

## FAQ: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule

Updated: December 2023

The Office of the National Coordinator for Health Information Technology (ONC) <u>released</u> the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) proposed rule on April 11, 2023. ONC released the <u>final rule</u> in December 2023, with provisions becoming effective 30 days after publication in the Federal Register. The final rule implements provisions directed by the 21<sup>st</sup> Century Cures Act and makes enhancements to the ONC Health IT Certification Program. ONC hopes these provisions will advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information. AHIMA submitted <u>comments</u> on the proposed rule in June 2023.

ONC released a <u>fact sheet</u>, <u>at-a-glance document</u>, and <u>blog post</u> on the proposed rule in April 2023. In December 2023, ONC released a <u>press release</u> and <u>webpage</u> with an <u>at-a-glance document</u> on the final rule, as well as a <u>general overview</u>, and fact sheets on <u>decision support interventions and predictive</u> <u>models</u>, the <u>Insights Condition</u>, <u>information blocking</u>, and <u>key dates</u> for implementation.

## Key Provisions of the Proposed Rule:

- Standards and Certification Criteria Proposals Under the Certification Program
  - Adopting the United States Core Data for Interoperability (USCDI) Version 3 as the new baseline
    - Finalized as proposed.
  - Revising electronic case reporting certification criterion to be based on industry developed standards developed by Health Level 7 (HL7)
    - Finalized as proposed.
  - Renaming and revising the existing clinical decision support (CDS) certification criterion as the decision support interventions (DSI) certification criterion, with goals including:
    - Revising ONC's existing decision support certification criterion to include AI, ML, and other predictive decision support
    - Promoting consistent and routine electronic access to technical and performance information on predictive decision support
    - Promoting transparent risk management for governance of predictive decision support
    - Finalized as proposed, with additional updates including clearer transparency requirements related to expanded source attributes for DSIs created by health IT developers.
  - Renaming the patient demographics certification and observations criterion and adding new data elements
    - Finalized as proposed.
  - Adopting a new patient requested restrictions certification criterion that revises an existing criterion to support additional tools for implementing patient requested



"privacy" restrictions and enabling providers to flag patient health data that should be restricted from disclosure

- Finalized the proposed requirement for Health IT Modules certified to the "view, download, and transmit to a 3<sup>rd</sup> party," certification criterion to support an internet-based method for a patient to request a restriction. The remaining proposals in this section were not finalized.
- Revising and standardizing the Application Programming Interfaces (API) Condition and Maintenance of Certification requirements
  - Finalized as proposed.
- Implementing the Electronic Health Record (EHR) Reporting Program as new Condition and Maintenance of Certification requirements (thus establishing the Insights Condition) for developers of certified health IT
  - Finalized as proposed.
- Information Blocking Regulations Proposals
  - Defining "offer health IT" to narrow the applicability of the "health IT developer of certified health IT" definition by explicitly excluding certain activities from what it means to "offer" health IT
  - Renaming the Content and Manner Exception and include a new condition related to participation in the Trusted Exchange Framework and Common Agreement (TEFCA)
  - Revising the Infeasibility Exception and adding two new conditions
  - All changes were finalized as proposed.

If you have questions, please contact the AHIMA Advocacy and Policy team at <u>advocacy@ahima.org</u>.