Meeting Notes

Health Information Technology Advisory Committee
March 19, 2019, 09:30 a.m. – 04:15 p.m. ET
In Person

The March 19, 2019, meeting of the Health IT Advisory Committee (HITAC) was opened at 9:30 a.m. ET by **Lauren Richie**, Designated Federal Officer (DFO), Office of the National Coordinator for Health IT (ONC).

Roll Call

MEMBERS IN ATTENDANCE

Carolyn Petersen, Individual, Co-Chair
Robert Wah, Individual, Co-Chair
Michael Adcock, Individual
Christina Caraballo, Audacious Inquiry
Tina Esposito, Advocate Aurora Health
Cynthia A. Fisher, WaterRev, LLC
Brad Gescheider, The Learning Corp
Valerie Grey, New York eHealth Collaborative
Anil Jain, IBM Watson Health
John Kansky, Indiana Health Information Exchange
Kensaku Kawamoto, University of Utah Health
Steven Lane, Sutter Health
Leslie Lenert, Medical University of South Carolina
Arien Malec, Change Healthcare
Denni McColm, Citizens Memorial Healthcare
Aaron Miri, The University of Texas at Austin, Dell Medical School and UT Health Austin
Brett Oliver, Baptist Health
Raj Ratwani, MedStar Health
Steve L. Ready, Norton Healthcare
Sasha TerMaat, Epic
Andrew Truscott, Accenture LLP
Sheryl Turney, Anthem BCBS
Denise Webb, Individual

FEDERAL REPRESENTATIVES

Ram Sriram, National Institute of Standards and Technology (NIST)
Lauren Thompson, DoD/VA Interagency Program Office

MEMBERS NOT IN ATTENDANCE

Kate Goodrich, Federal Representative, Centers for Medicare and Medicaid Services (CMS)
Clement McDonald, National Library of Medicine
Terrence O'Malley, Massachusetts General Hospital
Chesley Richards, Federal Representative, Centers for Disease Control and Prevention
Patrick Soon-Shiong, NantHealth

ONC STAFF

Elise Sweeney Anthony, Executive Director, Office of Policy
Cassandra Hadley, HITAC Support
Steve Posnack, Executive Director, Office of Technology
Lauren Richie, Designated Federal Officer
Donald Rucker, National Coordinator

Call to Order

Lauren Richie called the meeting to order and turned the meeting over to Donald Rucker, National Coordinator.

Welcome Remarks

Donald Rucker thanked everyone for their hard work on the task forces. He noted that the 21st Century Cures Act (Cures): Interoperability, Information Blocking, and the ONC Health IT Certification Program Notice of Proposed Rule Making (NPRM) took some time to get out, but ONC feels that it is a thoughtful rule that allows patients to have control of their care. He reminded the group of CMS' Interoperability and Patient Access Proposed Rule which represents HHS' belief that this is the next step for the American public. He noted that the basic constructs of the rule are relatively simple, even though the rule is long. There is a request for information within the rule about price transparency. This is a first step to understand how to start shopping for care in America. He also shared that during tomorrow's meeting there will be a discussion about prior authorization.

Elisa Sweeney Anthony thanked the members for the huge amount of work they have taken on to contribute their feedback on the NPRM. She also thanked the ONC staff leads for their hard work. She noted for clarity that the annual report which will be reviewed during today's meeting is HITAC's report, not ONC's. She thanked everyone for their feedback and contributions that informed the annual report. She noted that during tomorrow's meeting there will be a discussion about prior authorization.

She shared that during today's meeting there will be a lot of feedback and discussion but reminded the HITAC that ONC could not interpret the rule.

Robert Wah thanked everyone for stepping up and providing feedback on the NPRM. He thanked everyone for their patience with the batches of materials that were distributed. He reminded everyone to stay for a photo before the lunch break. On a personal note, he shared that he will now be serving as an individual on the HITAC.

Approval of February Meeting Minutes

Robert Wah called for a vote to approve the minutes from the February 20, 2019 meeting. No comments or amendments were offered; the minutes were approved.

HITAC Annual Report Final Review and Approval

Aaron Miri, Co-Chair

Carolyn Petersen, Co-Chair

Members

Christina Caraballo
Brett Oliver
Chesley Richards

Carolyn Petersen first reviewed the members of the workgroup and thanked Michelle Murray and the other ONC staff for all their help creating a comprehensive document on behalf of the HITAC. She transitioned to review the details of the report.

Overarching scope: The workgroup will inform, contribute to, and review draft and final versions of the HITAC Annual Report to be submitted to the HHS Secretary and Congress each fiscal year. As part of that report, the workgroup will help track ongoing HITAC progress.

Detailed Scope: Provide specific feedback on the content of the report as required by the 21st Century Cures Act including:

- Analysis of HITAC progress related to the priority target areas
- Assessment of health IT infrastructure and advancements in the priority target areas
- Analysis of existing gaps in policies and resources for the priority target areas
- Ideas for potential HITAC activities to address the identified gaps

Next steps for FY18 report development:

- HITAC full committee reviews report and suggests any further edits
- HITAC full committee approves revised report
- HITAC forwards the final report to the National Coordinator for Health IT
- The National Coordinator forwards the final report to HHS Secretary and Congress

Goals for today are to discuss the updated draft.

FY18 Annual Report Outline

I. Executive Summary
II. Foreword and Overview
III. HITAC Progress in FY18 IV. Health IT Infrastructure Landscape Analysis
IV. Health IT Infrastructure Gap Analysis
V. Recommendations for Addressing Health IT Infrastructure Gaps

VI. Suggestions for Additional HITAC Initiatives
VII. Conclusion
VIII. Appendices

HITAC Priority Target Areas noted in Section 4003 of the 21st Century Cures Act covers the following areas:

- Interoperability: Achieving a health information technology infrastructure that allows for the electronic access, exchange, and use of health information
- Patient Access: The facilitation of secure access by an individual and their caregiver(s) to such individual's protected health information
- Privacy and Security: The promotion and protection of privacy and security of health information in health IT
- Any other target area related to the above target areas that the HITAC identifies as an appropriate target area to be considered on a temporary basis with adequate notice to Congress

Aaron Miri and Carolyn Petersen opened for discussion.

Discussion

Andy Truscott thanked the workgroup for the work on the report. He asked how the HITAC can help over the next 12-months and support the agenda.

- **Aaron Miri** noted that for the first version of the report there was a learning curve, for the next version the workgroup is hoping to have more engagement and to begin sharing sooner.

Steven Lane commented that there might be a need to harmonize consolidated clinical document architecture (C-CDA) and fast healthcare interoperability resources (FHIR).

Christina Caraballo thanked the co-chairs for their hard work. She commented as a lesson learned, it would be helpful to have a transparent document with draft outlines that include more detail throughout the process. She suggested that a shared online collaborative document might be helpful for the future.

Arien Malec thanked the co-chairs for their hard work. He thought it might be appropriate for future reports to draw out the policy recommendations that Congress may need to pay attention to, providing a state of the state in respect to health IT, interoperability, and patient access. The U.S. healthcare system can make substantial progress, but it needs steering in a particular direction. He thought it would be useful to identify the progress made, where things are stuck, where the HITAC tried to do too much, and additional policy considerations that need a legislative approach versus a regulatory approach.

- **Aaron Miri** noted that the workgroup did try to show the lineage, but the workgroup will look into these suggestions for the FY19 report.
- **Ken Kawamoto** questioned what happened to his previous suggestions.
    - The co-chairs noted that his comments were held for the FY19 report.

Carolyn Petersen called for a vote to approve the report. The report was approved unanimously with no abstentions or disapprovals.

Robert Wah transitioned to the co-chairs of the Interoperability Standards Priorities Task Force (ISPTF).

Interoperability Standards Priorities Task Force Update

Steven Lane, Co-Chair

Ken Kawamoto, Co-Chair

Members

Ricky Bloomfield
Tina Esposito
Tamer Fakhouri
Cynthia A. Fisher
Valerie Grey
Edward Juhn
Anil K. Jain
Victor Lee
Leslie Lenert
Arien Malec
David McCallie Jr.
Clem McDonald
Terrence O'Malley
Ming Jack Po
Raj Ratwani
Ram Sriram
Sasha TerMaat
Andrew Truscott
Sheryl Turney
Scott Weingarten

Steven Lane started the discussion by reviewing the agenda for the ISPTF. The discussion will start with orders and results, then closed-loop and care coordination, closing the discussion with a preview of future domains.

ORDERS & RESULTS FINAL RECOMMENDATIONS

Priority 1: Results Ordering

- Priority 1A: Consistent encoding of Lab & Other test results
- Priority 1B: Results need to be sent to clinicians in codified format
- Priority 1C: Orderable tests need to be standardized between systems and with mapping to standard terminologies
- Priority 1D: Results need to be available for patients/proxies to effectively view, receive, and utilize

Priority 2: Standardization

- Priority 2A: Need a standard way to differentiate the Type of result
- Priority 2B: The C-CDA standard does not prescribe how to group components
- Priority 2C: Need standard interoperable methodology to specify and identify what has been ordered, and what is the Status of an order
- Priority 2D: Existing standard code sets are not unique or sufficiently granular to accurately determine the clinical equivalency of tests

- Priority 2E: Integrate external decision support
- Priority 2F: Support the integration of Prior Authorization into electronic health record (EHR) based ordering workflows
- Priority 2G: Result data exchanged between HIT systems may not include sufficient Provenance Metadata
- Priority 2H: Need vendors to send unique Reference IDs for results data
- Priority 2I: Tampering or other data modification may occur

Priority 1A: Consistent encoding of Lab & Other test results

- Standardized Logical Observation Identifiers Names and Codes (LOINC) & Systematized Nomenclature of Medicine - Clinical Terms (SNOMED-CT) coding must be provided by resulting agencies as a Clinical Laboratory Improvement Amendments (CLIA) requirement
- Identify and prioritize the most common/important results of each order type (including but not limited to lab, imaging, cardiac, pulmonary, neuro-muscular)
- Require and enforce the use of information models and terminology standards for all test orders and results
- Mapped codes must be included with results as they are maintained in and exchanged between health information technology (HIT) systems
- Resulting systems, e.g. electronic health records (EHRs) & laboratory information systems (LISs) should provide a mechanism that allows clients to map internal result codes to standard vocabularies
- Implement mechanisms to support and ensure proper LOINC encoding by resulting agencies, such as auditing or certification by CLIA

Priority 1B: Results need to be sent to clinicians in codified format

- Utilize US Core Data for Interoperability (USCDI) to assure that prioritized results are interoperable via Health Level Seven (HL7) version 2(v2) messages (where applicable), C-CDA, FHIR, and future transport standards
- Prioritize complete and accurate coding at the data source (e.g., laboratory information system (LIS), radiological information system (RIS) rather than trying to code or correct externally sourced data downstream
- Require that resulting agencies provide standardized metadata, (e.g., methodology, units, normal ranges) to ordering and copy to providers as well as patients
- Standard metadata must be maintained as result data is transmitted between systems (e.g., LISs, Imaging systems, EHRs, PHRs, HIEs, Payers, and Public Health)

Priority 1C: Orderable tests need to be standardized between systems with mapping to standard terminologies

- Develop and eventually require the use of standards-based catalogs of orderable tests with consistent mapping to associated code sets (e.g., LOINC) for all order types
- Utilize consensus development process to develop standard orderable for the most common/important tests of each order type, including the orders that link to prioritized results

- Standardize commonly used order panels, building on the ~2,000 order panels currently cataloged by LOINC
- Standardize orderables and order details with existing information models in mind (e.g., FHIR)

Priority 1D: Results need to be available for patients/proxies to effectively view, receive, and utilize

- Require that ordering providers make results available to patients/proxies within a reasonable timeframe, as allowed by state laws, assuring that, where appropriate, providers have an adequate opportunity to review and comment on results to facilitate patient interpretation
- Make all results in the EHR available to patients via APIs, whether or not results are LOINC/SNOMED-CT encoded
- Develop and require the use of standardized "patient friendly" result display names to patients based on LOINC and SNOMED-CT standards (in process)
- In the future consider requiring resulting agencies to make results available directly to patients. This could initially be required via CLIA regulations. As necessary, this could be required as a condition of payment for resulting agencies
- Alignment of state and federal policies to assure consistent and predictable patient data accessibility and interoperability. This should begin with a clear articulation of varying state requirements, followed by specification of national standards to promote maximal sharing of data with patients/proxies in both human and machine-readable formats

Priority 2A & 2B

- No standard way to differentiate the Type of result
  - Create a C-CDA standard component that identifies the different Result Types
  - Assure that FHIR specifications for test result components include the exchange of Result Type metadata
- The C-CDA standard does not prescribe how to send components
  - The C-CDA standard should be updated to require that result components sent with documents be grouped by procedure in order to keep the necessary context for interpretation on the receiving side

Priority 2C & 2D

- Need standard interoperable methodologies
  - Include Order Status as required component of interoperable metadata
  - Include in scope all orderable
  - Map priority orderable to standard codes. LOI standard could be useful. Potentially us LOINC for orderable, SNOMED for values
- Existing standard code sets are not unique
  - Create a means of interpreting the different codes and information available for procedures and result components so that when received, they can be uniquely identified.
  - This new way of translating codes would then be adopted by all EHRs and other systems exchanging results data.

Priority 2E & 2F

- Integrate external decision support
  - Support the advancement of standards such as CDS Hooks
  - Support the development of Hooks that can be activated/utilized when a provider or patient receives and/or is reviewing a result
- Support the development and use of standards to determine and expose/display net pricing and suggested alternative order information to relevant stakeholders Support the integration of Prior Authorization into EHR-based ordering workflows
  - There is a need for standard methodologies to integrate external decision support for clinicians, patients, and other stakeholders, into the full range of order and results workflows

Priority 2G

- Result data exchanged between HIT systems may not include sufficient Provenance Metadata
  - Require interoperability of provenance metadata with orders and results
  - Provenance data inclusion should be independent of transport mechanism (e.g., HL7 v2, LOI, LRI, C-CDA, FHIR)

Priority 2H

- Vendors do not consistently send unique reference identifiers (IDs) for discrete results data
- All systems should generate, use, and send unique and consistent Reference IDs for all orders, procedures and result components
- Require interoperability of order/result reference ID metadata with orders and results such that receiving systems can recognize a specific order or result as having been received previously
- Internal identifiers must be persistent and not change over the life cycle of an order or result
- Internal identifier data inclusion should be independent of transport mechanism

Priority 2I

- Vendors do not consistently send unique reference IDs for discrete results data
  - With the advancement of consumer-mediated exchange, clinicians may not be able to tell if an order, result or document has been tampered with while under the control of the patient or un-regulated HIT vendor system
  - Explore the value of requiring digital signatures on appropriate order and result data
  - A digital signature should allow the originating system to be confirmed, and the values to be verified, and reveal any tampering that may have occurred

CLOSED-LOOP REFERRALS & CARE COORDINATION FINAL RECOMMENDATIONS

- **Priority 1**
  - Priority 1A: Closed-Loop Communications
  - Priority 1B: Clinical Data collected prior to and sent when referring a patient
  - Priority 1C: Clinician-to-Clinician Patient-Specific Messaging
  - Priority 1D: Referral Management and Care Coordination

  - Priority 1E: Governance
- **Priority 2**
  - Priority 2A: Automatically incorporate relevant patient information into EHR
  - Priority 2B: Patient-to-Clinician Messaging
  - Priority 2C: Multi-Stakeholder, Multi-institutional Care Plan
  - Priority 2D: Real time text messaging

Priority 1A: Lack of Closed-Loop Communications

- Establish minimum baseline requirements for HIT solutions supporting closed-loop referral management
  - Encourage/support pilots of the 360X project with a variety of EHR systems and healthcare organizations
  - Iteratively enhance 360X approach based on real-world feedback
  - Support the 360X standards for Patient Identity Management and the further development and expansion of these capabilities to allow all referral orders to be tracked to completion.
  - Encourage/support efforts to harmonize existing approaches to representing Message Context
  - Investigate how FHIR-based approaches can best be leveraged to support closed-loop referral and care coordination messaging workflows.

Priority 1B: Standard clinical Data should be collected prior to referring a patient

- Identify an organization to develop and evolve recommendations
- Identify, catalog and, as necessary, manage and evolve best practice standard data elements
- Potential collaborators:
  - American Medical Association (AMA) Integrated Health Model Initiative (IHMI)
  - 360X Project Group - Council of Medical Specialty Societies (CMSS)
  - Physicians' Electronic Health Record Coalition (PEHRC)
  - Physicians Consortium for Performance Improvement (PCPI)
  - Health Services Platform Consortium (HSPC)
  - Healthcare Information and Management Systems Society (HIMSS)
  - Electronic Health Record Association (EHRA)
  - HL7 Da Vinci Project - ONC FHIR at Scale Task force (FAST)
- Consider piloting FHIR Argonaut Questionnaires to support referral workflows
- Explore the use of referral management apps (e.g., using SMART technology solutions) to support referral management workflows and associated information exchange

Priority 1C: Clinician-to-Clinician Patient-Specific Messaging

- Support and incentivize EHR and clinician user adoption of functionality needed to fully utilize compatible transport mechanisms (e.g., Direct)

- Investigate how FHIR-based approaches can be leveraged to support clinical messaging for referrals and care coordination

Priority 1D: Provider Directories

- Support the development and advancement of a nationwide standard for provider directories and their management to support referrals and care coordination, including cross-organizational clinical messaging

Priority 1E: Governance

- Include access to and governance of push messaging, and the associated technical and workflow requirements necessary to support referrals and care coordination, in the scope of the final Trusted Exchange Framework and Common Agreement (TEFCA)

Priority 2A: Automatically incorporate patient information into EHR

- Support transition to secure, cross-organizational, cross-vendor, EHR integrated electronic messaging between providers, payers, and all care team members

Priority 2B: Patient-to-Clinician Messaging

- Support pilots of patient to provider messaging using multiple available technology solutions, e.g., Direct, FHIR
    - Provide flexibility to individuals/patients to select the messaging tools of their choice and to manage messaging with care team members utilizing disparate HIT solutions
    - Viable messaging solutions will integrate with established clinician workflows for portal-based messaging

Priority 2C: Patient-centric, Multi-Stakeholder, Multi-institutional Care Plan

- Investigate various approaches, such as those based on the FHIR and C-CDA Care Plan
- Ensure that patient, caregiver and family goals and wishes are incorporated into the care plan

Priority 2D: Real-time text messaging

- Explore the usage of and development of standards for the use of secure, real-time text messaging that supports appropriate integration with EHR documentation and workflows

Additional Closed Loop Referral Draft Recommendations

- Technology needs to support both Care Coordination and Orders & Results
    - Identify opportunities for harmonization of technology standards and governance support of various instances of closed loop exchanges
- Transitions of Care
    - Identify opportunities for harmonization of technology standards and governance support of various instances of Transitions of Care
- Custom interoperability solutions add cost and complexity
    - Actively seek out and identify opportunities to consolidate, simplify and render cost-effective the health IT interoperability landscape

- Health data interoperability needs with no clear single best approach
    - Avoid ”picking winners” prematurely and remain open to potential alternative approaches which may ultimately be superior for a given problem or in a larger context that considers various use cases

MEDICATION & PHARMACY DOMAIN PREVIEW

Priority 1

- Priority 1A: Medication administration/dispensation information is not universally available
- Priority 1B: Medication reconciliation at transitions of care is challenging
- Priority 1C: US Core FHIR profiles do not require transmittal of free-text sigs
- Priority 1D: Access to prescription drug monitoring program (PDMP) data can be cost prohibitive
- Priority 1E: It is difficult to know the net price of prescribed medications
- Priority 1F: Need standards to integrate Prior Authorization into prescribing workflows

Priority 2

- Priority 2A: National Library of Medicine RxNorm API does not return codes for discontinued drugs
- Priority 2B: Free text sigs are prevalent, but difficult to interpret/use when structured information is needed
- Priority 2C: There is currently not a way to "forward" an eRx to an alternate pharmacy

PREVIEW OF FUTURE DOMAINS

- Evidence-based Disease Management
- Price Transparency
- Prior Authorization
- All of these uses of health information technology include the need to
    - Collect appropriate patient information
    - Send patient information to a service that analyzes it relative to a set of rules/requirements
    - Return recommendations to the requestor which must be incorporated into the workflow

Discussion

Sheryl Turney commented that some of the topics that were discussed are included in the NPRM. She questioned whether there would be alignment and additional consideration based on the NPRM.

- **Steven Lane** noted that there is a strong connection with the USCDI and there will be additional work to align with the NPRM.
- **Ken Kawamoto** commented that the goal is to eliminate unnecessary, duplicative work.

Brett Oliver questioned if there was talk about medication discontinuation from pharmacies which is a patient safety issue.

- **Steven Lane** commented that this would be great to add to areas that would help with advancement.

Christina Caraballo questioned removing social determinants of health. She noted that Steven said that there is work already happening, but she felt that this is the reason to keep it on the list. She felt that

there still is not an implementation guide available to help organizations to implement in a standardized way.

- **Steven Lane** agreed with Christina's comments. He noted that the ISPTF has a limited period to work and the group decided where they wanted to focus their attention. There is a great opportunity for the HITAC and other interested members of the public to provide insight.
- **Ken Kawamoto** added that social determinants of health are an example of something that could work well through the USCDI.
- **Andy Truscott** agreed with Christina's comments. He noted that social determinants of health could be picked up. He emphasized the point that just because someone isn't doing something, it does not mean that there isn't a standard to do it.

Arien Malec commented on medication discontinuation; he noted that one of the interoperability issues is that even if there is a standard, it might not be adopted by the ecosystem. It might be important to consider some of the ecosystem effects.

Aaron Miri suggested diving into patient-reported outcomes (PROs). There is a gap in standards, and it would be beneficial to have more standards so that it can be universally adopted, resulting in better outcomes.

- **Carolyn Petersen** followed up to Aaron's comment related to PROs and to started thinking about patient-generated health data (PGHD).

Denni McColm asked what happens next.

- **Steven Lane** commented that there would be a report sent to ONC sharing the findings and recommendations. It will be up to ONC how that gets moved forward.

Tina Esposito commented that it would be helpful to identify what work hasn't been picked up due to the limited time the task force has to meet.

Steve Posnack thanked the ISPTF for all their work. Some areas not addressed by the ISPTF could be represented as the finding that doesn't get precise recommendations. The priorities can be implemented in parallel with ONC or with a respected private sector partner. It might be helpful to think about parallel processes. US FHIR Core profiles could be implemented through HL7, as an example. Identifying what will make the most impact would be helpful.

Donald Rucker commented that it is a wonderful list, but want to be sure that each item is mapped to how it will get done. This will help with the boundary case. Some of the items are harder because it is hard to identify where the landscape starts.

Ken Kawamoto shared that the recommendations do have specific actors for taking up the work.

Cynthia Fisher noted her support for the patient-oriented comments. She emphasized the need to work to allow mobile access for the patient.

Robert Wah transitioned to the chairs of the Information Blocking Task Force.

Information Blocking Task Force Update

Michael Adcock, Co-Chair
Andrew Truscott, Co-Chair

Members

Cynthia A. Fisher
Valerie Grey
Anil K. Jain
John Kansky
Steven Lane
Arien Malec
Denni McColm
Aaron Miri
Sasha TerMaat
Lauren Thompson
Sheryl Turney
Denise Webb

Andy Truscott noted that the group is diverse with extremely varied opinions. He thanked the contributions by the ONC staff, noting the amount of work that went into preparing the regulations and the support that has been provided to the task force throughout the process. He encouraged the public to be active and to provide comments during the calls to inform their work. He reviewed the goals of the workgroup.

Overarching Charge: Provide recommendations on policies related to information blocking; the "information blocking," "assurances," and "communications" conditions and maintenance of certification requirements; and the enforcement of all the conditions and maintenance of certification requirements.

Specific Charges: Provide recommendations on the following topics:

- Information Blocking:
  - ONC definitions/interpretations of certain statutory terms and provisions, including the price information request for information (this does not include the definition of information blocking which is defined in Cures)
  - Seven exceptions to the information blocking definition, and any additional exceptions (request for information)
  - Complaint process
  - Disincentives for health care providers (request for information)
- "Information blocking," "assurances," and "communications" conditions and maintenance of certification requirements
- Enforcement of all the conditions and maintenance of certification requirements

Andy Truscott turned the review over to his co-chair **Michael Adcock**.

WORKGROUP 1 - RELEVANT STATUTORY TERMS AND PROVISIONS

Topics

- Health information networks/exchanges
- EHI, including the price information request for information
- Practices that may implicate the information blocking provision
- Parties affected by the information blocking provision and exceptions

Members

- Sheryl Turney
- John Kansky
- Denni McColm
- Cynthia Fisher

Workgroup 1 – Progress and Recommendations

- Health information networks/exchanges (HIE/HIN)
  - The definitions for and distinction between HIE and HIN should be clearer
    - Discussed whether the scope of proposed definitions align with the intent of the Cures Act
    - Working on recommendations for revisions to regulation text and preamble
- EHI definition
  - **Proposed recommendation:** Add language in the preamble that clarifies that "information" is inclusive of human or machine-readable form
- Price information
  - Multiple views on addressing price transparency in this rule
    - Price transparency is important, but out of scope for this rule; must consider unintended consequences
    - View that patients need price transparency now and this rule is the appropriate lever for addressing the issue
  - Reviewing ONC's Request for Information (RFI) regarding price information and will provide more detail about the scope and parameters of price information that would be included
  - Considering the implications of including such information in the definition
- Practices that may implicate the information blocking provision
  - Discussed scope and implications of examples of potential information blocking
  - Considering updates to examples
- Parties that may implicate the information blocking provision
  - Discussed ONC's use of the term "actors" for regulated entities under the information blocking provision
  - Discussed examples of entities that would/would not be considered an "actor" under the proposed definitions of health care provider, health IT developer of certified health IT, health information network, and health information exchange
  - Considering clarifying language and examples in the preamble

Discussion

- **Arien Malec** questioned the definition of health information network (HIN) which places a number of actors that seem to be outside of the intent of Congress (e.g., banking could be considered a health information network). He felt the group should address the needs for health information network and health information exchange around this.
    - **Andy Truscott** commented that they encourage feedback on the recommendations for the definitions.
- **Cynthia Fisher** commented that for the definition of network or health information network, it is important that the definition should remain broad-based on the function that the entity is engaged in. The entire health care industry is shifting with new lines of data exchange taking place. Policy makers need to consider these broad definitions to ensure that legal obligations are kept with respect to information blocking. She suggested the preamble include examples.
- **John Kansky** commented that policy is a blunt instrument. The intent is to whack the bad moles. If the definition is too broad, too many will get squashed.
    - **Andy Truscott** commented that the HITAC is starting to see how the impact of this will be felt by all actors.
- **Sasha TerMaat** suggested that the group might need to consider the broad definition of electronic health information. She also questioned the definition of health IT developer. She thought it seemed narrowly defined as only those with health IT products. If other provisions are broad, the health IT developer definition might also need to be broader.
    - **Andy Truscott** noted there was a discussion about the latter point and they learned that it is not the intent. He also noted there is a difference between the regulatory text and preamble.
- **Aaron Miri** commented that there could be a better job in the preamble of how patients interact with their data, in regards to how patients receive their data (e.g., Spanish speaking populations, as he considers this to be information blocking).
- **Cynthia Fisher** expressed concern about the use of individually identifiable health information in the definition of electronic health information (EHI). Congress did not use these terms.
- **Arien Malec** noted if the right definition is used then the right downstream structure will follow. Making data flow faster, better, and cheaper, but preserve an ecosystem that enables information flowing and addresses enrichment of information as it flows, there might be regulatory information that addresses blockers. Getting the definition of EHI and information exchange right is important.
- **Les Lenert** commented on the group level transfers in the NPRM. There is a need to preserve the competition in the EHR market and is an important aspect of information blocking. To restore competition in the market there has to be a route to migrate from one EHR to another that includes the billing and financial data to do it successfully.
    - **Andy Truscott** noted that there is some drafting around this in the workgroups.
- **Denise Webb** reiterated the points made by Sasha TerMaat. It is confounding that the definition of EHI is so broad and covers so many actors.
    - **Andy Truscott** requested a joint meeting to discuss amongst task forces.
- **Steven Lane** noted that there is the ability for the provider to switch EHRs, but the patient also needs to be able to switch EHRs. Patient data needs to be ingestible into other systems; this needs to be spelled out. This is a big lift for vendors.
- **Les Lenert** noted that the provenance of the data has to go with the data. The data needs a unique identifier.

WORKGROUP 2- EXCEPTIONS

Andy Truscott reviewed the work discussed in Workgroup 2.

Topics

- Exceptions Topics
- Preventing Harm
- Promoting the Privacy of EHI
- Promoting the Security of EHI
- Recovering Costs Reasonable Incurred
- Responding to Requests that are Infeasible
- Licensing of Interoperability Elements on RAND Terms
- Maintaining and Improving Health IT Performance
- Additional exceptions (request for information)
- Complaint process
- Disincentives for health care providers (request for information)

Members

- Valerie Grey
- Anil Jain
- Arien Malec
- Steven Lane

Workgroup 2 – Progress and Recommendations

Preventing Harm

- Corrupt or inaccurate data, (a)(1): Concern that this could become a large exception loophole (e.g., most people's records have some level of inaccuracy)
    - Considering proposal to restrict requirement to true data corruption
- Misidentification of patient's EHI, (a)(2): Suggestion to limit to cases where a data holder knows that the data is not applicable to the patient and to create a test
- Proposal to define "organizational policy"
- Proposal to clarify the documentation requirement for when there is an individualized finding

Promoting the Privacy of EHI

- Concern regarding potential overhead requirements for organizations; proposal to address in preamble
- Proposal to add language that organizational policies must comply with federal, state, and local laws
- Sub-exception for precondition not satisfied: Proposal that consent (or dissent) should be documented/recorded
- Sub-exception for health IT developer of certified health IT not covered by Health Insurance Portability and Accountability Act (HIPAA): Proposal to define/explain meaning of "meaningfully disclosed"

Promoting the Security of EHI

- Proposal to clarify the documentation requirement when there is an individualized finding
- Consensus that when the requestor is the data subject (patient), then security is no reason to prevent sharing, unless there is legitimate doubt of the identity of the patient

- Determining whether to make a recommendation

Recovering Costs Reasonably Incurred

- Proposal to clarify "objective and verifiable"
- Proposal to be clearer in regulation text that reasonable profits are allowed
- Concerns about the application of this exception in real life
  - Operational burden for finance/accounting, technical accounting, pricing, legal, etc.
- Proposal to clarify meaning of "non-standard" implementation
- Proposal to clarify "intangible asset"
- Discussed distinction between exceptions for costs reasonably incurred and RAND licensing

Responding to Requests that are Infeasible

- Concern that "start-ups" with "limited" resources (talent and capital) could use this exception to not participate in the information sharing
  - Determining whether to make a recommendation
- Discussion of meaning and application of providing a "reasonable alternative."
  - Determining whether to make a recommendation
- Requirement that the actor "timely respond" is unclear
  - Determining whether to propose a revision/clarification

Licensing of Interoperability Elements on RAND Terms

- Proposal to add requirement that licensors must publicly post contact info for requestors to contact them and that requestors must use that publicly posted list to contact licensors
- Proposal that 10-day response period in (a) is unreasonable for initial offer
  - Considering proposing alternate time frame
- Proposal to build in timeframe for licensor to acknowledge receipt of request into the overall response timeline
  - Suggestion of 72 hours to acknowledge receipt
- Discussion about meaning of "royalty" and whether it is the right term
  - Considering proposing alternative language
- Discussion about use "standards-essential technologies."
  - Considering proposing alternative language

Maintaining and Improving Health IT Performance

- Must consider this exception in the context of vendor planned and unplanned downtime and impact of vendor Service Level Agreements that may shift responsibility from healthcare entities to vendors that are congruent with this exception
  - Considering proposing additions to exception
- Proposal to address situation where one customer does not agree to the proposed period of unavailability which is required to maintain or improve the system, but others do

Additional exceptions (request for information)

- Need to see final TEFCA before reaching conclusions about TEFCA exception
- Discussed Business Associate Agreements (BAA) and how they interact with the Cures Act
    - Considering recommendation to clarify whether the Cures Act preempts BAAs, or alternatively to propose a BAA exception
- Complaint process – Not yet discussed
- Disincentives for health care providers (RFI) – Not yet discussed

Discussion

- **Aaron Miri** asked if under preventing harm if there was a discussion about not sharing with someone who may have cybersecurity concerns. Underpromoting privacy, has there been consideration about adding the Family Educational Rights and Privacy Act (FERPA)?
- **John Kansky** noted that about recovering costs not reasonably incurred, he has concerns whether a tiered model will be okay. He is sharing as unintended consequences (e.g., smaller organizations paying more because tiers are no longer allowed).
- **Arien Malec** noted that the regulatory text does not have text around reasonable profit, only in preamble. No standard for reasonableness. If the comment that there needs to be a reasonableness test, what is the process for logical outgrowth?
    - **Elise Sweeney Anthony** noted that it is helpful to know about terms that need to be defined.
    - **Mike Lipinski** noted that the details around business associate agreements (BAAs) are addressed in how contracts are used to information block.
    - **Arien Malec** noted that this is about clearinghouses, not a theoretical issue, it would be helpful for clarity and he will provide recommendations.
    - **Donald Rucker** noted that detailed comment should be provided. For a broader perspective, the public is unhappy with what is happening in healthcare.. A BAA may need to be rewritten. It would be most helpful to understand the broader intent of the law. There have been complaints from stakeholders about licensing agreements that have precluded sharing.
- **Les Lenert** the exemptions should not be used to deny requests from government agencies or the investigation of EHR safety. This needs to be stated.
- **Sasha TerMaat** expressed support for the workgroups attempt to simplify. There is a lot of use of subjective language in the way the definitions are proposed – this doesn't meet the goal of being clear and predictable.

WORKGROUP 3 - CONDITIONS AND MAINTENANCE OF CERTIFICATION

Michael Adcock reviewed the work done by Workgroup 3.

Topics

- Information blocking
- Assurances
- Communications
- Enforcement of all the conditions and maintenance of certification requirements

Members

- Denise Webb
- Sasha TerMaat

- Lauren Thompson
- Aaron Miri

Work Group 3 – Progress and Recommendations

- **Assurances**
  - **Proposed recommendation**: For products that are withdrawn by the developer, a retention period of 3 years after the withdrawal is sufficient.
  - **Proposed recommendation**: ONC should retain records on the Certified Health IT Product List (CHPL) indefinitely for ongoing reference of which products were certified over which time period (as it does today).
  - **Proposed recommendation**: Revisit TEFCA RFI to make recommendations when revised TEFCA is published (or have the TEFCA Task Force address it).
- **Communications**
  - **Proposed recommendation**: Adjust definitions to clarify that administrative functions of HIT could be "non-user facing aspects" based on the assessment that those communications are not matching the purpose described in 21st Century Cures and also affect a limited set of users.
  - **Proposed recommendation**: (D)(2)(iii) should be amended to a list of which third party content might appear in a screen. Enumerating elements per screen is not feasible.
  - **Proposed recommendation**: Unintended consequences of "fair use" and other usages should be further explored by ONC. There are concerns about risks to vendor intellectual property that the task force wishes to be sensitive to; do not wish to impinge upon innovation. Also, ONC should draw a distinction around purpose of use in relation to "fair use" of screenshots, with the intention that the discloser is responsible for ensuring the appropriateness of the purpose.
  - **Proposed recommendation**: ONC should revise estimate in Regulatory Impact Analysis. Effort for notice and contracting is underestimated at 40 hours for a clerk. More roles are involved than clerks, including work involved on the part of the recipients
  - **Proposed recommendation**: Amend (b)(2)(i) and (b)(2)(ii) as proposed in underlines:
    - (b)(2)(i) A health IT developer must not establish, renew, or enforce any contract or agreement that contravenes paragraph (a) of this section.
    - (b)(2)(ii) If a health IT developer has a contract or agreement in existence at the time of the effective date of this final rule that contravenes paragraph (a) of this section, then the developer must in a reasonable period of time, but not later than two years from the effective date of this rule, agree with the relevant client on a plan to amend the contract or an agreement to remove or void the contractual provision that contravenes paragraph (a) of this section.
    - (b)(2)(iii) The plan required by paragraph (ii) of this section must be completed within five years of the effective date of this rule.
  - **Proposed recommendation**: ONC should add a category of communications titled "Unprotected Communications" to their framework. Communications in this category would not be extended these protections, including communications such as false communications, communications protected by attorney-client privilege, etc. "Unprotected Communications" should not receive unqualified protection or necessitate permitted restrictions.
- **Enforcement**

- **Proposed recommendation:** ONC should use both email and certified mail for notices of initiating direct review, potential non-conformity, non-conformity, suspension, proposed termination, and termination.

- **Ban**
  - **Proposed Recommendation:** Indefinite communication of past records (ban with start and end date, if lifted) seems appropriate.
  - **Proposed Recommendation:** We do not recommend establishing a minimum time period over which a ban must last, even if the health IT developer is a repeat offender.
- **Self-developers**
  - **Proposed Recommendation:** Call out an exception to (a)(2)(ii)(A) for self-developed systems, so that communications by health IT users aren't restricted by virtue of being employees of the same company doing the development.

Discussion

Raj Ratwani noted that it seems the intent is to open up the ability to communicate and have more transparency; this can be done in three ways:

- Conduct usability and safety tests
- Allow participation in studies
- Communicate the information

The last two items are addressed, but concerned about the first part. There could be blocking of testing and if that is the case, cannot communicate.

- **Andy Truscott** asked for more specifics, recognizing that not all developers are created equal.

Lauren Richie opened the lines for public comment.

Public Comments

John Travis, Cerner, there needs to be clarity between infeasibility and offering licensing exemptions. He expressed concern around RAND efforts that may demark what is infeasible. On the interoperability elements offered on RAND, there need to be considerations for tiers.

- Does what is being requested exist?
- Need to allow for distinguishing available offerings (e.g., clients with old versions of technologies that are not the basis of certified technology)

Robert Wah thanked the group for their hard work and then broke for lunch and a group photo.

Lunch Break

Robert Wah welcomed everyone back after lunch and reminded everyone that the HITAC has a commitment to the public with specific times for comments and will try to do what is necessary to keep that commitment. He turned the meeting over to Denise Webb and Raj Ratwani, co-chairs of the Conditions and Maintenance of Certification Task Force.

Conditions and Maintenance of Certification Task Force Update

Raj Ratwani, Co-Chair

Denise Webb, Co-Chair

Members

Kensaku Kawamoto
Leslie Lenert
Carolyn Petersen
Sasha TerMaat
John Travis

Denise Webb reviewed the day's agenda and the members of the task force. She reviewed the charge, as noted below.

- **Overarching Charge**: Provide recommendations on the application programming interface (API)," "real world testing," and "attestations" conditions and maintenance of certification requirements; updates to most 2015 Edition health IT certification criteria; changes to the ONC Health IT Certification Program; and deregulatory actions.
- **Specific Charge**: Provide recommendations on the following:
    - "API," "real world testing," and "attestations" conditions and maintenance of certification requirements
    - Updates to the 2015 Edition certification criteria: "Standardized API for patient and population services," "electronic health information export," "electronic prescribing," "clinical quality measures – export," and privacy and security-related attestation criteria ("encrypt authentication credentials" and "multi-factor authentication")
    - Modifications to the ONC Health IT Certification Program (Program)
    - Deregulatory actions related to certification criteria and Program requirements

OVERARCHING RECOMMENDATIONS

- Clarity on Rationale for Maintaining a "2015" Edition
    - In review of the records retention requirements for ONC-ACBs but applicable to many sections of the proposed rule, the CMCTF questioned why ONC proposed to modify the 2015 Edition as opposed to creating a new Edition. There are broad-sweeping changes to the 2015 Edition as a result of this proposed rule. By not updating to a new Edition, users of the CHPL would be confused about which version of 2015 Edition is being referenced. Also, there are records retention implications for ONC-ACBs and Health IT developers when an Edition is continually modified rather than retired and replaced by a new Edition that may require retention for an inordinate amount of time that would not otherwise be required if a new Edition is established instead when there are significant modifications to an Edition by rulemaking.
    - **Recommendation 1**: ONC should introduce a new Edition of certification rather than propose changes to the 2015 Edition.

Denise Webb turned the discussion over to her co-chair **Raj Ratwani** to review Real World Testing.

Real World Testing

- **Recommendation 2**: ONC should reconsider the due date for real world testing plans. The CMCTF recommends ONC provide more flexibility for deadline - avoid holidays, avoid overload for ONC-ACBs/federal government. The CMCTF recommends an alternative: anniversary date tied to the certification anniversary for the CEHRT being tested.
    - The CMCTF supports the idea of a pilot year and recommends having ONC-ACBs assess plans from pilot year then come up with a template for vendors to use.
- **Recommendation 3**: ONC should provide more clarity around care settings/venue to what the test plan must cover. The goal is to make minimum expectations clear in regards to applicable care settings and venues (which settings, sufficient number of settings) for the health IT product.
- **Recommendation 4**: ONC should provide guidelines or a template for a test plan. The template will help the process. The CMCTF supports the proposed pilot year and recommends that ONC-ACBs assess plans from the pilot year then provide a template for vendors to use addressing the minimum requirements for an acceptable test plan.
- **Recommendation 5**: ONC should provide clarity around how successful real-world testing is met: (1) continued compliance with certification criteria (including standards and code sets), (2) exchange in intended use settings, and (3) receipt and use of electronic health information in the certified EHR. The CMCTF reviewed and determined not all three elements are possible for all certification criteria proposed for real world testing.
- **Recommendation 6**: ONC should clarify and define the terms, “scenario” and “use case” and if these terms mean the same thing, then choose and use just one of these terms in the rule. ONC should also clarify the term “workflow” as it is used in real world testing.
- **Recommendation 7**: We recommend vendors be given discretion to incorporate permissible testing approaches, including, for example, automated testing and regression testing (also possibly automated).
- **Recommendation 8**: ONC should provide clarification around testing the exchange of information, or about the use of the information. Testing the use of that information requires consideration of human factors and usability to understand whether the intended users efficiently and effectively use the presented information. When there are no end users of the product being tested, use-based testing would not be pertinent.
    - Use of data testing, if expected, would be pertinent to the receipt of data in the EHR. If the health IT developers are testing the use, they need to have the providers involved in the testing to determine if the providers can process and use that information when there is an exchange. The providers were not considered in the cost estimates for real world testing in the proposed rule preamble.
- **Recommendation 9**: ONC should clarify the expected involvement of providers and third parties to support the “real world” nature of the testing.
    - The CMCTF suggests providers using the certified technology should be involved in real world testing with the health IT developers, but the final rule needs good guidance on testing options that address the use of simulated data and address requirements for unidirectional versus bidirectional test cases. For example, the final rule should clarify whether the health IT developer is required to provide testing for both endpoints/sides in a bi-directional testing scenario.
    - If there is provider involvement, ONC should adjust provider estimates in the cost impact analysis in the proposed rule.

- **Recommendation 10**: ONC should allow for flexibility for vendors with regard to real world testing where there is no difference in the testing approach, result or capability. The CMCTF suggests:
  - Common capability – test once across all settings and test cases if truly the same capability for the same requirement
  - Unchanged capability – allow the vendor to attest to capabilities that remain unchanged from prior year
  - Common requirement – test once if the requirement does not vary across all settings and test cases for requirements such as secure communication
  - Production experience – clarify whether real world testing is required for what already has long-standing evidence and history of operating in real-world production environments
  - Clarify applicability of requirement for various practice and care settings. For example, clarify whether all of the named CDA/document types apply to every venue
  - Attestation – allow for attestation instead of retesting
- **Recommendation 11**: ONC should include a description of "measurement." ONC should provide clarity about the role of measurement and specify for what kinds and for what purposes or proof points. After the pilot year, consider updating metric expectations: where the real-world testing is of both interoperability and use of received data, consider there be at least one metric of interoperability and one metric of use, which might correspond with metrics of use used in safety enhanced design testing.
- **Recommendation 12**: ONC should elaborate and provide more clarity on the standards version advancement process when a version of standards is available under this process but does not yet have testing tools available yet to determine conformance. It is fairly clear vendors must factor all claimed versions of standards into their real-world testing, but the final rule should clarify how the health IT developers are to address new versions for which tooling does not exist yet that they have attested to support and how the health IT developer and ONC-ACBs will judge or determine conformance. ONC should clarify whether testing will be required in a subsequent year's real-world testing plan once tooling is available or whether the health IT developer's previous attestation is sufficient.
- **Recommendation 13**: ONC should clarify the role and expectations of third parties over which the health IT developers have no control or authority over. For example, some third parties (immunization registries) and EHR developers are likely to receive many requests to participate in other parties' real-world testing. While these entities can try to be helpful, they will not have unlimited resources to assist other groups. Clarify whether declining to participate in real-world testing is considered to be information blocking. ONC should consider how reasonable protections can be provided for those who have limited resources and therefore are unable to participate in an unlimited set of tests. The rule should provide reasonable assurances to health IT developers who have tried to engage third parties in testing yet were not successful in getting their commitment to participate in testing.
- **Recommendation 14**: ONC should review and revise Regulatory Impact time estimates that would be required to ensure they are accurate and align to the clarified understanding of the real-world testing proposal.

Attestations

- **Recommendation 15**: ONC should include a specific deadline at the middle of the year and the end of year/ beginning of the year. It would provide flexibility for the ONC-ACBs to work with developers to get those in rather than specifying a predefined 14-day window of time which seems too prescriptive

and subject to problems should the period of time fall during a holiday, or government closures, etc. ONC could specify, for example, that the deadline for the health IT developers to submit their semi-annual attestations to the ONC-ACB is the last Friday of January and July (this avoids holidays).

Raj Ratwani turned it over to **Denise Webb** to review Application Programming Interfaces.

Application Programming Interfaces (API)

- **Recommendation 16**: ONC should clarify and make an explicit statement of an acceptable relationship between the API Technology Supplier and the API User, or clarify what activities are expected or permitted to occur between the API Technology Suppliers and API Users. There are multiple relationships supported in this environment and this particular relationship is not sufficiently addressed in the proposed rule. Relationships prior to the involvement of an API Data Provider are particularly of interest.
- **Recommendation 17**: ONC should adopt solely FHIR Release 4 in the final rule for reference in proposed § 170.315(g)(10) (Option 4). This was recommended as the first normative version, supporting enhanced capabilities (such as bulk data), and not dividing the focus of the industry with multiple standards.
    - HITAC: Discuss considerations for FHIR Release 2.
- **Recommendation 18**: ONC should move forward with implementation specifications and implementation guides to ensure everyone is working from the same set of specifications as this would enhance interoperability and reduce implementation complexity and potentially cost. The CMCTF sees value in health IT developers harmonizing to a specified version/release.
- **Recommendation 19**: ONC should address the legitimate and expected activity for SMART Guide to protect patient data with respect to providing persistent tokens to applications and their ability to keep the token confidential. The CMCTF recommends ONC further clarify. Someone will need to ascertain that API Users provided a persistent token are creating products that secure the token appropriately, but it is not clear who plays that role. ONC will need to clarify who it is and how the determination is made.
- **Recommendation 20**: The CMCTF has concerns over ONC not proposing a standard way for a request for multiple patients' data and recommends ONC specify a standard approach (which is available in FHIR R4). There are concerns because each developer could implement this differently and invest time in non-standard ways and then likely have to spend time/money transitioning to the standard way. The CMCTF also recognized there is an immediate need now to satisfy this type of request.
- **Recommendation 21**: The CMCTF was puzzled by requirements to update API documentation (6 months) prior to the requirement to update API capabilities (24 months). ONC should clarify what happens at 6 months and what happens at 24 months.
- **Recommendation 22**: ONC should further clarify the requirements and expectations around the app registration condition of certification based on a number of issues the CMCTF identified regarding app registration. The CMCTF recommends clarification in the rule that would address the following:
    - What the practice of "registration" consists of and does not consist of and who is the party responsible for keeping a list of registered apps.
    - What "verifying the identity" of an API user consists of and does not consist of and who is the party responsible for performing this. If this is optional, specify that those who haven't

performed it are clearly excused from possible cases where API users misrepresent themselves.

- What "vetting" an app (in contrast to verifying identity of a user) consists of and what falls outside the definition of vetting and who is the party responsible for vetting and who is prohibited from vetting. If vetting is optional and not performed, specify that those who haven't performed it are clearly excused from any possible consequences attributable to poorly designed or malicious apps.
- Identifying any tasks (such as an API Data Provider whitelisting a particular app for the first time or an API Data Provider endorsing particular apps) that fall outside of "registration," "identity verification," and "vetting." Describe the tasks, and identify the parties that can and cannot perform them. If they aren't performed, provide clarity that the party is not liable.

Electronic Health Information Export

- **Recommendation 23**: ONC should provide clarity around the scope of the EHI export. The CMCTF recommends it be limited to EHI collected and retained by the certified EHR technology and apply only to the EHI that is part of the legal medical record. Narrowing to the legal medical record was important in particular for research data stored in an EHR.
- **Recommendation 24**: ONC should clarify that the export process must accommodate manual review by the API Data Provider to comply with state/local laws prior to being released. A state may have laws prohibiting release of certain EHI to a patient and the EHI export process would need to accommodate compliance.
- **Recommendation 25**: ONC should include audit log data for transitioning systems use case (not for patient use case due to privacy of health system staff).
- **Recommendation 26**: ONC should not require specific timeframe restrictions for data export, due to complexity experienced by health IT developers complying with the time frame flexibility/timeframes in the View, Download, Transmit certification criterion.
- **Recommendation 27**: ONC should make e-Rx transactions that are not applicable to all settings and/or need piloting optional. If all transactions are required, this could jeopardize the timeline specified for availability/production use. The CMCTF recommends the revisions below:
  - (11) Electronic prescribing. (i) Enable a user to perform whichever subset of the following prescription-related electronic transactions are relevant to their domain and system design and have been piloted and are ready for widespread use in accordance with the standard specified in § 170.205(b)(1) and, at a minimum, the version of the standard specified in § 170.207(d)(3) as follows:
  - (A) Optional. Ask mailbox (GetMessage).
  - (B) Relay acceptance of transaction (Status).
  - (C) Error response (Error).
  - (D) Create new prescriptions (NewRx, Optional: NewRxRequest, Optional: NewRxResponseDenied).
  - (E) Change prescriptions (RxChangeRequest, RxChangeResponse).
  - (F) Renew prescriptions (RxRenewalRequest, RxRenewalResponse).
  - (G) Optional. Resupply (Resupply).

- (H) Return receipt (Verify)
- (I) Cancel prescriptions (CancelRx, CancelRxResponse).
- (J) Receive fill status notifications (RxFill, Optional: RxFillIndicatorChange).
- (K) Optional. Drug administration (DrugAdministration).
- (L) Optional. Transfer (RxTransferRequest, RxTransferResponse, RxTransferConfirm).
- (M) Optional. Recertify (Recertification).
- (N) Request and receive medication history (RxHistoryRequest, RxHistoryResponse).
- (O) Optional. Complete risk evaluation and mitigation strategy transactions (REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse). (ii) For each transaction listed in paragraph (b)(11)(i) of this section, the technology must be able to receive and transmit the reason for the prescription using the diagnosis elements in DRU Segment if that segment is supported by the standard for that transaction. (iii) Optional. For each transaction listed in paragraph (b)(11)(i) of this section, the technology must be able to receive and transmit the reason for the prescription using the indication elements in the SIG Segment if that segment is supported by the standard for that transaction. (iv) Limit a user's ability to prescribe all oral liquid medications in only metric standard units of mL (i.e., not cc). (v) Always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.

Clinical Quality Measures - Export

- **Recommendation 28**: ONC should update the quality measurement proposal with a table the CMCTF shared. ONC proposes that all products adopt both the CMS ambulatory IG for QRDA III and CMS inpatient IG for QRDA I. We see this as an important technical correction for quality reporting use cases
- **Recommendation 29**: The CMCTF agrees quality reporting using FHIR is a good aspirational direction to take and a future recommendation, but it is not ready today

Privacy and Security-Related *Attestation* Criteria

- **Recommendation 30:** ONC should apply privacy and security attestations only to new certifications/new products after this rule is finalized, not to products already in widespread use, where the widespread publication of the attestation on these criteria might create a vulnerability and unintended consequences if malicious actors had this information about existing production systems.
- **Recommendation 31**: ONC should add a text box for developers to describe their yes/no attestations in certification. This would also help with clarity for use cases (login, signing EPCS, etc.).

Denise Webb turned it over to **Raj Ratwani** to review deregulatory actions.

Deregulatory Actions

Removal of Randomized Surveillance Requirements

- **Recommendation 32**: ONC should not remove the prohibition on consecutive selection of one health IT module (preserve (c)(6)). The goal is that if the proposed deregulation is implemented

to remove the requirement on ONC-ACBs to conduct random surveillance, ONC-ACBs may still randomly surveil but cannot consecutively select the same HIT module for random surveillance more than once in a 12-month period. If through random surveillance, an ONC-ACB discovers non-conformance in a HIT module, they would still be able to follow up on the same HIT module within the 12-month period through its reactive surveillance authority.

Removal of Certain 2015 Edition Certification Criteria

- **Recommendation 33**: ONC should adopt a general principle of not duplicating data capture criteria within the certification criteria (such as demographics) for data classes included in USCDI and based on this principle, the CMCTF recommends ONC consider other criteria, such as demographics, that could also be removed and do so in the final rule.

Discussion

Arien Malec thanked the CMCTF for their recommendations. With respect to real-world testing, he has been advocating the delegation of certification and real-world testing to designated entities. The best real-world testing is demonstrated in the product.

- **Steve Posnack** commented that this is accommodated as part of the proposal. Developers might choose to include in their plan that they are part of CommonWell, as an example, to meet the certification criteria within the scope of real-world testing. He noted this is in the preamble, but comments should be provided if this is not clear.

Arien Malec also commented that with respect to bulk data, the Argonaut Project had taken this on as a project to demonstrate real-world viability. ONC has put regulatory flexibility in place to work through a process like Argonaut or others to get the standard right. If the right evolution is FHIR, but name Quality Reporting Document Architecture (QRDA) in regulation, there is no appropriate regulatory flexibility to switch to FHIR. The reason to vet or validate with respect to patient access is to make it clear which applications (apps) are trusted and not, in order to access the apps of their choice.

- **Steve Posnack** commented on the vetting, ONC does not explicitly require vetting to be conducted. There are guidelines and guardrails that can be followed without information blocking. Vetting is about the authenticity of the app developer, not judging the app itself.

Andy Truscott noted in regard to the retention period it might make sense to align between task forces.

- In regard to FHIR Release 2 (R2) versus Release 4 (R4), putting versioning in the regulation does not meet future uses well. He suggested putting the ownness on HL7, allowing them to maintain the standards they create.
- Recommendation 26 around export, when something is hard there is no obligation to do it, it generally doesn't get done. He asked the CMCTF to clarify the recommendation.

Elise Sweeney Anthony commented on the FHIR 2 versus FHIR 4 version advancement process.
She noted that there is a proposal in the rule around this update process which would allow cases where a floor is established, that developers could move upward from that and be held accountable once they decide to move up a version to performing at that version. She gave an example that if a decision was made to start at FHIR 2, if developers decided to move up to FHIR 4, then they would be held accountable to performing at that level, per those requirements.

- **Steve Posnack** noted there are regulations about regulations. Need to comply with incorporation by reference process, need to incorporate baseline requirement in the rule.

Arien Malec noted that R4 is the only release of which forward compatibility is guaranteed by HL7. At HIMSS Argonaut stakeholders met and there was a strong consensus to go with R4.

Donald Rucker noted his appreciation for the detail in the recommendations coming out of the task forces. He emphasized that every comment received will be reviewed. He encouraged that all HITAC members encourage comment from their stakeholders.

Ken Kawamoto commented in regard to FHIR, giving ONC the flexibility to choose the latest version makes sense. If there are provider aspects to the real-world testing, want to be careful about unintended consequences, can take a lot of resources. In regards to provenance, suggest adding role. In terms of the security and privacy, it would be good to have specific guidance that data is HIPAA compliant (minimum necessary). He expressed concern about the reference to Argonaut; it is a closed group that is not open to public feedback. He felt strongly that Argonaut not be referenced.

Steve Posnack commented that he was happy to make himself available to answer any specific questions.

- With respect to the 2015 Edition the group is grappling with the same context that ONC had. ONC is coming out with a new Edition at the same time that this is required for the first time from CMS and with somewhat minimal changes to 2015 Edition.
- On the six-month aspect in relation to the API recommendation, there are three API certification criteria today. A lot of the API conditions would apply directly to them upon the final rule. Need a timeframe to apply the full suite of the conditions of certification to the existing certification. The six months is about applying to the current API certification.
- Recommendation 24 – overextension of the API data provider, this is not used in the EHI export certification criterion.
- In regards to electronic prescribing (e-prescribing), all transactions are required by CMS for Part D prescribing. Aiming to realign with CMS.

Denise Webb asked about where the information in regards to the six months already exists in the preamble. Steve Posnack noted he would share this information.

Arien Malec commented that a standard is a standard, as long as it is aligned with a standards organization and it is used and tested in practice.

Sasha TerMaat noted that in regards to the e-prescribing standard, that she doesn't think that any product would have to support all transaction types. Pharmacy to pharmacy transactions, don't make sense for all products that would go through certification, as an example.

- **Steve Posnack** noted that this is a helpful commentary to add to the recommendations.

Denise Webb noted that Ken's comment on provenance is applicable to the U.S. Core Data for Interoperability (USCDI) Task Force.

Robert Wah turned the meeting over to Christina Caraballo, co-chair of the USCDI Task Force.

U.S. Core Data for Interoperability Task Force Update

Christina Caraballo, Co-Chair
Terrence O'Malley, Co-Chair

Members

Tina Esposito
Valerie Grey
Kensaku Kawamoto
Steven Lane
Leslie Lenert
Clem McDonald
Brett Oliver
Steve L. Ready
Sheryl Turney

Christina Caraballo reviewed the phase one charge for the USCDITF.

PRINCIPLE CHARGE FOR PHASE 1

- **Principle Charge for Phase 1**: Review the newly specified Data Elements proposed in the USCDI v1
- **Specific Charge**: Provide recommendations on the following:
  - Inclusion of Provenance Data Elements
  - Inclusion of Clinical Notes Data Elements
  - Inclusion of Pediatric Vital Signs Data Elements
  - Inclusion of Address and Phone Number Data Elements
  - Missing Data Elements within Proposed Data Classes
- ONC is seeking recommendations for Phase 1 on the following:
  - Provenance
  - Clinical notes
  - Pediatric Vital Signs
  - Address and phone number

New Patient Demographics data elements proposed by ONC for inclusion in USCDI v1

- Address; Phone Number

Task Force recommendations:

- Address
  - Standardize format and content of Address
  - Standards for individuals experiencing homelessness and refugees
- Phone Number
  - Use mobile phone number
- See AHIMA, USPS, Association for Healthcare Documentation Integrity, current requirements for certified electronic health record technology (CEHRT)
- Additional data elements proposed for discussion:
  - Nickname; last 4 digits of SSN; personal ID (e.g., driver's license, passports, etc.); e-mail; alternative address (e.g., work, school)

Discussion

Arien Malec commented that he endorsed the use of alternative methods for identification in the work that CommonWell and other HIEs have done in regards to patient identification. There is a hope that artificial intelligence (AI) will get to a perfect match on known demographic information. There is a substantial upper limit that you can get to with core demographic information, and other attributes are helpful to link records. Driver's license and mobile phone are secondary attributes that will greatly facilitate patient matching and linking.

Aaron Miri commended the recommendations. He suggested certain elements related to personal IDs that could dissuade folks from seeking care. In certain communities, if asked for identification, it can scare individuals from seeking treatment.

Andy Truscott noted that this is about consistency and identification. Are we suggesting that there could be a level of validation? If collecting information, something should be done with it. There could be a false level of security if not verifying information.

Steven Lane commented that the USCDI is about the data content, in regard to verification that is about the process of collection. The process has not been discussed in the task force.

Andy Truscott commented that they don't want to diminish the importance and utility of data in USCDI.

Tina Esposito mentioned that this relates back to provenance, ensuring the accuracy of this information.

Andy Truscott noted that there has been experience in other places that should be leveraged, such as Australia, the United Kingdom, and Canada.

Steve Posnack noted that phase two of this task force will get into some of the items discussed. It will be a large task to identify what makes it into USCDI.

Provenance - Data Element Recommendations

- New Provenance data elements proposed by ONC for inclusion in USCDI v1:
  - Author; Author's Time Stamp; Author's Organization
- Task Force recommendations:
  - Author – Specify a permitted "Author Type" by data type? (e.g., lab director for labs, surgeon for procedure note)
    - Does this include setting, context, location? (e.g., vital signs collected at home, pharmacy, clinic, or hospital)
  - Chain of Trust
    - Minimum Original Author and immediate source (if different from author)
- Additional Data Elements proposed for discussion:
  - Unique identifiers (original ID of data, supplemental ID, Medicare code, National Provider Identifier)

Discussion

Sasha TerMaat noted that in conversations about provenance it seems that an implementation guide is needed. This is going to be very complex, and it will be most prudent to figure out where to focus in detail for a couple of examples. She suggested expanding over time, building on expertise.

Aaron Miri noted that the chain of trust is critical. It would be useful to have use cases or an implementation guide. In concept, it works, but it could get tricky (e.g., patient-generated health data).

Leslie Lenert noted that this needs to be broken into two components. The first would be useful to prevent duplication of data elements. The second component is more complicated. It may be difficult to do an assessment of fitness for purpose. He suggested this might be too much to take on in the first pass. If the identifier allows referencing back to where it came from, that might be all that is needed.

Andy Truscott provenance is vital. Sasha's point about the delegation of authority is interesting. This could be a lift for developers but is necessary.

Arien Malec endorsed Leslie Lenert's point. There is a lot of duplicative work done to maintain data sets. The other consideration is relative to patient-reported outcomes, to be able to distinguish the immediate source of the data.

Steve Posnack commented that some of this is deja vu. In the context of the USCDI, the intent is minimally viable provenance when data is exchanged today, not even meeting the paper equivalent of provenance. Need some assurance to the authenticity of the data being exchanged. To move forward, there is a need to simplify.

- **Steven Lane** expressed back what he heard from Steve Posnack; he essentially was saying to keep it simple from the start and build a coalition beyond initial uses.

Sheryl Turney noted that she was sharing a different use case perspective as a payer information. Payers need to be concerned about provenance, as well. Recommendation needs to be broad enough to support different use cases. She recommended looking at an instructional guide and noted that this is very complex.

Cynthia Fisher noted going back to what Steve Posnack and Andy Truscott mentioned. Looking at the banking industry, we wouldn't allow it if we couldn't see our finances. She asked the HITAC to look seriously at deploying timely feasibility to make this happen. This is an important area to address.

Steven Lane noted when this was first reviewed by the USCDITF, his initial reaction was that the items identified were just not enough, but based on the discussion he is seeing it differently.

Christina Caraballo reviewed the USCDITF work plan, noting that the next review will be on clinical notes. She also noted that the USCDITF will go on to a phase two charge after providing feedback on the NPRM.

Steven Lane questioned the intent of Phase 2. He questioned why it was missing items that were proposed from v1 of USCDI. How will that work be brought back into the process?

- **Steve Posnack** noted that there will be something for the USCDI task force to react to as part of Phase 2. There is a proposal for how to deal with the data and the class of data. The hope is to democratize the process of identifying what data is out there. Want to be able to use the regulatory floor to push the laggards along over time.

Health IT for the Care Continuum Task Force Update

Carolyn Petersen, Co-Chair
Chris Lehmann, Co-Chair

Members

Chip Hart
Susan Kressly
Aaron Miri
Steve Waldren

Carolyn Petersen reviewed the members and the charge of the Health IT for the Care Continuum Task Force (HITCCTF).

Overarching Charge: Provide recommendations on ONC's approach, recommendations, and identified 2015 Edition certification criteria to support pediatric care and practice settings; related criteria to support multiple care and practice settings; and a request for information on how health IT can support the treatment and prevention of opioid use disorder.

Specific Charge: Provide recommendations on the following:

- The ten ONC recommendations to support the voluntary certification of health IT for pediatric care, including whether to remove a recommendation
- Identified 2015 Edition certification criteria for supporting the certification of health IT for pediatric care and practice settings
- Pediatric technical worksheets
- 2015 Edition data segmentation for privacy (DS4P) and "consent management for APIs" certification criteria
- How health IT can support the treatment and prevention of opioid use disorder in alignment with the HHS strategy to address the opioid crisis

HEALTH IT FOR PEDIATRIC CARE AND PRACTICE SETTINGS

- In response to the requirements set forth in section 4001 of the Cures Act, ONC has:
    1. Developed ten recommendations for the voluntary certification of health IT for pediatric care that does NOT include a separate certification program for pediatric care and practice settings.
    2. Identified current and proposed new 2015 Edition certification criteria that support pediatric care and practice settings.
    3. Focused on non-regulatory initiatives that are nimble and responsive to stakeholders, including development of informational resources to support setting-specific implementation that aligns with the ONC Health IT Certification Program.

Recommendations for Pediatric Health IT Voluntary Certification Criteria

1. Use biometric-specific norms for growth curves and support growth charts for children
2. Compute weight-based drug dosage

3. Ability to document all guardians and caregivers
4. Segmented access to information
5. Synchronize immunization histories with registries
6. Age- and weight-specific single dose range checking
7. Transferrable access authority
8. Associate mother's demographics with newborn
9. Track incomplete preventative care opportunities
10. Flag special health care needs

Proposed new 2015 Edition Criteria:

- United States Core Data Set for Interoperability (USCDI)
- Electronic prescribing
- FHIR-based API
- Data segmentation for privacy

Four Broad Questions

- What relevant gaps, barriers, safety concerns, and/or resources (including available best practices, activities, and tools) may impact or support feasibility of the recommendation in practice?
- How can the effective use of IT support each recommendation as involves provider training, establishing workflow, and other related safety and usability considerations?
- Should any of the recommendations not be included?
- Should any of the functional criteria listed under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification Criteria" be removed as a correlated item to support any of the recommendations?

Summary of Recommendations

Recommendations 1-6

- Consensus that all functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed

Recommendations 7 – 10

- Tentative consensus that all functional criteria under the "Alignment with 2015 Edition Certification Criteria" and the "Alignment with Proposed New or Updated Certification" should be retained as listed

Supplemental Children's EHR Format Requirements

Plans to discuss further in future TF meetings

Recommendation 1

- Use biometric-specific norms for growth curves and support growth charts for children
- **Description:** The system shall include the ability to use pediatric age-specific norms for weight, height/length, head circumference, and BMI to calculate and display growth percentiles and plot them over time on standardized Centers for Disease Control and Prevention (CDC)/World Health Organizations (WHO) growth curves as appropriate.
    - Alignment with 2015 Edition Certification Criteria – Common Clinical Data Set (CCDS)
        - Demographic

        - Clinical Decision Support (CDS)
        - Application Programming Interfaces (APIs)
    - Alignment with Proposed New or Updated Certification Criteria
        - United States Core Data for Interoperability (USCDI)
        - Application Programming Interfaces (APIs)
- Comments on relevant gaps, barriers, safety concerns, and/or resources (including available best practices, activities, and tools) that may impact or support feasibility of recommendation 1 in practice:
    - Safety Concerns:
        - Displayed value must be able to reference correct data sets
- Additional Implementation Considerations:
    - Should include a visual display to serve as an alert
        - Limit to data that are in the public domain and evidence based

Recommendation 2

- Compute weight-based drug dosage
- Description: The system shall compute drug dose, based on appropriate dosage ranges, using the patient's body weight and body surface area, and shall display the dosing weight and weight-based dosing strategy (when applicable) on the prescription.
    - Alignment with 2015 Edition Certification Criteria
        - Electronic Prescribing
    - Alignment with Proposed New or Updated Certification Criteria
        - USCDI
        - Electronic Prescribing
- Comments on relevant gaps, barriers, safety concerns, and/or resources (including available best practices, activities, and tools) that may impact or support feasibility of recommendation 2 in practice
- Significant safety concerns with usability
    - Should be limited to liquid medications
    - Should be displayed in mL
    - Calculators - should not be able to round more than what is humanly measurable
- Additional implementation Considerations:
    - Prescription final dose should be transmitted with metadata – additional information in text on how dose was derived
    - Include original weight for calculation

Recommendation 3

- Ability to document all guardians and caregivers
    - Description: The system shall provide the ability to record information about all guardians and caregivers (biological parents, foster parents, adoptive parents, guardians, surrogates, and custodians), siblings, and case workers, with contact information for each.
- Alignment with 2015 Edition Certification Criteria
    - Care Plan
    - Transitions of Care
    - Application Programming Interfaces
    - Transitions of Care
    - Demographic

- Alignment with Proposed New or Updated Certification Criteria
  - Unites States Core Data for Interoperability (USCDI)
  - Data Segmentation for Privacy
  - Application Programming Interfaces
- Additional Implementation Considerations:
  - Guardian and caregiver information should be documented in a structured way (including role)
  - Encourage nomenclature in the future
    - no current standard to reference to
  - Should have infinite ability to add list for all relevant contacts of the family (no limited fixed number)
  - Ability to manage list
    - remove, archive, or start/end date (active vs. historical participants)

Recommendation 4

- Segmented access to information
  - Description: The system shall provide users the ability to segment health care data in order to keep information about minor consent services private and distinct from other content of the record, such that it is not exposed to parents/guardians without the minor's authorization.
- Alignment with 2015 Edition Certification Criteria
  - Data Segmentation for Privacy
  - Transitions of Care
- Alignment with Proposed New or Updated Certification Criteria
  - United States Core Data for Interoperability (USCDI)
  - Data Segmentation for Privacy
  - Application Programming Interfaces (APIs)
- Relevant gaps, barriers, safety concerns, and/or resources (including available best practices, activities, and tools) that may impact or support feasibility of recommendation 4 in practice:
  - Preventing what information gets sent out relevant to dependents on family-based insurance (e.g., billing information)
  - Limited by lack of legal and clinical standards on what is appropriate
  - Different state privacy rules
  - Various usability issues – dependency and burden on users
- Additional Implementation Considerations:
  - Allow EHR to grant user access level to tag
    - Provide protection when user adds data
    - Prevent tagged data from showing in CDA, portal, or exit note given to another provider
  - Future work considerations:
    - Transmission and sharing of data
    - How end-users use the data received
    - Level of granularity involved with tagging

Recommendation 5

- Synchronize immunization histories with registries
- Description: (A) The system shall use the messaging standards established through meaningful use requirements to send data to immunization information systems or other HIEs. (B) The system shall use the messaging standards established through meaningful use requirements to receive data from immunization information systems or other HIEs.
    - Alignment with 2015 Edition Certification Criterion
        - Transmission to Immunization Registries
        - View, Download, and Transmit to Third Party (VDT)
    - Alignment with Proposed New or Updated Certification Criteria
        - United States Core Data for Interoperability (USCDI)
        - Application Programming Interfaces (APIs)
- Relevant gaps, barriers, safety concerns, and/or resources (including available best practices, activities, and tools) that may impact or support feasibility of recommendation 5 in practice:
    - Functional issues with usability
        - Not currently reliable for users
            - Receiving incorrect information from Immunization Information Systems (IIS)
        - Lag on adoption curve & timing of updates
    - Additional Implementation Considerations:
        - Needs future work into consolidating state immunization forecasting model into single resource
        - Reduce amount of time to update forecasting
        - Look into onboarding practices for immunization forecasting
        - Clinicians should be able to verify source origins

Recommendation 6

- Age and weight-specific single-dose range checking
- Description: The system shall provide medication dosing decision support that detects a drug dose that falls outside the minimum-maximum range based on the patient's age, weight, and maximum recommended adult dose (if known) or maximum recommended pediatric dose (if known), for a single dose of the medication.
- Alignment with 2015 Edition Certification Criteria
    - Clinical Decision Support (CDS)
    - Application Programming Interfaces (API)
- Alignment with Proposed New or Updated Certification Criteria
    - United States Core Data for Interoperability (USCDI)
    - Application Programming Interfaces (API)
- Relevant gaps, barriers, safety concerns, and/or resources (including available best practices, activities, and tools) may impact or support feasibility of the recommendation in practice?
    - Minimum dose range recommendations are of dubious value
- Additional Implementation Considerations:
    - Consider similar limitations on dose calculations as seen in Recommendation 2 (Compute weight-based drug dosage)
    - Existing sources for dose range recommendations should be integrated into workflow
    - Allow user access to best practices or standards (demonstrating correct information source + element of shown work for clinician to verify)

- Ability to test EHR accuracy » Include in QA/QI testing process

Remaining Topics for TF Discussion/Charge

- Recommendations 7-10 (tentative consensus)
  - Supplemental Children's EHR Format Requirements
  - Opioid Use Disorder (OUD) Request for Information (RFI)
  - 2015 Edition "DS4P" and "consent management for APIs" certification criteria

Discussion

Arien Malec commented that we should be careful what we wish for because we might get it. With respect to pediatric dosing, the recommendation to limit it to liquids only, the typical practice is to handle this through sig instructions because of the need for clinician supervision. In regards to immunization registries, state registries are typically underfunded. EHR vendors would appreciate standardization as the complexities are on the registry side. In regards to data segmentation for privacy (DS4P), there are a lot of issues in regards to disclosure requirements. It will be useful to accompany DS4P standards with policy guidance because the issues are complex.

Ken Kawamoto commented that for a lot of these functionalities it would make sense for the information to be provided by external services.

Raj Ratwani suggested a general recommendation around usability and safety: 1) More rigorous usability safety test cases; 2) Having pediatric participants which are not required currently; 3) Evidence of a usability and safety process.

- **Chris Lehmann** noted that a lot of these items were discussed in a meeting he had earlier in the day and he will be sharing with the task force for future discussions.

Andy Truscott commented that where there are existing things in place, those should be leveraged. There is a fine line between functional requirements and certification. Some of the concepts around guardianship already have state regulation and fall into other groups. A lot of this work has already been done by EHR developers. He questioned if immunization systems fall into scope.

- **Elise Sweeney Anthony** suggested looking at the information blocking section which is designed around the actors that Congress identified, then look at the definition of EHI section. Taking those together, determine if the entity would be covered. Then determine if there is an exception that would take them out of the coverage for that particular action. If the definitions are too broad or too narrow, ONC needs to know this.

Chris Lehmann noted his appreciation for the potential that this could have for other specialties downstream.

Lauren Richie opened the lines for public comment.

Public Comment

Comments received in person

John Travis, Cerner cautioned ONC about the voluntary pediatric criteria. He referred to ONC's press release which mentions criteria; he noted this is recommendations, not criteria. There are functional gaps. Cerner will comment that it will be good for ONC to identify functional gaps or limitations in the criteria.

There were no comments on the phone.

Comments received in the public chat feature of Adobe during the meeting

Rita Torkzadeh: Another consideration with SSN is its reduced availability (collection)

Rita Torkzadeh: CMS SSN removal initiative probably contributes to its reduced capture and utility

Next Steps and Adjourn

Carolyn Petersen thanked the HITAC members for their engagement and efforts to keep things moving. She noted her appreciation for all the work that has occurred in the meeting and the task forces.

Robert Wah thanked the members for their participation. It is great to see so many members participating and helping to move things forward. He thanked ONC staff for all their help and contributions. He also asked for feedback on ways to improve the process going forward.

Aaron Miri noted his thanks for the chairs.

Denise Webb asked if the transcript could be shared from each of the task force presentations to inform next steps.

Lauren Richie noted that the April meeting would be in-person. She adjourned the meeting at 4:15 p.m. ET