HTI-1 Proposed Rule Task Force 2023 Recommendations – HITAC Vote

Steven Lane, Co-Chair/Group 1 Lead

Steven Eichner, Co-Chair/Group 2 Lead

Hung Luu, Group 3 Lead

June 15, 2023

Agenda

- Task Force Roster

- Task Force Charge

- Key Takeaways

- HTI-1 Proposed Rule Topics Reviewed

- Review of Recommendations

- Referrals to HITAC Annual Report Workgroup

- Discussion

- HITAC Vote

HTI-1 Proposed Rule Task Force 2023 Roster

Name	Organization	Name	Organization
Steven Eichner* (Co-Chair)	Texas Department of State Health Services	**Steven Lane* (Co-Chair)**	Health Gorilla
Medell Briggs-Malonson*	UCLA Health	Deven McGraw*	Invitae Corporation
Hans Buitendijk*	Oracle Health	Aaron Miri*	Baptist Health
Hannah Galvin*	Cambridge Health Alliance	Eliel Oliveira*	Dell Medical School, University of Texas at Austin
Adi Gundlapalli**	CDC	Kikelomo Oshunkentan*	Pegasystems
Jim Jirjis*	HCA Healthcare	Naresh Sundar Rajan*	CyncHealth
Hung Luu*	Children's Health	Fillipe Southerland*	Yardi Systems, Inc.
Anna McCollister*	Individual	Sheryl Turney*	Elevance Health
Clem McDonald*	National Library of Medicine		

* HITAC Member
** HITAC Federal Representative

HTI-1 Proposed Rule Task Force 2023 Charge

Overarching Charge:

The HTI-1 Proposed Rule Task Force 2023 will evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule.

Specific Charge: Provide recommendations on ONC's proposals that would:

- Rename all certification criteria within the ONC Health IT Certification Program (Program) as "ONC Certification Criteria for Health IT" and discontinue year themed "Editions"

- Establish a new baseline version of the United States Core Data for Interoperability (USCDI) from Version 1 to Version 3

- Implement the Electronic Health Record (EHR) Reporting Program as a new Insights Condition and Maintenance of Certification for health information technology (health IT) developers under the Program

- Enhance information sharing under the information blocking regulations

HTI-1 Proposed Rule Task Force 2023 Charge (continued)

Specific Charge: Provide recommendations on ONC's proposals that would:

- Adopt new and revised standards and certification criteria, including:
- Electronic case reporting certification criterion;
    - Clinical decision support (CDS) and decision support interventions (DSI) certification criteria;
    - Application programming interfaces (APIs) for patient and population services;
    - FHIR US Core Implementation Guide STU version 5.0.
    - HL7 CDA® R2 IG: C–CDA Templates for Clinical Notes STUR2.1 Companion Guide, Release 3 US Realm;
    - A new patient requested restrictions certification criterion; and
    - Requirements for health IT developers to update their previously certified health IT.

- Establish additional Assurances Condition and Maintenance of Certification requirements

- Solicit requests for information (RFIs) on Program standards, certification criteria, and information blocking to inform potential future rulemaking

Recommendations due to the HITAC by the end of the 60-day public comment period.

HTI-1 Proposed Rule Task Force 2023 Approach

- The members of the Task Force were separated into three groups and topics from the NPRM were distributed amongst these groups

- ONC developed a work plan for the duration of the Task Force and scheduled assigned topics and applicable ONC subject matter experts for each group task force meeting

- External subject matter experts were also invited on behalf of the Task Force to provide their perspective on key components of the NPRM

- All three groups met weekly to discuss scheduled topics

- The ONC program leads developed key takeaways from each Task Force meeting which were distributed to the members of the task force

- ONC also developed meeting minutes and produced a video of each Task Force meeting, all of which can be found at https://www.healthit.gov/hitac/committees/hti-1-proposed-rule-task-force-2023

NPRM Topics Reviewed by Task Force

NPRM Topics Reviewed by Task Force (1 of 3)

- The ONC Certification Criteria for Health IT and Discontinuing Year Themed "Editions"

- The United States Core Data for Interoperability Standard (USCDI) v3

- C-CDA Companion Guide Updates

- Electronic Case Reporting (eCR)

- Decision Support Interventions (DSI) and Predictive Models

- Standardized API for Patient and Population Services

- FHIR United States Core Implementation Guide STU Version 5.0.1

- Patient Requested Restrictions Certification Criterion

- Requirement for Health IT Developers to Update their Previously Certified Health IT

NPRM Topics Reviewed by Task Force (2 of 3)

- Assurances Condition and Maintenance of Certification Requirements

- Insights Condition and Maintenance of Certification

- Requests for Information (RFIs)

  - Laboratory Data Interoperability RFI

  - RFI on Pharmacy Interoperability Functionality Within the ONC Health IT Certification Program Including Real-Time Prescription Benefit Capabilities

  - Clinical Decision Support Hooks RFI

  - FHIR Subscriptions RFI

  - FHIR Standard for Scheduling RFI

  - SMART Health Links RFI

NPRM Topics Reviewed by Task Force (3 of 3)

- Information Blocking (IB) Defined Terms – Proposals

- IB Infeasibility Exception Proposals
    - Revise Existing Condition: Uncontrollable Events
    - New Condition: Third Party Seeking Modification Use

- New Condition: Manner Exception Exhausted

- IB Manner Exception - TEFCA Manner Proposal

- IB RFI 1 – Additional Exclusions for Offer Health IT

- IB RFI 2 – Possible Additional TEFCA Reasonable and Necessary Activities

- IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access

HTI-1 Proposed Rule Task Force 2023 Key Takeaways

- Overall, HTI-1 continues to both advance and refine the interoperability standards framework with a focus on serving patients and populations.
- HTI-1 clarifies and expands exceptions in information blocking regulations to increase certainty for regulated actors.
- HTI-1 defines standards supporting electronic case reporting, a critical component of information sharing for public health purposes.
- The proposed Insights Condition and Maintenance of Certification requirement should be specified to align with other existing federal programs.
- The proposed Information Blocking TEFCA Manner Proposal, as written, could inadvertently disincentivize participation in the new interoperability framework.
- The various Requests for Information included in HTI-1 provide an opportunity for broad input to inform future rulemaking.

- Many of the Task Force's recommendations include a specified rationale and/or comments which are included in the full report to HITAC.

Recommendations

ONC Health IT Certification Program Updates

The ONC Certification Criteria for Health IT and Discontinuing Year Themed "Editions"

HTI-1-PR-TF-2023_ Recommendation – 01

- Recommend that ONC establish and maintain Internet-accessible, human and machine-readable tables of information for each relevant Health IT certification criterion.

The ONC Certification Criteria for Health IT and Discontinuing Year Themed "Editions" (Continued)

HTI-1-PR-TF-2023_ Recommendation – 02

- Recommend that ONC consider that, if the approach to standards adoption is to change from edition-level to line level advancement, any change in any line item, or any additional line item should be assessed for its impact on the overall scope and effort of implementation for all involved parties across all items, including all other HIT updates that need to be managed.

The ONC Certification Criteria for Health IT and Discontinuing Year Themed "Editions" (Continued)

HTI-1-PR-TF-2023_ Recommendation – 03

- Recommend that ONC consider the impact of shifting to line-level standards progression may have on the exchange of data between certified and non-certified HIT.

The ONC Certification Criteria for Health IT and Discontinuing Year Themed "Editions" (Continued)

HTI-1-PR-TF-2023_ Recommendation – 04

- Recommend that ONC collaborate with the Centers for Medicare and Medicaid Services (CMS) to align standards in programs such as Promoting Interoperability with the standards and criteria addressed in the HTI-1 Rule and mutually adopt a common naming convention that clarifies what "certified" means. Particular focus should be given to addressing language that refers to "Certified Electronic Health Record Technology" or "Certified HIT" and clarify what specific certifications and technologies may be used to meet requirements such as those in the CMS Merit-based Incentive Payment System (MIPS) program.

The United States Core Data for Interoperability Standard (USCDI) v3

HTI-1-PR-TF-2023_ Recommendation – 05

- Task Force is supportive of moving to USCDI v3.

The United States Core Data for Interoperability Standard (USCDI) v3 (Continued)

HTI-1-PR-TF-2023_ Recommendation – 06

- Recommend that ONC, in conjunction with the change to USCDI v3, establish a practical means and/or framework by which specialty EHRs and non-EHRs can certify to applicable certification criteria for generating C-CDAs, (b)(1), (b)(2), (b)(9), (e)(1), (g)(6), (g)(9), and FHIR based APIs, (g)(10), for data in USCDI that those specialty EHRs and non-EHRs manage within the scope of their applicable care domain(s), thereby facilitating and promoting USCDI uptake across the care continuum.

The United States Core Data for Interoperability Standard (USCDI) v3 (Continued)

HTI-1-PR-TF-2023_ Recommendation – 07

- Recommend that ONC work with industry to clarify and communicate that, even though the capability to exchange USCDI data elements may exist, the exchange of all USCDI data elements is not required in all circumstances, especially where data is deemed sensitive, until or unless mature standards are available to support granular data segmentation.

C-CDA Companion Guide Updates

HTI-1-PR-TF-2023_ Recommendation – 08

- The Task Force is supportive of the adoption of HL7 CDA C-CDA Templates for Clinical Notes STU Companion Guide Release 4 (US Realm) which implements USCDI V3.

Electronic Case Reporting

HTI-1-PR-TF-2023_ Recommendation – 09

- Recommend that ONC require that if a HIT Module is certified only for CDA or FHIR transmission of initial eCR data, to receive certification the HIT Module must also successfully complete real-world testing with a commercially-available service to transform the data to the format not implemented as part of the HIT Module. This change is necessary to support connectivity between health care providers and public health agencies across the country. Without this modification, there is risk that messages will not be able to be successfully exchanged between health care providers and public health authorities.

Electronic Case Reporting (Continued)

HTI-1-PR-TF-2023_ Recommendation – 10

- Recommend that ONC require that if an HIT Module is certified only for CDA or FHIR exchange of RR data, to receive certification the HIT module must also successfully complete real-world testing with a commercially-available service to transform the data into the format not implemented as part of the HIT Module.

Electronic Case Reporting (Continued)

HTI-1-PR-TF-2023_ Recommendation – 11

- Recommend that ONC replace the current "real world" testing approach, that enables HIT developers to self-certify they have completed real world testing for ECR, to require real world testing with "live" public health information systems, or systems specified by the public health community.

Decision Support Interventions (DSI) and Predictive Models

HTI-1-PR-TF-2023_ Recommendation – 12

- Recommend that ONC define and implement transparency requirements for Patient Characteristics and Attributes utilized in DSI development and training

Decision Support Interventions (DSI) and Predictive Models (Continued)

- **HTI-1-PR-TF-2023_ Recommendation – 13**

- Recommend that ONC include as a certification criteria the successful production of warning messages to the user by the DSI when:
  - Critical input data supplied by the HIT Module or DSI user is missing,
  - The data provided to the DSI is outside of the range/code set/value set expected by the DSI, or
  - The use of the particular DSI is contraindicated by a field value or combination of values from the patient's health record such as a particular diagnosis, test result value, or demographic factor.

Decision Support Interventions (DSI) and Predictive Models (Continued)

- **HTI-1-PR-TF-2023_ Recommendation – 14**

- Recommend that ONC collaborate with the Food and Drug Administration (FDA) and relevant stakeholders to develop certification and DSI approval criteria requiring the participation of clinicians and patients in the identification of relevant data inputs and outputs to and from the DSI module and for inclusion in the DSI module. Criteria should include the release of public documentation of how this was accomplished.

Decision Support Interventions (DSI) and Predictive Models (Continued)

HTI-1-PR-TF-2023_ Recommendation – 15

- Recommend that ONC collaborate with DSI and other HIT developers, the FDA, and other stakeholders to implement a standards-based approach for sharing both machine-readable and human-readable tables/lists of DSI attribute information. As a first phase of this effort, ONC should produce a document format for DSI developers to use in conveying information to EHR developers and interface specialists.

Decision Support Interventions (DSI) and Predictive Models (Continued)

HTI-1-PR-TF-2023_ Recommendation – 16

- Recommend that ONC collaborate with the FDA and other stakeholders to develop a format, similar to the nutrition label required on food products or medication information labels, that standardizes the presentation of DSI attribute information that is patient-friendly and meets accessibility requirements.

Decision Support Interventions (DSI) and Predictive Models (Continued)

- **HTI-1-PR-TF-2023_ Recommendation – 17**

- Recommend that ONC collaborate with the FDA to require that DSI developers include the ability for clinicians and patients to provide feedback to developers about potential risks for using the DSI in special sub-populations of patients, such as patients with specific rare conditions, who may have not been sufficiently represented in the DSI development or testing data sets.

Decision Support Interventions (DSI) and Predictive Models (Continued)

- **HTI-1-PR-TF-2023_ Recommendation – 18**

- Recommend that ONC limit the interfacing or incorporation of "large language models" of AI/DSI into certified HIT unless the DSI developer can clearly articulate the data sources and logic used to produce outputs, until such time when these new models are better understood and the industry/government develops better insight into how to mitigate potential risks.

Decision Support Interventions (DSI) and Predictive Models (Continued)

HTI-1-PR-TF-2023_ Recommendation – 19

- Recommend that ONC clarify the distinction between "enables" and "interface." There appears no difference in the obligation of the developer of a certified HIT Module regarding the documentation to be provided about EHR interactions with the DSI service/capability. "Enabled" indicates "to or through a standalone app" and "interface" indicates "outside of the HIT Module."

Standardized API for Patient and Population Services

HTI-1-PR-TF-2023_ Recommendation – 20

- The Task Force supports the proposed changes to the "Standardized API for Patient and Population Services" certification criterion.

FHIR United States Core Implementation Guide STU Version 5.0.1

HTI-1-PR-TF-2023_ Recommendation – 21

- The Task Force supports the adoption of FHIR US Core 6.0.0.

  - The Task Force notes that FHIR US Core 6.0.0 may require additional critical updates in proximity with adoption of the Final Rule. ONC should consider the then most current version as part of the Final Rule, and if needed, rapid inclusion in the SVAP.

Patient Requested Restrictions Certification Criterion

HTI-1-PR-TF-2023_ Recommendation – 22

- Recommend that ONC utilize a standards-based approach incorporating the following standards:
  - HL7 CDA DS4P IG,
  - HL7 v2.9 ARV Access Restriction standard,
  - HL7 FHIR DS4P IG, and
  - HL7 FHIR Core Security Labeling module as the implementation guide for the format of recording labels and the source of the latest and most recent standard codes.

Patient Requested Restrictions Certification Criterion (Continued)

HTI-1-PR-TF-2023_ Recommendation – 22 (Continued)

- In order to accomplish this, the Task Force recommends that ONC: (1 of 5)

1. Work with relevant stakeholders including providers, HIT developers, and patients to define standard policies/rules with an associated maturity model based on those flags and other already available data (e.g., condition, test codes, result values, self-pay) that can become a common superset (not per provider) for patients to express their restrictions/consents in a computable format, yet easy for patients and other users to understand.

Patient Requested Restrictions Certification Criterion (Continued)

HTI-1-PR-TF-2023_ Recommendation – 22 (Continued)

2. (of 5) Collaborate with health care providers, patients, and HIT developers to explore and support pilots, such as a hub-and-spoke infrastructure, enabling a patient to have a single virtual location where their restrictions on data use and/or release may be maintained and stored.

The patient should be able to maintain their restriction settings using a variety of technologies and interfaces, such as through a patient portal hosted by a provider or an app made available directly to the patient by a third party.

This data store should be secure, but accessible by authorized users such as health care providers and applied in real time to any usage of patient data that is within the user's control.

Patient Requested Restrictions Certification Criterion (Continued)

HTI-1-PR-TF-2023_ Recommendation – 22 (Continued)

3. (of 5) Adopt a maturity model for implementing data segmentation and granular consent that would support progressively greater capabilities. As a first step, require developers and users of certified HIT to gain meaningful experience with the standards for a limited scope of functionality and data classes so as to prepare for future broadening of capabilities rather than attempting to include all data in a first iteration.
ONC should include in the first iteration of disclosure-related functionality the following USCDI data classes: Patient Demographics/Information, Problems, Medications, Tests, Results (i.e., Clinical Tests, Diagnostic Imaging, and Laboratory), Clinical Notes, and Health Status Assessments.

Patient Requested Restrictions Certification Criterion (Continued)

HTI-1-PR-TF-2023_ Recommendation – 22 (Continued)

4. (of 5) Limit the scope to require the following subset of existing standard codes for security labels, including Confidentiality, Sensitivity, and common Obligations and Refrains:

- Confidentiality: Unclassified (U), Normal (N), and Restricted (R) at time of data sharing

- Sensitivity: MH (mental health), SUD (substance use disorder), SDV (sexual assault or domestic violence), and SEX (sexual and reproductive health) are the most stable codes.

- Instructions: https://terminology.hl7.org/ValueSet-v3-GeneralPurposeOfUse.html represents the most stable General Purpose of Use value set.

Patient Requested Restrictions Certification Criterion (Continued)
HTI-1-PR-TF-2023_ Recommendation – 22 (Continued)

5. (of 5) Include in regulations that disclosure limitations selected by the patient should apply to a wide range of exchange and sharing capabilities including HL7 CDA, RESTful APIs (HL7 FHIR), HL7 V2, NCPDP, and proprietary message types.

Patient Requested Restrictions Certification Criterion (Continued)

HTI-1-PR-TF-2023_ Recommendation – 23

- Recommend that ONC assure through HIT Certification requirements that when individuals' HIPAA right to request a restriction on certain uses and disclosures of their PHI is used as the reason to restrict access to PHI via a portal or API that this be recorded in the HIT Module and that relevant metadata is included in transaction/log files.
- Whether or not the provider can honor the patient's request limiting the disclosure, the transmission of data should include relevant metadata regarding the requested restriction.
- When received by Certified Health IT, the receiving system should have the ability to receive, view, and operationalize the restrictions requested and/or placed on the data at the originating organization, as applicable.

Patient Requested Restrictions Certification Criterion (Continued)

HTI-1-PR-TF-2023_ Recommendation – 24

- Recommend that ONC add a requirement that patient-facing certified HIT modules include the capability to provide educational materials regarding the patient's options about disclosure, the potential impacts of limiting disclosure, and instructions regarding how to change disclosure limitations.

Patient Requested Restrictions Certification Criterion (Continued)

HTI-1-PR-TF-2023_ Recommendation – 25

- Recommend that ONC clarify the technology support necessary for the exchange of flow down requirements including requirements within the Trusted Exchange Framework and Common Agreement (TEFCA) framework.
- This should particularly address elements of the FHIR Trust Contract profile with Labeling Capability Statements for real-time verification that applies when sender/receiver are bound under agreements such as the eHealth Exchange Data Use and Reciprocal Support Agreement (DURSA) or the Qualified Health Information Network (QHIN) Technical Framework and consistently applied to any exchanges under TEFCA.

Requirement for Health IT Developers to Update their Previously Certified Health IT

- The Task Force reviewed this proposal and had no comments or recommendations in this area.

Assurances Condition and Maintenance of Certification Requirements

- The Task Force reviewed this proposal and had no comments or recommendations in this area.

Insights Condition and Maintenance of Certification

HTI-1-PR-TF-2023_ Recommendation – 26

- The Task Force is supportive of the proposed implementation of the Cures Act mandated EHR Reporting Program as the Insights Condition and Maintenance of Certification Requirement.

Insights Condition and Maintenance of Certification

HTI-1-PR-TF-2023_ Recommendation – 27

- Recommend that ONC coordinate with CMS's Promoting Interoperability/MIPS programs to enable providers to readily grant access to HIT Module data to HIT Developers for the generation of Insights measure reporting.

Insights Condition and Maintenance of Certification (Continued)

HTI-1-PR-TF-2023_ Recommendation – 28

- Recommend that ONC aligns the Insights program with the Real World Testing program so that applicable Insights measures can also be used for the Real World Testing program to reduce burden.

Insights Condition and Maintenance of Certification (Continued)

HTI-1-PR-TF-2023_ Recommendation – 29

- Recommend that ONC work with CMS to support the alignment of the definition of Encounters between ONC's Insights program and CMS' Quality Measurement program to maintain consistency.
- Further, recommend enhancing the definition of **Encounters** to address the inconsistency in encounter types referenced in the proposed definition and the encounter types that are valid for use in FHIR US Core and CDA C-CDA.
- ONC and CMS should align their definition(s) with those used in the supporting CDA C-CDA and FHIR US Core implementation guides or provide clear mapping to the permissible encounter types

Insights Condition and Maintenance of Certification (Continued)

HTI-1-PR-TF-2023_ Recommendation – 30

- Recommend that ONC reference a limited scope of the FHIR measures by including only the FHIR APIs supporting the USCDI version referenced in regulation.

Insights Condition and Maintenance of Certification (Continued)

HTI-1-PR-TF-2023_ Recommendation – 31

- Recommend that ONC, in the definition of Insights Condition **document exchange metrics**, require that all documents are counted, whether considered duplicates or not.

Insights Condition and Maintenance of Certification (Continued)

HTI-1-PR-TF-2023_ Recommendation – 32

- Recommend that ONC, in the definition of Insights Condition **volume measures**, consider whether increases or decreases are truly indicative of desired advancement.

Insights Condition and Maintenance of Certification (Continued)

HTI-1-PR-TF-2023_ Recommendation – 33

- Recommend that ONC, in the definition of Insights Condition document reconciliation metrics, consider including documents reconciled not only by human users, but also recognize the use of automated tools which reduce the need for manual review and reconciliation of data, e.g., already known data to the HIT or new data not requiring human review.

Insights Condition and Maintenance of Certification (Continued)

HTI-1-PR-TF-2023_ Recommendation – 34

- Recommend that ONC consider extending the burden provisions and criteria of the Insights Condition and other Base EHR criteria to include specialty and non-EHR HIT developers.

Insights Condition and Maintenance of Certification (Continued)

HTI-1-PR-TF-2023_ Recommendation – 35

- Recommend that ONC consider and support the development of metrics regarding usage of interoperability standards, including versions and variations (e.g., ELR, Immunization guides) in deployed Health IT.

Insights Condition and Maintenance of Certification (Continued)

HTI-1-PR-TF-2023_ Recommendation – 36

- Recommend that ONC include in the Insights Condition the proposed measure entitled Individuals' Access to Electronic Health Information

Laboratory Data Interoperability Request for Information

HTI-1-PR-TF-2023_ Recommendation – 37

- Recommend that ONC coordinate with HHS partners (e.g., FDA, CMS, CDC), Standards Development Organizations (SDOs), STLTs and other stakeholders to further define an interoperable information model based on existing CLIA requirements and the HL7 v2 LOI, HL7 v2 LRI, HL7 FHIR US Core, as well as the emerging HL7 FHIR LIVD implementation guides, and subsequently incorporate this model into ISA and the USCDI. Such an information model should define information standards for interoperable clinically interpretable data, for patient self-management, and for public health. In particular, it should specify that:

- All laboratory orders be specified with LOINC codes and other codes needed for purposes of billing like CPT or Healthcare Common Procedure Coding System (HCPCS) administrative procedural codes as needed for purposes of billing.

Laboratory Data Interoperability Request for Information (Continued)

HTI-1-PR-TF-2023_ Recommendation – 37 (Continued)

- All laboratory results should include a code, value, reference range, and other CLIA required elements that affect the result interpretation, etc., with associated terminology standards and that such results should use:
  - LOINC for the performed test,
  - UCUM for units of measure of numeric results,
  - SNOMED-CT for qualitative results (mapped to SNOMED organism, clinical finding and qualifier hierarchy as appropriate),
  - HL7's HL0078 standard for Test Interpretation codes (High, Low, Normal, Abnormal, etc.),
  - SNOMED-CT for specimen information (mapped to SNOMED specimen hierarchy) as appropriate, and
  - UDI data for test kit and other relevant device data.

Laboratory Data Interoperability Request for Information (Continued)

HTI-1-PR-TF-2023_ Recommendation – 38

- Recommend that ONC, in coordination with the FDA, SDOs, manufacturers, and industry stakeholders, including SHIELD, enhance the ability for test results to include identification of the instruments and test kits used to perform the test using the Device manufacturer and model, Device Identifier, or preferably the UDI, while streamlining the documentation of such identification as the test is performed and documented.

Laboratory Data Interoperability Request for Information (Continued)

HTI-1-PR-TF-2023_ Recommendation – 39

- Recommend that ONC, in conjunction with other federal partners, SDOs and industry stakeholders, create and implement mechanisms to support and ensure proper and consistent LOINC, SNOMED CT encoding across result sources (e.g., laboratories, imaging centers) by resulting organizations.

Laboratory Data Interoperability Request for Information (Continued)

HTI-1-PR-TF-2023_ Recommendation – 40

- Recommend that ONC focus on vocabulary/data quality/completeness and targeted adoption of LOI and LRI profiles (not the full guides) to optimize benefits using mature implementations.

Request for Information on Pharmacy Interoperability Functionality Within the ONC Health IT Certification Program Including Real-Time Prescription Benefit Capabilities

HTI-1-PR-TF-2023_ Recommendation – 41

- Recommend that ONC establish a certification criteria using the NCPDP Real-Time Prescription Benefit (RTPB) Version 13 standard.

Request for Information on Pharmacy Interoperability Functionality Within the ONC Health IT Certification Program Including Real-Time Prescription Benefit Capabilities

HTI-1-PR-TF-2023_ Recommendation – 42

- Recommend that ONC require HIT support for both NDC and RxNorm.

Request for Information on Pharmacy Interoperability Functionality Within the ONC Health IT Certification Program Including Real-Time Prescription Benefit Capabilities (Continued)

HTI-1-PR-TF-2023_ Recommendation – 43

- Recommend that ONC require certified HIT to support either the XML or EDI format as a transitional step until all users migrate to the final JSON format rather than requiring an intermediary migration.

Request for Information on Pharmacy Interoperability Functionality Within the ONC Health IT Certification Program Including Real-Time Prescription Benefit Capabilities (Continued)

HTI-1-PR-TF-2023_ Recommendation – 44

- Recommend that ONC work with CDC and CMS to support Prescription Drug Monitoring Programs (PDMP) in being able to receive data utilizing the new standards.

Request for Information on Pharmacy Interoperability Functionality Within the ONC Health IT Certification Program Including Real-Time Prescription Benefit Capabilities (Continued)

HTI-1-PR-TF-2023_ Recommendation – 45

- Recommend that ONC require use of ICD-10 as the primary diagnosis code set within the RTPB standard with SNOMED CT as a required addition to, and not a replacement for ICD-10.

Clinical Decision Support Hooks Request for Information

HTI-1-PR-TF-2023_ Recommendation – 46

- Recommend that ONC adopt implementation guides that use CDS Hooks when sufficiently mature and available.
- Focus should be on implementation guides, such as the Prior Authorization, and utilizing high value hooks such as: Patient-view, Order-select, and Order-sign.
- Encourage the use of hooks directed toward patients as well as silent alerts that may function within an HIT system to drive workflows without the need to present alerts to a human user.

FHIR Subscriptions Request for Information

HTI-1-PR-TF-2023_ Recommendation – 47

- Recommend the ONC focus on establishing implementation guides for high-value subscription use cases that would benefit from certification.

FHIR Subscriptions Request for Information

HTI-1-PR-TF-2023_ Recommendation – 48

- Recommend the ONC work with HL7 to determine the compatibility of FHIR R5 Subscriptions with FHIR R4 Subscription content.

FHIR Standard for Scheduling Request for Information

HTI-1-PR-TF-2023_ Recommendation – 49

- Recommend the ONC track and support the development and maturation of the SMART Scheduling Links standards and implementation guide.

- The Task Force noted the following current barriers
  to widespread implementation when advancing standards:
  - While there has been an increase in providers' use of FHIR, not all providers are FHIR-enabled;
  - Not all providers have been able to adopt interoperable health IT, including those with limited resources or not included in the prior EHR incentive program;
  - Scheduling systems are not universally integrated into EHRs;
  - Multiple approaches currently exist to request available slots, not all being suitable to every source of appointment slots.
- Certification to a single approach would not be beneficial, as using different FHIR based queries for appointment slots are valid alternatives.

SMART Health Links Request for Information

HTI-1-PR-TF-2023_ Recommendation – 50

- Recommend that ONC identify high-value use cases where Quick Response (QR) encoding is valuable, while also recognizing the limitations on what can be included in the QR code directly vs. what can be made accessible based on a provided QR code.
- Recommend that specific use cases and associated implementation guides be considered for certification as appropriate.
- Such specific guides should address not only the protocol, but the necessary content as well.

Information Blocking Enhancements

Information Blocking (IB) Defined Terms – Proposals

HTI-1-PR-TF-2023_ Recommendation – 51

- Recommend that ONC clarify that providing access to registries and similar data services provided by public health authorities are not considered providing health IT, regardless of the route used to request/access/receive data (e.g., through direct logon to a public health information system, via an app or third-party tool, or via HIN/HIE).

IB Infeasibility Exception Proposals :
1. Revise Existing Condition: Uncontrollable Events

HTI-1-PR-TF-2023_ Recommendation – 52

- Recommend that ONC expand the definitions within the Uncontrollable Events Condition to include impediments of data access, exchange, or use "because of" any disaster/emergency declared by an authorized governmental entity.

IB Infeasibility Exception Proposals :
2. New Condition: Third Party Seeking Modification Use

HTI-1-PR-TF-2023_ Recommendation – 53

- Recommend that ONC work towards updating certification requirements in a manner that will support providers' ability to utilize third party applications (i.e., other than the primary EHR) with write access to USCDI data elements maintained in certified HIT while minimizing risk to data security and EHR performance (e.g., write access utilizing existing APIs and support for user-created fields).

New Condition: Manner Exception Exhausted

HTI-1-PR-TF-2023_ Recommendation – 54

- Recommend that ONC further clarify what is meant by entities "similarly situated" to the requester to clarify that responding actors are responsible to exchange data for the purpose and in the manner requested, if they are able to do so, even if they are not accustomed to utilizing the requested transaction pattern.

Information Blocking Manner Exception - TEFCA Manner Proposal

HTI-1-PR-TF-2023_ Recommendation – 55

- Recommend that, in lieu of the Manner Proposal as presented, ONC work with OIG to establish a general safe harbor for TEFCA participation, creating a rebuttable presumption that an actor who participates in TEFCA as a QHIN, Participant or Subparticipant is not information blocking for any exchange purpose which is supported by the TEFCA with a final published Standard Operating Procedure (SOP), absent evidence that notwithstanding "participation in TEFCA," information blocking (with the requisite level of knowledge) occurred in a particular circumstance

Information Blocking Manner Exception - TEFCA Manner Proposal (Continued)

HTI-1-PR-TF-2023_ Recommendation – 56

- If the TEFCA Manner Proposal goes forward, recommend that ONC limit the requirement to utilize TEFCA exchange when offered to apply only to those use cases for which a TEFCA SOP has been finalized and published by the Recognized Coordinating Entity (RCE), and for which responses are required and operational under TEFCA. This change is necessary because to require the use of TEFCA exchange before the relevant use cases and technical requirements have been finalized may inadvertently disincentivize TEFCA participation.

Information Blocking Request for Information 1: Additional Exclusions for Offer Health IT

HTI-1-PR-TF-2023_ Recommendation – 57

- Recommend that ONC clarify that a consultant organization providing HIT development to a provider in a "work for hire" arrangement should be treated like the provider and be considered not offering HIT with respect to the work performed for the provider, whether or not they are also developers of certified HIT and would be considered offering HIT based on other activities.

Information Blocking Request for Information 1: Additional Exclusions for Offer Health IT (Continued)

HTI-1-PR-TF-2023_ Recommendation – 58

- Recommend that ONC clarify that meeting one (or more) exclusions in one role/offering does not mean an entity is not covered by the Rules with respect to other products/services that are within the definition of "offering" certified health IT.

Information Blocking Request For Information 2 – Possible Additional TEFCA Reasonable and Necessary Activities

- The Task Force reviewed this RFI and had no comments or recommendations in this area.

Information Blocking Request For Information 3 – Health IT Capabilities for Data Segmentation and User/Patient Access

HTI-1-PR-TF-2023_ Recommendation – 59

- Recommend that ONC work with the Department of Health and Human Services' Office of Civil Rights (OCR), the American Health Information Management Association (AHIMA), other relevant industry partners, patient representatives and organizations to develop **standardized patient education materials** regarding the consequences and limitations of requested restrictions, and that ONC encourage and/or require actors who receive and manage individual requests for restrictions to provide such education.

Information Blocking Request For Information 3 – Health IT Capabilities for Data Segmentation and User/Patient Access

HTI-1-PR-TF-2023_ Recommendation – 60

- Recommend that ONC work with OCR, AHIMA, other relevant industry partners, patient representatives and organizations to develop recommendations and standards regarding the need to periodically **review and validate applied restrictions** with the individual/representative so as to prevent unintended restrictions of data access.

IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access (Continued)

HTI-1-PR-TF-2023_ Recommendation – 61

- Recommend that ONC work with industry partners to explore how **revocations** of previously applied/deployed restrictions can and should be shared with recipients of restricted data so as to prevent unintended restrictions of data access.

IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access (Continued)

HTI-1-PR-TF-2023_ Recommendation – 62

- Recommend that ONC work with OCR to implement established HITECH provisions for providing patients/representatives with a more comprehensive **accounting of disclosures** of their health information, with the goal of establishing certification criteria.

- This recommendation is also being referred to the HITAC Annual Report Workgroup for discussion and the consideration of further recommendations.

IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access (Continued)

HTI-1-PR-TF-2023_ Recommendation – 63

- Recommend that ONC support further pilots and development of a patient-centric "hub-and-spoke" consent registry model of capturing, storing, updating, and exchanging individuals' data sharing preferences and restrictions in a centralized, patient-selected application, allowing other HIT systems to access and utilize a single source of truth regarding patient requested restrictions.

IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access (Continued)

HTI-1-PR-TF-2023_ Recommendation – 64

- Recommend that ONC require certified health IT to manage and respect patient restrictions, insofar as possible, as **data is exchanged via messages** (including HL7 v2 and possibly NCPDP), in addition to documents (HL7 C-CDA) and RESTful APIs (HL7 FHIR).
- This is dependent on guidance and standards to support set of sensitivity and confidentiality flags that everybody can start to use and share, as well as standard policies/rules based on those flags and other already available data (e.g., condition, test codes, result values, self-pay.) that can become a common superset (not per provider) for patients to express their restrictions/consents in a computable format, yet easy to understand.

IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access (Continued)

HTI-1-PR-TF-2023_ Recommendation – 65

- Recommend that ONC assure that information regarding restrictions on the access, exchange and/or use of health information be **maintained and exchanged** with the restricted information AND support the ability of recipients of data for which a restriction has been requested by the patient to honor such requests insofar as possible.

IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access (Continued)

HTI-1-PR-TF-2023_ Recommendation – 66

- Recommend that ONC, in addition to efforts to support patient restrictions requested under HIPAA, develop future requirements for certified HIT to support the following **four use cases** to respect patient preferences and comport with applicable law.
- The metadata regarding these restrictions should be maintained with the restricted data when the restricted data is subsequently released, at least until such time that a user or the individual determines that the exception is no longer appropriate.
- Also recommend that ONC support the advancement of ongoing work to develop guidelines regarding what metadata should be shared.

IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access (Continued)

HTI-1-PR-TF-2023_ Recommendation – 66 (Continued)

1. When **data flagged as self-pay restricted** at one institution is exchanged, a recipient at another institution should receive metadata regarding the restriction and have the opportunity and technical capability to respect the restriction.

2. When **data flagged as exceptional under the Information Blocking rules** (e.g., invoking the Harm or Privacy exceptions) at one institution is exchanged, a recipient at another institution should receive all available metadata regarding what data was restricted including the exception on which the restriction is based, at what date/time, with any available discrete or free text explanation of why the exception was invoked, as well as the institution and role of the user placing the restriction. The receiving institution should have the technical capability to review and respect the restrictions as applicable.

IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access (Continued)

HTI-1-PR-TF-2023_ Recommendation – 66 (Continued)

3. When **data flagged as restricted from parent/guardian access based on adolescent confidentiality** due to applicable state law at one institution is exchanged, a recipient at another institution should receive all available metadata regarding what data was restricted, at what date/time, with any available discrete or free text explanation of why the restriction was invoked, as well as the institution and role of the user placing the restriction. The receiving institution should have the technical capability to review and respect the restrictions as applicable.

4. Patient or provider **requests to delay or prevent release of data** (e.g., to a portal, API, or VDT access), including restrictions made for a period of time or until a specific event, e.g., review by or with a provider.

IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access (Continued)

HTI-1-PR-TF-2023_ Recommendation – 67

- Recommend that ONC include a requirement that Certified Health IT incorporate patient-facing services which provide patients the ability to use patient-friendly terminology mapped to a concept model to select and place restrictions on the sharing of specific data fields based on patient-identified values within an included data class. ONC should collaborate with patients, providers, health IT developers, and other stakeholders to establish an initial, defined set of sensitivity and confidentiality flags that all parties can initially adopt. The filtering capabilities of Certified Health IT should expand over time as capabilities mature.

Referrals to Annual Report Workgroup for Consideration

Referral Topics and Information

Information Blocking Defined Terms

- ONC should consider clarifying whether non-profit and other private organizations that operate disease or patient registries are considered actors with respect to providing health IT and treated the same as public health with respect to providing access to registry data.

Information Blocking Infeasibility Exception

- ONC should consider and address concerns raised with the 10-day response timeline for determination of infeasibility under the information blocking rule exceptions, as for more complex tissues, his time window may be too short. While there must be clarity on a reasonable and certain response, ONC should explore extending this to 14 days across the board, with the possibility of requiring a single additional extension of 7 or 14 days in case of extenuating circumstances.

Referral Topics and Information

Health IT Capabilities for Data Segmentation and User/Patient Access

- ONC should work with OCR to implement established HITECH provisions for providing patients/representatives with a more comprehensive **accounting of disclosures** of their health information, with the goal of establishing certification criteria.
- Note: This is also listed as Recommendation # 62

Decision Support Interventions (DSI) and Predictive Models

- From the patient and care partner perspective, recommend:
    - ONC more specifically clarify the role and expectation of patients and care partners as stakeholders and co-creators in the future of responsible DSI
    - ONC ensures diverse representation of the patient voice in workgroups and task forces centered around future DSI work, such as consensus around FAVES definitions and defining priority of minimum attributes

Discussion

HITAC Vote