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

Mark Sendak, Co-Chair

August 28, 2024

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 **Conditions and Maintenance of Certification Requirements**

- Vaishali Patel, Deputy Director of Technical Strategy and Analysis Division, ASTP

- Sara McGhee, Policy Analyst, Regulatory and Policy Affairs, ASTP

11:20 AM **Discussion**

- Mark Sendak, Co-Chair

11:25 AM **Task Force Recommendation Sheet**

- Mark Sendak, Co-Chair

12:20 PM **Public Comment**

- Seth Pazinski, Designated Federal Officer, ASTP

12:25 PM **Next Steps**

- Mark Sendak, Co-Chair

2:30 PM **Adjourn**

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

* HITAC Member
** HITAC Federal Representative

Opening Remarks

Mark Sendak, Co-Chair

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.

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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.

- o Standardized API for Patient and Population Services 7/24
    - 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

- o 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

- o Patient, Provider, and Payer APIs – 8/7

- o 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

- o Electronic Prescribing and Real-Time Prescription Benefit – 8/22
    - Revised Electronic Prescribing Certification Criterion
    - New Real-Time Prescription Benefit Certification Criterion

- o <mark>Conditions and Maintenance of Certification – 8/28</mark>
    - Insights
    - Attestations

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Conditions and Maintenance of Certification Requirements

Vaishali Patel, Deputy Director of Technical Strategy and Analysis Division, ASTP

Sara McGhee, Policy Analyst, Regulatory and Policy Affairs, 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.

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

HTI-2: Insights Condition Proposals

Vaishali Patel, ASTP

Agenda

→ **Overview of Insights Condition**

→ **HTI-2 Proposals**

- Process for Reporting Updates

- Minimum Reporting Qualifications

- Measure Updates

HTI-1: Insights Condition

Insights Condition and Maintenance of Certification

EHR Reporting Program	▸▸▸▸▸	Insights Condition

The Cures Act laid the foundation for transparent reporting:

- Established the requirement to create an Electronic Health Record (EHR) Reporting Program to provide transparent reporting to measure the performance of certified health IT

- Specified its implementation as part of a Condition and Maintenance of Certification for developers of certified health IT

Insights Condition provides transparent reporting that:

- Addresses information gaps in the health IT marketplace

- Provides insights on the use of specific certified health IT functionalities

- Provides information about consumers' experience with certified health IT

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Insights Condition: Measures and Related Criteria

AREA	MEASURE	RELATED CRITERION/CRITERIA
Individuals' Access to EHI	Individuals' Access to Electronic Health Information Through Certified Health IT	§§ 170.315(e)(1) and (g)(10)
Clinical Care Information Exchange	C-CDA Problems, Medications, and Allergies Reconciliation and Incorporation Through Certified Health IT	§ 170.315(b)(2)
Standards Adoption & Conformance	Applications Supported Through Certified Health IT	§ 170.315(g)(10)
Standards Adoption & Conformance	Use of FHIR in Apps Through Certified Health IT	§ 170.315(g)(10)
Standards Adoption & Conformance	Use of FHIR Bulk Data Access Through Certified Health IT	§ 170.315(g)(10)
Public Health Information Exchange	Immunization Administrations Electronically Submitted to Immunization Information Systems Through Certified Health IT	§ 170.315(f)(1)
Public Health Information Exchange	Immunization History and Forecasts Through Certified Health IT	§ 170.315(f)(1)

Note: Metrics associated with the measures are described in the measure specification sheets published on ONC's website.

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HTI-2 Proposals

Process for Reporting

Finalized in HTI-1: Report the percentage of total customers as represented by hospitals for products used in inpatient settings and clinician users for products used in outpatient settings, that are included in their reported data for each metric for which developers submit a response.   This provides transparency regarding the degree to which the data are complete.

HTI-2 Proposal: Require developers of certified health IT to provide health care provider identifiers (e.g., National Provider Identifier (NPI), CMS Certification Number (CCN), or other type of unique national identifier) for providers included in the data submitted. The additional health care provider identifier information would help determine the representativeness of the data.

- Open to considering other alternatives that provide transparency on the completeness and representativeness of the data provided while reducing burden.
  - Remove requirement for developers to provide the percentage of total customers that are represented in the data and instead only require developers to provide health care provider identifiers for providers included in the data submitted.
  - Request comments for alternatives that may shift measurement from provider-based measures to patient-centered measures such as percentage and/or number of encounters or patients included in the data

Process for Reporting

Clarifications

- Developers to assess whether they meet Insights Condition requirements as of January 1st of the data collection period
  - Similar to real world testing reporting requirements which has a specified date for all developers to assess their eligibility

- If developers update their certified health IT using Inherited Certified Status after January 1st of the year prior in which the responses are submitted, a health IT developer must include the newer version of the certified Health IT Module(s) in its annual responses to the Insights Condition of Certification.

- All developers must provide responses to the Insights Condition of Certification on an annual basis regardless of how long a developer has or has had an active certification under the Program.

- Documentation must be available via a publicly accessibly hyperlink for both required and optional documentation.
  - This process is consistent with other documentation reporting processes that are part of the Certification Program

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Process for Reporting

Minimum Reporting Qualifications

- HTI-1 finalized that developers must have at least 50 hospital sites or 500 individual clinician users across the developer's certified health IT to report on the measure. We propose to revise this by removing the term "sites" from hospital sites as the term could be misinterpreted.

- Provide a definition for hospitals and clinician users
  - We seek to define those terms broadly and don't wish to limit reporting to those providers participating in CMS programs given that many clinicians do not participate fully in these programs.
  - The term "hospital" refers broadly to include various types of hospitals and is not limited to non-federal acute care hospitals, and could be identified with a CMS Certification number (CCN) or other unique identifier such as NPI or the American Hospital Association identifier.
  - Clinician users to include health care professionals consisting of a variety of backgrounds beyond physicians and nurse practitioners and would exclude clinicians who does not treat patients.
  - We could align the minimum reporting qualifications with definitions established for hospitals and clinicians by CMS, or in the Public Health Service Act (PHSA).

Measure Updates

Measure	Proposed Update
Individuals' access to electronic health information through certified health IT	Expand the measuring of access to include access authorized representatives Modify definition for measuring access using § 170.315(g)(10). From access token to return of data in response to a request (at least one FHIR resource).
Immunization administrations electronically submitted to immunization information systems through certified health IT	Separately count the number of immunizations administered electronically submitted to IISs that returned with an acknowledgement with the error of severity level E overall, and by IIS and age category Separately count the number of immunizations administered that were electronically submitted to IIS where an acknowledgement from an IIS is not received by certified health IT overall, and by IIS and age category
Immunization history and forecasts through certified health IT	Separately count the total number of queries responses returned with acknowledgements that had an error of severity level E, overall and by IIS Separately count total number of queries sent but where no acknowledgement was received from the IIS overall, and by IIS

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Measure Updates, Continued

Measure	Proposed Update
C-CDA Reconciliation and Incorporation Through Certified Health IT Measure	Updated measure to align with proposed updates to § 170.315(b)(2) in this proposed rule, including new types of data specified in § 170.315(b)(2) and support for automatic reconciliation and incorporation processes. Revising the number of unique patients with an associated C-CDA document metric to instead capture the number of unique patients with an encounter and associated C-CDA document.

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Attestations Condition and Maintenance of Certification Requirements

PROPOSAL

We propose to revise the Attestations Condition and Maintenance of Certification requirements and add a requirement in § 170.406(a)(2) that a health IT developer, as a Condition of Certification, attest to compliance with the Assurance Maintenance of Certification requirement in § 170.402(b)(4), if the health IT developer certified a Health IT Module(s) to the "decision support interventions" certification criteria in § 170.315(b)(11).

BENEFITS

Supports and enhances transparency and accountability in the Program and supports a health IT developers' ongoing compliance with Program requirements.

Discussion

Mark Sendak, Co-Chair

Task Force Recommendation Worksheet

Mark Sendak, Co-Chair

Discussion Time (Past Topics)

Row	Topics	Time
3	USCDI v4	3 min
4	SMART App Launch 2.2	3 min
5	Bulk Data Enhancements 2.0	3 min
6	User-Access Brands	3 min
7	Dynamic Client Registration Protocol	3 min
8 - 23	Modular API Capabilities in § 170.315(j) and (g)(10)	9 min
24 - 31	Patient, Provider, and Payer APIs	4 min
33	New Imaging Requirements	3 min
34	CIRI	3 min
35	MFA	3 min
36	End-user device encryption certification criterion + related standards	4 min
37	Certification Criterion for Encrypt Authentication Credential	4 min
39	Revised ePrescribing Certification Criterion	5 min
40	New Real-Time Prescription Benefit Certification Criterion	5 min

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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 <u>onc-hitac@accelsolutionsllc.com</u>

*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
9/3   11 AM-12:30 PM (Full Task Force Meeting)
9/4   11 AM-12:30 PM (Full Task Force Meeting)
9/5   11 AM-12:30 PM (Full Task Force Meeting)

HITAC Meeting Date
9/12 TF delivers recommendations to HITAC

Meeting Adjourned