HTI-1 Proposed Rule Task Force 2023

RECOMMENDATIONS ON THE HEALTH DATA, TECHNOLOGY, AND INTEROPERABILITY: CERTIFICATION PROGRAM UPDATES, ALGORITHM TRANSPARENCY, AND INFORMATION SHARING (HTI-1) PROPOSED RULE

Report to the Health Information Technology Advisory Committee

June 15, 2023

TABLE OF CONTENTS

BACKGROUND

The Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule Task Force 2023 has developed these recommendations to the HITAC regarding implementing provisions of the 21st Century Cures Act and making updates to the Office of the National Coordinator (ONC) Health IT Certification Program (Program) with new and updated standards, certification criteria, and implementation specifications in 45 CFR Part 170. The HTI-1 Task Force 2023 has also provided recommendations to the HITAC regarding multiple requests for information (RFI) to inform future rulemaking.

On April 18, 2023, ONC published its Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule. The HTI-1 Proposed Rule would implement the Electronic Health Record (EHR) Reporting Program provision of the 21st Century Cures Act by establishing new Conditions and Maintenance of Certification requirements for health information technology (health IT, HIT) developers under the Program. The Proposed Rule would also make several updates to health IT certification criteria and implementation specifications recognized by the Program, including a revised certification criterion for decision support and revised certification criteria for patient demographics and observations and standards for the transmission of electronic case reporting (ECR). This proposed rule would adopt a new baseline version of the United States Core Data for Interoperability (USCDI). Additionally, this Proposed Rule would provide enhancements to support information sharing under the 21st Century Cures Act information blocking regulations. The Proposed Rule also includes multiple RFIs to inform potential future rulemaking. RFI topic areas include electronic prior authorization, laboratory orders and results interoperability, predictive decision support interventions (DSI), and advanced Fast Healthcare Interoperability Resource (FHIR®) capabilities, among others across parts 170 and 171. As part of this public feedback process, ONC charged the HITAC and the HTI-1 Proposed Rule Task Force 2023 to make specific recommendations on the HTI-1 Proposed Rule.

ONC CHARGE TO HTI-1 PROPOSED RULE TASK FORCE 2023

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
- 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 Clinical Document Architecture (HL7 CDA®) R2 Implementation Guide (IG): C–CDA Templates for Clinical Notes STUR2.1 Companion Guide, Release 3 US Realm
    - A new patient requested restrictions certification criterion
    - Requirements for health IT developers to update 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

ADDITIONAL BACKGROUND INFORMATION

The HTI-1 Proposed Rule Task Force 2023 (Task Force) includes an engaged group of subject matter experts representing various stakeholder groups including direct patient care providers, public health, patients, health IT developers, standards development organizations, and others. The roster included in Appendix A to this document reflects the workgroup's membership at the time these recommendations were finalized.

To assist in the development of these recommendations, the Task Force invited several external subject matter experts to give testimony regarding their areas of expertise, interest, and work. These presenters also responded to questions from Task Force members to inform their deliberations and recommendations. These included:

- On May 3rd, 2023, Grace Cordovano from Enlightening Results presented DSI proposals from the patient & care partner perspective.
- On May 11th, 2023, Hans Buitendijk from Oracle Health (Task Force Member) and Sasha TerMaat from Epic Systems presented information regarding EHRA feedback on Insights Condition and Maintenance of Certification.
- On May 18th, 2023, Riki Merrick from the Association of Public Health Laboratories, Craig Newman from Altarum, Eric Crungnale from Sonic Healthcare and Erin Holt from the Tennessee Department of Health presented information regarding the laboratory data interoperability request for information.
- On May 19th, 2023, Jim Jirjis from HCA Healthcare (Task Force Member) and John Loonsk from Johns Hopkins University discussed steps involved in electronic case reporting and answered questions regarding the proposed technical standards.
- On May 23rd, and May 24th, 2023, Mohammad Jafari discussed health IT capabilities and evolving standards related to data segmentation and patient requested restrictions certification criterion.
- On May 25th, 2023, Shelly Spiro from Pharmacy HIT Collaborative, Margaret Welker from the National Council for Prescription Drug Programs, and Frank McKinney from Point-of Care Partners discussed pharmacy interoperability functionality within the ONC Health IT certification program Including the real-time prescription benefit capabilities RFI.
- On May 25th, 2023, Isaac Vetter from Epic Systems and Bryn Rhodes from Smile Digital Health presented concerning the clinical decision support hooks RFI.

- On June 1st, 2023, Brett Marquard from WaveOne Associates discussed FHIR related topics in RFIs.

RECOMMENDATIONS

INTRODUCTION

The focus of the HTI-1 Proposed Rule Task Force work was to make specific recommendations on the proposals and RFIs contained in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule The following recommendations represent the views of the Task Force regarding particular provisions of HTI-1.

TASK FORCE 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 tables should include the relevant regulatory reference, the common, recognizable name for the standard (e.g., "transmission to a cancer registry"), the name, version number, and URL of the immediate past standard and the date it was last valid; the name, version number, and URL of the current standard, the date it was first required for use, and the date it is scheduled to expire; and the name, version number, and URL of the replacement standard.
    - Rationale: This information is essential for providers, Health IT developers, public health, and other entities as a reference to help plan for implementing changes in standards. It will also support resolving discrepancies between what is currently the standard in regulation and the standard that is being used in practice.

- **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. A benefit of the line-level approach is increased flexibility. An impact may be an increased frequency of application of upgrades necessary to maintain certification, which may result in higher technology adoption costs and increased burden on providers, users, and technology staff to apply, be trained on, and use technology on an ad-hoc, rather than scheduled basis.

- **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. Non-certified technologies may not be able to be updated to incorporate standards changes at the same pace as technologies certified through the ONC program. This may result in incompatibilities and interfere with the successful exchange of information.

- **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.

- Rationale: Current CMS incentive programs utilize the term “Certified Electronic Health Record Technology” (CEHRT), which includes the ONC Base EHR Criteria and additional modular criteria. Specialty EHRs and non-EHR HIT, which may also be modularly certified, may not meet all of the elements necessary to qualify as CEHRT and therefore cannot be used by providers to meet CMS incentive program requirements. Adopting an approach that health IT may be separately certified to each criteria and referenced in a more granular, modular manner by CMS, state, territorial, local, and tribal public health authorities (STLTs), and other regulatory entities may reduce the economic burden of and enhance participation in incentive programs for providers who may not require all of the functions included in products meeting the current definition of CEHRT and/or technology that meets every certification criterion. This approach could increase the uptake of certified HIT across the care continuum and benefit home and community-based services, specialty care, and other provider types as well as their information trading partners, including other providers and public health authorities, by providing assurances, through the certification and compliance with standards, that significant barriers to exchange have been reduced. The adoption of such an approach may be beneficial for facilitating reporting from specialty care to STLTs where utilizing certified HIT is a criterion for program participation.

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.

- **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.
    - Rationale: Not all specialty EHRs or non-EHRs that provide critical patient care support roles in the care continuum need to manage the full range of data elements in the expanding USCDI. Flexibility in allowing specialty EHRs and non-EHRs to view, consume as needed, and make available for exchange USCDI data elements will remove a key adoption barrier for certified HIT in specialty sectors. Not requiring the ability to produce every USCDI data element encourages increased certification participation. Any flexibility in certification must not compromise the interoperability of data. The Task Force notes that certified HIT and USCDI adoption metrics may not be available or comprehensive for specialty EHRs and non-EHRs and recommends gathering insight as necessary via survey, study, and other resources such as the “ONC Approach and Stakeholder Opportunities for Advancing Health IT across the Care Continuum" framework, developed under the Cures Act Section 4001, to understand and address the needs of specialty sectors.

- **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 includes language regarding usage of USCDI V3.

- 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.
    - The Task Force notes that HL7 CDA C-CDA Templates for Clinical Notes STU Companion Guide Release 4 (US Realm) may require additional critical updates in proximity with adoption of the final rule. ONC should consider incorporating the most current version as part of the Final Rule, and if needed, rapid inclusion in the Standards Version Advancement Process (SVAP).

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.

- **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. This approach is necessary to ensure the provider can receive RR messages regardless of the format utilized by the public health authority. Without this type of requirement, the provider may be unduly burdened when satisfying required reporting.

- **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.
    - Rationale: This testing of system interconnectivity is particularly important when not all systems (both sending and receiving) have undergone certification testing. There is currently no certification program regarding public health data systems. As identified in the HITAC Public Health Data Systems Task Force Report, it is critical that the handoff of data between provider and public health information systems be well-tested.

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.

- **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.
    - Certification testing could be accomplished through the use of a test data set that incorporates synthetic patient records containing a wide range of demographic and health condition information, including rare diseases and conditions. DSI training and testing data should be developed in collaboration with provider, patient, research, and health IT stakeholders and made available to all parties in a standardized, computable format.

- **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.

- **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.
    - Rationale: This information is essential for:

- Sharing attribute information, including the relevant coding system, so that DSIs may be readily interfaced with EHRs and other technologies and for HIT Modules to republish attribute information for consumption by apps and other technologies interfaced with the HIT module,
- Providing necessary guidance to HIT developers to facilitate their compliance with transparency requirements,
- Providing access to critical information for providers and patients about DSI availability and performance. To support these activities, the DSI developer should be required to publish attributes toa public, searchable web page, without login requirements and without blocks limiting indexing/spidering by external entities. No access to the actual DSI tool is required, and
- Developing a comprehensive index of available DSI modules.

- **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. This label should include at a minimum DSI data sources, outputs, anticipated benefits, and any limitations in testing of which users should be aware. The development process should inform the development and adoption of additional attributes. Once a format is developed, it should be required for use in all patient-facing interfaces that access DSIs.

- **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. Once that feedback is assessed, risks regarding the application of the DSI to the specified population should be included in relevant warning messages and the DSI "nutrition label" referenced in an earlier Task Force recommendation.

- **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.

- **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." Both are interactions relying on capabilities outside the HIT Module. Any invoked DSI is subject to transparency requirements whether implemented by an HIT developer itself, connected to a HIT Module with a feedback loop, or a hand-off.

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 US 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.

- In order to accomplish this, the Task Force recommends that ONC:
  - 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.
  - 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.
  - 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.
    - Rationale: Despite the HIT certification standards referencing the DS4P CDA data segmentation standard for some time, there has been little real world adoption of this functionality. The new rule should incrementally push the industry forward to the use of the existing standards, which now also support segmentation of FHIR data. As much data is and will be exchanged via V2 and CDA for some time the certification requirements should apply to data regardless of the method of exchange. There are many circumstances where a patient may want to restrict access to or use of their data and these may change over time and by care circumstances.
  - 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.
  - 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.

- **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.

- **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.

- **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.

- **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.
    - Rationale: For developers of certified HIT to provide the required Insights measures to ONC, the developers must have access and authority to produce the measures from their clients' data. For many, this will require updates to their contracts to include such rights. Wider participation could be accelerated by having providers attesting to the use of CEHRT if it includes the ability for their vendors to access the necessary data to generate the Insights measures.

- **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.

- **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.
    - Rationale: The proposed definition references specific encounter types for inclusion, yet the CDA C-CDA and FHIR US Core implementation guides allow for substantially more encounter types within, for example, the branch SNOMED code 308335008. However, four of the five SNOMED encounter types are not in the SNOMED branch referenced. Furthermore, if the intent is to only consider the limited set of encounter types proposed it is not clear that only documents, FHIR API access, and/or transactions related to those encounter types should be counted. This potential limitation would not reflect the full range of interoperability in production.

- **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.

- Rationale: Certified HIT supports a wide variety of FHIR based APIs beyond those in support of USCDI. Insights measures would provide more context if the measures use a common scope of FHIR based APIs across all certified HIT.

- **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.
  - Rationale: Whether documents are duplicates or not, all must be processed, de-duplicated and reconciled. Removal of duplicates from the count does not accurately reflect the volume of documents that is being managed. Furthermore, it is hard to identify duplicate documents as document identifiers alone are not indicative of duplicates. Documents with different document identifiers can actually have duplicative material which requires a full content comparison to verify if the documents are duplicates. The Task Force does not believe that level of precision is necessary for the intended purpose of the measure to identify overall trends of adoption.

- **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.
  - Rationale: Increases or decreases in counts of exchanged documents do not necessarily indicate improvements in interoperability beyond the initial adoption phase. For example, improvements in sharing documents by proactively removing duplicate documents at the source would decrease the count of exchanged documents but improve interoperability. Sharing and re-sharing duplicate documents increases the count but increases burden on the receiver to de-duplicate and reconcile. Rather, measures that focus on the efficiency and effectiveness of de-duplication and reconciliation in combination with volume measures would provide better insights into the advancements in interoperability.

- **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.
  - Rationale: Tools are advancing that reduce the need for human users to review all documents, enabling them to focus on new data they do not have in their HIT that require human decision making, thus reducing burden.

- **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.

- **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.
  - Rationale: This approach will provide information regarding the usage of standards in the field, including data regarding the use of standards adopted through the Standards Version Advancement Process (SVAP). This information is critical in informing industry-wide readiness for the adoption of standards adopted through SVAP.

- **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.

Requests for 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.
    - 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.

- **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.
    - This should be for any device(s) of interest used to perform the test (e.g., test kits, analyzers, test platforms). The collection of these identifiers should be as close to the source as possible and automatically communicated with the result or through the use of barcode scanners.

- **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.
    - This could be accomplished using a mapping knowledge base searchable by IVD manufacturer, Device Identifier, or harmonized lab test method (e.g., SHIELD's proposed Laboratory Interoperability Data Repository).

- **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.
    - Rationale: LOI and LRI are fit for purpose for workflow but would require substantial investment for full implementation.

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.
    - Rationale: RTPB Version 13 includes patient demographic information that may be beneficial for purposes of patient matching and additional functionality not available in RTPB Version 12.

- **HTI-1-PR-TF-2023_Recommendation 42 –** Recommend that ONC require HIT support for both NDC and RxNorm.
    - Rationale: These standards are complementary and provide non-duplicative information.

- **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.

- **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.

- **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.
    - Rationale: The use of CDS Hooks is context sensitive, thus the context is essential to achieve consistent use and predictable interoperability. CDS Hooks v2 is effectively similar to HL7 v2, HL7 v3/CDA, and HL7 FHIR, basic standards that can be implemented differently for the same use case when used without additional guidance.

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.
    - Rationale: Subscription guidance is critical to be provided in the context of specific use cases to ensure consistent use where needed, e.g., the FHIR at Scale Taskforce (FAST) Shared Care Planning and Identity use cases.

- **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.
    - Rationale: Focusing on FHIR R5 would avoid costly re-work in the migration from FHIR R4 to FHIR R5 or 6 as the subscription approach has changed substantially from FHIR R4 to FHIR R4B and then to FHIR R5.

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.
    - Rationale: The SMART Health Links protocol provides a general approach towards utilizing QR codes. The current limitations on the quantity of data that can be encoded with the QR code may limit its utility and diminish advantages over other technology for certain use cases.

Information Blocking Enhancements

Information Blocking (IB) Defined Terms Proposal:

- **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).
    - Rationale: This change is necessary to provide users the flexibility to connect to the data resource in the manner of the user's choosing.

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.
    - Rationale: In addition to declared emergencies this would include response/recovery periods associated with natural disasters that impacted the availability of providers' information systems/data.

2. New Condition: Third Party Seeking Modification Us

- **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.
    - Rationale: ONC should be careful that these provisions aren't interpreted to allow actors covered by the information blocking rules to remain in their current/historical exchange patterns and practices, as the information blocking rules were intended to expand interoperability across a range of requesters and legally allowable use cases.

IB 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.
    - Rationale: Under the proposed TEFCA Exception, the data holder could require exchange via the TEFCA, even if the fees for such exchange are beyond what the requester could afford. This concern is present for all TEFCA use cases but may be of particular concern with respect to individual access use cases, for which no fees are permitted to be charged when the manner of exchange is through certified EHR, FHIR APIs or negotiated, machine-readable format and there is no manual effort involved in facilitating the exchange. The proposal in the NPRM could have the effect of disincentivizing TEFCA participation because a requester who is a TEFCA participant could be forced into paying higher fees as a result.

- **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.

IB Request for Information (RFI) 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.

- **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.

IB RFI 2 – Possible Additional TEFCA Reasonable and Necessary Activities

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

IB RFI 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.

- **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.

- **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.

- **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.
    - Rationale: 42 USC §300jj-12, adding Section 3002(b)(2)(B)(ii) of the 21st Century Cures Act identifies providing patients with an accounting of disclosures as a priority topic for the HITAC, yet the topic remains unaddressed. In 2013, the HIT Policy Committee advanced a set of recommendations to ONC regarding implementation of the original HITECH provisions expanding the HIPAA accounting of disclosure provisions, but those recommendations were not adopted. As exchange purposes and participants increase, e.g., under TEFCA, the transparency afforded by full accounting of disclosures are likely to become more important to individuals. One of the biggest obstacles identified by the HIT Policy Committee in that earlier effort was the lack of an available technological approach for identifying disclosures from a certified EHR The increase in electronic disclosures occurring through networks like HIEs (and ultimately, through TEFCA), which should have the capability to track disclosures/data exchange, should facilitate providing disclosure information to patients upon request.

- **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.

- **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.

- **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.
    - Rationale: Since requested restrictions do not have to be granted, either by the recipient of the request or subsequent recipients of the relevant health information, this gives entities receiving data for which a restriction has been requested an opportunity to review and discuss requested restrictions with the patient/representative and to grant or partially grant such restrictions as deemed appropriate, even if the restriction was not granted or respected by the initial recipient of the request.

- **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 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.
    - (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.

- (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.

- **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.

APPENDIX

TASK FORCE ROSTER

Name	Organization
Steven Lane* (Co-Chair/Group 1 Lead)	Health Gorilla
Steven (Ike) Eichner* (Co-Chair/Group 2 Lead)	Texas Department of State Health Services
Hung S. Luu* (Group 3 Lead)	Children's Health
Medell Briggs-Malonson*	UCLA Health
Hans Buitendijk*	Oracle Health
Hannah Galvin*	Cambridge Health Alliance
Adi V. Gundlapalli**	Centers for Disease Control and Prevention
Jim Jirjis*	HCA Healthcare
Anna McCollister*	Individual
Clem McDonald*	National Library of Medicine
Deven McGraw*	Invitae Corporation
Aaron Miri*	Baptist Health
Eliel Oliveira*	Dell Medical School, University of Texas at Austin
Kikelomo Oshunkentan*	Pegasystems
Naresh Sundar Rajan*	CyncHealth
Fillipe Southerland*	Yardi Systems, Inc.
Sheryl Turney*	Elevance Health

* HITAC MEMBER **FEDERAL REPRESENTATIVE