

Update and Provide Requirements under the ONC Health IT Certification Program

The HTI-1 proposed rule would require developers of certified Health IT to **update** their certified Health IT Modules to all applicable revised certification criteria and **provide** such updated health IT to their customers in a **timely** manner.

Two Forms of Compliance

1. Certification Criteria Requirements per § 170.315

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

2. Assurance Condition and Maintenance of Certification Requirements

- **Condition of Certification**

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.

- **Maintenance of Certification**

Update: 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: A health IT developer must provide all Health IT Modules certified to a revised certification criterion to its customers; and

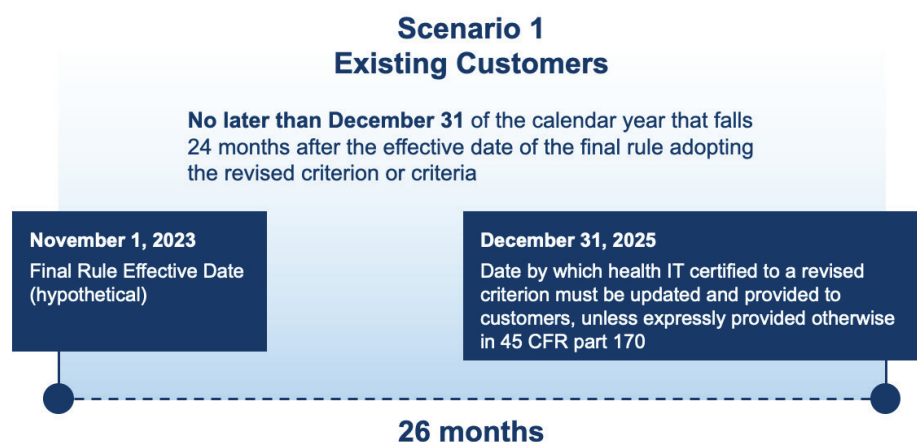
Timeliness: A health IT developer must follow the timeliness requirements identified in the proposed rule (recitations and illustrations provided below and on pages 2-3).

Assurances - Timeliness Requirements

Scenario 1: Existing Customers

The HTI-1 proposed rule states that a health IT developer must complete the “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.

This means developers must update and provide health IT certified to a revised criterion to existing customers by no later than **DECEMBER 31, 2025**.



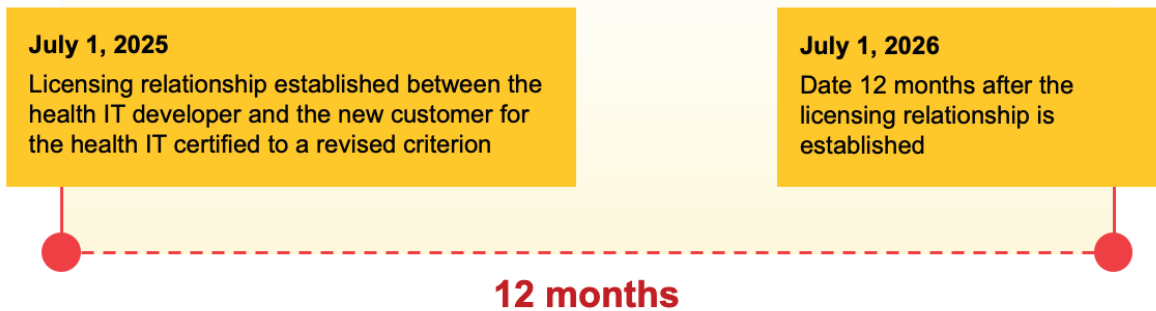
Scenario 2: New Customer A

If a developer obtains new customers (*i.e., new to the capabilities*) of health IT certified to a revised criterion after the effective date of the final rule adopting the revised criterion, 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 certification criteria or standards to a user who declined such updates.

Scenario 2 New Customer A

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 a revised criterion



Scenario 3: Whichever Timeframe Expires Last

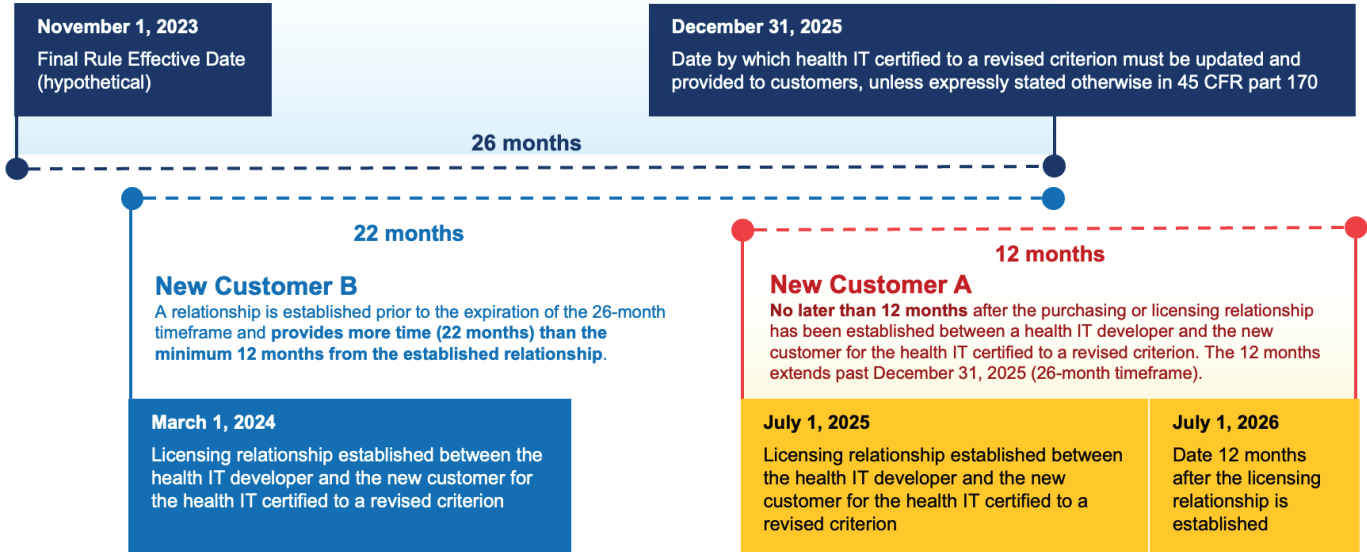
Scenarios 1 and 2 illustrate that health IT developers would have, at a minimum, no less than 12 months to provide health IT certified to revised certification criteria to new customers. Scenario 3, illustrated below, juxtaposes Scenarios 1 and 2. It also adds a “Scenario 3” where a new customer relationship is established prior to the expiration of the 26-month timeframe provided in Scenario 1 and the minimum 12 months from the established relationship expires **within** the 26-month timeframe. 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 Customers

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 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.

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.**



The newly released USCDI v3 is proposed to be added to the USCDI standard in § 170.213(b). The adoption of the current USCDI v1 standard would expire on January 1, 2025. In sum, health IT certified to a certification criterion 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.

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.

Proposed Revised Certification Criteria in the HTI-1 Proposed Rule

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



Visit healthit.gov/proposedrule for additional information. More updates will be added over time.

Disclaimer: This fact sheet describes select proposals described in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) proposed rule. While every effort has been made to ensure the accuracy of this fact sheet, it is not a legal document. Please refer to the HTI-1 proposed rule for full provision details.

