



# ASTP/ONC HTI-2 Proposed Rule Task Force 2024

## Group 2: Standards and Certification

Mark Sendak, Co-Chair

July 31, 2024





# Call to Order/Roll Call

Peter Karras, Acting Designated Federal Officer, ASTP/ONC

# HTI-2 Proposed Rule Task Force 2024 Roster

## Group 2: Standards and Certification

Name	Organization
<b>Mark Sendak* (Co-Chair)</b>	Duke Institute for Health Innovation
Suresh Balu	Duke Institute for Health Innovation (DIHI)
Hans Buitendijk*	Oracle Health
Steven Eichner*	Texas Department of State Health Services
Rajesh Godavarthi*	MCG Health, part of the Hearst Health network
Mary Beth Kurilo	American Immunization Registry Association (AIRA)
Hung S. Luu*	Children's Health
Meg Marshall**	Department of Veterans Health Affairs
Alex Mugge**	Centers for Medicare and Medicaid Services
Shantanu Nundy	Accolade
Dan Riskin*	Verantos
Fillipe Southerland*	Yardi Systems, Inc.
Naresh Sundar Rajan*	CyncHealth
Sheryl Turney	Elevance Health

\* HITAC Member

\*\* HITAC Federal Representative



# Opening Remarks

Mark Sendak, Co-Chair

# Agenda

- 11:00 AM**     **Call to Order/Roll Call**
  - Peter Karras, Acting Designated Federal Officer, ASTP/ONC
  
- 11:05 AM**     **Opening Remarks**
  - Mark Sendak, Co-Chair
  
- 11:10 AM**     **Modular API Capabilities Certification Criteria in § 170.315(j) + Structure of § 170.315(g)(10)**
  - Jeff Smith, ASTP/ONC
  - John Bender, ASTP/ONC
  - Scott Bohon, ASTP/ONC
  
- 11:40 AM**     **Discussion**
  - Mark Sendak, Co-Chair
  
- 12:00 PM**     **Task Force Recommendation Worksheet**
  - Mark Sendak, Co-Chair
  
- 12:20 PM**     **Public Comment**
  - Peter Karras, Acting Designated Federal Officer, ASTP/ONC
  
- 12:25 PM**     **Next Steps**
  - Mark Sendak, Co-Chair
  
- 12:30 PM**     **Adjourn**



# HTI-2 Proposed Rule Task Force 2024: Charge

**Overarching Charge:** The HTI-2 Proposed Rule Task Force will evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule.

## **Specific Charge:**

- Review and provide recommendations on the HTI-2 proposals on public health, standards and certification, and information blocking and TEFCA.
- Recommendations are due prior to the end of the 60-day public comment period.

## Subgroup 2: Standards and Certification

The Standards and Certification Subgroup will review and provide preliminary recommendations for Task Force consideration on the following HTI-2 proposed rule sections.

- **ONC Health IT Certification Program Updates – 7/24**
  - Standardized API for Patient and Population Services
    - The United States Core Data for Interoperability Version 4 (USCDI v4)
    - SMART App Launch 2.2
    - User-Access Brands and Endpoints
    - Bulk Data Enhancements
    - New Requirements to Support Dynamic Client Registration Protocol in the Program
  - **Modular API capabilities certification criteria in § 170.315(j) + Structure of § 170.315(g)(10) – 7/31**
    - New Certification Criteria for Modular API Capabilities
    - Revised structure for Patient and Population Services Criterion to Align with Modular API Capabilities
  - Patient, Provider, and Payer APIs – 8/7
    - Patient, Provider, and Payer APIs
- Select Revised Certification Criteria and New Certification Criteria – 8/13
  - New Real-Time Prescription Benefit Criterion
  - New Imaging Requirements for Health IT Modules
  - Revised Clinical Information Reconciliation and Incorporation Criterion
  - Revised Electronic Prescribing Certification Criterion
- Security Certification Criteria Revisions – 8/22
  - Multi-factor Authentication Criterion
  - Revised End-User Device Encryption Criterion + related standards
  - Revised Criterion for Encrypt Authentication Credentials
- Conditions and Maintenance of Certification – 8/28
  - Insights
  - Attestations



**Modular API Capabilities Certification Criteria in § 170.315(j) + Structure of § 170.315(g)(10)**

Jeff Smith, ASTP/ONC  
John Bender, ASTP/ONC  
Scott Bohon, ASTP/ONC



# Disclaimers and Public Comment Guidance

- The materials contained in this presentation are based on the proposals in the “Health Data, Technology, and Interoperability (HTI-2): Patient Engagement, Information Sharing, and Public Health Interoperability” 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.
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# Modular API Capabilities Certification Criteria in § 170.315(j) + Structure of § 170.315(g)(10)

# New Certification Criteria to Support Modular API Capabilities § 170.315(j)

## PROPOSAL

ASTP/ONC proposes to add 14 new certification criteria in § 170.315(j) titled “modular API capabilities.”

ASTP/ONC proposes to include 8 new certification criteria that are substantially similar to capabilities currently referenced in the § 170.315(g)(10) API criterion, such as functional registration and SMART app launch user authorization. Five additional criteria in § 170.315(j) reflect API workflow capabilities enabled by the HL7® FHIR® standard, such as HL7® CDS Hooks, SMART Health Cards, and FHIR® Subscriptions.

## BENEFITS

- Promotes the ONC Health IT Certification Program’s modular certification approach and enables different combinations of capabilities across Health IT Modules depending on use case needs.
- Enables more modularity and flexibility for health IT developers that wish to certify to more discrete functions, rather than large, multi-functionality, monolithic certification criteria.
- Supports a growing number of clinical, public health, and administrative use cases. Fosters innovation and competition in these spaces by providing flexibility for modular development approaches among developers of certified health IT.

# Modular API capabilities in § 170.315(j)

Proposed modular API capabilities derived from existing (g)(10) criterion

- **Functional registration**
- **Patient and user authentication**
- **System authentication**

New proposed modular API capabilities

- **Dynamic registration**
- **Certificate-based authentication**
- **Workflow triggers for CDS**
- **Verifiable health records**
- **Subscriptions**

(j)-criteria categories

**Registration**

**Authentication / Authorization**

**API workflow capabilities**

## Registration and SMART authentication / authorization

The following proposed criteria focus on non-standardized registration and SMART App Launch authentication and authorization capabilities:

- (j)(1) Functional registration
- (j)(6) SMART App Launch user authorization
- (j)(7) SMART Backend Services system authentication and authorization
- (j)(9) SMART Patient Access for Standalone Apps
- (j)(10) SMART Clinician Access for EHR Launch

## Dynamic registration and certificate-based authentication

The following proposed criteria focus on capabilities from the HL7 UDAP Security IG v1 including standardized dynamic registration, and certificate-based authentication and authorization capabilities:

- (j)(2) Dynamic registration
- (j)(5) Asymmetric certificate-based authentication for patient access
- (j)(8) Asymmetric certificate-based system authentication and authorization
- (j)(11) Asymmetric certificate-based authentication for B2B user access

# API workflow capabilities

The following proposed criteria focus on capabilities supporting standardized information access via specific API workflows:

- (j)(20) Workflow triggers for decision support interventions – clients
- (j)(21) Workflow triggers for decision support interventions – services
- (j)(22) Verifiable health records
- (j)(23) Subscriptions – server
- (j)(24) Subscriptions – client

## Workflow triggers for decision support interventions at § 170.315(j)(20) and (j)(21)

- We propose to adopt the CDS Hooks IG v2 at § 170.215(f)(1).
- We propose two certification criteria to support workflow triggers using the CDS Hooks IG v2:
  - (j)(20) criterion includes requirements for “clients” participating in API-based workflow triggers for decision support
  - (j)(21) criterion includes requirements for “services” providing decision support services to clients.
- We note that the proposed workflow triggers criteria in (j)(20) and (j)(21) do not define or propose specific workflows associated with decision support, including how and when clinicians use decision support capabilities.
- Rather, we propose to include standards-based interfaces in (j)(20) and (j)(21) to enable clinical systems to call other systems offering decision support services in a standardized manner to support the exchange and use of these services.



## Verifiable health records at § 170.315(j)(22)

- We propose to adopt the SMART Health Cards Framework version 1.4.0 standard (“SMART Health Cards”) in § 170.215(g)(1)(i).
- We propose that health IT certified to (j)(22) support the issuance of verifiable health records according to SMART Health Cards.
- We also propose to adopt the SMART Health Cards: Vaccination and Testing Implementation Guide version 1.0.0-rc – STU 1 Release Candidate in § 170.215(g)(2)(i).
- This IG leverages the SMART Health Cards Framework to describe standards-based methods for the issuance of verifiable health records for vaccination status and infectious disease-related laboratory testing.
- We are also aware that the SMART Health Cards standard is going through the ballot and publication process at HL7 over the next several months. If there is a published version of the SMART Health Cards standard prior to the publication of the final rule, we will consider adopting that version.

## Subscriptions at § 170.315(j)(23) and (j)(24)

- We propose to adopt the HL7 FHIR Subscriptions R5 Backport Implementation Guide version 1.1.0 (“Subscriptions IG”) in § 170.215(h)(1).
- We propose that health IT certified to (j)(23) or (j)(24) support API-based subscriptions according to HL7 FHIR Subscriptions Framework in the Subscriptions IG.
- The proposals in (j)(23) and (24) specify constraints on the Subscriptions IG to ensure health IT certified to (j)(23) or (24) can conform to separate but related aspects and functions of the Subscriptions IG.
- Similar to the proposals in (j)(20) and (21), we propose that Health IT Modules certified to (j)(23) support subscriptions as a “server” and Health IT Modules certified to (j)(24) support subscriptions as a “client”

## (j)(23) Subscriptions – server requirements

This proposed criterion requires support for subscriptions for the following data, including notifications and filters for notifications:

- **USCDI change notifications:** patient
- **AllergyIntolerance:** category, code, patient
- **CarePlan:** category, subject
- **CareTeam:** category, subject
- **Condition:** category, code, subject
- **Coverage:** beneficiary, type
- **DiagnosticReport:** category, code, subject
- **DocumentReference:** subject, type
- **Encounter:** reasonCode, subject, type
- **Goal:** category, description, subject
- **Immunization:** patient, vaccineCode
- **MedicationDispense:** category, medication[x], subject
- **MedicationRequest:** category, medication[x], subject
- **Observation:** category, code, subject
- **Patient:** identifier
- **Procedure:** category, code, subject
- **QuestionnaireResponse:** subject
- **RelatedPerson:** patient
- **ServiceRequest:** category, code, subject
- **Specimen:** patient, type

## (j)(23) Subscriptions – server requirements (continued)

- We seek public comment on the listed US Core resources proposed in § 170.315(j)(23)(v)(B) [see the previous slide].
- **Alternative Proposal:** We alternately propose to require client servers to support the ability for a client to subscribe to notifications filtered by all, meaning any, USCDI / US Core resources for “category,” “code,” and “subject” data elements where applicable.

# API criteria organizational patterns

## The (g)(10) – (35) criteria proposals:

- Generally follow a similar structure
- Reference (j)-criteria requirements in **Registration** and **Authentication / Authorization** sections
- Have tailored **Information Access** requirements to support the criterion's use case
- May include (j)-criteria references for **API workflow capabilities**

**Registration**

**Authentication / Authorization**

**Information Access**

**API workflow capabilities**

# Example API criterion referencing (j)-criteria

## (j)-criteria

### Registration

(j)(1)	Functional registration
(j)(2)	Dynamic registration

### Authentication / Authorization

(j)(6)	SMART user auth
(j)(7)	SMART backend auth
...	...

### API workflow capabilities

(j)(20)	Workflow triggers for DSI – clients
(j)(21)	Workflow triggers for DSI – services
...	...

## Illustrative (g)-criterion

### Registration

(j)(1)	Functional registration
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### Authentication / Authorization

(j)(7)	SMART backend auth
(j)(9)	SMART auth for patient access
(j)(10)	SMART auth for clinician access

### Information access

Tailored information access requirements:

- Support for HL7 FHIR R4 Resources or support for specific aspects of an IG (SMART app launch or CRD)

### API workflow capabilities

(j)(20)	Workflow triggers for DSI - clients
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# Revised (g)(10) Criterion: Patient and User Access

## Registration

(j)(1)	Functional registration
(j)(2)	Dynamic registration

## Authentication / Authorization

(d)(13)	Patient-facing multi-factor authentication
(j)(9)	SMART auth for patient access
(j)(5)	Certificate-based auth for patient access
(j)(10)	SMART auth for clinician access
(j)(11)	Certificate-based auth for B2B user access

## Information access

-	US Core read and search API
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## API workflow capabilities

(j)(22)	Verifiable health records
(j)(23)	Subscriptions

# Revised (g)(10) Criterion: System Access

## Registration

(j)(1)	Functional registration
(j)(2)	Dynamic registration

## Authentication / Authorization

(j)(7)	SMART backend auth
(j)(8)	Certificate-based system auth

## Information access

-	US Core read and search API
-	Bulk Data group export

## API workflow capabilities

(j)(23)	Subscriptions
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# Discussion

Mark Sendak, Co-Chair



# Task Force Recommendation Worksheet

Mark Sendak, 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](mailto: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*



# Next Steps

Mark Sendak, Co-Chair

# Upcoming Meetings

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## Task Force Meeting Date/Time

8/7 11 AM-12:30 PM

8/13 2-3:30 PM

8/22 1-2:30PM

8/28 11AM-12:30 PM

9/3 11 AM-12:30 PM (Full Task Force Meeting)

9/4 11AM-12:30 PM (Full Task Force Meeting)

9/5 11 AM-12:30 PM (Full Task Force Meeting)

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## HITAC Meeting Date

8/15 TF provides updates to HITAC

9/12 TF delivers recommendations to HITAC

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**Adjourn**