ASTP HTI-2 Proposed Rule Task Force 2024

Group 2: Standards and Certification

Mark Sendak, Co-Chair

August 7, 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

11:00 AM   **Call to Order/Roll Call**
- Seth Pazinski, Designated Federal Officer, ASTP

11:05 AM   **Opening Remarks**
- Mark Sendak, Co-Chair

11:10 AM   **Patient, Provider, and Payer APIs**
- Jeff Smith, ASTP

11:25 AM   **Discussion**
- Mark Sendak, Co-Chair

11:40 AM   **Task Force Recommendation Worksheet**
- Mark Sendak, Co-Chair

12:20 PM   **Public Comment**
- Seth Pazinski, Designated Federal Officer, ASTP

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
  - <mark>Patient, Provider, and Payer APIs – 8/7</mark>
    - Patient, Provider, and Payer APIs

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

Patient, Provider, and Payer APIs

Jeff Smith, 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.

- 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.

Patient, Provider, and Payer API Capabilities

PROPOSAL

ASTP proposes a set of certification criteria in § 170.315(g)(30) through (36). These proposed certification criteria reference a set of FHIR implementation specifications that ASTP proposes to adopt, on behalf of the Secretary, in § 170.215.

BENEFITS

- The proposed certification criteria align with CMS-established API requirements and recommendations and would enable implementers to ensure that APIs developed to meet the CMS regulations adhere to relevant interoperability standards and support other features important to effective information sharing.

- Reduce burden associated with certain administrative processes.

- Increase patient and provider access to important health care data held by payers.

Patient Access API

PROPOSAL

ASTP proposes to adopt the "Patient access API" certification criterion in § 170.315(g)(30) to specify requirements for health IT that can be used by payers to enable patients to access health and administrative information using a health application of their choice, including payer drug formulary information, and patient clinical, coverage, and claims information.

Proposes to reference standards including CARIN Blue Button IG, Da Vinci PDex IG, Da Vinci US Drug Formulary IG, and the US Core IG.

BENEFITS

- Access to data held by payers can increase patient understanding of their health and health care, helping patients to be more informed when making decisions about their care.

- Aligns with CMS requirements for payers to establish Patient Access APIs originally finalized in CMS' Interoperability and Patient Access final rule.

Provider Access API

PROPOSAL

ASTP proposes to adopt the "Provider access API – client" and "Provider access API – server" certification criteria at § 170.315(g)(31) and (g)(32) to specify requirements for provider and payer systems to support provider access to payer information. This information can include patient clinical, coverage, and claims information.

Proposes to reference standards including CARIN Blue Button IG, Da Vinci PDex IG, and US Core IG.

ASTP proposes to include the "Provider access API – client" in the Base EHR definition.

BENEFITS

- Provider access to data held by payers about their patients can help inform better care coordination as well as higher quality care and can support provider participation in value-based care.

- Aligns with CMS requirements for payers to establish a Provider Access API finalized in CMS' Interoperability and Prior Authorization final rule.

Payer-to-Payer API

PROPOSAL

ASTP proposes to adopt a "Payer-to-payer API" certification criterion in § 170.315(g)(33) to specify requirements for health IT that can be used by payers to support electronic exchange between payer systems.

Proposes to reference standards including CARIN Blue Button IG, Da Vinci PDex IG, and US Core IG.

BENEFITS

- The exchange of patient information between payers can allow health information to follow a patient when they switch insurance plans and can enable improved coordination of care, increased patient empowerment, and reduced administrative burden.

- Aligns with CMS requirements for payers to establish Payer-to-Payer Access APIs originally finalized in CMS' Interoperability and Patient Access and final rule and updated in the Interoperability and Prior Authorization final rule.

Prior Authorization API – Provider and Payer

ASTP proposes to adopt "Prior authorization API – provider" and "Prior authorization API – payer" certification criteria in § 170.315(g)(34) and (g)(35).

The proposed provider certification criterion specifies requirements for providers to request coverage requirements and assemble and submit documentation for prior authorization, while the payer criterion supports payers' ability to provide information about coverage and documentation requirements and receive prior authorization requests from providers.

Proposes to reference standards including Da Vinci Coverage Requirements Discovery IG, Da Vinci Documentation Templates and Rules IG, and Da Vinci Prior Authorization Support IG.

BENEFITS

- These criteria have the potential to reduce administrative burden associated with the largely manual prior authorization process which exists today.

- By streamlining the electronic prior authorization process, patients can receive more rapid information about whether treatments are approved, increasing

- Criteria align with CMS requirements for payers to establish Prior Authorization APIs, and with requirements for participants in the Promoting Interoperability programs to report on new Prior Authorization measures, both finalized in CMS' Interoperability and Prior Authorization final rule.

Provider Directory API – Health Plan Coverage

PROPOSAL

ASTP proposes to adopt a "Provider directory API – health plan coverage" certification criterion in § 170.315(g)(36), which specifies technical requirements for health IT that can be used by payers to publish information regarding the providers that participate in their networks.

Proposes to reference standards including Da Vinci PDex Plan Net IG.

BENEFITS

- Ability for patients to understand which providers, facilities, and pharmacies are covered by their current or future plan can improve patients' ability to find the right provider and health care plan.

Discussion

Mark Sendak, Co-Chair

Discussion

Row	Topic	Summary	Time (60 min)
24	**Patient, Provider, and Payer APIs**	ONC proposes a set of certification criteria in § 170.315(g)(30) through (36) that aim to complement and advance the policies that CMS has developed to increase patient, provider, and payer access to information. Health IT developers, including those that support payers, would be able to ensure that Health IT Modules certified to these proposed criteria, when used to satisfy the CMS requirements, have been tested for conformance with widely available industry standards designed to support interoperability for each use case. Proposes to adopt a set of HL7® FHIR® IGs in § 170.215 to support these certification criteria, and to incorporate these specifications by reference in § 170.299.	n/a
25	§ 170.315(g)(30)	Proposes to adopt a "patient access API" certification criterion in § 170.315(g)(30) to specify requirements for Health IT Modules that can enable patients to access their health and administrative information by using a health application of their choice.	8 min
26	§ 170.315(g)(31)	Proposes that a Health IT Module certified to the "provider access API – client" in § 170.315(g)(31) support specified capabilities to enable a provider to request and receive patient clinical and coverage information from a payer and receive and process the response.	16 min
27	§ 170.315(g)(32)	Proposes that a Health IT Module certified to the "provider access API – server" certification criterion in § 170.315(g)(32) would support capabilities to enable providers to request and receive patient health history and coverage information from payers.	
28	§ 170.315(g)(33)	Propose to adopt a "payer-to-payer API" certification criterion in § 170.315(g)(33) to specify requirements for Health IT Modules that can be used by payers to support electronic exchange between payer systems when patients transition between payers.	9 min
29	§ 170.315(g)(34)	Proposes to adopt a "prior authorization API – provider" certification criterion in § 170.315(g)(34), which establishes requirements for Health IT Modules that can be used to facilitate a provider's request of coverage information and request for a prior authorization decision.	9 min
30	§ 170.315(g)(35)	Proposes to adopt a complementary "prior authorization API – payer" certification criterion in § 170.315(g)(35), which establishes requirements for Health IT Modules that can be used by a payer to accept prior authorization requests from a provider, send requested documentation and coverage information, and send prior authorization decisions.	18 min
31	§ 170.315(g)(36)	Proposes to adopt a "provider directory API – health plan coverage" certification criterion in § 170.315(g)(36) which would specify technical requirements for Health IT Modules that can enable publishing of information regarding the providers that participate in a payer's network.	

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

*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
8/13 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)

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

Adjourn