

The Decision Support Interventions Certification Criterion

The HTI-1 final rule adopts the Decision Support Interventions (DSI) certification criterion (at 170.315(b)(11)). This represents the first substantial revision to the Certification Program's requirements for clinical decision support related capabilities since 2012. The DSI criterion's conformance updates reflect an array of contemporary functionalities and configuration requirements as well as an expanded set of information, or "source attributes," related to evidence-based DSIs and Predictive DSIs.

The final rule also establishes a definition for Predictive DSI to mean "technology that supports decision-making based on algorithms or models that derive relationships from training data and then produce an output that results in prediction, classification, recommendation, evaluation, or analysis."

In response to public comments, the final DSI criterion includes clearer more precisely scoped requirements for health IT developers. In particular, the final criterion requires that health IT developers are responsible for only the Predictive DSIs that they supply as part of their certified health IT. Additionally, health IT developers will need to adhere to certain ongoing maintenance requirements to keep their DSI "source attribute" information complete and up-to-date as well as implement risk management practices for Predictive DSIs they supply to address risk analysis, risk mitigation, and governance.

The HTI-1 final rule expands the number of source attributes that health IT certified to the DSI criterion must support, including 13 for evidence-based DSIs and 31 source attributes applicable to Predictive DSIs. Near-term, this set of Predictive DSI source attributes will help create a consistent, industry-wide baseline upon which public-private collaboratives can build as they advance structured "model cards" and other related initiatives. Over time, these source attributes will provide the transparency necessary for health care organizations and clinical users to better determine whether their Predictive DSIs are fair, appropriate, valid, effective, and safe (FAVES).

Key Dates

- **December 31, 2024:** Health IT developers will need to update health IT currently certified to the CDS criterion (170.315(a)(9)) to meet the DSI criterion's requirements and provide the updated certified health IT to customers by December 31, 2024.
- **Starting January 1, 2025:**
 - Developers with health IT certified to the DSI criterion must comply with the associated maintenance of certification requirement adopted at 170.402(b)(4).
 - The DSI criterion will become the criterion required for health care providers to have health IT that continues to meet the Base EHR definition and thus be in a position to have "Certified EHR Technology" for the purposes of certain Centers for Medicare & Medicaid Services programs.

1. Details and output of the intervention, including:

- Name and contact information for the intervention developer;
- Funding source of the technical implementation for the intervention(s) development;
- Description of value that the intervention produces as an output; and
- Whether the intervention output is a prediction, classification, recommendation, evaluation, analysis, or other type of output.

2. Purpose of the intervention, including:

- Intended use of the intervention;
- Intended patient population(s) for the intervention's use;
- Intended user(s); and
- Intended decision-making role for which the intervention was designed to be used/for (e.g., informs, augments, replaces clinical management).

3. Cautioned out-of-scope use of the intervention, including:

- Description of tasks, situations, or populations where a user is cautioned against applying the intervention; and
- Known risks, inappropriate settings, inappropriate uses, or known limitations.

4. Intervention development details and input features, including at a minimum:

- Exclusion and inclusion criteria that influenced the training data set;
- Use of variables in paragraph (b)(11)(iv)(A)(5)-(13) as input features;
- Description of demographic representativeness according to variables in paragraph (b)(11)(iv)(A)(5)-(13) including, at a minimum, those used as input features in the intervention;
- Description of relevance of training data to intended deployed setting.

5. Process used to ensure fairness in development of the intervention, including:

- Description of the approach the intervention developer has taken to ensure that the intervention's output is fair; and
- Description of approaches to manage, reduce, or eliminate bias.

6. External validation process, including:

- Description of the data source, clinical setting, or environment where an intervention's validity and fairness has been assessed, other than the source of training and testing data;
- Party that conducted the external testing;
- Description of demographic representativeness of external data according to variables in paragraph (b)(11)(iv)(A)(5)-(13) including, at a minimum, those used as input features in the intervention; and
- Description of external validation process.

7. Quantitative measures of performance, including:

- Validity of intervention in test data derived from the same source as the initial training data;
- Fairness of intervention in test data derived from the same source as the initial training data;
- Validity of intervention in data external to or from a different source than the initial training data;
- Fairness of intervention in data external to or from a different source than the initial training data;
- References to evaluation of use of the intervention on outcomes, including, bibliographic citations or hyperlinks to evaluations of how well the intervention reduced morbidity, mortality, length of stay, or other outcomes.

8. Ongoing maintenance of intervention implementation and use, including:

- Description of process and frequency by which the intervention's validity is monitored over time;
- Validity of intervention in local data;
- Description of the process and frequency by which the intervention's fairness is monitored over time;
- Fairness of intervention in local data.

9. Update and continued validation or fairness assessment schedule, including:

- Description of process and frequency by which the intervention is updated; and
- Description of frequency by which the intervention's performance is corrected when risks related to validity and fairness are identified.



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