Decision Support Interventions Criterion for Certified Health IT

- ONC finalized adoption of the DSI Criterion, a revision of the current CDS Criterion must be utilized in Certified Health IT no later than **December 31, 2024**
    - Delays in other certification requirements were made to allow developers of Health IT to focus on meeting DSI criterion in CY2024
- ONC finalized new definitions for "predictive decision support interventions" and "decision support interventions"
- ONC excluded Linked Referential Decision Support (InfoButtons) from the DSI criterion
- To attain certification, ONC defined required actions for by developers of Health IT/Health IT modules incorporating DSI into certified Health IT to ensure transparency and safety, including:
    - Relevant technical and performance information
    - Source attribution
    - Adoption of risk management practices
    - Participation in real world testing
- Scope of source attribution requirements will be limited to DSI created by the developer of certified Health IT modules, not third parties.

Definition of Evidence-Based Decision Support Interventions

- "Evidence-based DSIs, for purposes of certifying Health IT modules to DSI criterion, are limited to only those DSIs that are "actively presented" to users in clinical workflow to enhance, inform, or influence decision-making "related to the care a patient receives" and that do not meet the definition for Predictive Decision Support Intervention
    - "Actively presented" includes interruptive alerts, but not exclusive to interruptive alerts
        - Actively presented places decision support that initiates an action without a user's knowledge or occurs outside a user's normal workflow outside of the scope of HTI-1
    - "Related to the care a patient receives" includes at the point of care and use cases that impact the care the patient receives (for example, an evidence-based guideline for when a follow up visit should occur would be in scope)

Definition of Predictive Decision Support Interventions

- "Technology 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."
  - Technology estimates a value based on a relationship "learned" from using training data
  - Agnostic to specific purposes or intended uses
  - Does not consider/weigh a level of risk with use
    - Criteria is applicable regardless of the developer being the developer of Certified Health IT
- Predictive DSI includes:
  - Technology estimates a value based on relationships 'learned' in prior data
- Predictive DSIs include those based on:
  - Simple statistics or regression model or a risk calculator
  - Machine learning models (e.g., predicting healthcare costs; sepsis onset; no-show)
  - Widely used ASCVD and APACHE IV models used to predict opioid overdose, hospital bed capacity, and other emerging use cases
  - Bespoke machine learning models used to predict opioid overdose, hospital bed capacity, and other emerging use cases
  - Natural language processing (NLP) and large language models (LLMs)
- DSI may be presented in a broad array of forms (e.g., alerts, order sets, flowsheets)
- DSI does not include:
  - Simulation models that use modeler-provided parameters rather than training data
  - Unsupervised machine learning techniques that do not predict an unknown value

Decision Support Interventions Source Attribution Requirements

- ONC proposed Health IT Modules would be required to enable a user to review "source attributes" information for DSI no later than December 31, 2024
- "Source attributes would include elements currently required for Clinical Decision Support (CDS)
  - Bibliographic citation of the intervention
  - Developer of the intervention
  - Funding source of the intervention
  - Release, and if applicable, revision date(s) of the intervention
- New "Source Attributes" required would be:
  - Use in the intervention of specific demographic data
  - Use of social determinants of health data
  - Use of health status/assessment data
- Source attributes information must be available as a "plain language description" to end users "via direct display, drill down, or link out from a Health IT Module"

- o Intervention Details
    - Output
    - Intended Use
    - Out of Scope Use
  - o Intervention Development
    - Training and test data descriptions
    - External validation process (when available)
  - o Quantitative Performance Measures
    - Validity and fairness of prediction in test data
    - Validity and fairness of prediction in external data (when available)
    - References to evaluation of the use of the model and outcomes (when available)
  - o Ongoing Maintenance and Intervention Use
    - Ongoing validation schedule
    - Validity of prediction in local data (when available)
    - Fairness of prediction in local data (when available)
- Support Health Equity by Design by citing:
  - o Race Ethnicity and Language (REL) data elements used
  - o Sexual Orientation and Gender Identity (SOGI) data elements used
  - o Social Determinants of Health (SDOH) data elements used
  - o Health Status data elements used
- If a DSI is developed by a developer of certified health IT, information for all attributes are required, unless otherwise noted in regulation as "if available"
- For DSIs that interact with certified Health IT but are developed by third parties, health IT modules must clearly indicate when any attribute is not available for the user to review
  - o Third parties include health systems, third party developers, medical education publishers, etc.
  - o HIMSS anticipates that third party AI/predictive DSI source attribution will be an issue discussed as part of the US Department of Health and Human Services Artificial Intelligence task force, established by the White House Executive Order published October 30th, 2023
- Certified Health IT must have the functionality to allow the limited end-user pool to:
  - o author and/or revise source attributes and information
  - o provide feedback on the DSI through a computable export format on
    - intervention
    - action taken
    - user
    - date
    - location
    - user feedback

Predictive DSI Risk Management Requirements

- Certified Health IT developers must publicly disclose risk management (Integrated Risk Management or "IRM") and governance for predictive DSI. Disclosure must be publicly available through hyperlink without preconditions and reviewed annually for updates.
    - *Detailed documentation must be available to ONC upon request for each predictive DSI the certified health IT enables or interfaces with

- Disclosure must include:
    - Risk analysis for:
        - Validity
        - Reliability
        - Robustness
        - Fairness
        - Intelligibility
        - Safety
        - Security
        - Privacy
    - Risk mitigation practices during development
    - Governance processes, including data management

Oversight (Real World Testing) Requirements

- Certified Health IT developers must conform to proposed DSI requirements by participating in the Real World Testing (RWT) Program.
    - RWT is required for all DSIs, including:
        - Predictive DSI
        - Evidence based DSI
    - RWT plans and results will be posted annually on the Certified Health IT Product List (CHPL) https://chpl.healthit.gov