Meeting Notes

Health Information Technology Advisory Committee

April 25, 2019, 09:30 a.m. – 03:00 p.m. ET

Virtual The April 25, 2019, meeting of the Health IT Advisory Committee (HITAC) was called to order at 9:30 a.m. ET by **Lauren Richie**, Designated Federal Officer (DFO), Office of the National Coordinator for Health IT (ONC) and conducted roll call.

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
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
Ram Sriram, National Institute of Standards and Technology
Sasha TerMaat, Epic
Sheryl Turney, Anthem BCBS
Denise Webb, Individual

MEMBERS NOT IN ATTENDANCE

Patrick Soon-Shiong, NantHealth
Andrew Truscott, Accenture

FEDERAL REPRESENTATIVES

Kate Goodrich, Centers for Medicare and Medicaid Services (CMS)
Mark Roche, Centers for Medicare and Medicaid Services (CMS)

ONC STAFF

Elise Sweeney Anthony, Executive Director, Office of Policy
Cassandra Hadley, HITAC Support
Seth Pazinski, Director, Office of Planning, Evaluation and Analysis
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, National Coordinator

Donald Rucker thanked the committee members for their time and noted that a significant amount of recent work has been undertaken by the committee and shared the following:

- The public comment period has been extended by thirty days for the ONC and Centers for Medicare and Medicaid Services (CMS) interoperability rules**.** Comments for both rules are now due June 3.
- A growing number of individuals in the HIT community have voiced concern that providers and electronic medical record (EMR) vendors may be held liable if patients download their data and it is somehow accessed by a third party. Dr. Rucker clarified that language has been added to the frequently asked question (FAQ) section of the Health Insurance Portability and Accountability Act (HIPAA) Right of Access page stating that liability for stewardship of a patient's data ends once that patient downloads it.
- The Trusted Exchange Framework and Common Agreement (TEFCA) was released on April 19, 2019 and the comment period closes June 17, 2019. Dr. Rucker noted that the goal is to minimize disruption to current Health Information Exchanges (HIE) and explained that those that want to go to a national scope and scale can do so.
- Roster updates: Chesley Richards, MD from the Centers for Disease Control and Prevention (CDC) is stepping down temporarily. He'll be represented by Laura Conn. Also, Lauren Thompson will be stepping down. Donald expressed his gratitude for the efforts of both Chesley and Lauren and turned the meeting over to Elise Sweeney Anthony, Executive Director, Office of Policy.

Elise Sweeney Anthony thanked the members of the task forces as well as the committee members for their diligent efforts and offered her full support wherever needed.. She turned the meeting over to the HITAC co-chairs, Carolyn Petersen, and Robert Wah.

Review of Agenda and Approval of April 10, 2019 Meeting Minutes

Carolyn Petersen, Co-Chair

Robert Wah, Co-Chair

Carolyn Petersen thanked members of the task forces and the committee members and reviewed the meeting agenda.

Robert Wah thanked the members of the task forces as well as the committee members with a special thanks to the efforts to attend an early meeting for those on the West Coast. He went on to invite the committee members to offer suggestions or edits to the meeting notes. No input was offered, and the notes were approved by a voice vote with no objections or abstentions. Robert Wah turned the meeting over to Michael Adcock.

Information Blocking Task Force Update

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

Michael Adcock reviewed the Information Blocking Task Force agenda. He reminded the committee that the work was divided into three workgroups and provided updates for each. The following presentation contents can be viewed here.

- **Workgroup 1 - Definitions**
  - Discussed the definitions of electronic health information (EHI) including price information, health information exchange (HIE), health information network (HIN) and health IT developer of certified health IT.
  - Voted to advance the recommendation to expand the breadth of the definition of health IT developer / health IT developer of certified IT so that it is not anchored to certification.
  - Noted that there was majority approval of the definition of EHI.
- **Workgroup 2 – Exceptions**
  - Discussed exceptions for recovering costs reasonably incurred and licensing of interoperability elements on reasonable and non-discriminatory terms.
  - The task force will revisit the request for information regarding a possible information blocking exception for complying with the Trusted Exchange Framework and Common Agreement (TEFCA).
  - Finalizing recommendations for HITAC vote at the 5/13 meeting.
- **Workgroup 3 - Conditions and Maintenance of Certifications**
  - The task force will revisit the request for information in the Assurances section regarding TEFCA.
  - Finalizing recommendations for HITAC vote at 5/13 meeting.

Michael Adcock invited **Cynthia A. Fisher** to discuss her proposal regarding the definition of EHI, as there has been a lot of discussion in the task force about this definition and he thought it would be helpful to share her point of view with the HITAC.

EHI Definition Review

- **Cynthia Fisher** provided a bit of history and noted that as price transparency and the EHI definition were considered, she was referred back to the health information definition in HIPAA, where there are three levels of definitions. The 1996 Portability Act as HIPAA defines it, dealt with price transparency to enable patients to have a broad perspective with searchable prices and the ability to compare data with their health plans' negotiated rate.
- As such, she approached the EHI definition as any information that relates to health information transmitted through electronic media per §45CFR 160.103.
- Her recommendation is to create a broader definition for EHI that strikes out where it identifies the individual with respect to which there is a reasonable basis to believe the information can be used to identify the individual.
- Cynthia submitted a one-page document to the Information Blocking Task Force that explains the details of the background and the recommendation.
- She noted that identifiable EHI is different than that found within the Cures Act, where according to a proper reading of the statute, limiting identifiable information is a conflict.
- Finally, Cynthia expressed concern that the revision to the broader definition consistent with the 21st Century Cures (Cures) Act and HIPAA would not include information that's unrelated to the care or payment for the individual.

Discussion

- **Mark Knee** noted that the discussion about the EHI definition and price transparency ties together. Further, within the preamble price information is included in the definition of EHI. He then mentioned that the committee members needed to determine if they wanted to expand the recommendation of what price information would entail. He also noted that there is a list of questions included in the proposed rule that gets into more specificity about what price information and price transparency would entail. He suggested that Cynthia's discussion was likely in the minority opinion and suggested others on the committee should voice their opinion regarding this matter.
- **Terry O'Malley** asked 1) if anyone has a model about how pricing information is shared and 2) if there are specific data needs from U.S. Core Data for Interoperability USCDI that need to be considered to facilitate the sharing of pricing information.
    - **Cynthia Fisher** agreed to share the description she proposed for the revised EHI definition. She then addressed Terry O'Malley's questions regarding how the data sets need to be posted. Cynthia noted that after speaking with several technology companies, she determined that it's important to post, in a transparent way, the contract negotiated terms and rates so that those prices can be deemed acceptable by the relevant parties involved. She then suggested that as long as the data are in machine-readable form, quantified and bundled or unbundled, that a third-party could easily harmonize in a relatively reasonable amount of time, data across the spectrum. She suggested that although the goal is to deliver interoperability across the spectrum in the near term, there is a concern it could be bogged down with a decade of defining standards. Her goal is to present it and look to innovators to harmonize.
    - **Steven Lane** echoed the importance and relevance of Cynthia's statements and noted his shared goal to bring forward price transparency data in a meaningful and functional way.

Information Blocking Task Force - Price Information/Transparency

Michael Adcock asked **Arien Malec** to discuss conclusions of the Information Blocking Task Force.

Arien Malec provided an update on the progress made by the Information Blocking Task Force. The task force produced the following findings and conclusions:

- There are seven permitted exceptions to information blocking and information for permissible uses must flow unless the restriction is covered by one of the exceptions. He suggested that there is a perspective that attaching any fees to access 'exchange or use' constitutes blocking unless permissible.
- A framework exists under the following exceptions: §171.204 and §171.206 that subdivide two types of allowable fees. He went on to state that the best way to think about these sections is to assume that fees are not allowable unless they are allowable under §171.204 and §171.206.
- §171.206 was intended for licensing of individual property rights and §171.204 covers all other situations.
- It is recommended that ONC combine §171.204 and §171.206 into a single exception that covers permitted fees. This will make it easier to adjudicate whether a particular prospective fee an individual was charging or was being charged was permissible under the exceptions.
- Regarding the broad definition of EHI, there is a set of actors that are prospective information blockers under the Cures Act.
- The definition of *developer of certified technology* and *health information network* are all are very broad terms and the provider has a broad set of applicability.
- Regarding pricing and fees that are allowable, the task force formalized their shared concern into a set of recommendations about the attachment of various kinds of access exchange or use activities under the fee section.
- The task forces' framework combined with the breadth of actors and health information exchange was too broad to attach restrictive pricing fees.
- Fees are often used as a way to place gates to access, and intellectual property can be a deterrent to downstream access.
- To mitigate the concerns of information blocking the task force put together a framework by which certain kinds of activities attract additional scrutiny in terms of pricing.
- The task force defined a category called basic access. Basic access is intended to cover access to the legal medical record and/or the definition of data under the designated record set.
- Facts such as blood pressure findings cannot be considered intellectual property.
- The task force recommends creating a reasonable mapping to certified standards when certified health information technology accords to a principle relative to enabling that standards-based access.
- Cost-oriented fee restrictions should apply to a category of access. This is particularly true with regard to basic access that enables information to flow.
- Some intellectual property rights add value for which free and open marketplace should be the appropriate mechanism for setting prices. Other intellectual property rights deemed necessary for access, exchange or use will be considered *standards-essential* or *use-essential*.
- Additionally, the task force believed the reasonable and nondiscriminatory pricing structure that is used for standards-essential intellectual property was appropriate to apply for access, exchange, and use-essential intellectual property rights.

Michael Adcock thanked Arien Malec and each of the members of the Information Blocking Task Force and handed the meeting over to the chairs.

Carolyn Petersen thanked Michael Adcock and Arien Malec for the information they provided and turned the meeting over to Denise Webb.

Conditions and Maintenance of Certification Requirements Task Force Draft Recommendations and Vote

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

Denise Webb reviewed the agenda and noted the process that would be followed regarding committee members voting on each recommendation. She mentioned that all but one recommendation is final and ready for a vote. However, the task force was not able to come to a consensus on one draft recommendation, and Denise asked that, if time permits, the members provide their input. If time does not permit Denise invited the members to provide input via email to Raj and herself. Denise then shared the Conditions and Maintenance of Certification Requirements Task Force charge and membership. She thanked the task force members for the time they committed to reaching this point. She then reviewed the recommendations on the conditions and maintenance of certification for the three areas specified within the task force charge, starting with real-world testing. The following presentation contents can be viewed here.

Overarching Recommendation

- **Recommendation 1:** ONC should introduce a new Edition of certification rather than propose changes to the 2015 Edition.
    - **No vote today as this was previously approved by the HITAC on April 10, 2019.**

Real World Testing

- **Recommendation 2:** The Conditions and Maintenance of Certification Task Force (CMC TF) recommends ONC reconsider the due date for real world testing plans and provide more flexibility for the deadline to avoid holidays and avoid overloading the ONCACBs/federal government. The CMC TF recommends an alternative for 170.405(b)(1): instead of requiring submission of an annual real world testing plan to the ONC-ACB via a publicly accessible hyperlink no later December 15 of each year, require submission no later than the latest certification anniversary date each year for the health IT developers' applicable certified 2015 Edition Health IT Modules.
    - **The HITAC approved Recommendation 2 by voice vote. No members opposed. None abstained.**

- **Recommendation 3:** The CMC TF recommends ONC provide more clarity in the final rule preamble in section VII.B.5 around the care settings/venues the test plan must cover with the goal of making minimum expectations clear and establishing which settings and the number of settings for the applicable certified Health IT Modules.

- **The HITAC approved Recommendation 3 by voice vote. No members opposed. None abstained.**

- **Recommendation 4:** The CMC TF recommends ONC provide guidelines in the final rule preamble for a test plan. The TF supports the proposed pilot year and recommends including the pilot year in the final rule. After the pilot year, the TF suggests creation of a standardized template incorporating the elements of an acceptable test plan.
  - **The HITAC approved Recommendation 4 by voice vote. No members opposed. None abstained.**

- **Recommendation 5:** The CMC TF recommends ONC provide clarity in the final rule preamble on how successful real world testing is met for the following: (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 TF reviewed and determined not all three elements are possible for all certification criteria proposed for real world testing.
  - **The HITAC approved Recommendation 5 by voice vote. No members opposed. None abstained.**

- **Recommendation 6:** The CMC TF recommends ONC clarify and define the terms, "scenario" and "use case" (§ 170.405(b)(1)(iii)(A)). If these terms mean the same thing, choose and use just one of these terms in the final rule regulatory text and in the preamble. In the final rule preamble, the TF also recommends ONC clarify the term "workflow" as it is used in section VII.B.5 of the proposed rule preamble regarding real world testing. The TF acknowledges the variability that exists in provider workflows and is concerned this could require an infinite number of test cases for a health IT developer's customer base. The TF recommends the final rule preamble be clear and reasonable with what is intended where the preamble states "...developers can and should design scenario-based test cases that incorporate multiple functionalities as appropriate for the real-world workflow and setting." The TF recommends ONC clarify in the final rule preamble where existing interoperability testing (such as that performed by The Sequoia Project or other existing networks) can satisfy expectations for real world testing. The TF recommends ONC clarify in the final rule preamble where existing interoperability testing (such as that performed by The Sequoia Project or other existing networks) can satisfy expectations for real world testing.
  - **The HITAC approved Recommendation 6 by voice vote. No members opposed. None abstained.**

- **Recommendation 7:** The CMC TF recommends modifying § 170.405(b)(1)(iii)(A) to also include as permissible testing approaches automated testing and regression testing: (A) The testing method(s)/methodology(ies) that will be used to demonstrate real world interoperability and conformance to the certification criteria's requirements, including scenario, use case-focused, automated, or regression testing.
  - **The HITAC approved Recommendation 7 by voice vote. No members opposed. Clem McDonald and Cynthia A. Fisher abstained.**

- **Recommendation 8:** The CMC TF recommends ONC provide clarification in the final rule preamble in section VII.B.5 around testing the use of information received through exchange versus testing the exchange of information (sending and receiving). When there are no end users of the health IT product being tested, use-based testing would not be pertinent. The TF recommends ONC expect that if health IT developers are testing the use of data received through exchange, the health IT vendors should have intended users involved in usability testing. Users (providers) were not considered in the cost estimates for real world testing in the proposed rule preamble. Therefore, the TF recommends ONC revise real world testing cost estimates in the final rule preamble section XIV.C.2.a.3.6 to incorporate this. To reduce cost, the TF further recommends ONC prioritize real world testing criteria based on risk.
    - **Clem McDonald** expressed his lack of clarity on what the recommendation is seeking, specifically regarding the word 'testing' within the text "…testing the use of information received…". Much discussion followed with a decision to delay consideration of Recommendation 8. **As such, Denise Webb will take the comments under advisement and elicit additional input outside the current HITAC meeting, amend Recommendation 8 if necessary and report back at the next HITAC meeting.**

- **Recommendation 9:** The CMC TF recommends ONC clarify in the final rule preamble the expected involvement of providers and third parties to support the "real world" nature of the testing. The TF recommends ONC provide guidance in the final rule preamble 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.
    - **The HITAC approved Recommendation 9 by voice vote. No members opposed. None abstained.**

- **Recommendation 10:** The CMC TF recommends ONC allow in the final rule preamble for flexibility for vendors with regard to real world testing where there is no difference in the testing approach, result or capability. The TF suggests the preamble address the following: 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.
    - **The HITAC approved Recommendation 10 by voice vote. No members opposed. None abstained.**

- **Recommendation 11:** The CMC TF recommends ONC include in the final rule preamble section VII.B.5 a description of "measurement" and provide clarity on the role of measurement and specificity for what kinds and for what purposes or proof points. The TF recommends ONC

consider including updated metric expectations after the pilot year. Where the real world testing is for both interoperability and use of received data, the TF recommends ONC consider specifying in the final rule preamble section that there be at least one metric for interoperability and one metric for use, which might correspond with metrics of use used in safety enhanced design testing.

- **The HITAC approved Recommendation 11 by voice vote. No members opposed. None abstained.**

- **Recommendation 12:** The CMC TF recommends ONC elaborate and provides more clarity in the final rule preamble section VII.B.5 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 preamble 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. The TF further recommends ONC 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.
  - **Clem McDonald** expressed concern and asked if this recommends that all versions will need to be supported and tested.
  - **Carolyn Petersen** answered that it means the health IT developer must test all real-world versions to their certifications. She went on to describe that the proposed rule states that they can attest that they meet the standard because they did the testing of their product to meet the requirements of that particular standard. She recommended there be clarification on when those conformance tools become available, and what and when they will need to retest. She invited others to clarify further if she missed anything and there was broad agreement among the members that she captured the spirit of the language as written.
  - **After further discussion, Robert Wah determined that the vote should be delayed to another time while additional input is captured which may help ease member concerns.**

- **Recommendation 13:** The CMC TF recommends ONC clarify in the final rule preamble 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 have limited resources to assist other groups. The TF further recommends ONC clarify whether declining to participate in real world testing is considered to be information blocking. The TF recommends ONC consider and clarify in the final rule preamble 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 final rule preamble should provide reasonable assurances for health IT developers who have tried to engage third parties in testing yet were not successful in getting their commitment to participate.

- **Terry O'Malley** shared a concern that the recommendation implies that if a vendor doesn't have the resources to perform testing, then they are absolved from that responsibility.
- **Denise Webb** answered that vendors are not absolved from testing. She went on to note that this recommendation is directed toward small provider organizations or others who receive requests to test who are unable to take part in their vendors' real-world testing due to limited resources. In these cases, they wouldn't be considered to be information blocking by declining to participate.
- **Clem McDonald** suggested changing 'those' in the sentence "protections can be provided for those who have limited resources" to 'third parties' to keep from absolving vendors from their responsibilities to test.
- **Sasha TerMaat** suggested not using 'third parties,' preferring instead to use the term 'recipients of testing requests' as health IT developers could be the recipients of testing requests.
- **Arien Malec** suggested that the spirit of this recommendation is clear and seeks that ONC to clarify the conditions under which an individual or organization can or cannot decline to participate in testing.
- **Cynthia A. Fisher** shared her concern that by writing the recommendation in such a prescriptive way that innovators may be dissuaded from entering the market.
- **After further discussion, there was agreement among the members that the vote should be delayed to another time while additional input is captured which may help ease member concerns.**

- **Recommendation 14:** The CMC TF recommends ONC reviews and revises the Regulatory Impact Analysis time estimates that would be required to ensure they accurately reflect and align with the clarified understanding of the real-world testing expectations in the final rule.
  - **The HITAC approved Recommendation 14 by voice vote. No members opposed. None abstained.**

Attestations

- **Recommendation 15:** The CMC TF recommends ONC include a specific deadline at the middle of the year and the end of year/ beginning of year for attestations in the final rule preamble section VII.B.6. This would provide flexibility for the ONC-ACBs to work with developers to get the attestations 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. The TF recommends ONC consider, for example, setting the deadline for the health IT developers to submit their semi-annual attestations to the ONC-ACB to the last Friday of January and July (this avoids holidays).
  - **The HITAC approved Recommendation 15 by voice vote. No members opposed. None abstained.**

Application Programming Interfaces

- **Recommendation 16:** The CMC TF recommends ONC clarify in the final rule preamble section VII.B.4.b what is considered 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 preamble. Relationships prior to the involvement of an API Data Provider are of particular interest.

- **Clem McDonald** asked for clarifications on what the problematic issues are.
- **Denise Webb** stated that there's more than just a relationship between the data provider and the actual users. In some cases, third-party app developers are engaged in a relationship with the technology suppliers. She went on to state that the goal of this recommendation is more to provide clarification around the expectations of what that relationship looks like, just as they describe what the relationship looks like between API technology supplier and the API data provider.
- **The HITAC approved Recommendation 16 by voice vote. No members opposed. None abstained.**

- **Recommendation 17:** The CMC TF recommends ONC solely adopt FHIR Release 4 (or a subsequent 4.x version if one is created with errata) in the final rule for reference in proposed § 170.315(g)(10) (Option 4) and in the preamble section VII.B.4.c and VII.B.4.c.i. The TF is making this recommendation because FHIR Release 4 provides the first normative version, will support enhanced capabilities (such as bulk data), and will focus and unify the industry on a single release of the standard versus multiple releases of the standard.
  - **Steven Lane** agreed that the committee should support the release of the latest version of Fast Healthcare Interoperability Resources (FHIR). However, if the committee writes 'release 4' into regulations, it will limit flexibility. He suggested that they phrase the recommendation in such a way so that any subsequent valid version through the standards advancement process be written into the regulation.
  - **Denise Webb** suggested that ONC must be definitive within the regulatory text as to which release it is specifying and pre-existing coverage for subsequent releases exists through the standards advancement process.
  - **The HITAC approved Recommendation 17 by voice vote. No member opposed. None abstained.**

- **Recommendation 18:** The CMC TF recommends ONC move forward in the final rule 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 TF sees value in health IT developers harmonizing to a specified version/release.
  - **The HITAC approved Recommendation 18 by voice vote. No members opposed. None abstained.**

- **Recommendation 19:** The CMC TF recommends ONC require compliance with HL7 US Core FHIR Implementation Guides (IGs) rather than specifying the Argonaut implementation guides in the final rule regulatory text § 170.215(a)(3) and (4) and preamble section VII.B.4.c.ii. Where HL7 IGs are not available for the corresponding and required Argonaut functionality, the TF recommends ONC assist in facilitating their inclusion in the HL7 US Core FHIR IGs.

- **Clem McDonald** asked what was missing in the core versus the Argonaut. He went on to note that the notice of proposed rulemaking (NPRM) recommends that 15 distinct resources be supported by every medical record vendor and wondered how that relates to Argonaut.
- **Arien Malec** noted that this recommendation has no bearing on which profiles are or are not included and questioned what Clem's question had to do with Recommendation 19. He went on to note that this recommendation is just fine and is the normal process that Argonaut follows.
- **The HITAC approved Recommendation 19 by voice vote. No members opposed. Arien Malec abstained.**

- **Recommendation 20- Amended:** The CMC TF recommends ONC address the legitimate and expected activity for SMART Guide to protect patient data with respect to providing ~~persistent~~ refresh tokens to applications and the applications' ability to keep the token confidential. Someone will need to ascertain that API Users provided a persistent token are developing products that secure the token appropriately, but it is not clear who plays that role. The TF recommends the ONC clarify who it is and how the determination is made in the final rule preamble section VII.4.c.iii.
  - **Arien Malec** suggested this belonged in an implementation guide and not within regulatory text. He reiterated that this should be addressed within the testing process or the Health Level Seven (HL7) process to ensure this is properly addressed in a security consideration section.
  - **Denise Webb** answered that within the proposed rule it wasn't clear who is responsible whether an app meets this or not. She went on to suggest that 'how the determination is made' should be removed as it's a standard process covered in implementation guides.
  - **Sasha TerMaat** noted that the challenging part is that implementation guide says that the expected practice is to provide a persistent token only if the application is a confidential client. However, ONC in their guidance specifically overrules the implementation guide and instead of having that be an optional component mandates that it offers a persistent token, leaving the interrelationship unclear. Finally, she noted that if it completely deferred to the implementation guide that will be preferable but ONC is already calling this out as a special case.
  - **Arien Malec** elaborated that he agrees that if ONC wants to overrule the implementation guide and create effective additional regulation, that regulation needs to have the same effect as the implementation guide and clarify roles and responsibilities. He then offered his conditional agreement with this recommendation but maintained that his general recommendation is that this is something classically that should be punted to implementation guide.
  - **Steve Posnack** commented that in large part ONC has proposed to adopt what was included in the SMART Application (app) Launch Framework Implementation Guide which references two types of tokens 1) access tokens and 2) refresh tokens. He went on to state that ONC does not require what has been referred to as persistent tokens. He clarified that ONC has just proposed to follow what the implementation guide lays out. However, ONC requires that refresh tokens be provided which is not a

requirement in the implementation guide. Otherwise, the proposal as a whole defers to the implementation guide itself.
    - **Sasha TerMaat** suggested that 'refresh token' should have been used in place of 'persistent token.'
    - **Robert Wah** acknowledged the change from 'persistent' to 'refresh.' Robert gave the committee another chance to provide feedback on the amended language and asked that the members vote.
    - **The HITAC approved the amended Recommendation 20 by voice vote. No member opposed. Arien Malec, Clem McDonald, and Leslie Lenert abstained.**

- **Recommendation 21:** The CMC TF recommends ONC work with OCR and other responsible agencies to provide formal guidance on current uses of FHIR APIs, such as in SMART on FHIR applications or CDS Hooks services, with respect to compliance with relevant privacy and security regulations, such as HIPAA (e.g., the inappropriate sending of full patient demographic details, the inappropriate use of broadly-scoped data access tokens). This deliberation can leverage the work and recommendations of the prior HIT Policy Committee and HIT Standards Committee Joint API Task Force as a starting point (https://www.healthit.gov/sites/default/files/facas/APITF_Links_to_API_comments_and_recommendations_from_HITSC_and_HITPC_2015-11-30.docx).
    - **Clem McDonald** commented that clinical decision support (CDS) hooks don't have much SMART on the medical records side. He went on to suggest that HL7 should figure out some logic on the medical records side but agrees that this is a good suggestion as it stands.
    - **Ken Kawamoto** answered that all real implementations of CDS hooks use 'trigger guards' which is another way of saying they require a rules engine to restrict when things are sent. The standards themselves often don't detail this.
    - **Clem McDonald** asked if there's an effort to formalize the logic on the medical record side.
    - **Ken Kawamoto** answered they are looking to see if they can address it in the standards.
    - **The HITAC approved Recommendation 21 by voice vote. No members opposed. None abstained.**

- **Recommendation 22:** The CMC TF has concerns over ONC not proposing a standard way for a request for multiple patients' data and recommends ONC specify a standard approach that will be available in FHIR R4. Otherwise, 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 CMC TF also recognized that there is an immediate need now to satisfy this type of request. If ONC identifies FHIR R4 for implementation in the final rule, the FHIR R4 standard could be used for bulk queries but on a different timeline than implementation of more established R4 implementation guides that support a search for a single patient's data. The TF would like to see successful implementations of products that search for multiple patients using the FHIR R4 standard prior to requiring adoption across the industry of this 2015 Edition certification criterion for multiple patients.

- **Arien Malec** commented that successful transition to FHIR based API access for patients was done in much the same grounds as ONC is proposing for bulk data export. ONC is proposing functional specification at first with an intent in the preamble to switch to a standard, which Arien considers acceptable. It is appropriate to let the community test bulk data export and make sure it's a fit for purpose as well as addresses portability requirements, risk adjustments or quality measurements, etc. Arien went on to recommend additional preamble clarifying ONC's intent. He suggested that the only appropriate way to address this is to not included it as a requirement or included it as a functional requirement with preamble text which explains what this recommendation is addressing. In Arien's opinion, either ONC does not establish certification criteria, or they establish functional certification criteria with the preamble clarifying ONC's intent to switch sometime in the future to a FHIR based implementation guide.
- **Clem McDonald** did not want this recommendation to block forward progress. He suggested as it is currently stated that he can foresee it blocking progress on FHIR.
- **Denise Webb** asked Arien what is in the currently proposed rule that would prevent each developer from implementing this differently.
- **Arien Malec** answered that this is exactly what happened with the Patient API Regulatory Framework where ONC established a functional specification for access to APIs, and at the same time, many of the EHR vendors collaborated around transition to FHIR based API's. He went on to note that it provided flexibility for EHR vendors to be certified to affect a proprietary method for addressing the functional requirement but provided an incentive for the community to transition to a standards-based way of doing this.
- **Denise Webb suggested taking Recommendation 22 back to the task force to discuss further and received consent from the members.**

- **Recommendation 23:** The CMC TF recommends ONC clarify what happens at 6 months and what happens at 24 months concerning publication of API documentation by revising the preamble text as specified below. The CMC TF was puzzled by requirements to update API documentation (6 months) prior to the requirement to update API capabilities (24 months). Revise preamble text in section VII.B.4.d.iii to read: "For the purposes of the specific transparency conditions proposed in § 170.404(a)(2) and their relationship and applicability to API Technology Suppliers with products already certified to § 170.315(g)(7), (8), or (9), we propose to establish a compliance date of six months from the final rule's effective date (which would give developers approximately eight months from the final rule's publication date) to revise their existing API documentation to come into compliance with the final rule for these criteria."
  - **Denise Webb** noted there were three words added (red text above).
  - **The HITAC approved Recommendation 23 by voice vote. No members opposed. None abstained.**

- **Recommendation 24:** The CMC TF recommends ONC further clarify the requirements and expectations around the app registration condition of certification based on a number of issues

the CMC TF identified regarding app registration. The TF recommends clarification in the final rule preamble 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.
- **The HITAC approved Recommendation 24 by voice vote. No member opposed. None abstained.**
-

Applicability of Conditions and Maintenance of Certification Requirements for Self-Developers

- **Recommendation 25 [Placeholder]:** The CMC TF will be advancing a recommendation to the HITAC for consideration at the May 13 HITAC meeting regarding the applicability of the Conditions and Maintenance of Certification requirements for real world testing, APIs, and attestations to self-developers and their certified Health IT Modules. The TF is still deliberating on this recommendation and has not come to consensus yet.

Electronic Health Information Export

- **Recommendation 26:** The CMC TF recommends ONC provide clarity in the final rule preamble around the scope of the EHI export in the 2015 Edition certification criteria. The TF recommends the EHI Export scope be limited to EHI collected and retained by the certified EHR technology and apply only to the EHI that is commonly understood to be part of the legal medical record. The CMC TF further recommends that health IT developers be required to provide a plain language definition of EHI typically included in the legal medical record held by their certified Health IT Module as part of their export documentation.
  - **The HITAC approved Recommendation 26 by voice vote. No members opposed. None abstained.**

- **Recommendation 27:** The CMC TF recommends ONC clarify in the final rule preamble section IV.B.4 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.

- **The HITAC approved Recommendation 27 by voice vote. No members opposed. None abstained.**

- **Recommendation 28:** The CMC TF recommends ONC include audit log data for the EHI Export transitions between health IT systems use case (but not for the EHI Export patient use case due to privacy of health system staff) in the final rule preamble section IV.B.4.
  - **The HITAC approved Recommendation 28 by voice vote. No member opposed. None abstained.**

- **Recommendation 29:** The CMC TF recommends ONC not require in the final rule preamble section IV.B.4 that the EHI export criterion include capabilities to permit health care providers to set date ranges/specific time period for EHI export due to the complexity experienced by health IT developers in complying with date range/time period flexibility in the View, Download, Transmit certification criterion. Additionally, patients should have access to all of their data regardless of time period.
  - **The HITAC approved Recommendation 24 by voice vote. No member opposed. None abstained**.

Electronic Prescribing

- **Recommendation 30:** The CMC TF recommends ONC make in the final rule regulatory text § 170.315(b)(11) and preamble section IV.B.2 e-Rx transactions optional that are not applicable to all settings and/or need piloting. If all transactions are required, this could jeopardize the timeline specified for availability/production use. The TF recommends the revisions below:
  - Prescriber applicable:
    - NewRxRequest
    - NewRxResponseDenied
    - RxFillIndicatorChange
    - RxChangeRequest, RxChangeResponse
    - RxRenewalRequest, RxRenewalResponse (note this is also new, and could be implemented after 1/1/2020 without loss of current functionality)
  - Optional prescriber applicable:
    - REMSInitiationRequest
    - REMSInitiationResponse
    - REMSRequest
    - REMSResponse Electronic Prescribing
  - LTC only:
    - Resupply
    - DrugAdministration
    - Recertification
  - Pharmacy only:
    - RxTransferRequest
    - RxTransferResponse
    - RxTransferConfirm
  - Not applicable:

- GetMessage. Get Message is an obsolete method of message retrieval that essentially is unused since intermediated electronic transacting came into being through RxHub and SureScripts back about 2007 or 2008.

Discussion

- **Terry O'Malley** sought clarification on his understanding that GetMessage is for the process and message types, but not for specifying the message content.
- **Sasha TerMaat** answered that SureScripts standard specifies transactions and each transaction has a format which would include the content. Each transaction has intended purposes. She went on to note that they are identifying in this recommendation that some of these, for example, a Pharmacy to pharmacy message, would not be applicable for requiring in-certification of, for example, an ambulatory EHR product. As such it would potentially have content as defined by the SureScripts standard.
- **Terry O'Malley** noted that some data elements are missing from these very valuable transaction types. For example, 'indication' or 'associated diagnosis' were currently found in USCDI, and he wondered if these should stay in USCDI or be placed in electronic prescribing.
- **Sasha TerMaat** answered that it's already accommodated into ONC's proposal and they include putting an indication in when the transaction accommodates that.
- **The HITAC approved Recommendation 30 by voice vote. No members opposed. None abstained.**

Clinical Quality Measures - Export

- **Recommendation 31:** The CMC TF recommends ONC update the clinical quality measurement proposal in the final rule regulatory text § 170.315(c)(3) and preamble section IV.B.3 per the table below. ONC proposes that all products adopt both the CMS ambulatory IG for QRDA III and CMS inpatient IG for QRDA I. If this change is not made, developers will not know how to comply with requirements for QRDA in domains that are not relevant to the care settings supported by their products. Inpatient Implementation Guides include hospital information (for example, hospital identifiers) that would not be relevant to an ambulatory setting and vice versa. We see this as an important technical correction for quality reporting use cases
  - **The HITAC approved Recommendation 31 by voice vote. No members opposed. None abstained.**

- **Recommendation 32:** The CMC TF agrees quality reporting using FHIR-enabled APIs is a good aspirational direction for ONC to take and include in future rulemaking, but they are not ready today to replace or complement QRDA reports for quality reporting and improvement.
  - **The HITAC approved Recommendation 32 by voice vote. No members opposed. None abstained.**

Privacy and Security-Related Attestation Criteria

- **Recommendation 33:** The CMC TF recommends ONC apply privacy and security attestations only to new certifications/new products after this rule is finalized (preamble section IV.B.6), 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.

- **The HITAC approved Recommendation 33 by voice vote. No members opposed. None abstained.**

- **Recommendation 34:** The CMC TF recommends ONC add a text box for developers to describe their yes/no attestations in certification (modify final rule regulatory text in § 170.315(d)(12)(i) and (ii) and § 170.315(d)(13)(i) and (ii), and preamble section IV.B.6). This would also help with clarity for use cases (login, signing EPCS, etc.). This will allow developers to provide clarity to stakeholders as to what use cases, third party considerations, workflows, etc., that they considered when attesting yes or no. The information provided will also be useful to ONC.
  - **The HITAC approved Recommendation 34 by voice vote. No members opposed. None abstained.**

Deregulatory Actions

- **Recommendation 35:** The CMC TF recommends ONC not remove the prohibition on consecutive selection of one Health IT Module in the final rule regulatory text (preserve § 170.556(c)(6)) and preamble section III.B.1. 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 Health IT Module for random surveillance more than once in a 12-month period. If through random surveillance, an ONC-ACB discovers non-conformance in a Health IT Module, they would still be able to follow up on the same Health IT Module within the 12-month period through its reactive surveillance authority. Removal of Certain 2015 Edition Certification Criteria
  - **The HITAC approved Recommendation 35 by voice vote. No members opposed. None abstained.**

- **Recommendation 36:** The CMC TF recommends ONC adopt a general principle in the final rule preamble section III.B.4 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 TF recommends ONC consider other criteria, such as demographics, that could also be removed and do so in the final rule.
  - **The HITAC approved Recommendation 36 by voice vote. No members opposed. None abstained.**

- **Denise Webb** noted that the task force continues to work on the recommendation of self-developers and invited the broader committee to share their perspectives on this topic so she can bring that information back to the task force. She also invited the members to email their thoughts if that was more convenient for them. Denise went on to mention that she was generally interested to know if her fellow committee members were in favor of requiring self-developers to meet the real-world testing requirements and to share if they have any concerns.
  - **Steven Lane** mentioned that he thought this had come up in a number of task force discussions regarding whether somebody is certified or not, self-developing or not and noted that the standard for app developers and apps should be standard across-the-board. He then noted that there should not be loopholes that allow people to bring

things to market and into their system without appropriate oversight. He concluded by saying testing is part of that appropriate oversight.

- **Aaron Miri** agreed and noted that his organization builds a lot of homegrown apps in addition to using a lot of commercial products and it would be quite difficult if suddenly there were two different standards and he felt the task force should encourage harmonization of both sides of the coin.
- **Denise Webb** noted that some members of her task force were greatly concerned about the Maintenance of Certification if not within the first year of real-world testing then with maintaining and satisfying the requirements each year. A few members thought applying the conditions for maintenance of certification around real-world testing would stifle innovation. She commented that self-developers are generally considered, within the information blocking definition, to be providers or provider organizations and as such are subject to information blocking regardless of whether they decide to certify their product or not.
- **Aaron Miri** shared an example by noting as the chief information officer (CIO), everything rises up to him at some point, and as such, he sees just about every system built or installed. He went on to describe a situation where he was speaking to one of their bright self-developers who did not consider the privacy security ramification. Finally, he noted that everyone can do their parts internally or within their organization, but there will be a hodgepodge in the environment if not everybody has the same level of rigor.

Trusted Exchange Framework and Common Agreement Draft 2 Overview

Zoe Barber, Senior Policy Advisor, Office of Policy, ONC
Alex Kontur, Public Health Analyst, Office of Technology, ONC

Lauren Richie called the meeting to order after the break and introduced Zoe Barber as the presenter of the Trusted Exchange Framework and Common Agreement Draft 2 Overview.

Zoe Barber introduced herself and noted she served as a Senior Policy Adviser at ONC. She also introduced her colleague Alex Kontur who serves as a subject matter expert. Zoe then began the presentation where she reviewed the following presentation contents can be viewed here:

- The Trusted Exchange Framework and Common Agreement Draft
- Major updates to Draft 2 of the Trusted Exchange Framework (TEF) and Minimum Required Terms & Conditions (MRTCs)
- What is the structure of the Common Agreement?
- How do you become a qualified health information network (QHIN)?
- What can the Common Agreement be used for?
- What are the next steps?
- Questions:
  - **John Kansky** referenced the new QHIN eligibility rules, and asked if it's clear that EHR vendors will or will not be eligible to apply to be QHIN's
    - **Zoe Barber** answered that as long as the entity applying meets the definition of the Health Information Network and are operating an existing network within a

live clinical environment, with participants currently exchanging data in that environment. And as long as the network meets all applicable federal and state law, they should be eligible to apply for that QHIN. She went on to note that the Regulatory Compliance Engineer (RCE) will make the determination on whether entities are eligible to apply.

Lauren Richie thanked Zoe and turned the meeting over to Christina Caraballo and Terry O'Malley.

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

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

Christina Caraballo and **Terry O'Malley** presented the U.S. Core Data for Interoperability Task Force Draft Recommendations where they reviewed the following: Presentation contents can be viewed here.

- Task Force Phase 1 Charge
- Task Force Members
- Recommendations: Introduction
- Patient Demographics: Use Cases
- Patient Demographics: ONC Proposed Data Elements
- Patient Demographics: Additional Data Elements
- Provenance: Use Cases
- Provenance: ONC Proposed Data Elements
- Provenance: Additional Recommendations
- Clinical Notes: Use Cases
- Clinical Notes: ONC Proposed Data Elements

Clinical Notes: Additional Data Elements

- Pediatric Vital Signs: Use Cases
- Pediatric Vital Signs: ONC Proposed Data Elements
- Proposed Data Classes: Additional Data Elements
- Additional Data Class: Quality Measures Data Class

Recommendations: Patient Demographics

- **Recommendation 1.** The TF recommends including Address in USCDI v1 with the following additional sub-recommendations:
    - Use both current and previous addresses
    - Require addresses to be entered using standardized format and content*
    - Include a designation for individuals experiencing homelessness, including displaced persons and refugees
    - Explore the feasibility of using and/or supporting an international address standard given the increasing international exchange of health data

Discussion

- **Sasha TerMaat** noted that it seemed like the sub list of Recommendation 1 requires action from different actors. She suggested that it might be clearer for voting if the actors necessary are identified within the recommendation.
- **Christina Caraballo** agreed that listing the actor(s) for each sub recommendation made sense and agreed to make that change.
- **Clem McDonald** suggested the system support the entry of a standardized address, but he was unsure if that could be imposed.
- **Steven Lane** suggested the focus for the USCDI Task Force should be on the data rather than the workflow.
- The USCDI Task Force Chairs agreed to take Recommendation 1 back to their task force to take the input received into consideration and attempt to modify for subsequent voting.

- **Recommendation 2.** The TF recommends including Phone Number in USCDI v1 with the following additional sub-recommendations:
  - Use mobile phone number as the primary phone number and landline as the secondary phone number
  - When entering a phone number in a child's record, make a clear distinction between whether the number is that of the parent/guardian or whether it belongs exclusively to the child

Discussion

- **Clem McDonald** asked why it is important to identify which one is primary if there are separate fields for each of them.
- **Steve Posnack** suggested that for new fields it would be something the task force is going to consider over time related to the expansion model for the USCDI. He went on to say that if there was something unique for this particular rule-making effort, recommendations from other stakeholders about data they believe should be included in the USCDI will be considered. In addition, he stated that considerations will need to be made in terms of the substantive nature of the proposals from public comment as well as whether or not standards are available to support them.
- After much discussion, **Christina Caraballo** updated Recommendation 2 with language similar to: "Provide a field for both mobile phone number and a field for a landline phone number."

- **Recommendation 3.** The TF recommends that the following additional Patient Demographics Data Elements also be included in USCDI v1:
  - Destination(s) for electronic communications
  - Preferred method(s) and destination(s) of communication
  - The individual with authority to consent to treatment and data use
  - Last four digits of the Social Security Number
  - Optional identifiers including IDs issued by State or Federal governments
  - Self-reported gender identity

Discussion

- **Denise Webb** referred to 'Optional identifiers including IDs issued by state or federal governments' sub recommendation and asked how one would distinguish between different types of numbers entered into the referenced optional field.
- **Christina Caraballo** answered that they recommended fields, labeled according to the field type, to support those additional IDs. She went on to note that when data is available, it is collected, and when the patient wants to give that information, then it can be collected. She also mentioned that it was meant as a way to help improve patient matching and identity verification.
- **Sasha TerMaat** noted that there were different sets of addresses that were envisioned for A and B, some were email addresses, some that might be direct addresses, and a URL was also mentioned. She went on to note that from a technical perspective, you would not want to co-mingle some of those things and made the point that the recommendation should permit flexibility so those can be stored in a way that makes sense and be used for whatever communication methods would be pertinent.
- **Terry O'Malley** thanked Sasha for her comment but noted that some members may be getting more detailed than necessary and reiterated Steven Lane's comment about focusing on the data elements themselves and if they are reasonable and useful.
- **Sasha TerMaat** referred to Terry O'Malley understanding that the USCDI Task Force is focused on whether the data elements are reasonable and useful as the overriding principle and specifically not on the design of how they are implemented. As such, she suggested that an overarching clarification be made to that effect to ensure it is not later misunderstood.
- **Terry O'Malley** agreed to add this new overarching principle**.**
- **Steven Lane** referred to a comment earlier about whether these recommendations apply to this generation, or generations forward. He noted that his understanding is that the specific charge to consideration of the USCDI task force was to provide feedback on USCDI Version 1, as referenced.

Recommendations: Provenance

- **Recommendation 4.** The TF recommends the use of Author's Organization for USCDI v1 as the appropriate first level to establish provenance, with the following additional sub-recommendation:
  - Use Author's Organization in place of Author
  - Employ a standard nomenclature to uniquely identify each Organization
  - Consider NPI as an appropriate identifier for an organization
  - Unique Patient Identifier needed for patient generated data

- **Recommendation 5.** The TF recommends limiting the use of Author for USCDI v1, with the following additional sub-recommendations:
  - Use Author only when the Author is easily and unambiguously established
  - Use Author's Organization as the primary level of identity
  - Propose more granular definitions of Author in later versions of USCDI

- **Recommendation 6.** The TF recommends replacing Author's Time Stamp with Author's Organization's Time Stamp for USCDI v1.

- **Recommendation 7.** The TF recommends creating a unique and persistent identity for each data element in USCDI v1, with the following additional sub recommendation:
    - Use four components (Uniquely identified Source Organization, Author's Organization's Time Stamp, Unique Local Identification Code, Data Type)
    - Maintain the unique identify when the data element is changed
    - Establish a governance structure for data labelling

Discussion

- **Clem McDonald** voiced concern that a unique identifier is not something that can currently be handled. He explained that the unique identifier is in the resource record, not the provenance, and choosing the original element is problematic and may cause a quagmire for developers. Clem finally noted that it is ok to insist on a unique identifier, but not to dictate where it goes.
- **Terry O'Malley** noted they're proposing to use the elements of provenance with two other currently existing data elements: data type and source code.
- **Steven Lane** noted that two things are being confused. 1 USCDI are the data elements (independent of the standard meant to transport it). 2 the structure of FHIR resources and he clarified that USCDI is agnostic to FHIR.
- **Robert Wah** noted that he appreciated the input but suggested the USCDI Task Force return to their members and take the input from the patient demographics and provenance sections and report back to HITAC on their progress at a later date.
- Due to timing and the initial feedback from the HITAC, the co-chairs did not discuss the rest of the recommendations, and they decided to go back to the Task Force level and look at all the recommendations with an eye toward some points that came out regarding the first few.

Robert Wah turned the meeting over to **Carolyn Petersen.**

Health IT for the Care Continuum Task Force Update

Carolyn Petersen, Co-Chair

Carolyn Petersen delivered the presentation for Health IT for the Care Continuum Task Force where she reviewed the following slides. Presentation contents can be viewed here.

- Membership
- Health IT for the Care Continuum Task Force Charge
- Clarifications/Summary of ONC Pediatric Recommendations
- Summary of ONC Pediatric Recommendations

Discussion

- **Sasha TerMaat** sought confirmation that "additional implementation considerations" are not proposed as certification criteria, but just guidance for the future.
- **Carolyn Petersen** answered that they are things that have come out of the HITCC Task Force discussions. They are framed as considerations on the slides.

- **Arien Malec** shared an example regarding starting with liquids as it was easier and commented there were observations based on what it would take in the real world to get some of this down.
- **Sasha TerMaat** replied that there seemed to be different expectations assigned to different bullets. She suggested clarifying who the intended actors were for each bullet.
- Related to Recommendation 3, **Sasha TerMaat** asked that if not text, then what is the format proposed for authorized non-clinician viewers of EHR data. For example, if a patient wanted to authorize a parent, would the parental relationship be entered into the nomenclature?
- **Carolyn Petersen** suggested this wasn't something the task force had previously discussed and will bring the issue back to the HITCC Task Force members for consideration.
- Related to Recommendation 4, **Sasha TerMaat** asked what does "Allow EHR to grant user access level to tag" mean.
- **Carolyn Petersen** noted that the task force was looking into some of the data segmentation for privacy for DS4P standard. One of the physicians felt it was important that EHR's allow the user-level to tag individual items such as problems, notes, medications which the user can protect in some way. Another individual noted it is important to try to avoid solving this issue in a way that can become an implementation or workflow challenges. She went on to note that it was a discussion that involved a lot of different perspectives which is why it was suggested as something to consider, but not something that they asked HITAC to vote on and adopt.
- **Sasha TerMaat** understood this explanation and suggested this be spelled out for the benefit of the context within the letter to avoid confusion. Carolyn and Arien agreed.
- **Clem McDonald** suggested some of the tagging considerations impacted adults as well as children.
- **Steven Lane** agreed that the implementation considerations are interesting and may not apply only to pediatrics but suggested that the members not overstep the way that the implementation considerations are phrased in Recommendation 4. The system provided the ability to prevent something, but it's really a judgment call based on clinical and privacy and workflow considerations as to what data should be sent and not sent.
- Regarding Recommendation 4, **Steven Lane** sought clarification on the meaning of "Provide protection when user adds data."
- **Carolyn Petersen** referenced the notes and answered that they showed a discussion referencing that the task force should not get stuck in the perfect end-goal. The notes also mentioned that the right answer is to start to lead EHRs to protect granular data elements. There was also a suggestion that the data segmentation has standard nomenclature that lets people know that something has been withheld. Carolyn finally suggested that there's a need to understand the lack of legal standards and sometimes for different things beyond just the fact that there are differences among states. And she stated that members need to be careful about putting the burden on clinicians as the gatekeepers of this knowledge. She also mentioned that a highly patchworked field is going to be a struggle without the legal standards in the clinical understanding of the program.
- **Clem McDonald** asked if it was being suggested that in the practice setting, a clinician might hide a given drug or diagnosis.

- **Carolyn Petersen** answered that this issue is highly nuanced, and provided an example of a child who may have received a diagnoses based on a troubled home life, but which is no longer applicable when they are removed from the troubled situation, or grow to develop better coping mechanisms, and it might do that child a disservice in the care they receive or in their progression to other homes by labeling them as something that may no longer apply.
- **Steven Lane** shared that another important use-case is in the area of adolescent confidentiality and the fact that there is some data in the charts the adolescent themselves can consent to treatment and have the legal right to keep that data private from their parents/guardians. He went on to say that it gets tricky when data is shared between organizations because the receiving organization might not have the same standard for protecting the adolescent's confidential data and it could sneak out to the parents/guardians that could endanger the safety of the child or adolescent.
- **Arien Malec** mentioned that on the national and state level people are rethinking some of the data segmentation because it is impacting real-world clinical care
- **Brett Oliver** suggested he's concerned the precedent set by this type of data segmentation. He then shared an example of a provider who may know that the patient may have been in a bad home situation and be labeled with something but that that is still an important part of their past history in order to deliver the proper future care for that person. He asked if an adult who didn't like a diagnosis also be able to hide it or segment it for future providers. There is currently a way to correct the chart, and he thinks that should be considered prior to deciding to segment data further. He also mentioned that one of the important parts of the task force and of the HITAC is to focus on interoperability and the exchange of information and this strikes him as counterintuitive to that.
- **Clem McDonald** suggested doctors would be sued or refuse to see patients because the patient may have hidden data.

Carolyn Petersen reviewed recommendations for the request for Information (RFI) on Health IT and Opioid Use Disorder (OUD) Prevention and Treatment and the
Data Segmentation for Privacy (DS4P) and Consent Management for APIs Certification Criteria.

Discussion

- **Sasha TerMaat** noted that the Trusted Exchanged Framework draft 2 identified a data segmentation for privacy proposal which this task force might learn from. She went on to say that given the questions that are raised about governance and how this would be implemented focusing on a specific use case, for example, opioids, might make sense for the implementation. She also felt it would be worthwhile for the task force to review TEFCA draft 2 to see that proposal.
- **Carolyn Petersen** agreed this was a great point and asked that the mentioned portion of the TEFCA draft 2 be shared.
- **Clem McDonald** noted that someone has to mark these things as being protected in various ways. He went on to state that patients will have the ability to take every result at every date and specify who can see it, when they can see it and where they can see it. He wondered how there will be time for an office to explain to a patient that they are able to do this and how secrecy will be maintained. And finally, he noted that use-cases covering these and other aspects should be considered.

- **Carolyn Petersen** answered that the task force has not considered the specifics around office practices per se, for example, of how you would keep a secret about a narrative. She went on to state that it is not something that ONC has specifically asked the task force to address.

Closing Remarks

Robert Wah noted his commitment to helping the committee to produce the best possible product. He then reminded the members that there was a meeting scheduled for May 13 and noted that the plan is to include the remaining task force recommendations on that date. He recapped that feedback has been provided to the two task forces who presented, and they will go back to their committees and refine the recommendations. Further, he mentioned that the other two task forces from today also had comments that they will feed into their discussions and bring back to HITAC with their final recommendations.

Terry O'Malley commented on the HITAC process and noted the high degree of overlap between the issues being considered and discussed amongst each of the task forces and asked if there was an opportunity to consider shared issues with the other task forces who may benefit.

Lauren Richie responded that some sharing is already occurring internally within ONC. She noted that each of the task forces are meeting on a weekly basis for that exact reason. She went on to note that they will consider expanding on this and think about a meeting of the task force co-chairs and are open to additional suggestions.

Public Comment

Adrian Gropper, Patient Privacy Rights, urged the committee to seek guidance or make recommendations around clarity around dynamic client registration as mentioned in the draft and the importance of dynamic client registration to satisfying the without special effort requirement. In particular, to note that dynamic client registration does not mean consent for actual information exchange and so not offering dynamic client registration is simply a barrier-to-use in a wider and more interoperable ecosystem.

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

Cynthia Fisher: Cynthia Fisher is on

Cynthia Fisher: Yes

Laura conn: Laura Conn is on

Lauren Richie: thank you Laura

Sasha TerMaat: Don, I thought you indicated that the OCR FAQ clarified liability for both providers and health IT developers, but it seems in my read to only cover covered entities and app developers, not the health IT developers who provide software to covered entities as business associates. Is there more guidance I'm missing?

Sasha TerMaat: https://www.hhs.gov/hipaa/for-professionals/faq/572/does-a-hipaa-covered-entity-bear-liability.html

John Kansky: John Kansky just joined. I will be on the phone only.

Lauren Richie: Thank you John

Sheryl Turney: waiting to be let in

Sasha TerMaat: Question for the demographic recommendations - when things like "use both current and previous addresses" is recommended, is this a recommendation that certification accommodate both addresses or that some mechanism require entry of both addresses?

Sasha TerMaat: To state my question/request more succinctly, could each of the sub recommendations identify the actor expected to accomplish the listed task?

Sasha TerMaat: For recommendation 2, I have the same question about which actors are pictured. I would recommend clarifying the wording in this case also.

Sasha TerMaat: Is there a reason you have recommended using author's organization in place of author rather than simply removing "author" from the proposed provenance requirement and retaining "author's organization"?

Sasha TerMaat: For recommendation 5, I think you want to replace "Use" with "Require in certification". You don't want to limit use of author unnecessarily. But you don't want to prematurely require it in certification given the uncertainty already discussed. Recommendation (5)(c) seems to be a directive to ONC, correct?

Sasha TerMaat: For recommendation 7, is it correct to understand (a) and (b) as expectations for certified HIT, while (c) is a directive to ONC?

Sasha TerMaat: Regarding clinical notes, is the expectation of adding additional notes (8) that certification would include all of the additional CCDA templates for those types? I'm trying to understand the impact on development estimates by EHR developers.

Steven Lane: For recommendation 4, I do not think that we are actually using Author's Org IN PLACE OF Author, so much as deemphasizing the requirement for Author, reserving that for data types for which this can be clearly defined, while always requiring the inclusing of Author's Organization and time stamp.

Sasha TerMaat: Thanks Steven, perhaps that could be clarified in the recommendation? I found it a bit confusing.

Steven Lane: I can pinch hit as a user of EHR in the care of pediatric patients.

Aaron Miri: Steven you're definitely a utility player in HIT. Thank you for offering to help!

Sasha TerMaat: So, confirming, "additional implementation considerations" are not proposed as certification criteria, just advice for the future?

Sasha TerMaat: What is the format proposed for authorized non-clinician viewers of EHR data, if not text?

Sasha TerMaat: What does "Allow EHR to grant user access level to tag" mean?

Steven Lane: Thanks Sasha. I had the same question. I would also ask for clarification of "Provide protection when user adds data".

Brett Oliver: Disagree with data segmentation. It is all a part of the patient's history that can impact future care.

Sasha TerMaat: ONC's TEFCA proposal asked for comment on a subset of particular DS4P use cases as prioritized (rather than all possible permutations of the standard, even when there is not a clear use case). It would be interesting for the task force to consider that approach.

Sasha TerMaat: Clem raises important points about narrative filters and also about the potential impact on usability.

Sasha TerMaat: Terry, the language is: (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 DRUSegment.

Terrence O'Malley: Thanks, Sasha.

Laura Conn: For future meeting date consideration - the Sept in person meeting conflicts with the HL7 Working Group meeting in Atlanta that week.

Next Steps and Adjourn

Lauren Richie adjourned the meeting at 3:00 p.m. ET