAA covered providers (or hybrid entities and non-covered programs)? If there's a breach of a system outside of a HIPAA covered program under 21st Century, how will that be addressed?

Steven Lane: @Sheryl - Good opportunity to test out the website for reporting InfoBlocking!

Steven Lane: <https://inquiry.healthit.gov/support/plugins/servlet/desk/portal/6>

Aaron Miri: +1 Elise. Patient First. Always.

rachel nelson: Applicable date of information blocking regulations in 45 CFR part 171: April 5, 2021.

Julie Maas: A standard identity verification and authentication approach for patient access is an essential component of this conversation-rather than "not too much" or "not too little".

Kathryn Marchesini: Here is the HHS HIPAA Privacy Rule Patient Access Guidance/FAQ referenced: <https://www.hhs.gov/hipaa/for-professionals/faq/2061/is-a-covered-entity-responsible-if-it-complies/index.html#:~:text=Covered%20entities%20are%20responsible%20for%20breach%20notification%20for%20unsecured%20transmissions,third%20party%20in%20an%20unsecure>

Chantal Worzala: The infeasibility exception includes a requirement that an actor provide a written response within 10 business days of request with the reason(s) why it is infeasible. When does that clock start, given that the actor and requestor may need to clarify what is being requested and in what manner?

Rita Torkzadeh: How is PGHD viewed from the context of EHI and information blocking rule?

Aaron Miri: Thank you Kathryn!

Steven Lane: <https://www.ama-assn.org/system/files/2020-02/patient-records-playbook.pdf>

Denise Webb: <https://www.ama-assn.org/system/files/2020-02/patient-records-playbook.pdf>

Aaron Miri: thoughtful, reasonable, and informed data sharing (including email) does not mean sticking your head in the sand and forbidding a technical modality. Patient first.

Shannon Vogel: Thank you, HITAC!

FINAL REMARKS

Mike Berry reminded members that the next meeting of the HITAC will be held on March 10, 2022. All materials from the current meeting would be made available at <https://www.healthit.gov/hitac/events/health-it-advisory-committee-42>.

Denise and **Aaron** thanked everyone for their participation and robust discussion.

ADJOURN

The meeting was adjourned at 2:20 p.m. ET.

