HTI-1 Proposed Rule Task Force 2023

Group 2: ONC Health IT Certification Updates – New and Revised Certification Criteria Meeting #8

Steven Eichner, Co-Chair/Group 2 Lead

Steven Lane, Co-Chair

May 10, 2023

Call to Order/Roll Call

Mike Berry, Designated Federal Officer, ONC

HTI-1 Proposed Rule Task Force 2023 – Group 2 Roster

Name	Organization
Steven Eichner* (Co-Chair/Group 2 Lead)	Texas Department of State Health Services
Steven Lane*(Co-Chair)	Health Gorilla
Medell Briggs-Malonson*	UCLA Health
Hans Buitendijk*	Oracle Health
Jim Jirjis*	HCA Healthcare
Anna McCollister*	Individual
Aaron Miri*	Baptist Health
Kikelomo Oshunkentan*	Pegasystems
Naresh Sundar Rajan*	CyncHealth
Fillipe Southerland*	Yardi Systems, Inc.
Sheryl Turney*	Elevance Health

* 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**
- Steven Eichner, Co-Chair/Group 2 Lead
- Steven Lane, Co-Chair

10:40 AM   **New Regulatory Approach for Certification Criteria ("Edition-less")**
- Michael Lipinski, ONC
- Kate Tipping, ONC

11:00 AM   **Discussion**
- Steven Eichner, Co-Chair/Group 2 Lead
- Steven Lane, Co-Chair

11:40 AM   **Planning for May 17th HITAC Meeting Task Force Update**
- Steven Eichner, Co-Chair/Group 2 Lead
- Steven Lane, Co-Chair

11:50 AM   **Public Comment**
- Mike Berry, Designated Federal Officer, ONC

12:00 PM   **Adjourn**

HTI-1 Proposed Rule Task Force Charge

Steven Eichner, Co-Chair/Group 2 Lead

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

*The highlighted part will be the focus of this meeting

HTI-1 Proposed Rule Task Force 2023 (continued)

Specific Charge: Provide recommendations on ONC's proposals that would:

- <mark>Adopt new and revised standards and certification criteria, including:</mark>
    - 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
    - <mark>Requirements for health IT developers to update their previously certified health IT.</mark>

- <mark>Establish additional Assurances Condition and Maintenance of Certification requirements</mark>

- 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 2: ONC Health IT Certification Updates – New and Revised Certification Criteria

- Decision Support Interventions (DSI) and Predictive Models

- <mark>"The ONC Certification Criteria for Health IT" and Discontinuing Year Themed "Editions"</mark>

- <mark>Assurances Condition and Maintenance of Certification Requirements</mark>

- <mark>Requirement for Health IT Developers to Update their Previously Certified Health IT</mark>

- Electronic Case Reporting

- Patient Requested Restrictions Certification Criterion

New Regulatory Approach for Certification Criteria ("Edition-less")

Michael Lipinski, ONC

Kate Tipping, ONC

Disclaimers and Public Comment Guidance

- The materials contained in this presentation 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 presentation is not a legal document. The official proposals are contained in the proposed rule.

- 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.

Discontinuing Year-Themed "Editions"

Proposal

Discontinue year-themed editions and establish a single set of certification criteria, "ONC Certification Criteria for Health IT."

Benefits

- Allows the Certification Program and health IT developers to more effectively utilize new and updated standards and functionality in a timely manner

- Allows users of health IT to work in partnership with health IT developers to update their systems for new standards or functionality in the manner that works best for their unique needs

- Assists health care industry participants in other HHS programs that reference Certification Program standards and criteria, such as CMS's Promoting Interoperability Program, by ensuring developers provide timely updates for any new or updated certification criteria

- Supports users of health IT by reducing potential confusion of tracking use of different editions of certified health IT

Establishing Applicability and Expiration Timelines for Certification Criteria and Standards

Proposal

- Establish the dates by which a prior version of a criterion is no longer applicable when a new, revised, or updated version of that criterion is adopted

- Establish applicable timelines, including expiration dates, for the adoption of standards when a new, revised, or updated version of the standard is adopted for the same purpose

Benefits

- Support establishment of clear timelines associated with the specific criterion or standard

- Facilitate ease of reference for federal, state, local or tribal programs seeking to align their program requirements to the standards and implementation specifications available in certified health IT

- Ensure that customers are provided with timely technology updates

Two Forms of Compliance

Certification Criteria

Health IT developers with a Health IT Module certified to any *revised* certification criterion must <u>*update*</u> their certified Health IT Modules and <u>*provide*</u> such updated health IT to their customers in accordance with the timelines defined for a specific criterion and/or standard included in § 170.315.

Assurances Condition and Maintenance of Certification Requirements

<u>Condition</u>: A health IT developer must provide an assurance that it will not interfere with a customer's timely access to interoperable health IT certified under the Program.

<u>Maintenance of Certification</u>**:**

- *Update:* ONC proposes that a health IT developer must update a Health IT Module, once certified to a certification criterion adopted in § 170.315, to all applicable revised certification criteria, including the most recently adopted capabilities and standards included in the revised certification criterion;

- *Provide:* ONC proposes that a health IT developer must provide all Health IT Modules certified to a revised certification criterion to its customers; and

- *Timeliness:* **A health IT developer must follow the timeliness requirements identified in the rule.**

Revised Certification Criteria

Revised certification criterion (or criteria) means a certification criterion that meets at least one of the following:
(1) has added or changed the capabilities described in the existing criterion in 45 CFR part 170;
(2) has an added or changed standard or implementation specification referenced in the existing criterion in 45 CFR part 170; or
(3) is specified through notice and comment rulemaking as an iterative or replacement version of an existing criterion in 45 CFR part 170.

Revised Certification Criteria	
§ 170.315(a)(5)	Clinical - Patient demographics and observations (currently Demographics)
§ 170.315(a)(9)	Clinical - Clinical decision support (CDS) (to be recategorized as "Care Coordination § 170.315(b)(11)")
§ 170.315(b)(1)	Care Coordination - Transitions of care
§ 170.315(b)(2)	Care Coordination - Clinical information reconciliation and incorporation
§ 170.315(e)(1)	Patient Engagement - View, download, and transmit to 3rd party
§ 170.315(f)(5)	Public Health - Transmission to public health agencies - electronic case reporting
§ 170.315(g)(10)	Design and Performance - Standardized API for patient and population services

Revised Certification Criteria (standards updates)	
§ 170.315(a)(12)	Clinical - Family health history
§ 170.315(b)(6)	Care Coordination - Data export
§ 170.315(b)(9)	Care Coordination - Care plan
§ 170.315(c)(4)	Clinical Quality Measures - Clinical quality measures - filter.
§ 170.315(f)(1)	Public Health - Transmission to immunization registries.
§ 170.315(f)(3)	Public Health - Transmission to public health agencies - reportable laboratory tests and values/results
§ 170.315(f)(4)	Public Health - Transmission to cancer registries
§ 170.315(g)(3)	Design and Performance - Safety-enhanced design
§ 170.315(g)(6)	Design and Performance - Consolidated CDA creation performance
§ 170.315(g)(9)	Design and Performance - Application access - all data request

Assurances - Timeliness Requirements

Timeliness: Unless expressly stated otherwise in 45 CFR part 170, a health IT developer must complete the proposed "update" and "provide" requirements according to the following:
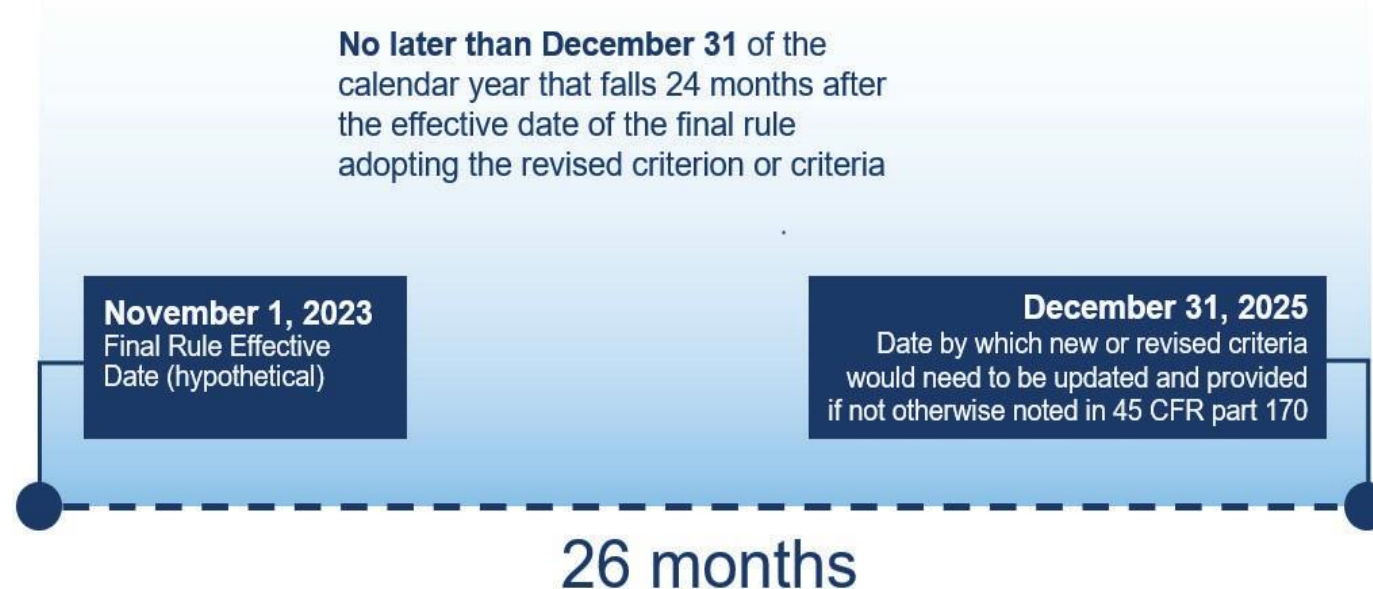
- By no later than December 31 of the calendar year that falls 24 months after the effective date of the final rule adopting the revised criterion or criteria. This would mean that, depending on the day when the final rule effective date fell, a health IT developer would have between two years and potentially up to almost three years to update a Health IT Module

- If the developer obtains new customers of health IT certified to the revised criterion **after** the effective date of the final rule adopting the revised criterion or criteria, then the health IT developer must provide the health IT certified to the revised criterion to such customers within whichever of the following timeframe that expires last:

  - By no later than December 31 of the calendar year that falls 24 months after the effective date of the final rule adopting the revised criterion or criteria; or

  - No later than 12 months after the purchasing or licensing relationship has been established between the health IT developer and the new customer for the health IT certified to the revised criterion

Assurances: Timeliness Requirements (Hypothetical Example)

Scenario 1: For Existing Customers

The HTI-1 Proposed Rule states that a health IT developer must complete the proposed "update" and "provide" requirements by **no later than December 31 of the calendar year that falls 24 months after the effective date of the final rule**, unless expressly stated otherwise in 45 CFR part 170.

Scenario 1: Existing Customer

No later than December 31 of the calendar year that falls 24 months after the effective date of the final rule adopting the revised criterion or criteria

November 1, 2023
Final Rule Effective Date (hypothetical)

December 31, 2025
Date by which new or revised criteria would need to be updated and provided if not otherwise noted in 45 CFR part 170

26 months

Assurances: Timeliness Requirements (Hypothetical Example)

Scenario 2: New Customer A (customers new to the capability)

If the developer obtains new customers of health IT certified to the revised criterion after the effective date of the final rule adopting the revised criterion or criteria, then the health IT developer must provide the health IT certified to the revised criterion to such customers **no later than 12 months after the purchasing or licensing relationship has been established** between the health IT developer and the new customer for the health IT certified to the revised criterion.

Developers would not be required to provide technology updates for certified criteria or standards to a user who declined such updates.

Scenario 2: New Customer

No later than 12 months after the purchasing or licensing relationship has been established between the health IT developer and the new customer for the health IT certified to the revised criterion

October 1, 2025
Licensing relationship established between the health IT developer and the new customer for the health IT certified to the revised criterion

October 1, 2026
Date 12 months after licensing relationship established
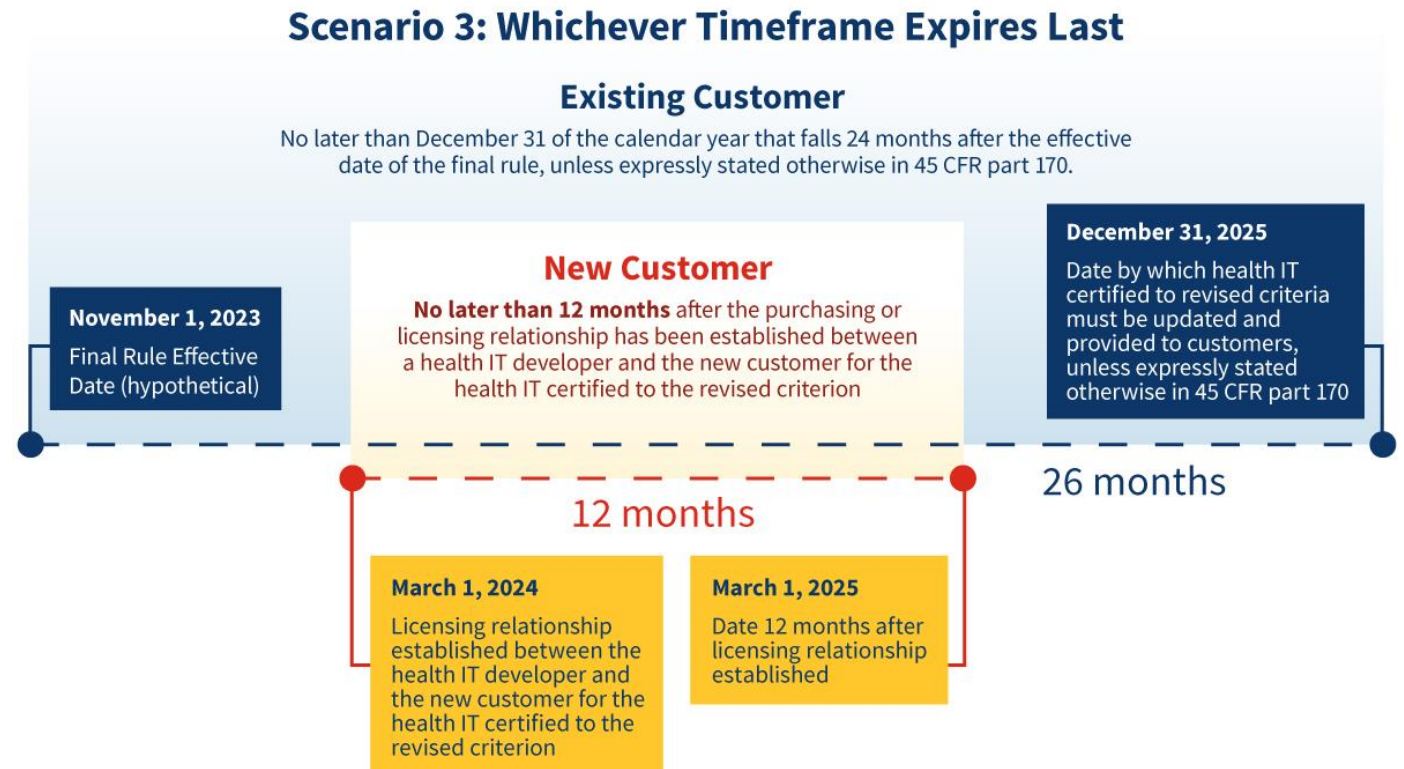
12 months

Assurances: Timeliness Requirements (Hypothetical Example)

Scenario 3: Whichever Timeframe Expires Last

Scenarios 1 and 2 illustrate that health IT developers would have, at a minimum, no less than 12 months to provide health IT certified to revised certification criteria to new customers. Scenario 3, illustrated here, juxtaposes Scenarios 1 and 2 and adds a "Scenario 3" where a new customer relationship is established prior to the expiration of the 26-month timeframe provided in Scenario 1. A health IT developer that obtained **new customers** after the effective date of the final rule, must provide health IT certified to the revised criterion **by whichever timeframe expires last:**

- By no later than December 31 of the calendar year that falls 24 months after the effective date of the final rule adopting the revised criterion or criteria; **or**

- No later than 12 months after the purchasing or licensing relationship has been established between the health IT developer and the new customer for the health IT certified to the revised criterion.

Scenario 3: Whichever Timeframe Expires Last

Existing Customer

No later than December 31 of the calendar year that falls 24 months after the effective date of the final rule, unless expressly stated otherwise in 45 CFR part 170.

November 1, 2023
Final Rule Effective Date (hypothetical)

New Customer

No later than 12 months after the purchasing or licensing relationship has been established between a health IT developer and the new customer for the health IT certified to the revised criterion

December 31, 2025
Date by which health IT certified to revised criteria must be updated and provided to customers, unless expressly stated otherwise in 45 CFR part 170

12 months

March 1, 2024
Licensing relationship established between the health IT developer and the new customer for the health IT certified to the revised criterion

March 1, 2025
Date 12 months after licensing relationship established

26 months

Assurances: Timeliness Requirements (Hypothetical Example)

Scenario 4: "Unless Expressly Stated Otherwise in This Part (45 Part 170)"

By way of example via a proposal in the HTI-1 proposed rule, the "Unless expressly stated otherwise in this part" proposed in § 170.402(b)(3)(iii) would override the proposed timelines (*e.g.,* 24 months or more in some cases) for updating and providing health IT certified to USCDI v3. The newly released USCDI v3 is proposed to be added to the USCDI standard in § 170.213(b) and the adoption of the current USCDI v1 standard would expire on January 1, 2025. In sum, health IT certified to criteria referencing USCDI v1 would need to be updated to USCDI v3 and that health IT would need to be provided to customers before January 1, 2025.

Scenario 4: Unless Expressly Stated Otherwise in This Part

No later than December 31 of the calendar year that falls 24 months after the effective date of the final rule, **unless expressly stated otherwise in 45 CFR part 170.**

November 1, 2023
Final Rule Effective Date (hypothetical)

December 31, 2024
Date by which health IT certified to revised criteria referencing USCDI v1 would need to be updated to USCDI v3 and provided to customers.

14 months
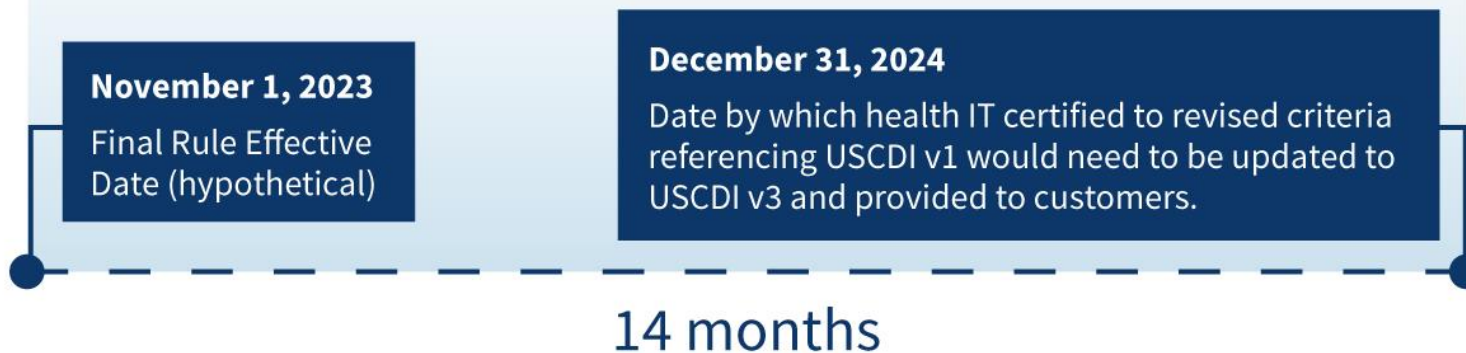
Contact ONC

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Discussion

Steven Eichner, Co-Chair/Group 2 Lead

Steven Lane, Co-Chair

Group 2: Discussion topics

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"

- Provide recommendations on ONC's proposals that would adopt new and revised standards and certification criteria, including requirements for health IT developers to update their previously certified health IT.

- Establish additional Assurances Condition and Maintenance of Certification requirements

Planning for May 17th HITAC Meeting Task Force Update

Steven Eichner, Co-Chair/Group 2 Lead

Steven Lane, Co-Chair

Task Force Topics Worksheet

Steven Eichner, Co-Chair/Group 2 Lead

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
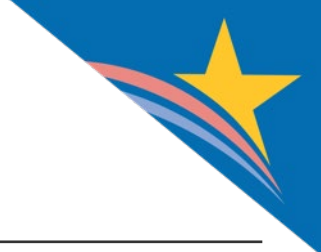
Upcoming Meetings

Month	Task Force/HITAC Meeting Dates	Task Force Topics
May	**5/17 (HITAC)**	• **TF Update**
	5/19	• Electronic Case Reporting
	5/24	• Patient Requested Restrictions Certification Criterion
	5/31	• TBD
June	6/6 (Full TF)	• Develop transmittal report/slides
	6/7 (Full TF)	• Develop transmittal report/slides
	6/8 (Full TF)	• Develop transmittal report/slides
	6/13 (Full TF)	• Develop transmittal report/slides
	6/15 (HITAC)	• **Final Recommendation and Vote**

Adjourn