HTI-1 Proposed Rule Task Force 2023

Group 3: ONC Health IT Certification Program Updates – Insights Condition, Standards Updates, and RFIs
Meeting #6

Hung Luu, Group 3 Lead

Steven Eichner, Co-Chair

Steven Lane, Co-Chair

May 04, 2023

Call to Order/Roll Call

Seth Pazinski, Acting Designated Federal Officer, ONC

HTI-1 Proposed Rule Task Force 2023 – Group 3 Roster

Name	Organization
Steven Eichner* (Co-Chair)	Texas Department of State Health Services
Steven Lane*(Co-Chair)	Health Gorilla
Hung Luu* (Group 3 Lead)	Children's Health
Hans Buitendijk*	Oracle Health
Elaine Johanson**	FDA
Meg Marshall**	Department of Veterans Affairs (VA)
Clem McDonald*	National Library of Medicine
Naresh Sundar Rajan*	CyncHealth
Fillipe Southerland*	Yardi Systems, Inc.

* HITAC Member
** HITAC Federal Representative

Agenda

10:30 AM **Call to Order/Roll Call**
- Seth Pazinski, Acting Designated Federal Officer, ONC

10:35 AM **HTI-1 Proposed Rule Task Force Charge and Timeline Update**
- Hung Luu, Group 3 Lead
- Steven Eichner, Co-Chair
- Steven Lane, Co-Chair

10:40 AM **(USCDI) v3, C-CDA, and FHIR US Core Revisions /Standardized API Updates**
- Carmela Couderc, ONC
- Kyle Cobb, ONC

11:50 AM **Public Comment**
- Seth Pazinski, Acting Designated Federal Officer, ONC

12:00 PM **Adjourn**

HTI-1 Proposed Rule Task Force Charge

Hung Luu, Group 3 Lead

Steven Eichner, Co-Chair

Steven Lane, Co-Chair

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

HTI-1 Proposed Rule Task Force 2023 (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 are due to the HITAC by the end of the 60 day public comment period.

Group 3: ONC Health IT Certification Program Updates– Insights Condition, Standards Updates, and RFIs

- Insights Condition and Maintenance of Certification
- The United States Core Data for Interoperability Standard (USCDI) v3
- C-CDA Companion Guide Updates
- Standardized API for Patient and Population Services
- FHIR US Core Implementation Guide STU version 5.0.1
- Requests for Information

HTI-1 Proposed Rule Task Force Timeline Update

Hung Luu, Group 3 Lead

Steven Eichner, Co-Chair

Steven Lane, Co-Chair

Upcoming Meetings

Month	Task Force/HITAC Meeting Dates	Task Force Topics
May	5/11	• Insights Condition and Maintenance of Certification
	5/17 (HITAC)	• **TF Update**
	5/18	• Requests for Information
	5/25	• Update and Revise Recommendations
June	6/1	• TBD
	6/6 (Full TF)	• Develop Transmittal Report/Slides
	6/7 (Full TF)	• Develop Transmittal Report/Slides
	6/8 (Full TF)	• Develop Transmittal Report/Slides
	6/13 (Full TF)	• Develop Transmittal Report/Slides
	6/15 (HITAC)	• **Final Recommendation and Vote**

ONC | HealthIT ADVISORY COMMITTEE

(USCDI) v3, C-CDA, and FHIR US Core Revisions / Standardized API Updates

HTI-1 Proposed Rule Subgroup 3

Presented by Carmela Couderc, Kyle Cobb

May 4, 2023

Disclaimers and Public Comment Guidance

- The materials contained in this presentation are based on the proposals in the "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing“ proposed rule. While every effort has been made to ensure the accuracy of this restatement of those proposals, this presentation is not a legal document. The official proposals are contained in the proposed rule.

- ONC must protect the rulemaking process and comply with the Administrative Procedure Act. During the rulemaking process, ONC can only present the information that is in the proposed rule as it is contained in the proposed rule. ONC cannot interpret that information, nor clarify or provide any further guidance.

- ONC cannot address any comments made by anyone attending the presentation or consider any such comments in the rulemaking process, unless submitted through the formal comment submission process as specified in the Federal Register.

- This communication is produced and disseminated at U.S. taxpayer expense.

The **What**

… answering the three **“whats”** you want to know

What's In a Name?

Health Data, Technology, and Interoperability:

Certification Program Updates, Algorithm Transparency, and Information Sharing

- **Suffix:** Certification Program Updates, Algorithm Transparency, and Information Sharing
- **Numbering:** One (1)

What's In the Rule?

1. New Regulatory Approach for Certification Criteria ("edition-less")
2. Certification Standards and Functionality Updates
3. Decision Support Interventions (DSI) and Algorithmic Transparency
4. Insights Condition and Maintenance of Certification Requirements (EHR Reporting Program)
5. Information Blocking
6. Opportunities for Comment

What's the Why?

Implementing the 21st Century Cures Act

- EHR Reporting Program
- APIs that allow EHI to be accessed, exchanged, and used without special effort
- Reasonable and necessary activities that do not constitute information blocking

Achieving the goals of the Biden-Harris Administration Executive Orders

- E.O. 13994 "Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats"
- E.O. 13985 "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government" and E.O 14091 "Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government"

Leveraging Health IT and Advancing Interoperability

- HITECH Act
- Interoperability Advancement
- ONC Health IT Certification Program

Certification Standards and Functionality Updates

Select New and Revised Standards and Certification Criteria

- **Standards**
  - United States Core Data for Interoperability Standard Version 3
  - HL7 C-CDA Companion Guide Release 3*
  - HL7 FHIR US Core Implementation Guide 5.0.1*
  - Minimum Standard Code Set Version Updates
    - SNOMED CT, RxNorm, LOINC, NDC, etc.

- **New and Revised Certification Criteria**
  - Electronic Case Reporting § 170.315(f)(5)
  - Clinical Decision Support § 170.315(a)(9)**
  - Standardized API for Patient and Population Services § 170.315(g)(10)
  - ***New*** Patient Requested Restrictions Criteria in § 170.315(d)(14)
  - Patient Demographics and Observations Certification Criterion in § 170.315(a)(5)
  - Updates to Transitions of Care Criterion in § 170.315(b)(1)

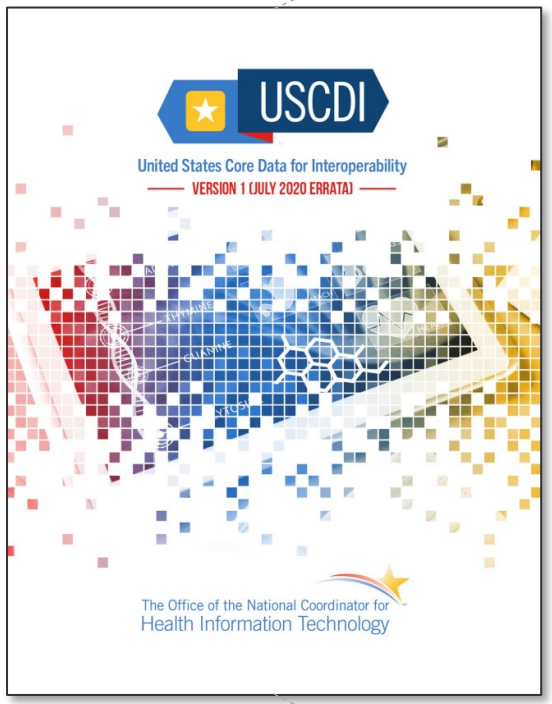
USCDI

* Based on the annual US Core and C-CDA release cycles, we believe *US Core IG v6.0.0* and *C-CDA Companion Guide Release 4* will be published before ONC issues a final rule. It is our intent to consider adopting the updated IGs that support the data elements in USCDI v3 since we propose to adopt USCDI v3 in this rule.

**Not impacted by USCDI v3

USCDI Background

- **Standard established by ONC in the 2020 21st Century Cures Act Final Rule**
- **Minimum dataset required for interoperability**
  - Defines required data elements and vocabulary standards
  - Focuses on *patient access/care coordination* use cases
- **Updated on an annual cycle with federal agency and industry input**
  - Updates based on multiple criteria including standards maturity and public/industry priority



USCDI v1 Summary of Data Classes and Data Elements

Allergies and Intolerances
- Substance (Medication)
- Substance (Drug Class)
- Reaction

Assessment and Plan of Treatment
- Assessment and Plan of Treatment

Care Team Members
- Care Team Members

Clinical Notes
- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals
- Patient Goals

Health Concerns
- Health Concerns

Immunizations
- Immunizations

Laboratory
- Tests
- Values/Results

Medications
- Medications

Patient Demographics
- First Name
- Last Name
- Previous Name
- Middle Name (incl Middle Initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address

Problems
- Problems

Procedures
- Procedures

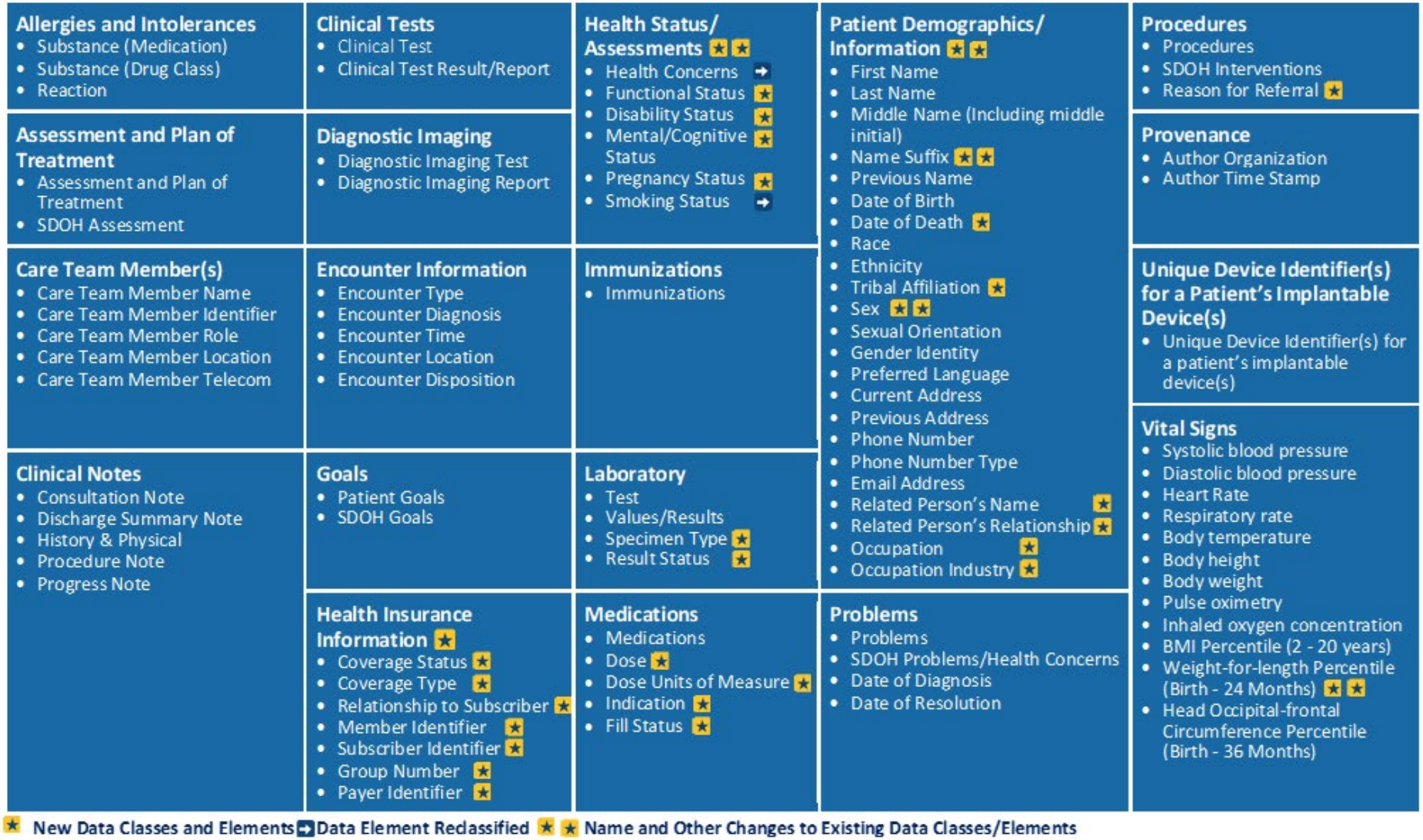
Provenance
- Author Time Stamp
- Author Organization

Smoking Status
- Smoking Status

Unique Device Identifier(s) for a Patient's Implantable Device(s)
- Unique Device Identifier(s) for a Patient's Implantable Device(s)

Vital Signs
- Diastolic Blood Pressure
- Systolic Blood Pressure
- Body Height
- Body Weight
- Heart Rate
- Respiratory Rate
- Body Temperature
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2 - 20 Years)
- Weight-for-length Percentile (Birth - 36 Months)
- Head Occipital-frontal Circumference Percentile (Birth - 36 Months)

USCDI v3


Allergies and Intolerances
• Substance (Medication)
• Substance (Drug Class)
• Reaction
Assessment and Plan of Treatment
• Assessment and Plan of Treatment
• SDOH Assessment
Care Team Member(s)
• Care Team Member Name
• Care Team Member Identifier
• Care Team Member Role
• Care Team Member Location
• Care Team Member Telecom
Clinical Notes
• Consultation Note
• Discharge Summary Note
• History & Physical
• Procedure Note
• Progress Note
Clinical Tests
• Clinical Test
• Clinical Test Result/Report
Diagnostic Imaging
• Diagnostic Imaging Test
• Diagnostic Imaging Report
Encounter Information
• Encounter Type
• Encounter Diagnosis
• Encounter Time
• Encounter Location
• Encounter Disposition
Goals
• Patient Goals
• SDOH Goals
Health Insurance Information
• Coverage Status
• Coverage Type
• Relationship to Subscriber
• Member Identifier
• Subscriber Identifier
• Group Number
• Payer Identifier
Health Status/ Assessments
• Health Concerns
• Functional Status
• Disability Status
• Mental/Cognitive Status
• Pregnancy Status
• Smoking Status
Immunizations
• Immunizations
Laboratory
• Test
• Values/Results
• Specimen Type
• Result Status
Medications
• Medications
• Dose
• Dose Units of Measure
• Indication
• Fill Status
Patient Demographics/ Information
• First Name
• Last Name
• Middle Name (Including middle initial)
• Name Suffix
• Previous Name
• Date of Birth
• Date of Death
• Race
• Ethnicity
• Tribal Affiliation
• Sex
• Sexual Orientation
• Gender Identity
• Preferred Language
• Current Address
• Previous Address
• Phone Number
• Phone Number Type
• Email Address
• Related Person's Name
• Related Person's Relationship
• Occupation
• Occupation Industry
Problems
• Problems
• SDOH Problems/Health Concerns
• Date of Diagnosis
• Date of Resolution
Procedures
• Procedures
• SDOH Interventions
• Reason for Referral
Provenance
• Author Organization
• Author Time Stamp
Unique Device Identifier(s) for a Patient's Implantable Device(s)
• Unique Device Identifier(s) for a patient's implantable device(s)
Vital Signs
• Systolic blood pressure
• Diastolic blood pressure
• Heart Rate
• Respiratory rate
• Body temperature
• Body height
• Body weight
• Pulse oximetry
• Inhaled oxygen concentration
• BMI Percentile (2 - 20 years)
• Weight-for-length Percentile (Birth - 24 Months)
• Head Occipital-frontal Circumference Percentile (Birth - 36 Months)
New Data Classes and Elements
Data Element Reclassified
Name and Other Changes to Existing Data Classes/Elements

United States Core Data for Interoperability (USCDI) v3

- **Proposal:** Adopt USCDI v3 as the new baseline for certification.
  - USCDI v3 to be codified in § 170.213(a).
  - Both USCDI v1 and v3 would be referenced as applicable in § 170.213 *up to and including* December 31, 2024. Only v3 could be used after December 31, 2024.
- **Benefits:** Expanding the data elements and data classes included in USCDI increases the amount of data available to be used and exchanged for patient care.
- **Specifics:** Health IT Modules certified to criteria that reference USCDI would need to update to USCDI v3 by the end of 2024 using the applicable US Core IG and C-CDA Companion Guide:
  - § 170.315(b)(1): Transitions of Care
  - § 170.315(b)(2): Clinical Information Reconciliation and Incorporation
  - § 170.315(b)(9): Care Plan
  - § 170.315(e)(1): View, Download, and Transmit 3rd Party
  - § 170.315(g)(6): Consolidated CDA Creation Performance
  - § 170.315(g)(9): Application Access-All Data Request
  - § 170.315(g)(10): Standardized API for patient and population services
  - § 170.315(d)(14): Patient Requested Restrictions (by January 1, 2026) (new)

C-CDA Companion Guide Updates

- **Proposal:** We propose to adopt C-CDA Companion Guide Release 3 (R3) as a standard to all the criterion related to C-CDA R2.1 starting January 1, 2025
  - ***Note*** *- if C–CDA Companion Guide Release 4 (R4), which supports USCDI v3, is published before the final rule, we* will consider adopting the updated IG

- **Benefits:** Consistent with adoption of previous C-CDA Companion Guides, we expect R3 will:
  - Accommodate new data elements in USCDI v2
  - Provide supplemental guidance and technical clarifications for specifying data in C-CDA R2.1

- **Specifics:**
  - Health IT Modules certified to the criteria below would need to update to C-CDA Companion Guide R3 by January 1, 2025
    - § 170.315(b)(1)(iii)(A): Transitions of Care
    - § 170.315(b)(2)(i), (ii), and (iv): Clinical Information Reconciliation and Incorporation
    - § 170.315(b)(9)(ii): Care Plan
    - § 170.315(e)(1)(i)(A) and (B): View, Download, and Transmit to 3rd Party
    - § 170.315(g)(6)(i): Consolidated CDA Creation Performance
    - § 170.315(g)(9)(i): Application Access—all Data Request
  - The adoption of C-CDA Companion Guide Release 2 expires on January 1, 2025

HL7 FHIR US Core Updates

- **Proposal:** We propose to adopt HL7 FHIR US Core Implementation Guide 5.0.1* as a standard to the Standardized API for Patient and Population Services criterion starting January 1, 2025
  - ***Note** - if HL7 FHIR US Core IG 6.0.0, which supports USCDI v3, is published before the final rule, we* will consider adopting the updated IG
- **Benefits:** Consistent with adoption of previous US Core IGs, we expect 5.0.1 will:
  - Accommodate new data elements in USCDI v2
- **Specifics:**
  - Health IT Modules certified to the criteria below would need to update to HL7 FHIR US Core IG 5.0.1 by January 1, 2025
    - § 170.315(g)(10): Standardized API for Patient and Populations Services
  - The adoption of HL7 FHIR US Core 3.1.1 expires on January 1, 2025

Minimum Standard Code Set Version Updates

Minimum Standard Code Set Version Updates

Proposal

ONC proposes to update minimum code set versions for vocabulary standards used in several certification criteria

Code sets with updated versions in this NPRM:

- SNOMED CT US Edition March 2022
- LOINC Database version 2.7.2, February 16, 2022
- NDC – Vaccine NDC Linker, updates through July 19, 2022
- CDC Race and Ethnicity Code Set Version 1.2 (July 2021)
- RxNorm July 5, 2022 Full Monthly Release

Benefits

This proposal would promote semantic interoperability, accurate quality measure and public health reporting, and support research by:

- Establishing a new, more recent baseline version developers of certified health IT must use for several vocabulary code sets and certification criteria
- Enabling developers of certified health IT to use newer versions of these adopted standards on a voluntary basis as these vocabulary code sets update, which may be several times per year

Updates to Standardized API Requirements: Criterion and Conditions Updates

Revised Criterion: 170.315(g)(10) - Standardized API for Patient and Population Services

- **Proposal(s):** ONC is proposing several revisions to 170.315(g)(10) including:
  - Adoption of new standard baselines for USCDI v3, US Core IG 6.0.0, and SMART App Launch Framework Version 2 (SMART v2)
    - Both SMART v1 and SMART v2 will be available for purposes of certification until January 1, 2025, after which time only SMART v2 will be available for certification
  - Revisions to functional requirements for *authentication and authorization for patient and user scopes* and *token introspection* to be standards-based requirements, leveraging SMART v2
  - Functional clarification for *patient authorization revocation* requiring that revocation occur within 1 hour of a request

- **Benefits:** Together, these proposed revisions would expand the data available through standardized APIs (via USCDI v3, using US Core IG 6.0.0) and require Health IT Modules certified to (g)(10) to adopt the next major release of the SMART App Launch Framework. SMART v2 would include several benefits, such as:
  - Aligning with industry consensus to provide technical improvements and reflect security best practice
  - Improving the authentication and authorization security layer provided by the SMART v1 Guide
  - Enabling increased capabilities and functionality for individuals to share information with apps of their choice in more explicit ways
  - Addressing privacy and security concerns by empowering patients to limit an app's access at a granular level, as they determine

SMART v2 Guide New and Revised Requirements Would Improve Security and Patient Privacy

- Major requirements new to the SMART v2 Guide include:
  - Support for the OAuth 2.0 security extension Proof Key for Code Exchange (PKCE), as well as a revision of the scope syntax.
    - PKCE is an industry standard security extension for OAuth 2.0 to mitigate the known security vulnerability of authorization code interception attacks.
    - The requirement of PKCE especially improves the security of native apps, or apps that operate from an individual's phone or tablet, which were particularly vulnerable to authorization code interception attacks.
  - Revision of the syntax of scopes provided to apps to align with the FHIR interactions of "Create", "Read", "Update", "Delete", "Search", collectively known as "CRUDS"
    - Scopes in SMART v2 are constructed to consist of combinations of five types of permissions corresponding to the CRUDS interactions.
    - The use of this CRUDS scope syntax permits improved patient choice for persistent access as more specific combinations of permissions can be granted to apps as opposed to the scope syntax used in the SMART v1 Guide, which only used two permission types of "read" and "write."

Optional SMART v2 Guide Features ONC Proposes As Required

- As part of this proposal, ONC proposes to adopt several sections specified as “optional” in the SMART v2 Guide as “required” for purposes of the ONC Health IT Certification Program. These include optional requirements that would:
  - Ensure better backward compatibility between SMART v2 and SMART v1 through scopes mapping
  - Improve security with asymmetric client authentication
  - Give patients greater control over their health data with an ability to select granular permissions with fine-grained FHIR resource constraints
  - Empower individuals, clinicians, and other users to deny authorization for online or offline access
  - Facilitate interoperability through a standardized process for token introspection

Scopes Mapping and Asymmetric Authentication

- **Mapping between SMART v1 and SMART v2 scopes**
  - For the purposes of interoperability with existing API deployments implementing the SMART v1 Guide, we propose to require that servers advertise the “permission-v1” capability in their “well-known/smart-configuration” discovery document, return SMART v1 scopes when SMART v1 scopes are requested and granted, and process SMART v1 scopes according to the backward compatibility mapping specified in SMART v2 Guide “3.0.2 Scopes for requesting clinical data.”

- **Asymmetric client authentication for confidential clients**
  - Client authentication is the process by which the authorization server verifies the identity of the client requesting authorization
  - SMART v1 Guide specifies client authentication in terms of symmetric client authentication, in which authentication is based on a secret key shared by both the authorization server and the client
  - SMART v2 specifies asymmetric client authentication as an optional profile, which relies upon public key cryptography for authentication, with the client having public and private keys
  - Asymmetric client authentication would be a security benefit for servers to provide clients the option to use asymmetric client authentication over symmetric client authentication and would improve interoperability for clients by making this API security feature consistently available across § 170.315(g)(10)-certified APIs.

Fine-grained resource constraints using search parameters aka “Granular Scopes”

- **Finer-grained resource constraints using search parameters**
  - This feature uses the FHIR REST API search parameter syntax to specify permissions more granular than the FHIR resource level
    - SMART v1 enabled read/search for Observations
    - SMART v2 enables read/search for laboratory observations, for example, using the “category” search parameter instead of all Observation resources
  - This granular scope functionality would empower patients with greater control over what types of information applications of their choice receive from a Health IT Module; improve patients’ ability to select granular permissions to grant persistent access to applications.
  - However, the SMART v2 Guide leaves this new functionality as optional and does not specify specific search parameter requirements for finer-grained scope constraints
  - We understand that a baseline set of requirements for search parameters for scopes will be developed in the US Core IG v6.0.0 that will guide developers to support a minimum number of search parameters for granular scopes, which we anticipate will be available by mid-2023

Scopes for online refresh tokens and standards-based token introspection

- **Scopes for requesting a refresh token**
  - This functionality would empower individuals, clinicians, and other users to deny authorization for online or offline access by applications of their choice
    - “permission-online” - Can be used to obtain a new access token to replace an expired token, and that will be usable for as long as the end-user remains online
    - “permission-offline” - Can be used to obtain a new access token to replace an expired token, regardless of whether the end-user is online

- **Standards-based token introspection**
  - ONC currently has a token introspection requirement in § 170.315(g)(10)(vii), but this requirement does not specify a standard
    - ONC encouraged industry to coalesce around a common standard, such as OAuth 2.0 Token Introspection (RFC 7662) in Cures Act Final Rule
  - SMART v2 Guide introduces a profile for OAuth 2.0 Token Introspection in “7 Token Introspection,” which would standardize a process for token introspection
  - Adoption of this optional requirement would improve interoperability for FHIR clients and resource servers by defining specific expectations around what information a Health IT Module’s authorization server returns about a token when queried by a client or resource server

Access Token Revocation

- In the ONC Cures Act Final Rule, ONC established a requirement in § 170.315(g)(10)(vi) for Health IT Modules certified to § 170.315(g)(10) to be able to revoke an authorized application's access at a patient's direction
  - This required capability is intended to enable patients to “definitively revoke an application's authorization to receive their EHI until reauthorized, if ever, by the patient” (85 FR 25747).
  - The requirement at § 170.315(g)(10)(vi) was finalized as a functional requirement to allow health IT developers the ability to implement it in a way that best suits their existing infrastructure and allows for innovative models for authorization revocation to develop
  - Industry feedback indicates a lack of specificity in the current requirement has led to some confusion among health IT developers and application developers
- We considered a shorter timeframe, but we concluded that 1 hour would be both an appropriate expectation for developers to meet and would be consistent with industry standards for revocation of an application’s access. We also expect that many or most developers would institute a process that results in revocation of access in a timeframe much less than 1 hour. Investigation into industry best practice leads ONC to believe that a 1-hour requirement to revoke an authorized application’s access at a patient’s direction is an appropriate baseline requirement

Patient Authorization Revocation

- **Proposal:** ONC propose to revise the requirement in § 170.315(g)(10)(vi) to specify that a Health IT Module's authorization server must be able to revoke and must revoke an authorized application's access at a patient's direction within 1 hour of the request.

- **Benefits:** This proposal would provide clarity and create a consistent expectation that developers revoke access within 1 hour of a request, regardless of their internal approach to fulfilling a patient's request to revoke access. This proposal would also assure patients that once requested, an application's access to their data would be revoked within 1 hour.

- **Revised regulation text:** "A Health IT Module's authorization server must be able to revoke and must revoke an authorized application's access at a patient's direction within 1 hour of the request."
  - Industry feedback indicates a lack of specificity in the current functional requirement in § 170.315(g)(10)(vi) has led to some confusion among health IT developers and application developers. ONC believes a 1-hour limit would be both an appropriate expectation for developers to meet and would be consistent with industry standards for revocation of an application's access.
    - We also anticipate that many or most developers would institute a process that results in revocation of access in a timeframe much less than 1 hour.
    - Investigation into industry best practice leads ONC to believe that a 1-hour requirement to revoke an authorized application's access at a patient's direction is an appropriate baseline requirement

API Conditions & Maintenance of Certification Requirements: Enhancing FHIR Endpoint Requirement

- **Proposal(s):** ONC proposes to reference specific standards for publicly publishing service base URLs in § 170.404(b)(2) using HL7 FHIR and US Core IGs. Additionally, developers with Health IT Modules certified to § 170.315(g)(10) would be required to review these URLs quarterly and, as necessary, update.

- **Benefits:** In conjunction with existing requirements that service base URLs for all customers be published at no charge for use, regardless of whether the Health IT Modules certified to § 170.315(g)(10) are centrally managed by the Certified API Developer or locally deployed by an API Information Source, these proposals would:
  - Align industry approaches to publishing service base URLs based on familiar standards
  - Improve the availability of service base URLs for patient access to their information without special effort
  - Ensure that service base URLs are actively monitored for errors or defects and updated, as needed, quarterly
  - Support scalable endpoint directories for Trusted Exchange Framework and Common Agreement (TEFCA)

FHIR Endpoint Specifics

The Acme Example

Experience to-date indicates that the name of the organization associated is typically formatted as free text (i.e., String), with no unique identifier to know which organization is being supported by the service base URL. For example, the organization name given by the endpoint, “Acme Children’s Hospital,” could be mapped to six possible organization names, including “Acme’s Children’s Hospital Anesthesiology,” “Acme’s Children’s Hospital - Urgent Care,” and “Acme Children’s Hospital – Ambulatory Care Center Pharmacy,” among others. This endpoint might map to any one of these organizations, making a definite match difficult to determine. Even more complicated is the possibility of a single endpoint representing all six of the “Acme Children’s Hospital”

- ONC proposes to require that service base URLs must be formatted as follows:
  - “Endpoint” resource format according to the standard adopted in § 170.215(a) (FHIR R4)
  - “Organization” resource formatted according to the implementation specifications adopted in § 170.215(b)(1) (US Core), containing
    - organization name, location, and provider identifiers (e.g., National Provider Identifier (NPI), CMS Certification Number (CCN), or health system ID) for each service base URL
  - Collected in a Bundle resource formatted according to the adopted standard in § 170.215(a) (FHIR R4)
- This information would give the public a standard way of knowing how published “Endpoint” and published “Organization” resources are linked and which organizational details apply to which service base URLs.

Discussion

Hung Luu, Group 3 Lead

Steven Eichner, Co-Chair

Steven Lane, Co-Chair

Task Force Topics Worksheet

Hung Luu, Group 3 Lead

Steven Eichner, Co-Chair

Steven Lane, Co-Chair

Public Comment

To make a comment please

Use the Hand Raise Function

If you are on the phone only, press "*9" to raise your hand

*(Once called upon, press **"*6"** to mute/unmute your line)*

All public comments will be limited to three minutes

You may also email your public comment to onc-hitac@accelsolutionsllc.com

Written comments will not be read at this time,
but they will be delivered to members of the task force and made part of the public record

Upcoming Meetings

Month	Task Force/HITAC Meeting Dates	Task Force Topics
May	5/11	• Insights Condition and Maintenance of Certification
	5/17 (HITAC)	• **TF Update**
	5/18	• Requests for Information
	5/25	• Update and revise recommendations
June	6/1	• TBD
	6/6 (Full TF)	• Develop transmittal report/slides
	6/7 (Full TF)	• Develop transmittal report/slides
	6/8 (Full TF)	• Develop transmittal report/slides
	6/13 (Full TF)	• Develop transmittal report/slides
	6/15 (HITAC)	• **Final Recommendation and Vote**

Adjourn