Meeting Notes

Health Information Technology Advisory Committee

May 13, 2019, 09:30 a.m. – 02:45p.m. ET

Virtual

The May 13, 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
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
Terrence O'Malley, Massachusetts General Hospital
Raj Ratwani, MedStar Health
Steve L. Ready, Norton Healthcare
Sasha TerMaat, Epic
Andrew Truscott, Accenture
Sheryl Turney, Anthem BCBS
Denise Webb, Individual

MEMBERS NOT IN ATTENDANCE

Terry Adirim, Department of Defense
Tina Esposito, Advocate Aurora Health
Kate Goodrich, Centers for Medicare and Medicaid Services (CMS)
Mark Roche, Centers for Medicare and Medicaid Services (CMS)
Patrick Soon-Shiong, NantHealth
Ram Sriram, National Institute of Standards and Technology

FEDERAL REPRESENTATIVES
Laura Conn, Centers for Disease Control and Prevention

ONC STAFF
Elise Sweeney Anthony, Executive Director, Office of Policy
Cassandra Hadley, HITAC Support
Lauren Richie, Designated Federal Officer
Seth Pazinski, Director of the Office of Planning, Evaluation, and Analysis
Jon White, Deputy National Coordinator

Call to Order
Lauren Richie called the meeting to order and turned the meeting over to Jon White, Deputy National Coordinator.

Welcome Remarks
Jon White, Deputy National Coordinator
Jon White thanked attendees for meeting and stated that he looks forward to considering the recommendations from the task forces. He noted that the Trusted Exchange Framework and Common Agreement (TEFCA) Task Force began working the previous week and their final recommendations are expected next month. He also formally introduced and welcomed **Terry Adirim**, the Deputy Assistant Secretary of Defense for Health Services Policy and Oversight at the Department of Defense, who will be serving as a federal representative.

Review of Agenda and Approval of April 25, 2019 Meeting Minutes
Carolyn Petersen, Co-Chair
Robert Wah, Co-Chair
Carolyn Petersen thanked attendees of the meeting and reviewed the meeting agenda and motioned for a vote to approve the meeting minutes from April 25, 2019.

- **The HITAC approved the April 25, 2019 meeting minutes by voice vote. No members opposed. None abstained.**

Robert Wah explained that the voting process followed at the 4/25/19 meeting will be maintained with committee members voting individually on some recommendations, while other recommendations will be voted on together.

Conditions and Maintenance of Certification Requirements Task Force Draft Recommendations and Vote
Denise Webb, Co-Chair
Raj Ratwani, Co-Chair
Raj Ratwani reviewed the overarching charge and the recommendations that were approved from the 4/25/19 meeting. He noted that the task force revisited some of the recommendations and will share the revisited material. The full presentation can be viewed here:

- **Recommendations 1-3, 5-7, 9-11, 14-21, 23-24, 26-36 were approved previously by the HITAC on 4/25/19 and were not discussed further.**

- **Recommendation 8:** ONC states that successful real world testing means: "Electronic health information is received by and used in the certified health IT." The CMC TF recommends ONC provide clarification in the final rule preamble in section VII.B.5 around testing the "receipt and use" of information received through exchange versus testing the exchange of information (sending and receiving). When the health IT being tested does not receive data in the criterion 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.
    - **Revisions were suggested at the 4/25/19meeting and were taken into consideration by the CMC TF. The TF proposed changes to this recommendation based upon the description of the usability testing.**

Discussion

- **Steven Lane** suggested changing the wording to include a wider breadth of users (e.g., nurses, health IT personnel) other than just providers. He moved to amend by adding the word 'including' before 'providers.'
- **Robert Wah** conducted a vote to amend Recommendation 8 to include this suggestion.
    - **The HITAC approved this amendment of Recommendation 8 by voice vote. No members opposed. None abstained.**
- **Andy Truscott** moved to amend so that the phrase 'use-based testing' should be changed to 'end user-based testing.'
- **Denise Webb** stated that the current wording is meant to convey that there is the possibility that data can be sent to a machine, so a user is not always necessary.
- **Robert Wah conducted a vote** to amend Recommendation 8 to include this suggestion.
    - **The HITAC approved this amendment of Recommendation 8 by voice vote. No members opposed. None abstained.**
- **The HITAC approved the newly amended Recommendation 8 by voice vote. No members opposed. None abstained.**

- **Recommendation 12: [WITHDRAWN]** The CMC TF recommends ONC elaborate and provide 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.

Discussion

- The CMC TF proposed to withdraw the recommendation.
- **Denise Webb** explained that the proposed rule sufficiently addresses the area, and the recommendation was no longer needed.
- **Andy Truscott** asked why the CMC TF had made this decision?
- **Denise Webb** responded saying that after re-reading the preamble, it was decided that the recommendation was not necessary.

- **Recommendation 13:** The CMC TF recommends ONC clarify in the final rule preamble the role and expectations of testing partners over which the health IT developers have no control or authority over. For example, some testing partners (for example: immunization registries,) other EHR developers and providers) are likely to receive many requests to participate in other parties' real world testing. While these testing partners can try to be helpful, they will have limited resources to assist other groups. The TF further recommends ONC clarify whether declining to participate as a testing partner 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 testing partners 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 testing partners in testing yet were not successful in getting their commitment to participate
  - During the **4/25/19 HITAC meeting**, the HITAC suggested that this recommendation be clarified. The CMC TF changed the term 'third party' to 'testing partners' after discussion in an effort to clarify. The CMC TF recommended clarifying the testing partners language within the preamble as well.

Discussion

- **Andy Truscott** suggested that using the word partners infers a certain type of relationship that may or may not be present. He suggested a clarification and moved to amend by adding "[who may or may not be subject to contractual requirements]" after the word partners.
- **Denise Webb** agreed that this would be an effective change.
  - **The HITAC approved this amendment of Recommendation 13 by voice vote. No members opposed. None abstained.**
- **Arien Malec** suggested that the wording in the recommendations should be changed. He proposed that the recommendation should state that it is from HITAC instead of CMC TF.
- **Denise Webb** replied by saying that it should remain as it is. The recommendations are from the CMC TF to the entire committee; once the committee accepts the recommendations, it will be changed to reflect recommendations from the HITAC.
- **The HITAC approved the newly amended Recommendation 13 by voice vote. No members opposed. None abstained.**

- **Recommendation 22**: The CMC TF recognizes additional standards and piloting work of bulk API queries is important, and to allow for that work, the TF recommends ONC require this functionality 12 months after other API updates are expected.
    - The CMC TF revised the recommendation to emphasize the timeline of requiring functionality 12 months after other application programming interface (API) updates are expected.
    - **The HITAC approved Recommendation 22 by voice vote. No members opposed. None abstained.**

- **Recommendation 25:** The CMC TF recommends ONC evaluate the appropriateness of requiring self-developers seeking and maintaining certification to meet all the requirements as proposed in the rule for the real world testing, APIs, and attestations to conditions of maintenance and certification for certified health IT modules that are not offered for commercial resale but must be certified in order for the providers using the modules to participate in certain federal programs. The TF recommends ONC specifically address the following in its evaluation and update the final rule preamble Section VII and regulatory text where appropriate: Real world testing: Permitting self-developers seeking and maintaining certification to use their production experience for the venues where they have deployed their software and their actual trading partner experience to meet the real world testing requirements assuming the certified capabilities otherwise meet the other criteria required for certification. Additionally, allowing self-developers of certified Health IT Modules to meet the requirements for Maintenance of Certification in subsequent years with results of the initial real world testing if nothing has changed in the way their self-developed certified product functions and operates. APIs: CMC requirements applicable to fees as these requirements may not apply to self-developers seeking and maintaining certification. If the self-developer is selling its API technology or charging for its use, the self-developer seeking and maintaining certification of its API technology would be subject to the CMC requirements related to API fees and permitted fee conditions in § 170.404.

Discussion

- **Aaron Miri** suggested that the self-developer requirement be reevaluated. He moved to amend by the addition of 'for capabilities that are relevant particularly to a limited set of trading partners' in the real world testing section after 'real word testing requirements.'
    - **The HITAC approved this amendment of Recommendation 25 by voice vote. No members opposed. None abstained.**
- **Andy Truscott** asked who, specifically, the recommendation would apply to?
- **Denise Webb** clarified that this recommendation only applies to developers that are undergoing certification.
- **Andy Truscott** asked whether a developer who is not undergoing certification is subject to the guidelines? He addressed both commercial developers and healthcare providers.
    - **Robert Wah** responded, saying that the topic would be covered in a separate meeting.
- **Mike Lipinski** clarified the original definition of a self-developer.

- **The HITAC approved the newly amended Recommendation 25 by voice vote. No members opposed. None abstained.**

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

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

Christina Caraballo reviewed the USCDI TF guiding principles, and patient demographics support prior to presenting the recommendations. The full presentation can be viewed here.

Patient Demographics

- **Recommendation 1**: The TF recommends including address is USCDI v1 as proposed by ONC with the following sub-recommendations:
  - Include both "current address" and "previous address"
  - Encourage the use of the USPS standardized addresses and recommend ONC request access for healthcare organizations to use the USPS standardized address for capture in clinical systems via APIs.
  - Explore the feasibility of using and/or supporting an international address standard

Discussion

- **Steven Lane** suggested that 'previous address' be modified to the plural form, 'previous addresses' to ensure the maximum amount of information is gained. He also suggested adding other addresses, such as school or work addresses.
- **Christina Caraballo** responded that the transmittal letter does actually have the plural form (addresses); the slide presented was incorrect. She stated that the work/school address was intentionally dropped from the recommendation for simplification purposes.
- **Clem McDonald** suggested clarifying that the person need not list all previous addresses, but rather just include any new addresses that have not been reported previously.
- **Terry O'Malley** clarified that the patient will be informed that the system has previous addresses, and to include new addresses only.
- **Andy Truscott** suggested that 'current address' also be made plural as an individual could have more than one current address. He also identified the difference between a prior address and a previous address.
- **Christina Caraballo** responded that it could become too complicated with the addition of multiple options. She suggested that it remain as a singular 'primary address.'
- **Clem McDonald** suggested the confusion that could occur for clerks during the check-in process if previous and prior addresses are differentiated as previously suggested.
- **Christina Caraballo** stated that in the letter, the 'previous addresses' is plural, but the 'current address' is singular.
- **Terry O'Malley** clarified that in the transmittal letter, both of the terms are plural, reading 'current and previous addresses.'

- **Recommendation 2:** The TF recommends including phone numbers in USDCI v1 as proposed by ONC with the following sub-recommendations:
  - Include designations for both mobile and landline number(s)
  - Include a designation indicating whether each phone number is only associated with the patient or of another party
  - Include a designation for each number as to whether the patient has approved leaving a confidential message.

- **Recommendation 3:** The TF recommends that ONC include designations for electronic communications.
  - Email address
  - The TF suggested requiring in future versions but to just support now.

- **Recommendation 4:** The TF recommends that ONC include contact information for the individual(s) with authority to consent to treatment and data use.

Discussion

- **Carolyn Petersen** noted that in practice, some patients have a different individual responsible for their daily decisions and others that are a part of more significant topics like advanced directives. She asked whether the TF has considered altering the language to allow for multiple responsible individuals for one patient.
- **Christina Caraballo** agreed that the language could be changed to state explicitly the utilization of various caregivers.
- **Terry O'Malley** suggested that the use of the word 'individual(s)' in the recommendation already implies the possibility of multiple people.
- **Carolyn Petersen** suggested that there should be an opportunity to specify whether the individual should be reached for daily, less substantial decisions, or if they are responsible for larger, more substantial decisions.
- **Terry O'Malley** suggested that the level of detail suggested by Carolyn is not appropriate or necessary, and the current phrasing of the recommendation is adequate.
- **Christina Caraballo** suggested the addition of 'specifying the level of authority of the individual' within the recommendation.
- **Carolyn Petersen** recommended the addition of the sentence 'Software should also support collection of the identity of the individuals with the authority to consent to decisions described in the advanced directives' in the transmittal letter.
- **Robert Wah** stated that he would make the change to the recommendation at a later time and the committee will vote on all of the Patient Demographic Recommendations except Recommendation 4 during this meeting.
- **Andy Truscott** noted that, in redrafting, it should be ensured that other types of consent (research consent directives, medical treatment consent directives) are not excluded.
- **Cynthia Fisher** commented that it is important that patients remain in control of their own information. She suggested to adopt a more fluid way for patients, and their caregivers to both have authority over their decisions.

- **Robert Wah** presented the amendment to Recommendation 4, adding the sentence 'Software should also support collection of the identity of the individual(s) with the authority to make decisions outlined in the patients advanced directive, including name, contact information, and relationship.'
- **The HITAC approved the amendment and the newly amended Recommendation 4 by voice vote. No members opposed. None abstained**.

- **Recommendation 5:** The TF recommends that ONC include the last four digits of the social security number.

Discussion

- **Christina Caraballo** explained the USCDI TF's understanding of patient privacy concerns associated with this recommendation but also emphasized its importance in patient matching.

- **Recommendation 6:** The TF recommends that ONC include optional identifiers such as identification numbers issued by State or Federal government.

- **Recommendation 7:** The TF recommends that ONC include self-reported gender identity.

Robert Wah motioned to approve Patient Demographics Recommendations 1-3 and 5-7.

- **The HITAC approved Recommendations 1-3 and 5-7 by voice vote. No members opposed. None abstained.**

Provenance

- **Recommendation 8**: The TF recommends to accept the author organization in USCDI v1 as proposed by ONC.

- **Recommendation 9**: The TF recommends to accept the Author in USCDI v1 as proposed by ONC with the following sub-recommendations:
  - ONC should require the identity of the Author for certain data classes where the Author is straightforward and important (clinical notes, medication prescriptions)
  - The term "Author's Organization" should be used for all data classes other than clinical notes and medical prescriptions.

- **Recommendation 10:** The TF recommends to amend "Author's Time Stamp" as proposed by ONC for USCDI v1 to "time stamp". The time stamp should be implemented locally. Each system can apply its own standard for time stamp in order to assert provenance.

- **Recommendation 11:** The TF recommends to include a unique organization identity if an adequate candidate is identified.

- **Recommendation 12:** The TF recommends to include a designation to indicate when the patient is the author of the data.

- There were no comments or discussion by the committee about the Provenance Recommendations. **Robert Wah** conducted a vote to approve Provenance Recommendations 8-12.
    - **The HITAC approved Recommendations 8-12 by voice vote. No members opposed. None abstained.**

Clinical Notes

- **Recommendation 13**: The TF recommends to accept the following Clinical Notes in USCDI v1 as proposed by ONC
    - Consultation Note
    - Discharge Summary Note
    - History and Physical
    - Procedure Note
    - Progress Note

- **Recommendation 14**: The TF recommends amending "imaging narrative" as proposed by ONC in USCDI v1 to "diagnostic imaging report"
    - Diagnostic imaging report type is a rapidly gaining space

- **Recommendation 15:** The TF recommends omitting the Laboratory Report Narrative as proposed by ONC in USCDI v1.
    - Duplicative of the Laboratory Results data class

- **Recommendation 16:** The TF recommends omitting the Pathology Report Narrative as proposed by ONC in USCDI v1.
    - Duplicative of the pathology results data class

- **Recommendation 17:** The TF recommends that ONC include a Continuity of Care Document in the Clinical Notes USCDI v1.
    - A commonly used note that contains a subset of the information included in a discharge summary.

- **Recommendation 18:** The TF recommends that ONC include an Operative Note in the Clinical Notes USCDI v1.
    - Only utilized in appropriate settings.

- **Recommendation 19:** The TF recommends that ONC include Miscellaneous Notes in USCDI v1.
    - Left only for things than cannot be transmitted effectively in another type of note.

- **Recommendation 20:** The TF recommends that ONC include Transfer Summary Note as optional in USCDI v1.
    - Includes the information for the next care team to provide safe and appropriate care.

- **Recommendation 21**: The TF recommends that ONC include Advance Care Planning note as optional in USCDI v1.

- **Recommendation 22:** The TF recommends that ONC include Care Plan Note as optional in USCDI v1.

- **Recommendation 23:** The TF recommends including a Referral Note in the Clinical Notes in future iterations of USCDI.

- **Recommendation 24:** The TF recommends including a Long Term Services and Supports Care Plan Note in Clinical Notes in future iterations of USCDI.
    - Allow for a bridge between medical and support services.

- There were no comments or discussion by the committee about the Clinical Notes Recommendations. **Robert Wah** conducted a vote to approve Clinical Note Recommendations 13-24.
    - **The HITAC approved Recommendations 13-24 by voice vote. No members opposed. None abstained.**

Pediatric Vital Signs

- **Recommendation 25**: The TF recommends to accept 'BMI percentile per age and sex for youth' as a new Pediatric Vital Sign data element to be included in USCDI v1 as proposed by ONC with the following sub-recommendations:
    - Require this data element if the IT system already stores it. Require that weight, age and sex are shared for all patients so recipient systems can perform their own calculations.
    - Require the storage of this data element regardless of format whenever provided to the patient/guardian.

- **Recommendation 26:** The TF recommends to accept 'Weight for age per length and sex' as a new Pediatric Vital Sign data element to be included in USCDI v1 as proposed by ONC with the following sub-recommendations:
    - Amend data element to "weight for length percentile by age and sex for youth 2-20"
    - Require this data element if the IT system already stores it. Require that weight, age and sex are shared for all patients so recipient systems can perform their own calculations.
    - Require the storage of this data element regardless of format whenever provided to the patient/guardian.

- **Recommendation 27:** The TF recommends to accept 'Occipitofrontal circumference under 3 years old' as a new Pediatric Vital Sign data element to be included in USCDI v1 as proposed by ONC.

Discussion

- **Andy Truscott** asked who the word 'required' applies to in the context of the sub-recommendations?

- **Terry O'Malley** replied that the ONC would be requiring the framework described in the recommendations as part of the certification of handling the data.

- **Robert Wah** conducted a vote to approve Pediatric Vital Sign Recommendations 25-27.
  - **The HITAC approved Recommendations 25-27 by voice vote. No members opposed. None abstained.**

Missing Data Elements

- **Recommendation 28:** The TF recommends to add the following provider demographic data elements to Care Team Members Data Class in USCDI v1:
  - Name
  - Contact information
  - Identifier (NPI, Certification, State license)

Discussion

- **Carolyn Petersen** asked whether the TF considered including a procedure to include providers that do not have an identifier (like exercise class instructors)?
- **Steven Lane** suggested adding the phrase 'where available' in regard to the identifier of the provider.
- **Andy Truscott** asked how, if 'where available' was added, it would be ensured that all providers that do have an identifier are including it, and are not skipping it since it is not required? He suggested that this would make the identifier optional, and therefore may not be reported by all providers that have one.
- **Terry O'Malley** responded by saying that the identifier is not a crucial piece of information in determining the provider so it would not be detrimental if the information was not given by the provider.

- **Robert Wah** conducted a vote to approve Missing Data Elements Recommendation 28.
  - **The HITAC approved the amendment of Recommendation 28 by voice vote. No members opposed.**

- **Recommendation 29:** The TF recommends adding an indication and/or associated diagnosis for each medication in USCDI v1 Medications Data Class.

- **Recommendation 30:** The TF recommends including a designation and address entry standard for individuals experiencing homelessness, including displaced persons and refugees.

Additional Recommendations

- **Recommendation 31:** The TF recommends beginning the process to develop a Quality Measures Data Class.

- **Recommendation 32:** The TF recommends beginning the process to assign a unique and persistent identity for each data element and develop a governance structure to oversee its use.

- **Robert Wah** conducted a vote to approve Missing Data Elements and Additional Issues Recommendations 28-32.
    - **The HITAC approved Recommendations 28-32 by voice vote. No members opposed. None abstained.**

Robert Wah turned the meeting over to **Carolyn Petersen** to present the Health IT for the Care Continuum Task Force (HITCC TF) Update.

Health IT for the Care Continuum Task Force Update

Carolyn Petersen, Co-Chair
Christoph Lehmann, Co-Chair

Carolyn Petersen delivered the presentation for Health IT for the Care Continuum Task Force; the full presentation can be viewed here.

Summary of ONC Pediatric Health IT Recommendations

Discussion

- **Steven Lane** suggested specifying the type of authority by adding 'access and/or release 'of patient data in Recommendation 7.
- **Andy Truscott** suggested using the phrase 'access, exchange, or use' in regard to authority. He noted that this is standard ONC terminology.
- **Denni McColm** commented that the term 'access, exchange or use' concerned her as, in most cases, an individual is able to access, but they aren't authorized to release.
- **Steven Lane** answered that that's why 'or' was used in that statement.
- **Clem McDonald** noted that someone with medical decision-making authority does have the right to access data, suggesting they are not mutually exclusive.
- **Christoph Lehmann** clarified that the amendment is just stating that because a provider has access, it does not necessarily mean they have medical decision-making authority.
- **Sasha TerMaat** referenced the development of privacy practices of DS4P and asked who would be doing the development?
- **Carolyn Petersen** responded saying that the TF had not dictated who would do the development, but we're just recommending that it should occur.
- **Sasha TerMaat** noted that the incorporation of the DS4P is a significant project, and there are still many concerns regarding its use. She recommended focusing on specific use cases to understand policy issues prior to the expectations written in the broader proposals in the draft.
- **Christoph Lehmann** answered noting that Sasha made important points but noted that the task force considered this by asking if it would address some of the adolescent privacy issues that are so prevalent in EHR currently. The task force concluded that there is potential, but the comment Sasha mentioned falls outside the task force scope.
- **Carolyn Petersen** suggested that some issues associated with DS4P will not be found by looking at specific use cases and provided examples of discrimination of those with a disability, or ethnic background or a history of substance or spousal abuse, etc.

- **Clem McDonald** noted a number of concerns. 1) Patient care hasn't been adequately addressed with the focus instead on a small minority of people who might have a privacy issue. 2) Narrative – almost everything has the option of narrative, which means no data can be delivered if it has a narrative. 3) The responsibility once the data has been accepted has not been highlighted.
  - **Christoph Lehmann** noted that the individual patient has a right to decline providing information to a physician and that this right outweighs the physicians right to know everything about the patient. He also acknowledged that this was a difficult balance to maintain.
- **Sasha TerMaat** asked if there were particular recommendations the task force is making that are endorsing DS4P.
- **Carolyn Petersen** clarified that the TF has presented broad considerations but are not making specific recommendations.
- **Sasha TerMaat** asked where or how concerns could be noted in regard to the TF recommendations?
- **Robert Wah** suggested that **Sasha TerMaat** articulate the proposed language for the transmittal letter who would like to contribute and present at another time along with other members.

- **Robert Wah** conducted a vote to amend Recommendation 7 by adding 'access, exchange, or use 'before 'patient data.'
  - **The HITAC approved this amendment of Recommendations 7 by voice vote. No members opposed. None abstained.**
- **Robert Wah** conducted a vote to approve the pediatric Recommendations of the HITCC TF, on the condition that the transmittal letter would be reviewed once the new language was added.
  - **The HITAC approved the Recommendations of HITCC TF by voice vote. No members opposed. Clem McDonald and Andy Truscott abstained.**

Public Comment

There were no public comments.

Information Blocking Task Force Draft Recommendations and Vote

Andy Truscott, Co-Chair
Michael Adcock, Co-Chair

Andy Truscott began by noting that the Information Blocking Task Force (IBTF) previously presented and received feedback on the recommendations from Workgroups 1 and 3. He also noted additional comments from the IBTF were received late and hadn't had time to consider and discuss. The group discussed Workgroup 2 recommendations only. The full presentation can be viewed here.

Workgroup 2 - Preventing Harm

- **Recommendation 14:** Modify the regulatory text in (a) to read "…arising from any of the following --" prior to sub-items (1) – (3).

- **Recommendation 15:** Modify the regulatory text in (a) (1) to read "Technically corrupt (defined as data that has lost its base integrity and is no longer understandable by the information

technology system that created it) or inaccurate data accessed in a patient's electronic health record for intent of access, exchange or use".

- **Recommendation 16:** Add to the regulatory text a sub-item (d) that the practice should be documented in the electronic health record or system recording the EHI by the appropriate user when the exception arising from using conditions (a) - (c) and must contain the reasoning and criteria used in the judgement of the user who is engaging in the practice under this exception.

- **Recommendation 17:** The regulatory text in (b) is confusing; the word "practice" refers to the information blocking potentially occurring under an exception. Perhaps rephrasing "If the practice (referring to the permissible information blocking activity) relies on an organizational policy, the policy must be—".

- **Recommendation 18:** The regulatory text in (b) is confusing; the word "practice" refers to the information blocking potentially occurring under an exception. Perhaps rephrasing "If the practice (referring to the permissible information blocking activity) relies on an organizational policy, the policy must be—".

- **Recommendation 19:** Recommend adding clear guidance (in preamble) of when this exception should be used versus the exceptions for infeasibility and maintenance. Recommendation

- **Recommendation 20:** Consider adding examples of where exceptions related to preventing harm from corrupt or inaccurate data or incorrect patient identification may interact with the exception for infeasibility.

- There was no discussion or questions among the committee members regarding this section.
    - **The HITAC approved Recommendations 14 – 20, by voice vote. No members opposed. None abstained.**

Workgroup 2 – Promoting the Privacy of EHI

- **Recommendation 21:** The TF recommends adding language indicating that organizational policies must comply with federal, state, and local laws.

- **Recommendation 22:** The TF recommends that in section (b)(2) express consent (or dissent) should be documented and recorded.

- **Recommendation 23:** The TF recommends that in section (c)(3) the reference to "meaningful" is replaced with "clear and prior notice."

- **Recommendation 24:** The TF recommends that organizational practices that are extra to HIPAA or other relevant legislation should clearly be forbidden. For example, policies that restrict transmission to individuals via email where such is the requested form and format of access. In many cases documented organizational policies are used to deny access where access is required.

- **Recommendation 25:** The Task Force recommends that the final rule should specify that organizations should implement policies which ensure compliance with patient consent to information sharing (or lack of information sharing).

- **Recommendation 26:** The TF recommends that if an actor functions in multiple states, some of which have more restrictive laws, the actor should implement policies and procedures that accommodate those more restrictive laws only in circumstances where they are required and not extend those greater restrictions to situations where they are not required by law.

- There was no discussion or questions among the committee members regarding this section.
    - **The HITAC approved Recommendations 21 – 26, by voice vote. No members opposed. None abstained.**

Workgroup 2 –Promoting the Security of EHI

- **Recommendation 27:** The TF recommends that if the entity requesting patient information can be reasonably considered "legitimate" in that they have passed relevant authentication mechanisms and can reasonably be considered to have appropriate organizational policies in place to protect patient information, then ignorance of that requestor's specific controls is no reason to claim this exception.

- **Recommendation 28:** The TF recommends modifying the regulatory text to reflect that if the requestor is the patient (data subject) themselves, and the patient is fully informed to the risks of their information not being appropriately secured, this exception cannot be claimed.

- **Recommendation 29:** The TF recommends that actors should not have flexibility to adopt security practices, even when grounded in some standard, that are commercially unreasonable relative to leading practices for sensitive data, in ways that limit and restrict access to data for permissible purposes, unless there is some overriding legal obligation. As an example, although FedRAMP High or SRG High are defined standards, requiring FedRAMP High ATO as a standard for any data requester would serve to limit interoperability, unless there were some overriding security concern (e.g., MHS or VHA records that contain data relevant to national security).

- There was no discussion or questions among the committee members regarding this section.
    - **The HITAC approved Recommendations 27 – 29, by voice vote. No members opposed. None abstained.**

Workgroup 2 –Recovering Costs Reasonably Incurred

Andy Truscott noted this section was highly contentious among the members of the IBTF. He went on to review some background and conclusions related to how the IBTF crafted the recommendations within this section.

- **Recommendation 30:** The TF recommends that ONC combine the regulatory text currently supplied for 171.204 and 206 into a single allowed fee exception that clearly defines allowed and disallowed fee categories.

- **Recommendation 31:** The TF recommends ONC use terminology that distinguishes between pure cost or expense recovery with no provision for margin or profit where this is intended and use terms such as "cost-based pricing" where margin or profit is allowed and "market based pricing" where no restrictions on pricing are needed.

Discussion

- **Sasha TerMaat** noted that the task force recommends three different categories: 1) pure cost or expense recovery 2) cost-based pricing, and 3) market-based pricing but Recommendations 34 and 36 only use two of those categories (pure cost or expense recovery and market-based pricing). She asked if she missed the third, and if not, why was it left out.
  - **Arien Malec** replied that only two categories were applied in practice, but that the first section is meant to help ONC build a framework in case they don't agree with the recommendation as written.

- **Recommendation 32:** Where cost-based pricing mechanism are required, the TF recommends that the method for assessing the cost basis be reasonably associated with the complexity or cost of providing capabilities. Such methods could include reasonable heuristics, estimates or other commonly used methods. For example, size of organization, as measured in revenue or operating expense, is a commonly used heuristic to define pricing for exchange services, because revenue/expense is commonly available and directly correlated with patient flow, which is directly correlated with data volumes. Requiring activity-based accounting mechanism sufficient to account for the direct cost of providing, e.g., access services, is burdensome and is not a common or usual accounting practice. The Task Force believes that reasonable heuristics or estimates are sufficient to avoid arbitrary fees that could constitute information blocking without placing undue burden on actors.

Discussion

- **Cynthia Fisher** cited the final sentence in Recommendation 32 and noted that it was unclear or needlessly complex. She also asked for the difference between ONC's intent and how that compares to the text as written.
- **Steven Lane** attempted to clarify, noting that the goal as written is that pricing by the size of the customer organization is a reasonable heuristic and as such, that should be allowed to continue.
- **Arien Malec** addressed Cynthia's concern by noting that ONC is concerned about pricing practices that were discriminatory, particularly those based on the value in the data that could be provided to various actors. He went on to explain that the language in Recommendation 32 is meant to acknowledge the intent but to note that particular categories like operating expense and operating revenues are useful ways of looking at the cost and complexity of providing interoperability services for a particular actor and they should be allowed to stand.
- **Andy Truscott** suggested to Cynthia that if she approves of the sentiment in the recommendation, that perhaps they will focus on clarifying the language for the final draft. Cynthia agreed to this.

- **Denni McColm** suggested writing the language to disallow a vendor from charging different prices for the same product based solely on the size of the organization purchasing.

- **Recommendation 33:** The TF recommends that ONC distinguish between basic access (to the data or facts about the patient or patients, to the legal medical record or Designated Record Set, etc., including prospective patient specific pricing for procedures, etc.) through standards (from the core standards list) reasonably required to enable exchange or implement the intended use of a certified technology (e.g., HL7 LRI/LRO lab interfaces for a results and orders capability, or NCPDP SCRIPT standards for a prescribing capability); and other forms of value-added access, exchange and use (e.g., infrastructural systems, capabilities that translate, perform decision support, use artificial intelligence or machine learning, provide novel or clinically validated renderings of data, etc.).

Discussion

- **Ken Kawamoto** asked if prerequisite pricing is included in USCDI. He noted that prerequisite pricing is noted as 'basic.'
- **Arien Malec** answered Ken, stating that 'basic' doesn't necessarily mean easy. He went on to note that under their HIPAA rights, the patient has the right to prospective pricing where available as part of basic access. He also stated that this isn't easy or readily available via standards. He then clarified that what is referenced is not related to API's but rather any activity that aids access, exchange or use.
- **Ken Kawamoto** asked if 'basic' access is being defined as required by law.
- **Arien Malec** answered that Cures requires access, but this section is meant to provide the appropriate distinction to enable broad-based access while preserving the ability to offer value-added services to the industry. He went on to note that the definition of basic access within the recommendation is seeking (to the extent that pricing info is available) to ensure pricing is clearly included as part of basic access.
- **Sasha TerMaat** noted that Recommendation 33 is closely related to Recommendation 36 where the task force is proposing that anything that is in the basic access category not be allowed to have any profit because it's pure direct cost recovery basis only. She continued, stating that given this, software or technology development projects may have to be done at cost with no opportunity for profit. She also noted that Recommendation 36 expects these instances to be minimal, and if this is the case, Recommendation 33 should rely on those same standards. Finally, Sasha agreed with Ken that Recommendation 33 could be more precise.
- **Cynthia Fisher** noted that when patients don't have access to prices, this is an example of information blocking. She noted the proposed rule was meant to enable patients to have broad access to prospective pricing. She's also concerned about the language, "including prospective patient specific pricing for procedures."
- **Andy Truscott** asked Cynthia if she was suggesting that patients should have access to broad pricing that has not been individualized for them.
- **Cynthia Fisher** answered that she was suggesting 'as well as individualized.' She then directed an answer to Sasha TerMaat's comment, where she stated the cost of doing business is to show prices across the board, and her concern is that fees upon fees

might get substantially added to the patient. She agrees with ONC's previous position that the data should be free to the patient.

- **Steven Lane** moved to amend by removing the "or clinically validated" within Recommendation 33. He suggested the point the task force is trying to make is the 'novelty.'
  - **Andy Truscott** supported Steven Lane's proposed amendment

The HITAC approved the amendment and the newly amended Recommendation 33 by voice vote. No members opposed. None abstained.

- **Recommendation 34:** Notwithstanding the recommended distinction between basic and value-added capabilities, the TF recommends that when the output of value-added services are incorporated into, or form, an essential part of the legal medical record, or are routinely used for decision making, they constitute part of the set to which basic access is required (e.g., if a vendor supplies clinical risk scoring services based on the basic record, those services may be offered at market rates; if the risk score is incorporated into or used by clinical staff to make clinical decisions, the individual risk score accordingly becomes part of the record and forms part of basic access to which basic access fee regulation is applied).

Discussion

- **Les Lenert** sought clarification by asking if Recommendation 34 is an exception to Recommendation 33. He went on to state that his understanding is that Recommendation 33 is meant to create two classes of API access.
- **Andy Truscott** answered that the intent isn't to create classes of API as that is an implementation question which is being addressed elsewhere. He elaborated that the intent is to create two reasons for access: 'basic' and 'value added.' The 'value added' category is charged at a higher price with the exception that when an output for value-added services are incorporated into the legal medical record, it becomes basic access.
- **Cynthia Fisher** provided an example of a woman who wasn't able to get the care her child needed as she wasn't able to access her child's test results, specifically the *appearance, pulse, grimace, activity, and respiration* (APGAR) score along with other medical records. With regard to this example, she asked if the 'value added' charge would apply to a case such as this.
- **Arien Malec** answered Cynthia by noting that the test score in her example is a proprietary risk scoring method that takes advantage of machine learning or the like and is a good example of the type of innovation this recommendation is designed to incent as a market-based value-add. However, he went on to note that when a patient risk score becomes part of clinical decision making, it becomes part of the 'basic' record.
- **Ken Kawamoto** noted his concern that the notion of any data used for clinical decision-making being designated as basic might cause every piece of data that a person might care about be considered basic. He then stated that from a vendor perspective, there would be an incentive to do nothing but what is minimally required. Finally, he suggested that the task force and committee carefully consider the implications of saying everything should be basically at cost.

- **Mike Lipinski** commented that Recommendation 34 proposed a distinction between requesters and that any patients' request would be free if it is electronic access to EHI. Based on this, he asked if the task force is recommending that the patient be charged if the request falls into the category of value added.
- **Arien Malec** noted that it was an interesting comment and that Mike Lipinski's understanding was not the intent. He then stated that no limits have been placed on patients buying or provisioning services that are value added in nature at a market-based cost, but rather this is relative to access to the record.
- **Andy Truscott** responded to Mike Lipinski's comment by noting that there was an overwhelming sentiment across the task force to dissuade any costs to patients in their effort to access their EHI.
- **Cynthia Fisher** recommended writing an explicit sentence stating that basic and value-added access to a patients EHI would be free of charge. She also suggested adding language stating that patient-specific pricing should be included as well as broader access to pricing for the patient.

- **Recommendation 35:** The TF recommends that ONC distinguish between IPR that are essential to access and IPR that allow for value-added services. The former would include standards-essential IPR or any IPR licensing associated with terminology either defined in certified standards or reasonably required based on regulatory requirements or customary use.

- **Recommendation 36:** The TF recommends that allowed fees for basic access be on a pure direct cost recovery basis only. In many cases, where basic access is provided via widely deployed consensus-based certified standards built into health IT, such direct costs would be minimal. The Task Force does not recommend that the cost to develop standards be part of the cost basis for fees for basic access; rather any such costs should be a part of the fees for the health IT. The Task Force believes this approach provides a significant incentive to adopt standards; actors who do not provide access through widely deployed consensus-based standards would have an incentive to do so to reduce the total cost structure of access. The Task Force recommends that the cost basis for fees basic access not include reasonable mapping to standards (that is, such one-time costs would be a cost of producing Health IT, not a cost of access); such mapping would include mapping of proprietary terminologies used internally to the standard terminologies used externally (e.g., internal problem list terminologies to SNOMED CT, or proprietary medication databases to RxNorm). Exceptions would include cases where data or terminology sets exist that are not reasonable to include in mapping to standards AND where sufficient mechanisms of basic access exposing the non-standard data exist. In these cases, there are a market-based mechanism (e.g., systems integrators) sufficient to set prices for non-standard data mapping.

Discussion

- **Sasha TerMaat** noted that within Recommendation 36, there is a distinction between the direct cost recovery portion of the standard and other health IT. She suggested this distinction is critical to mitigating the possibility that large swaths of health IT development are disincentivized from innovating due to the lack of a profit motive. However, she went on to mention that she is concerned that the distinction of what

falls into the pure direct cost recovery basis piece and what falls into the rest of health IT is ambiguous and seeks to avoid arbitrating this through information blocking lawsuits. Finally, she recommended clarifying the distinctions in a way the task force intends.

- **Recommendation 37:** The TF recommends that allowed fees for access, exchange and use essential IPR be set on a RAND-basis. Such fees would not be "reasonable" if they materially discourage access, exchange or use, or impede the development of competitive markets for value-added exchange and use services. The TF recommends that access, exchange, and use-essential IPR license grants be sufficient for actors to provide access and/or deliver exchange and use services; for example, IPR grants for terminology sets that are access, exchange and use essential should be sufficient to allow access, exchange and use for permissible purposes. To put this another way, actors would not be able to accept IPR licenses that restrict access only those who also have IPR rights.

Discussion

- **Carolyn Petersen** asked where this recommendation, as written, leaves patient-powered research network members. She went on to note that these would be research networks operated and managed by patients contributing their own data in which case they may wish to transfer, exchange, and use data. Given this, she wondered if patients should be designated as actors.
- **Arien Malec** answered Carolyn, noting that nothing in Recommendation 37 limits the ability of patients to exchange data as Carolyn describes. He went on to describe that there is a legislative mandate issue where Cures doesn't regulate what patients can or cannot do.
- **Andy Truscott** recommended that this issue be documented by the co-chairs and slated for future study and consideration, and there was broad agreement to do so.

- **Recommendation 38:** The TF recommends no further restrictions on permitted fees; the Task Force believes that the above restrictions on permitted fees are sufficient to address monopoly rents or gatekeepers and enable market-based pricing for additional services.

Discussion

- **Arien Malec** detailed the information blocking rule for the committee members. He then spoke about the rule noting that its goal was to create a sensible and reasonable carveout that provides appropriate pricing mechanisms for access as well as seeking not to impede the exchange or use of information.

- **No vote was taken on Recommendations 30-38**
  - **Andy Truscott** suggested bringing the information gathered in the committee discussion and present the updated recommendations at a later date. There was an agreement from the HITAC co-chairs to do so.

Workgroup 2 –Responding to Requests that are Infeasible

- **Recommendation 39:** The TF recommends the following revisions to the regulatory text: To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times.
    - Request is infeasible.
    - The actor must demonstrate, in accordance with paragraph (a)(2) of this section, that complying with the request in the manner requested would impose a substantial burden on the actor that is unreasonable under the circumstances, taking into consideration whether similarly situated actors provide similar access, exchange, or use
    - Responding to requests: the actor must respond to all requests relating to access, exchange, or use of electronic health information, including but not limited to requests to establish connections and to provide interoperability elements in a timely manner under the circumstances which shall not exceed 10 business days. Such response shall include a detailed written explanation of the reasons why the actor cannot accommodate the request.
    - Provision of a reasonable alternative. The actor must work with the requestor in a timely manner to identify and provide a reasonable alternative means of accessing, exchanging, or using the electronic health information as applicable.
- There were no questions or discussion by the committee members on the Responding to Requests that are Infeasible Recommendation.
    - **The HITAC approved Recommendation 39 by voice vote. No members opposed. None abstained.**

Workgroup 2 –Licensing of Interoperability Elements on RAND Terms

- **Recommendation 40:** The TF recommends the following revisions to the regulatory text. To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times.
    - Responding to requests. Upon receiving a request to license or use interoperability elements, the actor must respond to the requestor within 10 business days from the receipt of the request by: (1) negotiating with the requestor in a reasonable and non-discriminatory fashion to identify the interoperability elements that are needed, (2) offering an appropriate license with reasonable and non-discriminatory terms, and (3) beginning negotiations with the intent to furnish a quotation for a license.
    - Reasonable and non-discriminatory terms. The actor must license the interoperability elements described in paragraph (a) of this section on terms that are reasonable and non-discriminatory.
    - Scope of Rights. The license must provide all rights necessary to access and use the interoperability elements for the following purposes, as applicable: (1)developing products or services that are interoperable using the licensed interoperability elements, (2) marketing, offering, and distributing the interoperable products and/or services to potential customers and users, (3) enabling the use of interoperability products or services in production environments, including assessing and enabling the exchange and use of electronic health information.
    - This recommendation was voted on with the Maintaining and Improving Health IT Performance Recommendations.

Workgroup 2 –Maintaining and Improving Health IT Performance

- **Recommendation 41:** The TF recommends that ONC generalize the maintenance exception to cover the following:
    - Rate limiting or disabling use of the health IT by user or actors whose use is unusual or would cause a degradation of overall performance.
    - Reasonable and usual practices where SLA or maintenance windows are not named in contract.
    - Out of SLA performance with reasonable good-faith activity to restore service in a timely matter.
    - Force majeure or other highly unusual events out of the control of the actor.
    - Failure to consider these exceptions raises the risk that ordinary failures to achieve good faith service restoration would be adjudicated as information blocking, rather than through normal contractual resolution processes, and would create a paradoxical incentive for actors to insist on negotiating lower SLA achievement targets.
    - While we understand that some actors have caused information blocking by abandoning technology, we believe such instances are rare and would not trigger the exceptions noted above.

- **Recommendation 42:** The TF recommends making the following revisions to the regulatory text. To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times.
    - Maintenance and improvements in health IT. An actor may make health IT under its control temporarily unavailable in order to perform maintenance or improvements to the health IT, provided that the actor's practice is: (1) a reasonable, good-faith activity lasting period of time no longer than necessary to achieve the maintenance or improvements for which the health IT was made unavailable; and (2) implemented in a consistent and non-discriminatory manner.
    - Practices that prevent harm. If the unavailability of health IT for maintenance or improvements is initiated by an actor in response to a risk of harm to a patient or another person, the actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.201 at all relevant times to qualify for an exception.
    - Security-related practices. If the unavailability of health IT for maintenance or improvements is initiated by an actor in response to a security risk to electronic health information, the actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.203 at all relevant times to qualify for an exception.
    - Responding to requests that are infeasible. If the unavailability of health IT is due to highly unusual events out of the control of the actor such as a natural disaster, the actor does not need to satisfy the requirements of this section, if the practice complies with all requirements of §171.205.

- **The HITAC approved the Recommendations 40-42 by voice vote. No members opposed. None abstained.**

Discussion

- **Mike Lipinski,** after the vote was conducted, asked why line 3 of Recommendation #42 had been removed. He suggested that without this line, a developer would be allowed to make a decision without consultation with other entities.
- **Andy Truscott** replied saying that the TF members decided to remove the line so that healthcare decisions were not made based solely on health IT. He stated that it was intentionally removed in an effort to prevent information blocking and encourage appropriate system management.
- **Michael Adcock** added that most contracts already address appropriate maintenance windows and SLAs, so they felt it was not necessary to include.

Workgroup 2 –Additional Exceptions (Request for Information)

- **Recommendation 43:** The TF recommends that the status of contractual obligations that may be in conflict with information blocking obligations be explicitly clarified by ONC as being void. The simplest solution would be to interpret the intent of Congress to preempt specific contractual terms that are in conflict with the 21st Century Cures Act.

- **Recommendation 44:** Trusted Exchange Framework and Common Agreement: In ONC's Proposed Rule, ONC noted that they are considering whether they should propose, in a future rulemaking, a narrow exception to the information blocking provision for practices that are necessary to comply with the requirements of the Common Agreement (CA). The release of the second draft of the Trusted Exchange Framework (TEF) late in the public consultation period for the Proposed Rule has given the IBTF the opportunity to comment upon the TEF and the CA. Considerable discourse has taken place, with two distinct views being articulated:
  - That compliance with the TEF should provide a "safe lane" which demonstrates to ONC/HHS Office of Inspector General (OIG) that information blocking is not taking place.
  - That providing a "safe lane" is a protectionist approach which should not be adopted and the TEF should be a series of good practice guidelines.
  - We urge ONC during the rulemaking process to consider carefully the enduring demand of the Cures Act to promote information sharing and prohibit information blocking amongst all actors involved in the provision and administration of care. We believe that a careful balance needs to be struck to encourage compliance to the information blocking provision, potentially through adoption of the TEF, and the need to investigate information blocking activities where warranted – and not inadvertently provide bad actors with an opportunity to circumvent regulation compliance.

- The IBTF supports ONC's proposal on the information blocking complaint process as it is written in the Proposed Rule with no further edits or comments.
  - **Andy Truscott** stated that if the HITAC has any concerns/suggestions about the proposed complaint process, the TF would welcome those.

Workgroup 2 – Disincentives for Health Care Providers (Request for Information)

- **Recommendation 45:** The TF recommends that ONC work with CMS to build information blocking disincentives into a broad range of CMS programs, and that ONC work with other

Federal departments and agencies that contract with providers (e.g., VHA, DoD MHS, IHS, CDC, etc.) to similarly build information blocking disincentives into contracting and other programs

- **Recommendation 46:** The TF recommends that providers attest to comply with information blocking requirements as a part of Conditions of Participation, Conditions for Coverage, contracts, and other similar relationships, covering both FFS, value-based care, and direct payment relationships, and that findings of information blocking by OIG, findings violations relating to information blocking attestations of the False Claims Act by FTC, or other similar enforcement actions trigger disincentives up to and including removing organizations from participation or coverage.
- The IBTF supports ONC's proposal on the Information Blocking Condition of Certification as it is written in the Proposed Rule with no further edits or comments.

- **The HITAC approved Recommendations 43-46 by voice vote. No members opposed. None abstained.**

Workgroup 3 –Assurances-Conditions of Certification

- **Recommendation 47:** The TF recommends the following revisions to the regulatory text:
  - Condition of Certification. A health IT developer must not take any action that could interfere with a user's ability to access or use certified capabilities for any purpose within the scope of the technology's certification, and the health IT developer shall provide honest communication and expert advice as required by a user.
  - 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. (iii) If for a shorter period of time, 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.
  - ONC will preserve on the CHPL (or in another format) a list of the start and end dates of each previously certified health IT product.
  - **There were no questions or discussion on this Recommendation. The HITAC approved Recommendation 47 by voice vote. No members opposed. None abstained.**

Workgroup 3 – Assurances (Request of Information)

- **Recommendation 48:** The release of the second draft of the TEF late in the public consultation period for the Proposed Rule has given the IBTF the opportunity to comment upon the TEF and

the CA. Considerable discourse has taken place, with two distinct views being articulated: That compliance with the TEF should provide a "safe lane" which demonstrates to ONC/OIG that Information Blocking is not taking place; and That providing a "safe lane" is a protectionist approach which should not be adopted and the TEF should be a series of good practice guidelines. We urge ONC during the rulemaking process to consider carefully the enduring demand of the Cures Act to promote information sharing and prohibit information blocking amongst all actors involved in the provision and administration of care. We believe that a careful balance needs to be struck to encourage compliance to the information blocking provision, potentially through adoption of the TEF, and the need to investigate information blocking activities where warranted – and not inadvertently provide bad actors with an opportunity circumvent regulation compliance.

- **Andy Truscott** stated that this recommendation will likely be removed as it is similar to previous recommendations. It was not voted on and will go back to the TF for consideration.

Workgroup 3 – Communications

- **Recommendation 49:** There was concern among the TF 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. The Task Force recommends the following revisions to the regulatory text:
  - Contracts and agreements. (i) A health IT developer must not establish, renew, or enforce any contract or agreement that contravenes paragraph (a) of this section. (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. (iii) The plan required by paragraph (ii) of this section must be completed within five years of the effective date of this rule.

Discussion

- **Raj Ratwani** asked whether the rule is taking immediate effect and if the five-year period is a time to make the gradual change?
- **Andy Truscott** confirmed that the time period given allows for contracts to be updated and the change to be made effectively. He stated that this recommendation was made in an effort to bring more clarity to recommendation 43. He stated that the TF recognized the burden on companies of re-negotiating contracts and wanted to allow for a substantial amount of time to do so to avoid unnecessary consequences.
- **Cynthia Fisher** suggested that two years is a reasonable time frame and that the extension to five years is unnecessary. She noted that the five-year period could result in delays and is a projection that is too far ahead. She suggested the long time frame

would harm patients and providers as they would not have access to necessary data in a timely fashion.
    - **Denise Webb** stated that the five-year time frame is reasonable for the contract revision, giving first-hand provider experience with the lengthiness of dealing with health IT contracts.

- **Recommendation 50:** It was discussed that attempting to enumerate on a screen what might be third-party content that was the intellectual property of a third party was infeasible. Instead, health IT developers could provide a list of third-party content that might be present. The Task Force recommends the following revisions to the regulatory text:
    - (iii) The developer has put all potential communicators on sufficient written notice 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.

- **Recommendation 51:** There was discussion of whether administrative functions of health IT could unintentionally reveal significant intellectual property of health IT developers. For example, the security configuration of health IT is less important in meeting the needs of communications protected under the Cures Act. The Task Force recommends clarifying in the preamble that appropriate administrative functions of health IT could be included as "non-user facing aspects" based on the assessment that those communications are not matching the purpose required by the Cures Act and that also affect a limited set of users.

Discussion

- **Mike Lipinski** clarified that the recommendation is stating that a security issue could arise by showing too much information on the development of the technology. He requested an example of such an instance.

- **Recommendation 52:** There was discussion of concerns of sharing screenshots, the value that health IT developers put on time spent designing and improving screens and user interfaces, and that there are valid reasons why screenshots are both required to be shared and could also be considered "fair use." The goal was that the communications protected under the Cures Act should not permit unintended use, such as using screenshots to attempt to copy screen designs from a competitor. Some members of the Task Force felt that the "fair use" provisions of the preamble already prohibited copying for competitive reasons. However, 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 intent of the Task Force was that the actor disclosing a screenshot is responsible for determining that the disclosure's purpose does meet the "fair use" expectations and that further redisclosures would have to similarly meet the fair use expectations, and in doing so appropriately protect from potential intellectual property infringements. The Task Force recommends the following revisions to the regulatory 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".

- The presented information was not accurate based on the TF discussion and will be updated and voted on at the next meeting.

- **Recommendation 53:** In (2)(i)(A), the group 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.

- **Recommendation 54:** In (2)(i)(C), the group 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.

- **Recommendation 55:** In (2)(i) the group 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 ONC would need to phrase it so that a whistleblower would not be able to leverage this as mechanism to avoid sanctions for other activities (e.g. performance etc.). The Task Force recommends the following addition to regulatory text:
  - (E) Communicating information about a health IT developer's failure to comply with a Condition of Certification, or with any other requirement of this part, to ONC or an ONC-ACB. 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

- **Recommendation 56:** The Task Force recommends 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. The Task Force recommends clarifying in preamble that the goal of the unprotected communications provision is to not extend protections of necessitate permitted restrictions for this category of communications. Specifically, where a communication is unlawful (such as violations of securities law or court orders); the content is false, deceptive, or likely to cause confusion (such as trade libel or trademark infringement); the content is protected by law from disclosure (such as attorney-client privileged communications); the content is subject to a lawful obligation on the health IT developer to prohibit or restrict such communication (such as third party intellectual property); or the content was obtained without authorization (such as by a hacker). The Task Force recommends the following addition to the regulatory text:
  - (a)(3) Unprotected Communications. Specific communications are not extended the protections or restrictions in this section, where those communications are considered unprotected in that they are either: (i) protected by other legislation or regulation; or (ii) false or unlawful

Discussion

- **Raj Ratwani** asked whether there was any discussion around the definition of the word 'screenshot.' He suggests the TF offer a more distinct definition.

- **The HITAC approved Recommendations 49-51 and 53-56 by voice vote. No members opposed. None abstained. Recommendation 52 was not voted on and will be re-evaluated by the TF.**

Workgroup 3 –ONC Review of Certified Health IT or a Health IT Developer's Actions

- **Recommendation 57:** The TF recommends the following addition to the regulatory text: § 170.505 Correspondence.
  - (a) Correspondence and communication with ONC or the National Coordinator shall be conducted by email, unless otherwise necessary or specified. The official date of receipt of any email between ONC or the National Coordinator and an applicant for ONC-ACB status, an applicant for ONC-ATL status, an ONC-ACB, an ONC-ATL, health IT developer, or a party to any proceeding under this subpart is the date on which the email was sent.
  - (b) In circumstances where it is necessary for an applicant for ONC-ACB status, an applicant for ONCATL status, an ONC-ACB, an ONC-ATL, health IT developer, or a party to any proceeding under this subpart to correspond or communicate with ONC or the National Coordinator by regular, express, or certified mail, the official date of receipt for all parties will be the date of the delivery confirmation to the address on record.
  - (c) Notices initiating direct review, of potential non-conformity, of non-conformity, of suspension, of proposed termination, of termination, of ban, or concerning the appeals process will be issued simultaneously via certified mail and email.
  - The TF recommends that ONC also clarify in preamble that ONC should use both email and certified mail for notices of initiating direct review, potential non-conformity, non-conformity, suspension, proposed termination, termination and ban. Notices regarding appeals would be the same.

Workgroup 3 –Certification Ban

- **Recommendation 58:** Indefinite communication of past records (ban with start and end date, if lifted) seems appropriate.

- **Recommendation 59:** 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.

Workgroup 3 –Request for Comment on Application of Conditions and Maintenance of Certification to Self-Developers

- **Recommendation 60:** The Task Force recommends that ONC call out an exception to (a)(2)(ii)(A) for self-developed systems, so that communications by health IT users aren't restricted by being employees of the same company doing the development. The corresponding addition to the regulatory text is as follows: § 170.403 Communications.
  - (a)(2)(ii)(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.

- There was no discussion or questions from the committee members regarding Recommendations 57-60.
    - **The HITAC approved Recommendations 57-60 by voice vote. No members opposed. None abstained.**

Lauren Richie opened the line for public comment.

Public Comment

There were no public comments.

Comments in the Public Chat feature of Adobe

Arien Malec: I have to drop to travel to the airport.

Terrence O'Malley: Would we be able to introduce an amendment to clarify 28c? To be added to the current text in the transmittal letter:"The use of an identifier is mandatory if the identifier is defined/provided/managed by a national or regional accreditation body. If there is no identifier provided by a national or regional accreditation body then the user shall indicate that no such identifier exists."The purpose of this amendment is to clarify that the identifier is required or in its absence an affirmation that none exists in order to prevent systems from defaulting to "none" when an identifier exists.

Gail Kocher: Not all entities that enumerate providers are accreditation bodies, e.g. NPPES,

Closing Remarks and Adjourn

Lauren Richie adjourned the meeting at 2:45 p.m. ET