



HTI-1 Proposed Rule Task Force 2023

Group 3: ONC Health IT Certification Program Updates – Insights Condition, Standards Updates, and RFIs Meeting #15

Hung Luu, Group 3 Lead

Steven Eichner, Co-Chair

Steven Lane, Co-Chair

May 25, 2023





Call to Order/Roll Call

Mike Berry, 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
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**
 - Mike Berry, Designated Federal Officer, ONC

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

- 10:40 AM** **Pharmacy Interoperability Functionality Within the ONC Health IT Certification Program Including Real-Time Prescription Benefit Capabilities RFI**
 - Alex Baker, ONC
 - Carmen Smiley, ONC
 - Shelly Spiro, Pharmacy HIT Collaborative
 - Margaret Weiker, National Council for Prescription Drug Programs
 - Frank McKinney, Point-of Care Partners

- 11:15 AM** **Clinical Decision Support Hooks RFI**
 - Alex Kontur, ONC
 - Isaac Vetter, Epic
 - Bryn Rhodes, Smile Digital Health

- 11:50 AM** **Public Comment**
 - Mike Berry, 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**



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

Alex Baker, ONC

Carmen Smiley, ONC

Shelly Spiro, Pharmacy HIT Collaborative

Margaret Weiker, National Council for Prescription Drug Programs

Frank McKinney, Point-of Care Partners



Disclaimer and Public Comment Guidance

- The materials contained in this document 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 document is not a legal document. The official proposals are contained in the proposed rule. Please note that other Federal, state and local laws may also apply.
- 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.
- This communication is produced and disseminated at U.S. taxpayer expense.



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

- **Overview of RFI:**
 1. Real-Time Prescription Benefit Certification Criterion
 2. Health IT Ecosystem for Pharmacy Interoperability
- **Real-Time Prescription Benefit Certification Criterion Background**
 - Section 119 of the Consolidated Appropriations Act, 2021 (CAA), requires PDP sponsors of prescription drug plans to implement one or more real-time benefit tools (RTBTs) after the Secretary has adopted a standard for RTBTs and at a time determined appropriate by the Secretary.
 - Also amended the definition of a “qualified electronic health record” in section 3000(13) of the PHSA to specify that a qualified electronic health record must include or be capable of including an RTBT.
 - To implement this provision, ONC intends to propose in future rulemaking the establishment of a real-time prescription benefit health IT certification criterion.
 - Requests comment on a criterion to certify health IT to enable a provider to view within the electronic prescribing workflow at the point of care patient-specific benefit, estimated cost information, and viable alternatives.
 - Requests comment on use of the NCPDP Real-Time Prescription Benefit standard version 12 as the basis for this criterion.



RFI Section 1: Real-Time Prescription Benefit Certification Criterion (Detailed Questions)

I. Potential Transactions and Capabilities To Test

- Is the set of testing scenarios described in the RFI appropriate for a real-time prescription benefit certification criterion?
- Should ONC consider other testing scenarios as part of a real-time prescription benefit certification criterion?
- Are there other testing considerations ONC should take into account in structuring a real-time prescription benefit certification criterion?
- What is the value of “negotiated price” to patients and prescribers to aid in their discussions and decision-making during prescribing?

II. Requirements for Use of XML or EDI Format

- Should the real-time prescription benefit certification criterion under consideration only require and test XML format or both XML and EDI formats?



RFI Section 1: Real-Time Prescription Benefit Certification Criterion (Detailed Questions)

III. Requirements for Use of NDC or RxNorm Codes

- Would requiring demonstration of compliance with both NDC and RxNorm in a real-time prescription benefit criterion support improved adoption, maintenance, and harmonization between code sets?
- How would requiring Health IT Modules to demonstrate compliance to both code sets for certification to a real-time prescription benefit criterion affect implementation of this capability? What benefits would this have for health care providers and other participants that support real-time prescription benefit transactions?
- What burden would demonstration of compliance with both code sets impose on developers of seeking or maintaining certification of Health IT Modules to this criterion?
- Would either NDC or RxNorm alone provide sufficient information for applications to provide reliable, accurate clinical decision support, such as dosing guidance, drug-drug interaction or drug allergy checks?
- What would be the consequences (positive or negative, intended or unintended) of establishing “RxNorm as the single source of clinical data for clinical care, research and administrative workflows, replacing NDC for such purposes,” as recommended by the HITAC?



RFI Section 1: Real-Time Prescription Benefit Certification Criterion (Detailed Questions)

IV. ICD–10–CM and SNOMED–CT in the Clinical Segment

- Should ONC require the Clinical Segment in the NCPDP RTPB standard version 12 as part of any future real-time prescription benefit certification criterion?
- Would a requirement to demonstrate use of both ICD–10–CM and SNOMED CT within the Clinical Segment as part of an RTPB certification criterion support a more seamless transition between ICD–10–CM and ICD–11, in the event ICD–11 is adopted? Are there other benefits to requiring certified Health IT Modules demonstrate compliance with both terminologies?
- What additional burden would demonstration of compliance with both ICD–10–CM and SNOMED CT impose on health IT developers seeking or maintaining certification of Health IT Modules to a real-time prescription benefit criterion?



RFI Section 1: Real-Time Prescription Benefit Certification Criterion (Detailed Questions)

V. Patient Specific Benefit Information

- Should ONC require conformance to the Patient Segment specified in NCPDP SCRIPT standard version 2022011 (replacing the NCPDP RTPB standard version 12 Patient (Demographic) Segment) as part of any future real-time prescription benefit certification criterion?
- Would requiring the Patient Segment identified in NCPDP SCRIPT standard version 2022011 as part of a real-time prescription benefit certification criterion support improved patient matching?
- What additional burden would requiring the Patient Segment identified in NCPDP SCRIPT standard version 2022011 as part of a real-time prescription benefit certification criterion impose on health IT developers seeking to certify Health IT Modules to this criterion?
- Should ONC consider requiring alternative or additional demographic data elements or sets of demographic data elements as part of a real-time prescription benefit certification criterion to further improve patient matching? For instance, should ONC consider requiring the Patient Demographics/Information data class identified in USCDI Version 3? What additional benefit would this offer to health IT developers, health care providers, patients, and the healthcare industry in general? What additional burden would these or other alternatives impose on health IT developers?



RFI Section 1: Real-Time Prescription Benefit Certification Criterion (Detailed Questions)

VI. System and Workflow Integration

- How can ONC most effectively address the definition of “qualified electronic health record” in PHSA § 3000(13)(C) as added by the CAA to achieve the benefits of workflow and data integration while minimizing potential burden on health IT developers seeking to certify health IT to the real-time prescription benefit tool criterion?
- Should ONC consider alternative paths to certification to a real-time prescription benefit criterion based on whether a Health IT Module relies on a third-party application or other intermediary to successfully demonstrate full integration and capacity to reuse the data that received from other systems involved in real-time prescription benefit information exchange?
- How should ONC address alignment of a real-time prescription benefit criterion to the electronic prescribing criterion in § 170.315(b)(3)?



RFI Section 1: Real-Time Prescription Benefit Certification Criterion (Detailed Questions)

VII. Real Time Prescription Benefit Certification Scope

- Should ONC require demonstration of support for products that are not defined as medications but may also be included in a RTPB transaction, namely vaccines and medical devices or supplies as part of any future real-time prescription benefit certification criterion?
- What benefits would come from supporting the exchange of prescription benefit information for vaccines, medical devices, or supplies?
- What challenges would be involved in supporting the exchange of prescription benefit information for vaccines, medical devices, or supplies?
- What additional burden would exchange of information on vaccines, medical devices, or supplies as part of a certification criterion impose on health IT developers?



RFI Section 1: Real-Time Prescription Benefit Certification Criterion (Detailed Questions)

VII. Real Time Prescription Benefit Certification Scope (continued)

- To what extent should ONC require as part of certification to a real-time prescription benefit criterion support for devices or supplies as defined within the NCPDP RTPB standard version 12?
- Alternatively, should ONC require conformance to the NCPDP Formulary and Benefit Standard for devices? The NCPDP Formulary and Benefit Standard supports the exchange of UDIs for devices, and adoption of this standard may support other critical RTPB processes. What are effective ways to support accurate device identification within and beyond the real-time prescription benefit workflow, while aligning with FDA regulations and related requirements?
- What additional opportunities might arise from requiring conformance to the NCPDP Formulary and Benefit Standard?



RFI Section 2: Health IT Ecosystem for Pharmacy Interoperability (Detailed Questions)

This section seeks information on formulary and benefit management and electronic prior authorization capabilities that work in tandem with real-time prescription benefit functionality in the context of electronic prescribing workflows.

I. Formulary and Benefit Management

- Should ONC propose a new certification criterion that would enable a user to use a Health IT Module to obtain formulary and benefits information using a more recent NCPDP Formulary and Benefit standard?
- What current challenges do health care providers face in obtaining formulary and benefit information and would a standards-based criterion help to address these challenges?
- Should ONC consider incorporating functionality using the NCPDP Formulary and Benefit standard within the potential real-time prescription benefit criterion discussed above, rather than creating an independent criterion for formulary and benefits functionality?
- What are the key benefits health care providers would likely experience from availability of functionality within certified health IT utilizing the most recent NCPDP Formulary and Benefit standard? If formulary check capabilities have already been widely adopted, how would certification of these capabilities benefit providers?



RFI Section 2: Health IT Ecosystem for Pharmacy Interoperability (Detailed Questions)

II. Electronic Prior Authorization

- Should ONC incorporate certain electronic prior authorization transactions within the “electronic prescribing” certification criterion and should we require certification to these transactions in future rulemaking?

III. Certification Approaches

- If ONC were to propose and finalize additional pharmacy interoperability certification criteria similar to those discussed in this RFI, what would be the challenges of testing each criterion individually?
- Could a bundled approach to testing more than one pharmacy interoperability criterion in a single testing event address these challenges? What other principles or parameters should be applied to such an approach?
- If ONC were to propose an alternate approach to bundled testing for related certification criteria, should such an approach be required for any product a health IT developer seeks to certify to multiple criteria within the bundle, or should it be optional?
- Might there be additional opportunities to reuse testing resources and streamline the testing experience for health IT developers while taking additional steps to ensure that certified health IT is optimized for prescribing safety, efficiency, and usability?



Discussion

Hung Luu, Group 3 Lead

Steven Eichner, Co-Chair

Steven Lane, Co-Chair



Clinical Decision Support Hooks RFI

Alex Kontur, ONC

Isaac Vetter, Epic

Bryn Rhodes, Smile Digital Health



CDS Hooks IG Background

- Two actors: (1) software performing CDS (CDS server/services), (2) software consuming CDS output (CDS client/EHR)
- CDS server provides CDS services defined as “hooks”
 - Includes info about CDS services (e.g. name, where it appears in workflow) & what data the CDS service requires as input (i.e. “context”)
- An event triggers a call from the CDS client to the CDS server to request a CDS service (e.g., clinician orders a medication)
- The CDS client uses HTTP to communicate with the CDS server, providing any information the server needs as input
 - The client can pass FHIR resources or give the server the ability to search for relevant resources using the client’s FHIR API
- The CDS server processes the input and generates a response in the form of a “card”.
 - A card is a JSON object (not FHIR) information the client can render to the user or otherwise process to take some action



FHIR RFI – CDS Hooks

- FHIR CDS Hooks specification:
 - Describes the RESTful APIs and interactions to integrate CDS between CDS Clients (e.g., EHRs) and CDS Services
 - Standardizes a technical approach for calling CDS services from within a workflow
 - Provides a consistent set of capabilities around which CDS developers can design CDS services
- Request for comment:
 - Whether to add a certification criterion for adoption of the FHIR CDS Hooks specification v1.0
 - Specific hooks for implementation
 - Use of CDS Hooks for supporting workflow improvement and reducing provider burden; readiness and feasibility of such use cases



Discussion

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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
June	6/1	<ul style="list-style-type: none">FHIR Subscriptions RFI, FHIR Standard for Scheduling RFI; SMART Health Links RFI
	6/6 (Full TF)	<ul style="list-style-type: none">Develop transmittal report/slides
	6/7 (Full TF)	<ul style="list-style-type: none">Develop transmittal report/slides
	6/8 (Full TF)	<ul style="list-style-type: none">Develop transmittal report/slides
	6/13 (Full TF)	<ul style="list-style-type: none">Develop transmittal report/slides
	6/15 (HITAC)	<ul style="list-style-type: none">Final Recommendation and Vote



HTI-1 Requests for Information Topics by Group

Group 1 – Information Blocking (IB)

- IB RFI 2 – Possible Additional TEFCA Reasonable and Necessary Activities
- IB RFI 3 – Health IT Capabilities for Data Segmentation and User/Patient Access

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

- Laboratory Data Interoperability Request for Information
- Request for Information on Pharmacy Interoperability Functionality Within the ONC Health IT Certification Program Including Real-Time Prescription Benefit Capabilities
- FHIR Subscriptions Request for Information
- Clinical Decision Support Hooks Request for Information
- FHIR Standard for Scheduling Request for Information
- SMART Health Links Request for Information



Adjourn