

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

April 2023

For important background on the proposals made in the HTI-1 proposed rule, please first visit the ONC Health IT Buzz Blog [Increasing the Transparency and Trustworthiness of AI in Health Care](#).

## What Proposals Are Included?

The HTI-1 proposed rule would revise the existing “clinical decision support” (CDS) certification criterion<sup>1</sup> for the first time since 2012 to reflect an array of contemporary and emerging functionalities, data elements, and software applications that aid decision-making in health care. The current criterion for CDS would be renamed as the “Decision Support Interventions” (DSI) certification criterion and be recategorized as part of the care coordination criteria in § 170.315(b). The proposal expands on existing requirements related to “source attributes” and configuration requirements for linked referential and evidence-based decision support intervention types.

The DSI proposal also includes several new requirements for Health IT Modules that enable or interface with technology intended to support decision-making based on predictive algorithms or models. This proposal would not require Health IT Modules to support predictive DSIs. However, there are additional requirements for those Health IT Modules and those developers of certified health IT that support predictive DSIs. We propose to define predictive DSIs as technology that is “intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis.”

## Why Is ONC Proposing These Changes?

ONC proposes these revisions to optimize the use of predictive and other DSI types in health care. Our primary proposals would:

- Improve transparency on how a predictive DSI was designed, developed, trained, evaluated, and should be used, addressing fundamental information asymmetries in the marketplace for predictive DSIs.
- Enhance trustworthiness through transparency on how certified health IT developers manage potential risks and govern predictive DSIs that their certified Health IT Modules enable or interface with.
- Support consistency in the availability of predictive DSI information, so that users may determine the DSI’s quality and whether its recommendations are fair, appropriate, valid, effective, and safe (FAVES).
- Advance health equity by addressing bias and health disparities that may be propagated by predictive DSIs to expand the use of these technologies in safe, appropriate, and more equitable ways.

## What Are the Details?

**Updated source attributes requirements** – The HTI-1 proposed rule would expand the number of source attributes and the kinds of information that must be available to users “via direct display, drill down, or link out from a Health IT Module.” These updates focus on ensuring that users know when race, ethnicity, social determinants of health, and other data salient to health equity are used by a DSI, including predictive DSIs.

**Predictive DSI requirements – Health IT Modules:** The HTI-1 proposed rule would require that Health IT Modules that enable or interface with predictive DSIs provide additional information as source attributes so users can determine the quality of a predictive DSI and whether and how to use the predictive DSI’s recommendations. These new source attributes would provide users with information to answer three basic questions: (1) What data was used to train the predictive DSI; (2) How should the predictive DSI be used, updated, and maintained; and (3) How does the predictive DSI perform using validity and fairness metrics in testing and in local data, if available.

**Predictive DSI requirements – Developers of Certified Health IT:** Developers of certified health IT are not required to have Health IT Modules that enable or interface with predictive DSIs certified to § 170.315(b)(11). However, the HTI-1 proposed rule would require developers with Health IT Modules that enable or interface with a predictive DSI to employ or engage in Intervention Risk Management practices. These practices include activities related to “risk analysis,” “risk mitigation,” and “governance.” These developers of certified health IT must also make summary information publicly available regarding Intervention Risk Management practices and review this information for updates annually.

**Author and revise source attributes:** The HTI-1 proposed rule would require that Health IT Modules must enable users to author and revise source attributes and information beyond those required by ONC to provide flexibility for users to design DSI source attributes unique to their circumstances.

**Feedback loop requirement:** To support quality improvement for all DSIs, the HTI-1 proposed rule would require that Health IT Modules enable users to provide feedback regarding the intervention and make available such feedback data for export in a computable format.

**Requirement to enable interventions based on additional data:** The HTI-1 proposed rule would update the data for which Health IT Modules certified to § 170.315(b)(11) must enable decision support interventions to reference the United States Core Data for Interoperability (USCDI) and newly included unique device identifiers and procedures.

## When Does the New DSI Criterion Take Effect?

Under the proposal, technology certified to the current CDS criterion would need to be updated to the new DSI criterion by **December 31, 2024**. Health IT certified to the revised DSI criterion would be required to comply with the Intervention Risk Management requirements by the December 31, 2024, deadline.

### Update to Base EHR Definition

ONC proposes to update the Base EHR definition<sup>2</sup> to include an option of either the existing CDS criterion or the revised DSI criterion for the period up to and including December 31, 2024, and to include only the revised DSI criterion effective January 1, 2025.

### Participation in Real World Testing

ONC proposes to add the CDS criterion to the list of applicable certification criteria for the Real World Testing Condition and Maintenance of Certification requirement for the time in between the finalization of the proposed rule and the December 31, 2024, deadline.<sup>3</sup> This would require developers of health IT certified to the existing CDS in § 170.315(a)(9) or revised DSI criterion in § 170.315(b)(11) to submit real world testing plans and results.

1. [https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170#p-170.315\(a\)\(9\)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170#p-170.315(a)(9))
2. [https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170#p-170.102\(2015%20Edition%20Base%20EHR\)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170#p-170.102(2015%20Edition%20Base%20EHR))
3. [https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-D/section-170.405#p-170.405\(a\)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-D/section-170.405#p-170.405(a))



Visit [healthit.gov/proposedrule](https://healthit.gov/proposedrule) for additional information. More updates will be added over time.

