Meeting Notes

Health Information Technology Advisory Committee
April 10, 2019, 09:30 a.m. – 04:30 p.m. ET
In Person

The April 10, 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
Cynthia A. Fisher, WaterRev, LLC
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
Clement McDonald, National Library of Medicine
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

MEMBERS NOT IN ATTENDANCE

Tina Esposito, Advocate Aurora Health
Chesley Richards, Federal Representative, Centers for Disease Control and Prevention
Patrick Soon-Shiong, NantHealth
Lauren Thompson, Federal Representative, DoD/VA Interagency Program Office

FEDERAL REPRESENTATIVES

Kate Goodrich, Centers for Medicare and Medicaid Services (CMS)
Mark Roche, Centers for Medicare and Medicaid Services (CMS)
Ram Sriram, National Institute of Standards and Technology (NIST)

ONC STAFF

Elise Sweeney Anthony, Executive Director, Office of Policy
Cassandra Hadley, HITAC Support
Thomas Mason, Chief Medical Officer
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 offered an opportunity for the HITAC members to voluntarily disclose any outside contractual activity with ONC.

The following individuals noted contractual activity with ONC for themselves or their organizations.

- Raj Ratwani
- Christina Caraballo
- Steven Lane
- Ken Kawamoto

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

Welcome Remarks

Donald Rucker, National Coordinator, apologized for the in-person meetings occurring so close together. He noted that he is looking forward to hearing about all of the hard work being done in the task forces. He shared the HITAC will hear from Alex Mugge from the Centers of Medicare and Medicaid Services (CMS) who will be sharing additional information about the CMS Interoperability and Patient Access Proposed Rule. He noted that Mark Roche will be joining the HITAC as federal representative. He also thanked Brad Gescheider for his service, as Brad had to step down from the HITAC.

Review of Agenda and Approval of March Meeting Minutes

Carolyn Petersen, Co-Chair
Robert Wah, Co-Chair

Robert Wah, co-chair, welcomed everyone and thanked the members for coming to a second meeting so close to the previous one.

Carolyn Petersen, co-chair, also thanked the members for their attendance and for all the work going on within the task forces. She noted that she was happy to report that the HITAC has shared the Annual Report for Fiscal Year (FY) 2018 and the Annual Report Workgroup is already working on the 2019 FY.

Carolyn Petersen called for a vote to approve the minutes from the March 20, 2019 meeting. No comments or amendments were offered; the minutes were approved.

She turned the meeting over to Thomas Mason to review the Prior Authorization Hearing.

HITAC Prior Authorization Hearing Recap

Thomas Mason, Chief Medical Officer

Thomas Mason noted that prior authorization was one of the top burdens and concerns identified in the Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs Report that needs to be addressed. He expressed a need to focus on technology to enable solutions for the current challenges. The hearing on March 20, 2019 was initiated to identify challenges and possible solutions.

The hearing started with the clinician perspective, providing a review of the current burden on clinicians. The next session focused on the Health Insurance Portability and Accountability Act (HIPAA) and the regulatory perspective. Then a standards perspective was shared and was separated into medication and non-medication workflow challenges. The Council for Affordable Quality Healthcare (CAQH) also shared data on the adoption rate and the low rate of adoption of the X12 standard. The hearing ended with a perspective from payers.

Thomas Mason thanked the National Committee on Vital and Health Statistics (NCVHS) for their participation and partnership. He noted that Donald Rucker and Bill Stead helped inform the discussion by identifying the following questions.

1. How to align clinical and financial data?
2. How to align clinical and information standards and avoid manual intervention?

He noted a theme focused on authorization automation, mechanisms to automate requirements of payers. There was discussion around payers and their role automating the process, in terms of their coverage guideline. He emphasized the need for payer involvement to identify solutions. The hearing was an opportunity to listen, learn, and identify solutions that ONC can support as a follow-up. He also shared that ONC plans to continue coordination with CMS to align clinical and financial data.

Donald Rucker commented that a combination of clinical and financial data is essential to moving this forward in healthcare, as there are opportunities here to establish a more seamless operation.

Les Lenert identified the need to simulate human judgment with technology which is possible today. Using artificial intelligence (AI), there are a lot of benefits that can be ascertained. There is the potential for patients to conduct prior authorization before their visits, but this requires a robust clinical summary and AI methods to identify if a procedure or a drug is appropriate for the individual.

Arien Malec requested that ONC work with CMS to possibly replicate something similar to what was done with application programming interfaces (APIs).

Steven Lane praised Les Lenert and expressed his support.

The meeting was turned over to Alex Mugge from CMS.

CMS Interoperability Rule Overview

Alex Mugge, Deputy Chief Health Informatics Officer, Centers For Medicare And Medicaid Services

Alex Mugge shared that CMS' recently released notice of proposed rulemaking (NPRM) is the first phase of interoperability regulation. The CMS rule brings in health plans who historically have not been a part of the interoperability effort. Unlike ONC's rule, the CMS rule is not statutorily mandated; it is homegrown. It was initiated because patients complain about not having access to their health information. Ironically while writing the rule, she shared that she was having trouble getting data from her provider. She also shared that CMS has heard many excuses for not sharing information such as technology, information blocking, and HIPAA.

Health Plans

The NPRM has a collection of policies for providers and payers. Health plans and payer proposals include: Medicare Advantage, Medicaid Fee for Service, Medicaid Managed Care, Children's Health Insurance Program (CHIP) Fee for Service, and CHIP managed care. The policies are designed to drive information flow:

- Requiring data to flow with these policies.
- Requiring implementation of a fast healthcare interoperability resource (FHIR) based patient accessed application programming interface (API).
- Providing the ability to obtain claims and clinical information.
- Providing the ability to access the API through a smart phone.
- Requiring provider directories be available through FHIR based APIs.
    - This will enable providers to find other providers through the patient, enabling information to flow.
- Providing the ability for Health plans and payers to exchange information with each other.
    - At the patient's request, the health plan will gather information for the last five years and aggregate it into the current health plan system. This allows data to flow with the patient. There is a requirement that health plans and payers join a trust network, allowing the ability to exchange.
- Requiring dually-eligible states to send enrollee benefit information daily so there is no gap in coverage. This engages the states and provides better care coordination.

Provider

There are hospital conditions of participation that require admission, discharge, and transfer information for a patient. This engages hospitals in the interoperability space and ensure patients aren't falling through the cracks. She noted that the Department of Health and Human Services (HHS) is taking a stand against information blocking and these actions will be publicly reported on the CMS website.

Requests for Information (RFIs)

There is an RFI around all future models of the Center for Medicare & Medicaid Innovation (CMMI) having interoperability requirements. The RFI asks what the requirements should look like.

She noted that accurate patient identification is essential. There is an RFI included in the NPRM around patient matching asking how ONC and CMS can provide better patient matching.

There is an RFI around how to better support post-acute care.

She concluded that through the NPRM, patients see increased access to health information, better engagement, and better consumer access overall. This is the first phase of policies. The policies in the NPRM allow providers to have a more comprehensive health history while enabling better care coordination. There is also an opportunity to improve the relationship that health plans have with enrollees.

Discussion

- **Valerie Grey** stated that on the provision that requires hospitals to share ADTs. Some health information exchanges share this information today.
    - **Alex Mugge** noted that the idea was to engage in a trust network and start to facilitate the flow of information.
    - **Les Lenert** commented that notifications have a lot of value and it is something health information exchanges (HIEs) are doing well.
    - **Alex Mugge** noted that CMS was intentionally vague about how the patient and the care team would be established but would appreciate comments.
- **Arien Malec** noted that payer needs clarification, payers under other regulatory networks are included.
    - **Alex Mugge** commented that health plans are private, payers are states and Medicare Fee for Service.
- **Aaron Miri** commented around consent, noting that it would be helpful for CMS to deal with consent to exchange information across entities. He questioned how patient-generated health data (PGHD) should be shared.
    - **Alex Mugge** noted that PGHD is not included in the rule.
- **Clem McDonald** questioned what the clinical data is? Is there anything related to personal health records?
    - **Alex Mugge** commented that health plans collect clinical information from providers. If that information is available, that should be shared. In the rule, the United States Core Data for Interoperability (USCDI) should be shared. In terms of the patient receiving the information, there will need to be patient engagement and education. They are working with developers to create applications (apps) useful to patients. There will need to be a promotion of those

apps. Once a patient chooses an app, the patient chooses where to send the data, and the payer would have to send the data there.
    - **Clem McDonald** suggested that this could be done at the time of registry. This would be pushing this to the patient.
    - **Alex Mugge** suggested submitting a comment.
- **Terry O'Malley** commented in regards to ADTs, recognizing it is a start, are there plans to push that out to post-acute care?
    - **Alex Mugge** noted that CMS is continuing to work with all providers in all settings. There is the RFI in the rule to look at things most useful to post-acute care.
- **Terry O'Malley** commented that the USCDI Task Force is working on the demographics section. Does CMS have a patient matching algorithm and do they match what is in the USCDI proposal?
    - **Alex Mugge** suggested submitting comments. No policies are in place currently.
- **Terry O'Malley** asked if there is anyone working on consent?
    - **Elise Sweeney Anthony** noted this is something that could be put on the list for HITAC task forces to take on. Some of that may involve the Office for Civil Rights (OCR) as well.
- **Steven Lane** noted that USCDI specified version 1, he suggested that USCDI in its current version be specified. He also noted that a lot of concern has been expressed of fully informing patients of their privacy protections. As things expand beyond Blue Button, what constitutes meaningfully informing the patient? This is important for liability and of course the patient.
    - **Alex Mugge** noted that terms and conditions can be difficult and many just click through them. The Blue Button team is working to layout terms and conditions to help patients understand what they are signing on for.
- **Elise Sweeney Anthony** reminded the HITAC members that there is an RFI in the ONC rule regarding appropriate disincentives across HHS.
- **Cynthia Fisher** supported Leslie Lenert and Clem McDonald's comments to empower patients with this data.
- **Carolyn Petersen** commented that there are a number of unresolved issues related to net neutrality, availability of internet access, growing prevalence of cognitive impairment, unable to maintain information securely. In favor of finding solutions for all users, she expressed concern about the use of email.
- **Andy Truscott** commented that there is a need to be cautious when moving to the bright, shiny, and new when there are already ways available to get things done.
- **Alex Mugge** noted that data belongs to the patient, so CMS is trying to find ways for the patient to access it. CMS is working to align everyone in a common direction so that data can be accessed and used.
- **Clem McDonald** reminded everyone that Apple Health is already doing this.
- **Denni McColm** commented on Apple Health as a good example. It is a limited set of data because it doesn't include the progress note or the radiology report. The information that is valuable needs to be exchanged.
- **Elise Sweeney Anthony** thanked CMS for the collaborative relationship.
- **Alex Mugge** thanked Elise as well and the HITAC members for their comments.
- **Aaron Miri** asked for encouragement to share as much information as possible.

Health IT for the Care Continuum Task Force Update Draft Recommendations

Carolyn Petersen, Co-Chair

Christoph (Chris) Lehmann, Co-Chair

Carolyn Petersen reviewed the task force charge, noting that Chris Lehmann her co-chair was on the phone.

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

Summary of Recommendations

Recommendation 1-6; Presented at HITAC 3/19

- 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 with additional implementation considerations

Recommendation 7 – 10 reviewed during today's meeting

- 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 with additional implementation considerations

Supplemental Children's EHR Format Requirements

- Consensus that the majority Supplemental Children's EHR Format Requirements should be retained as listed, with some exceptions and additional implementation considerations

Carolyn Petersen turned it over to **Chris Lehmann**.

Recommendation 7: Transferrable access authority

- Description: The system shall provide a mechanism to enable access control that allows a transferrable access authority (e.g., to address change in guardian, child reaching age of maturity, etc.).
- Alignment with 2015 Edition Certification Criteria
    - View, Download, and Transmit to Third Party (VDT)
    - Application Programming Interfaces

- Alignment with Proposed New or Updated Certification Criteria
  - Data Segmentation for Privacy
  - Application Programming Interfaces (APIs)
- Additional Implementation Considerations
  - This functionality is already implemented in most EHRs; however, more control needs to be at the end user (e.g., mark individuals with specific privileges until standard nomenclature can be developed)
  - Important to distinguish access vs. legal decision authorities
  - Recommend an ad hoc limited standard or best practice paper to be developed in the meantime
- Relevant gaps, barriers, safety concerns, and/or resources (including available best practices, activities, and tools) that may impact or support feasibility of recommendation 7 in practice
  - Complexities with varying state/local laws
  - Need for nomenclature to be developed based on state/local laws
  - Contradictory access - broad and vague at moment
    - Not accurately describing what the EHR can or should do (e.g., divorce cases)
    - EHR should be able to document via text field

Recommendation 8: Associate maternal health information and demographics with newborn

- Description: the system shall provide the ability to associate identifying parent or guardian demographic information, such as relationship to child, street address, telephone number, and/or email address for each individual child
- Alignment with 2015 Edition Certification Criteria
  - Care Plan
  - Transitions of Care
  - Demographics
  - Family Health History
  - Social, Psychological, and Behavioral Data
- Alignment with Proposed New or Updated Certification Criteria
  - United States Core Data for Interoperability (USCDI)
  - Application Programming Interfaces (APIs)
- Additional Implementation Considerations
  - Information should be available in a format that can be exported and easily digested by pediatric HER
  - Further integrate records between maternal and child (e.g., capability exists but mainly as text info such as family health history)
- Relevant gaps, barriers, safety concerns, and/or resources (including available best practices, activities, and tools) that may impact or support feasibility of recommendation 8 in practice
  - Currently, there is no good standard to point to
  - Further research is needed on existing transmission of this type of data

Recommendation 9: Track incomplete preventative care opportunities

- Description: The system shall generate a list on demand for any children who have missed recommended health supervision visits (e.g., preventative opportunities), according to the frequency of visits recommended in Bright Futures™.

- Alignment with 2015 Edition Certification Criteria
  - Clinical Decision Support (CDS)
  - Clinical Quality Measures
  - Application Programming Interfaces
- Alignment with Proposed New or Updated Certification Criteria
  - Application Programming Interfaces (APIs)
- Additional Implementation Considerations
  - Two-pronged approach
    - Generate lists for recall purposes
    - Flag patients – create alert for when patient falls outside expected values
- Relevant gaps, barriers, safety concerns, and/or resources (including available best practices, activities, and tools) that may impact or support feasibility of recommendation 9 in practice
  - Challenging to implement in EHR but TF acknowledges that this is critical since most EHRs fall short within first three years of care

Recommendation 10: Flag special health care needs

- Description: The system shall support the ability for providers to flag or unflag individuals with special health care needs or complex conditions who may benefit from care management, decision support, and care planning, and shall support reporting.
- Alignment with 2015 Edition Certification Criteria – Problem List
  - Clinical Decision Support (CDS)
  - Clinical Quality Measures
- Alignment with Proposed New or Updated Certification Criteria
  - United States Core Data for Interoperability (USCDI)
  - Application Programming Interfaces (APIs)
- Additional Implementation Considerations
  - Ability to determine generic flags
    - Pediatrician should be able to adjust flags to their needs
    - Build decision support on top of it
  - Ability to transmit in coded way from system to system
  - Ability to track mental health for children
- Relevant gaps, barriers, safety concerns, and/or resources (including available best practices, activities, and tools) that may impact or support feasibility of recommendation 10 in practice
  - Currently there is no code for a generic special health care need (generic flag)
    - Would like to see incorporated into SNOMED or ICD

SUPPLEMENTAL CHILDREN'S FORMAT REQUIREMENTS

ONC is seeking feedback about the relevance of potential Children's EHR format requirements and their correlation to specific Recommendations (1- 5 and 7)

Supplemental Children's Format Requirements for Recommendation 1

- Supplemental Children's Format Requirements for Recommendation 1 (Use biometric specific norms for growth curves and support growth charts for children)
- Title: Allow unknown patient sex

    - Description: The system shall provide the ability to record a patient's sex as male, female, or unknown, and shall allow it to be updated
- Title: Record Gestational Age Assessment and Persist in the EHR
    - Description: The system shall capture and display assigned gestational age as well as the diagnosis of Small for Gestational Age (SGA) or Large for Gestational Age (LGA) when appropriate
- Support growth charts for children
    - Description: The system shall support display of growth charts that plot selected growth parameters such as height, weight, head circumference, and BMI (entered with appropriate precision or computed as described in Req-2019) along with appropriate sets of norms provided by the CDC or in a compatible tabular format (typically based on Lambda-Mu-Sigma [LMS] curve fitting computational method).
- TF Recommendation:
    - Retain all supplemental requirements as is for Recommendation 1

Supplemental Children's Format Requirements for Recommendation 2

- Supplemental Children's Format Requirements for Recommendation 2: Compute weight-based drug dosage)
    - Title: Rounding for administrable doses
        - Description: The system shall enable calculated doses (e.g., weight-based) to be rounded to optimize administration convenience
    - Title: Alert based on age-specific norms
        - Description: The system shall provide the ability to present alerts for lab results outside of pediatric-specific normal value ranges
- TF Recommendation:
    - Consensus on removing "Alert based on age-specific norms" as a requirement

Supplemental Children's Format Requirements for Recommendation 3

- Supplemental Children's Format Requirements for Recommendation 3 (ability to document all guardians and caregivers)
    - Title: Ability to document parental (guardian) notification or permission
        - Description: The system shall provide the ability to document parental (guardian) notification or permission for consenting minors to receive some treatments as required by institutional policy or jurisdictional law
    - Title: Record parental notification of newborn screening diagnosis
        - Description: The system shall be able to track that the child's legal guardians were notified of any newborn screening-related diagnosis.
    - Title: Authorized non-clinician viewers of EHR data
        - Description: The system shall have the ability to identify members of the care team (including professional and nonprofessional members) and indicate their roles/relationships to the child.
    - Title: Document decision-making authority of patient representative
        - Description: The system shall have the ability to store, retrieve, and display information about an individual's right to authorize care, to release information, and to authorize payment for care on behalf of the patient, including time restrictions or

other limitations. This includes storing copies of the relevant consent and authorization forms in compliance with state and federal rules, and also includes cases of child foster care, state social services agencies, guardians, guarantors, and those recognized to have full or partial authority. The system shall allow for multiple individuals.

- TF Recommendation:
  - Consensus to retain all supplemental requirements for Recommendation 3
  - Additional implementation consideration for "Authorized non-clinician viewers of EHR data" requirement
    - Should not be provided as free text

Supplemental Children's Format Requirements for Recommendation 4

- Supplemental Children's Format Requirements for Recommendation 4 (Segmented access to information)
  - Title: Problem-specific age of consent
    - Description: The system shall provide the ability to access legal guidelines on consent requirements for reference, where available, and to record the age of consent for a specific treatment when these differ based on legal guidelines
- TF Recommendation:
  - Remove "Problem-specific age of consent" requirement from Recommendation 4
    - Without an approved centralized way to implement – vendors are not qualified to provide this functionality
    - General support for the idea, but should not be a requirement at this time due to the challenges of varying state and local laws

Supplemental Children's Format Requirements for Recommendation 5

- Supplemental Children's Format Requirements for Recommendation 5 (Synchronize immunization histories with registries)
  - Title: Produce completed forms from EHR data
    - Description: The system shall produce reports (e.g., for camp, school, or child care) of a child's immunization history, including the following elements: child's name, date of birth and sex, date the report was produced, antigen administered, date administered, route of administration (when available), and an indication of whether a vaccine was refused or contraindicated.
- TF Recommendation:
  - Currently a significant problem since there is no commonly defined child care form (varies from state and/or local)
  - There is also no computable language version of a school form that is universally acceptable
  - However, TF reached consensus to retain this supplemental requirement to provide a basic starting point when a basic standard form is created

Supplemental Children's Format Requirements for Recommendation 7

- Supplemental Children's Format Requirements for Recommendation 7 (Transferrable access authority)
  - Title: Age of emancipation

        - Description: The system shall provide the ability to record the patient's emancipated minor status.
- TF Recommendation:
        - Consensus to retain as is

Chris Lehmann turned it over to **Carolyn Petersen** to review the upcoming items that task force will review.

Carolyn Petersen noted that the task force will be reviewing the following items in their upcoming meetings.

- Opioid Use Disorder (OUD) Request for Information (RFI)
    - Health IT and Neonatal Abstinence Syndrome
- 2015 Edition data segmentation for privacy (DS4) and consent management for APIs certification criteria

Discussion

Clem McDonald commented that there was a recommendation that there was no way to store pediatric data; he didn't think that was true. He suggested reconsidering, as he believed there is a way to do it.

- **Chris Lehmann** noted that there are no standard nomenclatures and the same problem exists during end of life care.
- **Clem McDonald** noted that descriptors for the data may not be available.
- **Chris Lehmann** noted that it was about which part of the record should be linked, as the mother's data is included with the child's data.

Sasha TerMaat suggested having a written copy prior to doing a vote. She asked for clarity on what is being voted on.

- **Carolyn Petersen** noted there wouldn't be a vote today because there wasn't time for a transmittal letter.
- **Sasha TerMaat** asked for additional clarity on what should happen with the comments from the task force.
- **Chris Lehmann** noted that there was an assumption that the comments would inform ONC's work.

There was a lot of discussion about the way recommendations are brought forward to ONC. **Sasha TerMaat** encouraged the task force to make the recommendations clearer for review with the HITAC.

Cynthia Fisher asked about engagement with pediatrics in regards to parent/caregiver input. She asked that patient information be put into usability for developers. How can the parent or guardian control their child's information?

- **Steve Posnack** noted that the items discussed were the items prioritized.
- **Chris Lehmann** noted that input from patients, caregivers, and consumers was provided. What was discussed today was only a fraction of the items that were identified as important to take good care of children. The task force reviewed this as a starting point to get things moving.

Arien Malec noted that often what is optional becomes required. As an example, Medicaid could be tied to pediatric requirements. He noted that certification does not lead to a functional, usable electronic health record (EHRs). Certification is helpful for establishing a minimum threshold or a floor. He

encouraged the HITAC to address floor capabilities. Areas of expanding access to children and caregivers would be helpful but are also very complicated.

Christina Caraballo highlighted recommendation# 4 and expressed concern. She recommended looking at technology that could support minor access, such as proxy access for patient to delegate who can access data. As a default, there could be an option to flag and not share sensitive data. She highlighted that it is important to have the technology available to providers that fit into their practice.

- **Chris Lehmann** agreed with the comment. The recommendation is to take the requirement away from the vendor to figure it out. Providing technology to allow for it to be implemented locally is not off the table.

Steven Lane asked if Chris Lehmann could be available for the USCDI task force as there is overlap in the recommendations. He commented on the suggestion to remove alerts based on age-specific norms, he asked for clarity.

- **Chris Lehmann** noted that this was related to medication dosing. The age-specific dose ranges are not available in the public domain.

Denise Webb questioned recommendation #8; she wondered if there was a discussion about newborns who are privately adopted.

- Carolyn Petersen noted that it was not discussed.
- Chris Lehmann noted the challenge with the need for privacy versus the need for information that is pertinent to the care of the child.

Andy Truscott agreed with Arien's comments. Building on current criteria seems appropriate for moving forward. Regarding scope, he thought it would be helpful to capture the individuals who are responsible for the welfare of the minor.

- **Chris Lehmann** noted that work needs to be done for the safety of children is done outside of the EHR and is not beneficial for patients and providers.

Ken Kawamoto noted there are SMART on FHIR apps that are available. He felt that it was implied that CDS hooks could be used. He asked for validation that these types of items are not allowed.

Terry O'Malley commented that it might help him understand to create buckets of what is missing (e.g., functionality, standards, data and the gaps that exist).

Chris Lehmann noted that the task force would need more time, but would welcome it if ONC allows for it.

Aaron Miri commented that Ken Kawamoto's work has been discussed a number of times within the task force. He questioned if other task forces could help cover some of this work or the task force discuss this work further.

Carolyn Petersen noted that the task force would take these up if given that direction from ONC.

Sheryl Turney noted in regards to consent there could be something done to share the state requirements within the system. She noted that more needs to be done in regards to consent.

Arien Malec clarified that certification is best when it establishes a floor.

Carolyn Petersen noted that the feedback that was received will be reviewed with the task force and the group brings the recommendations back to the HITAC on April 25.

Lauren Richie opened the lines for public comments.

Public Comment

There was no public comment.

Lunch

Robert Wah welcomed everyone back from lunch and noted that he may need to leave earlier than planned.

Information Blocking Task Force Update

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

Andy Truscott noted that the exceptions work is still in process and will be reviewed during the next meeting on April 25. He welcomed members to join the next task force meeting to review exceptions. He turned it over to Michael Adcock.

Michael Adcock noted that there has been a tremendous amount of work done for workgroup 1: Relevant Statutory Terms and Provisions.

Workgroup 1: Relevant Statutory Terms and Provisions

Definition of Electronic Health Information

He reviewed the definition of electronic health information (EHI), red items are additions and changes since last presented to the HITAC.

Electronic Health Information (EHI) means— (1) Electronic protected health information (as defined in HIPAA); and (2) Any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in electronic media, as defined in 45 CFR 160.103, that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment(s) for the provision of health care to an individual., and (3) On the one year anniversary of the effective date of the final rule, an individual's consent directives including privacy, medical treatment, research, and advanced care.

Request for Comment and Request for Information Price Information

- Task Force believes that Price Transparency is a desirable goal that is achievable

- Further believe that policy levers are required to move the healthcare ecosystem in that direction given the nature of reimbursement
- Tying together Information Blocking regulations too tightly with the regulations required to promote Price Transparency may have the unintended consequence of slowing down Information Blocking regulation finalization
- Recognize that Price Transparency regulation drafting and consideration is underway
- Prices included in EHI should reflect all services and payment information by all parties including any contract terms, rebates or other forms of incentive payment or other form of remuneration
- Recognize many different players, for example, health care providers, health plans, contractors, administrators, pharmacy benefit managers (PBMs), pharmacies, group purchasing organizations (GPOs), technology companies, health IT developers, laboratories, medical devices, brokers and other similar market players)
- The definition of Electronic Health Information encapsulated within the draft regulations includes clear reference to "...or the past, present, or future payment(s) for the provision of health care to an individual". This ensures that the right information is being exchanged for Price Transparency Regulations could be built upon a solid interactive base
- Potential for ONC to instantiate through HITAC a Task Force under SEC.3002.b.D specifically charged with producing recommendations for regulations to specifically address improving Price Transparency across the healthcare ecosystem

Definitions of Health Information Exchange and Network

Proposed text

Health Information Exchange or HIE means the act of accessing, transmitting, processing, handling, or other such use of Electronic Health Information, or the organization or entity conducting that act. Health Information Network or HIN means an individual or entity that satisfies one or several of the following—(1) Determines, oversees, administers, controls, or defines policies or agreements that define business, operational, technical, or other conditions or requirements for Health Information Exchange between or among two or more individuals or entities. (2) Provides, manages, or controls, any technology or service that enables or facilitates Health Information Exchange between or among two or more individuals or entities.

Discussion points

- Multiple uses of "health information exchange" within 21st Century Cures (Cures), capitalized and otherwise, with differing contexts
- Recognize that "exchange" and "network" have multiple common uses in the industry right now
- Believe that promoting consistency of usage is advantageous
- Focus upon "exchange" as an act and "network" as an organizational construct
- Need to fit within the bounds of Cures usage, especially as enforcement is built around it
- Additional preamble to provide usage examples

Andy Truscott reviewed and summarized the Task Force's discussions to date.

Practices that may implicate the information blocking provision

Patient Access

- "Open" patient access to EHI about them is likely to implicate the Information Blocking rule.
- Obligation of actors to provide such access in real-time, and free of charge (beyond approved fee exemptions) is not one that is widely understood or implemented now (even in a "paid" manner)
- Providing patients with the tools to appropriate parse EHI to ensure it is understandable to them may potentially implicate and ONC should investigate whether this is the case.

Pricing Information

- Could readily implicate the Information Blocking rule
- This information is not routinely exchanged, and will require focus from multiple actors to ensure that the intent of Congress is met

Actors vs. Information type

- Information Blocking provision is designed to ensure that patient information moves without hindrance across the healthcare ecosystem with appropriate authorization to facilitate the provision and reimbursement of care services to patients
- These services are likely to be provided by an increasingly broad series of organizations, and these regulations must be structured so that these new entrants to the market are appropriately covered by the conditions herein
- It would not be advantageous to improving patient outcomes if some actors were implicated (through inclusion) and others were not (by the regulations being mute) as the regulations should be focused upon the blocking of information vs. the entity performing the blocking.

Parties affected by the information blocking provision

- Healthcare is moving forward, and our traditional view of what/whom is a "Provider," and how and where they provide care is changing
- Health IT Developers
    - Included if one or more products are "certified"
    - Requiring compliance based upon another products certification potentially problematic
    - Suggestion to focus upon utility of product for processing EHI
    - Potential to required certification for such products?
- The Task Force recommends that the definition of "Actors" be augmented to include a functional component followed by illustration of common-names for those actors.
- In addition, clarity is sought around those Health IT Developers who have elected for Certification as Certified Health IT vs. those developers of health IT that do not seek Certification. Belief that this will be an ever-increasing number over the coming years, for a number of reasons.
- New entrants to the health IT market that provide niche services to patients may not seek certification, especially if they are consumer focused vs clinical. New and existing entrants may not seek certification as they adopt alternative business models which reduce the cost of Health IT to end users, and thus have reduced incentive for certification. We need to clarify that a developer of Health IT is a developer because they create IT designed to perform the exchange, use, or access of EHI whether or not that IT is Certified.
- Organizations which may have some degree of ambiguity about whether they are considered an actor would include Retail Pharmacies, Line Insurance Companies, Life Insurance Companies, Retailers who develop and sell home health IOT devices – which might be alleviated by adopting a position of inclusion based upon their handling of Electronic Health Information.

Andy Truscott noted that the hours of discussion do not necessarily reflect the number of changes made. This goes to show the great work done by ONC, as after hours of discussion the task force ended up keeping ONC's suggested language.

Workgroup 3: Information Blocking, Assurances, and Communications Conditions and Maintenance of Certification and Enforcement

Information Blocking

- No changes to the actual definition of information blocking as a condition of certification were suggested.

Assurances

(b) Maintenance of Certification.

(1) A health IT developer must retain all records and information necessary to demonstrate initial and ongoing compliance with the requirements of the ONC Health IT Certification Program for: (i) A period of 10 years beginning from the date each of a developer's health IT is first certified under the Program; or (ii) If for a shorter period of time, a period of 3 years from the effective date that removes all of the certification criteria to which the developer's health IT is certified from the Code of Federal Regulations. or (iii) If for a shorter period of time and not due to decertification, a period of 3 years from the date of withdrawal by the health IT developer of a certified health IT product from certification.

(2) A health IT developer that must comply with the requirements of paragraph (a)(4) of this section must provide all of its customers of certified health IT with the health IT certified to the certification criterion in § 170.315(b)(10) within: (i) 24 months of this final rule's effective date, or (ii) 12 months of certification for a health IT developer that never previously certified health IT to the 2015 Edition. (3) ONC will preserve in an appropriate, publicly accessible format a list of the start and end dates of each previously certified health IT product.

Discussion Points

- Records should be retained concerning compliance with the Certification Program
- Desire to clarify timeframe for withdrawal
- Desire to ensure that a historic list of product certification dates is maintained
- This would codify the CHPL practice already put in place by ONC and ensure it is maintained

Request for information on participation in the Trusted Exchange Framework and Common Agreement (TEFCA)

- The Task Force believes it would not be responsible to make recommendations within this RFI until the next draft of TEF is available.
- Revisit this area to make recommendations when revised drafts of TEFCA are published (or have the other TEF Task Force address it).

Communications

Whistleblower Protection

- The task force suggested adding the following text: Any person who makes a communication covered by (2)(i) to an appropriate entity must not be subject to retaliatory action which could reasonably be considered due to their whistleblowing activity.
- Discussion Points
  - In (2)(i)(A), workgroup 3 felt that it was reasonable for health IT developers to request that they be notified when a disclosure required by law takes place, and that this was accommodated in the current regulatory text.
  - In (2)(i)(C), workgroup 3 felt that notification to health IT developers prior to (or simultaneous with, if prior was not possible) public reporting would be beneficial for resolving security vulnerabilities prior to the knowledge being widespread.
  - In (2)(i)(E) workgroup 3 felt that a specific protection might be called for those individuals who highlight information blocking practices, and identify them to the appropriate authorities so that the individual is not subject to retaliatory action by the actor identified by the whistleblower. Obviously would need to phrase that a whistleblower would not be able to leverage this as mechanism to avoid sanctions for other activities (e.g. performance etc.).

Unprotected Communications

The task force suggested adding the following:
(3) Unprotected Communications. Specific communications are not extended the protections or restrictions in this section, where those communications are considered unprotected in that that are either:

(i) protected by other legislation or regulation; or
(ii) false or unlawful

Discussion Points

- The Task Force suggested an additional category of communications that would not be protected (neither receiving unqualified protection nor their restriction necessitating a permitted restriction).
- The intent was that this category would include communications such as false communications, things protected by attorney-client privilege, and so forth.
- The Task Force did not intend for false communications such as libel to be protected as an unintended consequence.
- Other examples of unprotected communications might include communications sent by a person who improperly obtained the information or received it from somebody who did not have the right to provide the information, such as a hacker.

Intellectual Property Fair Use and Screenshots

The following changes were suggested (in red text):
(2) A health IT developer does not prohibit the fair use communication of screenshots of the developer's health IT, subject to the limited restrictions described in paragraph (a)(2)(ii)(D) of this section, and with the understanding that any actor disclosing the screenshots are responsible for ensuring that each use is being put to "fair use."

Discussion Points

- Administrative functions of HIT could unintentionally reveal significant intellectual property of health IT developers

- Concerns of sharing screenshots, inherent intellectual property of UI design vs. valid reasons why screenshots are both required to be shared and could also be considered "fair use."
- The goal was that the communications should not permit unintended use, such as using screenshots to attempt to copy screen designs from a competitor.
- The restriction that screenshots be permitted to be communicated under fair use principles is not in the regulatory text and the group felt that it deserved further consideration.

The following addition was also made:

(iii) The developer has put all potential communicators on sufficient written notice ~~of each aspect of its screen display that contains third-party content~~ of a list of third-party content included in the health IT that cannot be communicated because the reproduction would infringe the third-party's intellectual property rights; and (iv) Communicators are permitted to communicate screenshots that have been redacted to not disclose third-party content; and

Discussion Points

- Attempting to enumerate on a screen what might be third party content that was the intellectual property of a third party was infeasible
- Preferred approach would be for developers to provide a list of third-party content that might be present.

Timelines for Contract Updates

(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.

Discussion Points

- There was a concern that ONC's timeline for updates to contracts was insufficient and that the work was significantly underestimated by ONC's regulatory impact analysis.
- There was an example raised from a member of the group of needing to hire four additional lawyers to complete the work in that timeframe.
- The intent was to instead have health IT developers propose a plan for contract updates in 2 years and update contracts at next renewal or within 5 years.

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.

ONC review of certified health IT or a health IT developer's actions

- The following was suggested to be added: (c) Notices initiating direct review, of potential non-conformity, of nonconformity, of suspension, of proposed termination, of termination, of ban, or concerning the appeals process will be issued simultaneously via certified mail and email.

Discussion
The Task Force was concerned with the idea that direct review communications could be serious in consequence and email alone would not be a sufficient communication medium.

Public listing of certification bans and terminations

- Indefinite communication of past records (ban with start and end date, if lifted) seems appropriate.
- The sense of the Task Force was that knowledge of past bans was important for stakeholders.
- 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.
- The sense of the Task Force was that a minimum ban time period could have unintended consequences.

Applicability of Conditions and Maintenance of Certification for self-developers

- The provisions of information blocking and assurances would apply to self-developers also.
- Most of the provisions of Communications would also apply to self-developers.
- The Task Force identified one area that would require modification for self-developers, which was in (a)(2)(ii)(A) where the Task Force noticed that employees of a developer can have their communications restricted, but that this could have the consequence of limiting communications of users of the self-developed health IT for the reasons identified under Cures.

Proposed regulatory text: (A) Developer employees and contractors. A health IT developer may prohibit or restrict the communications of the developer's employees or contractors. Healthcare organizations self-developing certified systems are not permitted to restrict the communications of their user employees with respect to these provisions.

HITAC Discussion

Sheryl Turney commented that in regard to price transparency there are differences in variation when talking about costs in the past, present, and future. She noted that past is easier than the future; she suggested that the recommendations acknowledge this difference. As things evolve to value-based contracts, this will be difficult to represent. There needs to be more said about the different stakeholder groups in regards to pricing; there isn't one solution that will work for everyone. She suggested proposing recommendations that solve problems by stakeholder groups.

- **Andy Truscott** noted that the definition of EHI will support transactional price; the broader potential for price transparency is not something that the task force could comment on at this point. The focus is on the health IT policy and needs.

Clem McDonald questioned whether the screenshot was taken away? He suggested not taking it away completely. He noted that health information exchange and health information exchanges are being blurred.

- **Andy Truscott** noted the task force reviewed the different uses of HIEs and information exchange as a noun and a verb. Rather than changing the scope, the goal was to provide clarity regarding the uses. The goal is to make enforcement easier.

Raj Ratwani expressed concerns around communications and disclosing screenshots. He questioned if he was to post a screenshot, it is his obligation to ensure it is fair use and to ensure that anyone that uses the website

- **Andy Truscott** commented that the receiving party needs to understand that the screenshot should only be used for fair use. He noted the task force would try to clarify.

Raj Ratwani commented that fair use is not used in the NPRM. By adding this in, the burden seems to be put on the person sharing the screenshot. This seems to open the door for vendor intimidation; in many instances, vendors have more resources to legally pursue this.

- **Andy Truscott** commented that this is a good point. He welcomed input on how to best do this. He thought fair use was a good way to go about it.

John Kansky reacted to the point that Clem McDonald raised. Industry terms are a mess. As a member of the group, the definitions are written so broadly that provider networks with meet the definition of health information network. He thought it would be clearer to say that if you meet this, you are one of those.

Arien Malec commented that he has raised a concern with the way the language is, it includes organizations that were not intended to be included (e.g., banking services that reference claims, clearinghouse services). There is a need to be clear about where the intended boundaries are and where they are not.

- **Andy Truscott** shared that the task force looked at the function to describe the actor. If the task force is missing the mark, he asked for language to make the language clearer.

Cynthia Fisher noted her appreciation for the hard work of the group to end up where they did. She suggested that there be a place for consumers to have access to pricing information. She suggested that ONC should revise the definition of EHI. The goal is to define health information in a broader term as defined by HIPAA and Cures.

Ken Kawamoto agreed with Raj Ratwani's comments.

- **Sasha TerMaat** noted that the fair use concepts seemed to be a reasonable way to introduce this, the goals was to use a minimal amount of words, but maybe there is a better wording approach.
- **Mike Lipinski** noted that ONC tried to balance developer interest with what Congress was trying to achieve. ONC noted that screenshots were fair use with three restrictions: 1) PHI; 2) Third party intellectual property rights (IPR) for disclosure; 3) Can't distort the screenshot.
- **Andy Truscott** noted that the use of screenshots needs to be fair and appropriate for the vendor. That said, it is unfair for a vendor to say that screenshots shouldn't be shared.
- **Mike Lipinski** noted that Congress said that developers cannot restrict or inhibit the communications for certain topics: usability, interoperability, security, user experience information, business practices of developers related to the exchange of health information, and many of which the user has used the technology. ONC tried to balance developer interests. There are circumstances where developers can restrict within the categories. Outside of that, it is not in scope for this regulation. Screenshots are considered intellectual property (IP) by developers.

Andy Truscott thanked the members of the task force and HITAC for the input.

Break

Carolyn Petersen welcomed members back from the break.

Conditions and Maintenance of Certification Requirements Task Force Draft Recommendations

Raj Ratwani, Co-Chair
Denise Webb, Co-Chair

Denise Webb reviewed the charge of the task force.

Overarching Charge: Provide recommendations on the "application programming interfaces (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

Denise Webb noted that 33 recommendations were shared at the March 19, 2019 HITAC meeting. The feedback received from that meeting has been integrated into the recommendations. The transmittal letter has been drafted, and the task force will be looking for a vote. There won't be a review of the recommendations that were discussed during the last meeting. There are 36 recommendations; three recommendations were added. She noted that the numbering has changed since the last meeting. She noted that there are nine recommendations that have been updated. A quick review of the unchanged items will be conducted and then a more in-depth discussion of the items that have changes or are new.

- **No change - Recommendation 1:** ONC should introduce a new Edition of certification rather than propose changes to the 2015 Edition
  - **Steven Lane** asked ONC to comment
  - **Steve Posnack** noted that introducing a new addition could be confusing in regards to when that edition will be required which required CMS action. ONC previously tried having a version two of an edition which did not work. Different approaches have been tried in the past. ONC felt keeping the edition the same would cause the least amount of confusion.
  - **Andy Truscott** noted that given the importance of the regulations, he questioned why there wouldn't be a new edition.

- **Mike Lipinski** commented that it would require re-certification of the criteria that is not changing. It adds additional processes.
- **Steve Posnack** added that every time a certification is completed it creates a new certificate, ONC is trying to avoid having developers go through the entire process again versus just making updates.
- **Clem McDonald** noted that this is up to ONC; he questioned why anyone would care.
- **Denise Webb** noted that she was trying to understand how CMS' programs align with the certification.
- **Steve Posnack** noted that there are a lot of dynamics.

- **HITAC Vote: Recommendation 1 was approved**
  - Nay – One
  - Abstain – One

Real World Testing

Raj Ratwani continued the review of the recommendations.

- **No change - Recommendation 2:** ONC should reconsider the due date for real world testing plans. The CMC TF recommends ONC provide more flexibility for deadline - avoid holidays, avoid overload for ONC-ACBs/federal government. The CMC TF recommends an alternative: anniversary date tied to the certification anniversary for the CEHRT being tested. » The CMC TF 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.
- **No change - 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.
- **No change - Recommendation 4:** ONC should provide guidelines or a template for a test plan. The template will help the process. The CMC TF 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.
- **No change - 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 CMC TF reviewed and determined not all three elements are possible for all certification criteria proposed for real world testing.
- **No change - 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.
- **No change - Recommendation 7**: We recommend vendors be given discretion to incorporate permissible testing approaches, including, for example, automated testing and regression testing (also possibly automated).

Discussion

- **Mike Lipinski** questioned if the recommendations were for preamble or regulatory text. Changes in regulation text could require additional regulation.

- **Denise Webb** noted that the task force could work to make it clear in the recommendations.

Raj Ratwani continued to review the recommendations.

- **No change - Recommendation 9**: ONC should clarify the expected involvement of providers and third parties to support the "real world" nature of the testing. » The CMC TF 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.
- **No change - 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 CMC TF 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
- **No change - 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.
- **No change - 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 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.
- **No change - 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. ONC should 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.

- **No change - 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.

Raj Ratwani noted that this is the first recommendation that had a change.

Revised - 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 would be pertinent to the receipt of data in the EHR. If health IT developers are testing the use of data received through exchange, the health IT vendors should have users involved in the testing to validate providers can process and use that information. When certified health IT products receive "foreign" data, we have heard user feedback desiring it be presented in the same view as the "native" data to be useful and reduce burden on providers using the technology. The intent of this task force is not to prescribe certain design approaches but to encourage user-centered design. The CMC TF recommends use of data testing validate the data a user receives in the certified health IT is viewable, actionable, and reportable alongside the user's native data.~~, 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.~~
- The task force recognizes that the expense of this testing is significant, for both health IT developers and users of health IT. Users (providers) were not considered in the cost estimates for real world testing in the proposed rule preamble.

Discussion

- **Arien Malec** asked for the language to be revised to clarify.
- **Clem McDonald** commented that the changes made to Recommendation 8 are spectacular.
- **Don Rucker** commented that there is complexity to the real world. He suggested having a boundary. He felt some of the recommendations don't have a definable boundary so that there is something actionable. He expressed concern about having something for people to act upon.
- **Andy Truscott** suggested that there is an unintended consequence the way it is drafted (in the first section of changes). He agreed with Clem McDonald but felt that this could stifle innovation.
- **Sasha TerMaat** suggested that the task force reword the recommendations so that there is less ambiguity to move forward for the vote.

Denise Webb noted the new recommendations.

- **New - Recommendation 19:** ONC should require compliance with HL7 US Core FHIR Implementation Guides derived from the Argonaut implementation guides, rather than the

Argonaut implementation guides themselves. Where HL7 Implementation Guides are not available for the corresponding and required Argonaut functionality, ONC should facilitate their inclusion as HL7 standards. This is because Argonaut is a closed membership group with no opportunity for the vast majority of stakeholders such as EHR vendors and healthcare systems to provide input, whereas HL7 is an open-member, ANSI-accredited standards development organization which enables such stakeholder input.

- **New - Recommendation 21:** ONC should provide formal guidance on compliance with relevant privacy and security regulations such as HIPAA of current uses of FHIR APIs, such as in SMART on FHIR applications or CDS Hooks services (e.g., sending of full patient demographic details in all cases, the use of broadly-scoped data access tokens).
- **New – Draft Recommendation 25:** ONC should apply the Conditions and Maintenance of Certification requirements to all developers of certified health IT, including self-developers. In particular:
    1. Par level real-world testing for interoperability. Reinforce ability to point to use and participation of health information exchange as an option.
    2. Maintain or provide for moderation of burden to self-developers seeking certification when applying conditions of certification to them.
    3. ONC should evaluate the application of Conditions of Certification to self-developed products seeking certification.
    4. ONC should carefully weigh the benefits and costs of regulating self-developed products beyond certification purposes, as the referenced FDA Pre-Certification process is being considered for such purposes. Excessive regulation may lead to net harms to patients by stifling innovation.

       The CMC TF is still deliberating on a final recommendation for the committee concerning the Conditions and Maintenance of Certification requirements (real world testing, attestations, and APIs) applicability to self-developers and welcome questions/feedback from the committee.

Discussion

- **Aaron Miri** noted that the task force should share previous work that is relevant from the prior Health IT Policy Committee.
- **Arien Malec** asked the task force to reword Recommendation 19. He suggested removing some of the commentary and keeping the first two sentences. He also suggested that ONC should work with OCR with regard to scoping data requests relative to apps.

Carolyn Petersen thanked the CMC Task Force for their presentation and moved the discussion on to the USCDI Task Force.

U.S. Core Data for Interoperability Task Force Draft Recommendations

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

Christina Caraballo provided a review of the charge.

Principal Charge for Phase 1: Review the newly specified Data Elements proposed in the USCDI v1

Specific Charge: Provide recommendations on the following:

- Inclusion of New Patient Demographics Data Elements
- Inclusion of Provenance Data Elements » Inclusion of Clinical Notes Data Elements
- Inclusion of Pediatric Vital Signs Data Elements » Missing Data Elements within Proposed Data Classes

General Principles

- Be parsimonious with recommendations for new elements
- Divide recommendation into two groups:
  - Those that can be implemented now using current CEHRT functionality
  - Those that will require new functionality or programming
- Each section is organized as follows:
  - Slide 1: Displays ONC recommendations with Task Force response
  - Slide 2: Additional Task Force recommendations
  - Slide 3: Justification and discussion of proposed recommendations

Patient Demographics

Christina Caraballo noted that changed items appear in red.

ONC Proposed Data Element	USCDI Task Force Recommendations

Address	• Use standardized format and content for current Address and prior addresses
	  ○ See AHIMA (including use of USPS) and current requirements for CEHRTs for applicable standards (AHIMA: http://perspectives.ahima.org/wpcontent/uploads/2014/12/PatientMatchin gAppendixA.pdf)
	  ○ Consider an international standard Phone Number

Phone Number	• Use mobile phone number as primary; include “if child, indicate phone number as parent/guardian” • Landline as secondary

Patient Demographics: Additional Recommendations

ONC Proposed Data Element	USCDI Task Force Recommendations
Address	• Add preferred e-mail address
Other	• Add a section for “Pediatric Demographics”: - Contact information for individual(s) with consent authority - Multiple addresses for parents, school, guardian

	• Consider adding optional identifiers such as: - Last four digits of SSN - Vetted IDs such as: State driver's license, State issued ID, Passport number, Military ID - Direct address • Add a designation for individuals experiencing homelessness including displaced persons and refugees. Bring to USCDI once standards exist • Add self-reported gender identity

Patient Demographic Discussion of Recommendations

- Three principal use cases: Patient Matching, Clinical Care, and Identity Verification.
- Standard address including past addresses is a reasonable addition.
- Mobile phone number is one of the most stable patient identifiers.
- Future iterations of USCDI should consider biometrics, but they cannot be supported at this time.
- A Pediatric demographic set recognizes an immediate need of service providers to provide clinical care.
- Secondary attributes as complements to matching logic in USCDI are valuable and will facilitate downstream matching and linking.
- It is the opinion of the Task Force that the benefits of the proposed changes outweigh the burdens of implementation.

Christina Caraballo turned the meeting over to **Terry O'Malley.**

Provenance: Data Element Recommendations

ONC Proposed Data Element	USCDI Task Force Recommendations
Author	• Use "Agent/Entity" in place of "Author"
Author's Time Stamp	• Use "Agent/Entity" Time Stamp
Author's Organization	• Use "Agent/Entity" Organization to include name and location
Author Author Organization	• Consider more granular descriptions in later iterations for role of agent, agent type, agent identifier (NPI), reason, and signature (e.g., Vital signs collected at home vs pharmacy vs clinic vs hospital by MD vs RN vs Aide)
Other	• Create a unique and persistent identifier for each "instance" or "observation" to include: -The observation or instance type (e.g. lab, prescription, clinical note) -The

	"Agent/Entity" that generates the observation -The Time-stamp indicating when it was created -The local identification code assigned by the "Agent/Entity" • This will require the creation of a new metadata field

Provenance: Discussion Recommendations

- The Task Force recommends that the initial requirements for Provenance start with who ("Agent/Entity" which subsumes "Author /Author Organization) is responsible for its accuracy and when (time stamp: date/time) the instance or observation was created.
- The third component, the what (similar to what is found in the "observation" field), is a new addition to the ONC proposal. It applies to the type of data involved.
- The data element type should already be included by the observation category although the choices may need to be expanded
- Subsequent versions can be expanded as needed to include other observation attributes.
- We propose to use Provenance to create a unique and persistent identifier for each instance and observation, essential for the "Deduplication" use case
- This unique identifier may require a new metadata field
- We chose "Agent/Entity" instead of "Author" because it is more general
    - All authors are "Agents/Entities", but not all "Agents/Entities" are authors
    - "Agents/Entities" can include machines, data aggregators

Clinical Notes: Data Element Recommendations

ONC Proposed Data Element	USCDI Task Force Recommendations
Consultation Note	• Adopt
Discharge Summary Note	• Adopt
Imaging Narrative	• Adopt
Laboratory Report Narrative	• Adopt (clarify use restricted to special reports and narrative)
Pathology Report Narrative	• Adopt
Procedure Note	• Adopt (clarify whether this includes the "Operative Note")
Progress Note	• Adopt

Clinical Notes: Additional Recommendations

ONC Proposed Data Element	USCDI Task Force Recommendations
Other	• Amend "Data Element" to "Note" or "Document"

	• Add the following Clinical Note Types
	  ○ Continuity of Care Document
	  ○ Operative Note (if not included in Procedure Note)
	  ○ Referral Note
	  ○ Transfer Summary Note
	  ○ Care Plan Note

	• Add the following when standards established
	  ○ Reconciled Medication List (who, when)
	  ○ Advance Care Planning Note
	  ○ Long Term Services and Supports Care Plan Note

Clinical Notes: Discussion of Recommendations

- Some standardized C-CDA Note and Document types were omitted from original list.
  - Among those, the Transfer Summary Note is a better structure for assuring continuity of care than the Discharge Summary which is a regulatory requirement.
- New note types which reflect the clinical and communication needs of clinicians and service providers who are not hospital based or in ambulatory care practices. Their needs are not adequately represented by the original list.
  - Advance Care Planning and Reconciled Medication List are valuable as separate notes even though they might be included in other HL7 documents.
  - The Long-Term Services and Supports Care Plan is currently in ballot at HL7. It will provide the communication bridge between medical and supportive services.

Pediatric Vital Signs Recommendations

ONC Proposed Data Element	USCDI Task Force Recommendations
BMI percentile per age and sex for youth 2-20	• Omit. • Do not require sharing of values that are calculated from core data. Provide the core data instead.
Weight for age per length and sex	• Omit. • Amend data element to read "Weight for length percentile by age and sex for youth 2- 20".

	• Do not require sharing of values that are calculated from core data. Provide the core data instead.
Occipital-frontal circumference < 3 years old	• Adopt

Pediatric Vital Signs: Additional Recommendations

ONC Proposed Data Element	USCDI Task Force Recommendations
Provider Demographics (under Care Team in current draft)	• Add "length" to the pediatric vital signs as a complement to "height"
Consideration given to creating a standard quality query/response template for eCQMs	• Explicitly declare that the current USCDI Vital Signs apply to all age groups • Calculated values such as percentiles for age, gender is important, and when/if they're required, they should apply to all Vital Signs

Pediatric Vital Signs: Discussion of Recommendations

- There was a divergence of opinion regarding the requirement to calculate and then share important pediatric measures such as percentiles, BMI.
- One group of committee members held that by providing the raw data (height, weight, length, etc.) the receiving system could calculate these values in a way that is consistent with their usual practice thereby avoiding the exchange of data that might be calculated using different nomograms and data sets. As an example please see: https://apps.smarthealthit.org/app/growth-chart
- The other group of committee members felt that there would be value especially for patients and parents to have this information because they are unlikely to have the functionality to calculate and trend these data.
- The compromise was to encourage sites that already calculate and store this information to share it with the other vital signs.
- There are SMART on FHIR apps to do these calculations.

Additional Data Element Recommendations

ONC Proposed Data Element	USCDI Task Force Recommendations
Other	• Name • Role in the care of the patient • Specialty/Training • Contact Information • Identifier – NPI

	• Expand in future to include active areas of responsibility
Medicaid mandated pediatric measurements	• Query contains metric specifications (numerator, denominator, exclusions, data elements) • Response via a structured template • Goal is to measure quality metrics in the background

Discussion of Additional Recommendations

- Provider demographics are an important component of the Care Plan and enable the assignment of specific care plan responsibilities to a specific provider.
- Additional Pediatric measures which are part of Medicaid required reporting. Creates the platform for automated reporting and supports good clinical care.
- Quality measurement is its own category. Given its importance as a lever to improve clinical care, USCDI could help create a platform for quality measurement by implementing standardized query/response documents.

Patient Demographics: Questions for the HITAC

- Are there other priority use cases that should be addressed in addition to Patient Matching, Clinical Care, and Identity Verification?
- How should we assess benefit and burden of proposed changes?

Discussion

- **Clem McDonald** noted that the national provider identifier (NPI) has everything, except demographics. He noted that the idea of using a cell phone is good. He noted that in some families the husband and wife may have the same number.
- **Arien Malec** commented that with length and height being required as separate field adds complexity. He suggested just added height. He applauded the group for including identifiers.
- **Andy Truscott** asked for specificity around state identifiers. The use of cell phone numbers is valid as it doesn't have some of the privacy concerns that other identifiers do.
  Anil Jain noted that percentiles are based on the model at that time. Whatever information is available for the clinical decision support should be sent at that time.
- **Steven Lane** noted that this is a lot of data that needs to be stored, transmitted, and then stored again. He questioned the cost benefit.
- **Clem McDonald** commented that the data should be sent if it exists.
- **Andy Truscott** agreed with Clem McDonald and asked to identify what is being sent.
- **Steven Lane** asked that percentiles should be sent for all vital signs.

Provenance: Questions for the HITAC

- Is a unique identifier necessary for each data element?
- Should provenance be used to track a data element across multiple sites or is it sufficient to establish provenance between the current sender and receiver?

- If using a persistent identifier for each data element, do we need to know the entire history beginning with generation of the data element and each time it was exchanged, or just that it came from a trusted source in the last transmission?
- Does the proposed standardized metadata template adequately address provenance?

Discussion

- **Steven Lane** noted that the task force is suggesting to start with organization.
- **Arien Malec** commented that a stable identifier with a change identifier would be useful.
- **Sasha TerMaat** agreed that a stable identifier with a version identifier would be useful for provenance. She shared that she was puzzled as to what is expected for the entity in the USCDI. She noted concern that if items aren't done consistently, they will lose their value. For this to be implemented in a way that is useful, clarity will be needed for the different data classes. She suggested medications and notes as high-value use cases.
- **Clem McDonald** commented that there isn't a need for 'what,' as provenance doesn't stand alone. A unique identifier is valuable to get rid of clutter. He suggested an HL7 discussion to sort this out.
- **Andy Truscott** suggested a difference between a stable identifier and a stable identity. For nomenclature, he suggested using what is already available rather than creating something new.
- **Sasha TerMaat** suggested that the organization should be contextually based. She noted that users use health IT for different representation. There are considerations that are critical to implementing the provenance concept in a meaningful way.

Clinical Notes Discussion

- **Steven Lane** noted that adding the full range of document types in the Consolidated-Clinical Document Architecture (C-CDA) makes sense.
- **Andy Truscott** commented that he didn't want to appear to put something in place that eventually becomes outdated.
- **Arien Malec** noted that when there are semantic considerations, there is a need to be thoughtful about all note types to be included. There is a role for the unstructured note type, in regard to the Cures requirement that all data be available and exchanged.
- **Steve Posnack** noted that there is sensitivity because there is a wide catalog of standards that are produced. The difficulty is to gain as much insight from stakeholders before publishing the rule. Just because something is available, it does not necessarily mean these items will be well implemented when regulated.
- **Clem McDonald** agreed with Steve Posnack. There needs to be a critical mass of uses, but they need to be pushed a little to get over the hump.

Public Comment

There were no public comments received in the room or on the phone.

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

Didi Davis: Regarding Document types: Sequoia/eHealth Exchange is seeing evidence of a wider adoption of new document types now. in our content testing program. In addition, the

Carequality/Commonwell jointly published Content related Implementation Guide pushes additional types of document types to be required. https://s3.amazonaws.com/ceq-project/wp-content/uploads/2018/10/03211340/Carequality_CommonWell_Improve_C-CDA_06-15-2018_V1.pdf

Next Steps and Adjourn

Carolyn Petersen shared that the next meeting is on April 25, 2019, which is the final opportunity to vote on all of the NPRM recommendations. She suggested that additional time for that meeting may be needed. All materials from this meeting and past meetings can be found on the calendar on the ONC website. She also emphasized the importance of hearing from the public during the upcoming calls. She thanked everyone for their attention.

Lauren Richie adjourned the meeting at 4:30 p.m. ET