ASTP HTI-2 Proposed Rule Task Force 2024

Group 2: Standards and Certification

Mark Sendak, Co-Chair

August 13, 2024

Call to Order/Roll Call

Seth Pazinski, Designated Federal Officer, ASTP

HTI-2 Proposed Rule Task Force 2024 Roster Group 2: Standards and Certification

Name	Organization
Mark Sendak* (Co-Chair)	Duke Institute for Health Innovation
Suresh Balu	Duke Institute for Health Innovation
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

2:00 PM   **Call to Order/Roll Call**
- Seth Pazinski, Designated Federal Officer, ASTP

2:05 PM   **Opening Remarks**
- Mark Sendak, Co-Chair

2:10 PM   **New Imaging Requirements for Health IT Modules, Revised Clinical Information Reconciliation and Incorporation, and Revised Security Certification Criteria**
- Robert Anthony, Director, Certification & Testing Division, ASTP
- Jeffrey Smith, Deputy Director, Certification & Testing Division, ASTP

2:20 PM   **Discussion**
- Mark Sendak, Co-Chair

2:30 PM   **Task Force Recommendation Worksheet**
- Mark Sendak, Co-Chair

3:20 PM   **Public Comment**
- Seth Pazinski, Designated Federal Officer, ASTP

3:25 PM   **Next Steps**
- Mark Sendak, Co-Chair

3:30 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

- Select Revised Certification Criteria and New Certification Criteria – 8/13
    - New Imaging Requirements for Health IT Modules
    - Revised Clinical Information Reconciliation and Incorporation Certification Criterion
    - Multi-factor Authentication Certification Criterion
    - Revised End-User Device Encryption Certification Criterion + related standards
    - Revised Certification Criterion for Encrypt Authentication Credentials
- Electronic Prescribing and Real-Time Prescription Benefit – 8/22
    - Revised Electronic Prescribing Certification Criterion
    - New Real-Time Prescription Benefit Certification Criterion
- Conditions and Maintenance of Certification – 8/28
    - Insights
    - Attestations

New Imaging Requirements for Health IT Modules, Revised Clinical Information Reconciliation and Incorporation, and Revised Security Certification Criteria

Robert Anthony, Director, Certification & Testing Division, ASTP

Jeffrey Smith, Deputy Director, Certification & Testing Division, ASTP

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.

- The Assistant Secretary for Technology Policy/Office of the National Coordinator for Health IT (hereafter ASTP) must protect the rulemaking process and comply with the Administrative Procedure Act. During the rulemaking process, ASTP can only present the information that is in the proposed rule as it is contained in the proposed rule. ASTP cannot interpret that information, nor clarify or provide any further guidance.

- ASTP 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.

New Imaging Requirements for Health IT Modules

PROPOSAL

- ASTP proposes to revise the certification criteria found at § 170.315(b)(1) "transitions of care", § 170.315(e)(1) "view, download, and transmit", § 170.315(g)(9) "application access—all data request", and § 170.315(g)(10) "standardized API for patient and population services" to include certification requirements to support access, exchange, and use of diagnostic images via imaging links.

- ASTP is not proposing a specific standard associated with the support of this functionality, and notes that this requirement can be met with a context-sensitive link to an external application which provides access to images and their associated narrative.

- ASTP proposes by January 1, 2028, a health IT developer of a Health IT Module certified to any of the aforementioned certification criteria must update their Health IT Module and provide the updated version to their customers to maintain certification of that Health IT Module.

BENEFITS

Diagnostic images are often stored in systems external to an EHR, such as picture archiving and communication systems (PACS) and vendor neutral archives (VNA). ASTP believes that promoting access to and the exchange of images via ONC Health IT Certification Program requirements may encourage more widespread adoption and integration of these already existing pathways and reduce burdens caused by physical media exchange (e.g., CD-ROMs).

Revised Clinical Information Reconciliation and Incorporation Criterion

PROPOSAL

- ASTP proposes two options for revising the "clinical information reconciliation and incorporation" (CIRI) certification criterion in § 170.315(b)(2) to expand the number and types of data elements that Health IT Modules certified to this criterion would be required to reconcile and incorporate:

  - Primary proposal: Require CIRI of all USCDI data elements.

  - Alternative proposal: Require CIRI of a limited set of additional USCDI data elements.

- ASTP additionally proposes adding a new functional requirement to enable user-configured and rules-based automatic CIRI

BENEFITS

- Support for longitudinal patient record.

- New capabilities that would benefit providers by reducing the burden of reconciliation and incorporation in clinical workflows.

Multi-Factor Authentication

ASTP proposes to revise the "multi-factor authentication" (MFA) certification criterion in § 170.315(d)(13) and accordingly update the affected criteria and the privacy and security certification framework in § 170.550(h). The proposed updates would revise the MFA criterion by replacing the current "yes" or "no" attestation requirement with a specific requirement to support multi-factor authentication and configuration for three certification criteria:

- "view, download, transmit" (§ 170.315(e)(1));
- "standardized API for patient and population services" (§ 170.315(g)(10)) (for "patient-facing" access);
- and "electronic prescribing" (§ 170.315(b)(3)).

BENEFITS

- ASTP believes these updates match industry best practices for information security, particularly for important authentication use cases in health IT.

Revised End-User Device Encryption Criterion + Related Standards Proposals

PROPOSAL

- ASTP proposes to revise § 170.315(d)(7) to include a new requirements that Health IT Modules certified to this criterion encrypt personally identifiable information (PII) stored on end-user devices and server-side.

- Additionally, ASTP proposes to adopt the latest NIST FIPS Annex A approved algorithms for encryption in § 170.210(a), updating from the October 8, 2014, version to the October 12, 2021, version.

BENEFITS

- Encryption of server-side data prevents unauthorized data access in many scenarios, including those involving a server breach, theft, or improper disposal.

- Improved security by updating ASTP requirements to align the latest NIST approved encryption algorithms.

Revised Criterion for Encrypt Authentication Credentials

PROPOSAL

ASTP proposes to revise the "encrypt authentication credentials" certification criterion in § 170.315(d)(12).

ASTP proposes to replace the current "yes" or "no" attestation requirement with a requirement for Health IT Modules that store authentication credentials to protect the confidentiality and integrity of its stored authentication credentials according to the NIST Federal Information Processing Standards (FIPS) 140-2 (Draft, October 12, 2021) standard approved security functions. ASTP also proposes to change the name of this criterion to "protect stored authentication credentials," which would more appropriately describe the revised criterion.

BENEFITS

• Promotes protection of stored authentication credentials according to NIST standards.

• Critical defensive step to help ensure that stolen or leaked authentication credentials are useless to an attacker.

Discussion

Mark Sendak, Co-Chair

Task Force Recommendation Worksheet

Mark Sendak, Co-Chair

Discussion Time

Row	Select Revised Certification Criteria and New Certification Criteria including:	Time (50 minutes)
33	New Imaging Requirements for Health IT Modules	15
34	Clinical Information Reconciliation and Incorporation	15
35	Multi-factor authentication certification criterion	7
36	End-user device encryption certification criterion + related standards	7
37	Certification criterion for encrypt authentication credentials	6

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

Next Steps

Mark Sendak, Co-Chair

Upcoming Meetings

Task Force Meeting Date/Time
8/22 1-2:30 PM
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)

HITAC Meeting Date
8/15 TF provides updates to HITAC
9/12 TF delivers recommendations to HITAC

Register for 8/15 HITAC Meeting at: https://www.healthit.gov/hitac/events/health-it-advisory-committee-71

Adjourn