Health Data, Technology, and Interoperability: Decision Support Intervention

HITAC NPRM Subgroup

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April 25, 2023

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Agenda

1. HITAC TF Meeting #1 – April 25, 2023
   - Policy Overview
   - Context and Background
   - Proposed Revisions and Criterion Mechanics

2. HITAC TF Meeting #2 – April 26, 2023
   - Source Attributes

3. HITAC TF Meeting #3 – May 3, 2023
   - Intervention Risk Management
   - Oversight & Implementation

Policy Overview

Decision Support Interventions (DSI) Proposals

ONC proposes to revise the existing CDS criterion § 170.315(a)(9) to reflect an array of contemporary and emerging software functionalities that aid user decision-making in health care, including artificial intelligence (AI) and machine learning (ML).

This revision includes:

- A definition for "predictive decision support intervention"

- Updating the Base EHR definition to include the proposed revised DSI criterion in § 170.315(b)(11)

- Requirements for Health IT Modules that enable or interface with predictive DSIs to provide relevant technical and performance information to users

- Requirements for certified health IT developers to employ or engage in risk management practices related to predictive DSIs

- Requirements for certified health IT developers with Health IT Modules certified to DSI criterion to participate in Real World Testing
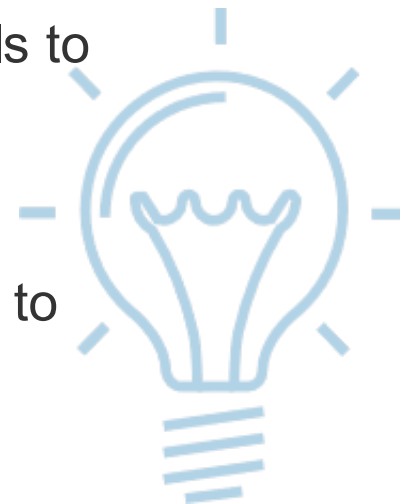
DSI Proposals – Intended Benefits

ONC proposes these revisions to optimize the use of predictive and other DSIs types in health care. These baseline requirements for transparency aim to improve the trustworthiness of predictive algorithms and support their widespread use in health care. Other intended outcomes include:

Improve Transparency

- Regarding how a predictive DSI is designed, developed, trained, evaluated, and should be used

Enhance Trustworthiness

- Through transparency on how certified health IT developers manage risks and govern predictive DSIs they enable or interface with

Promote Consistency

- In the availability of predictive DSI information to users, 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 Design

- By addressing bias and health disparities propagated by predictive DSIs to expand the use of these technologies in safer, more appropriate, and more equitable ways
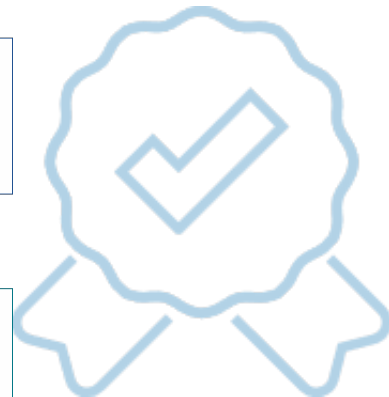
Proposed Definition: "Predictive Decision Support Intervention"

Predictive Decision Support Intervention Means:

"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 relationships 'learned' in training data

- Agnostic to specific purposes or intended uses

- Does not convey or consider a level of risk associated with its use

- Not dependent on who developed the algorithm or model (can be someone other than a certified health IT developer)

- Not limited by the specific nature of the data to be processed (includes models that analyze text or images)

- Examples include:

  - Simple statistics and regression models used in a risk calculator (e.g., such as the widely used ASCVD model, which predicts heart events, and APACHE IV model, which predicts in-hospital death for ICU patients)

  - Machine learning models of various complexity, including neural networks and gradient boosted machines (used, for example, to predict hospital readmission, sepsis onset, and patient no-shows) and large language models including generative pre-trained transformers (e.g., ChatGPT)

- Outputs of predictive model may be presented in a broad array of forms that DSIs can take (e.g., alerts, order sets, flowsheets, etc.)

Transparency Is A Prerequisite For Trustworthy AI

Data Transparency + **Predictive DSI Transparency** + **Organizational Transparency** = **Trustworthy Algorithms**
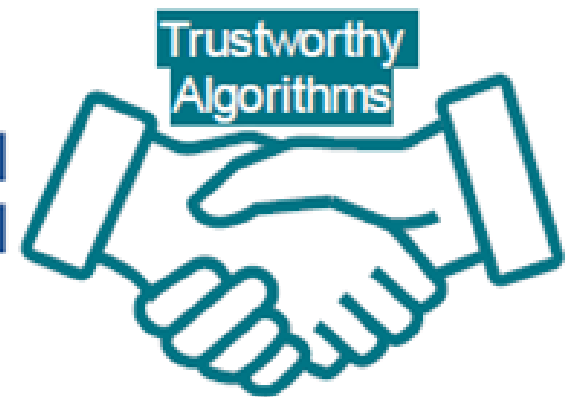
Proposed requirements would enable users to know when a DSI uses specific data elements relevant to health equity, including:

- Social Determinants of Health
- Race, Ethnicity, & Language
- Gender Identity
- Sexual Orientation

Proposed source attributes would enable users to have consistent and routine electronic access to technical and performance information on predictive DSIs

- Spanning intended use, training data descriptions, measures of fairness, and ongoing maintenance
- Information provided in plain language and available to users via direct display, "drill down" or "link out" functionality

Proposed requirement for certified health IT developers to employ or engage in risk management of predictive DSIs

- Analyze risks; mitigate risks; and establish governance for predictive DSIs
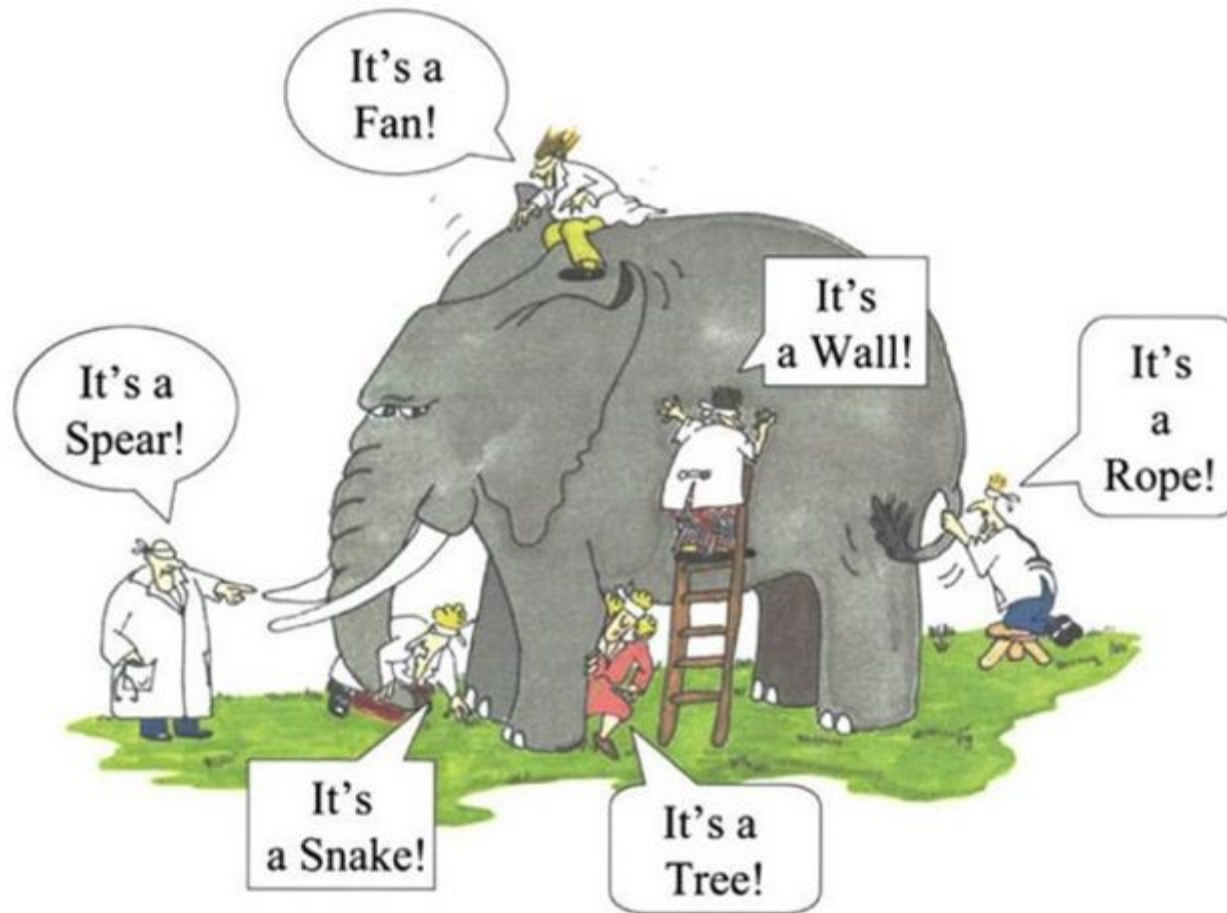- Report summary information publicly

F.A.V.E.S. as an Intended Outcome

- We posit that transparency regarding (1) the technical and performance dimensions of predictive DSIs and (2) the organizational and socio-technical competencies employed by those who develop predictive DSIs is foundational for users to determine whether their predictive DSI is fair, appropriate, valid, effective, and safe, or FAVES

- Proposals for source attribute and intervention risk management information would provide essential information to users determining whether and how to apply a predictive output to medical decisions at the time and place of care
  - ONC has worked extensively with the FDA to align proposals with recent CDS guidance

- Numerous and parallel efforts across industry, academia, and the public sector are developing means to communicate measures of FAVES including through
  - Model cards, model nutrition labels, datasheets, data cards, algorithmic audits, impact assessments, etc.
  - Proposals would provide a foundation for these efforts meant to shed light on the quality of predictive models in health care.

- While not guaranteeing whether a predictive DSI is FAVES, proposals would promote transparency necessary for a dynamic marketplace of high-quality predictive models to support decision-making in health care
  - We believe such transparency would also foster confidence and trust among interested parties that the technical and organization processes used in designing and developing the predictive DSI were FAVES and high-quality.
  - We believe that transparency can increase public trust and confidence in technology.

Background & Context for Proposals

Current View of Artificial Intelligence in Health Care

Image Source: https://medium.com/analysts-corner/companies-are-elephants-d9bf807bf217

ONC Blog Series on Artificial Intelligence and Machine Learning in Health Care

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Electronic Health & Medical Records

Getting the Best out of Algorithms in Health Care

Kathryn Marchesini; Jeff Smith and Jordan Everson | JUNE 15, 2022

" ONC's policy goal has been and continues to be centered on ensuring that certified health IT can support broad categories of decision support intervention types, while being agnostic as to the intended purpose of such decision support. This approach has led to a dynamic and flourishing landscape of decision support technologies, varied in purpose and scope, ranging from patient safety and clinical management to administrative and documentation functions.

" These technologies have the potential to drive innovation, increase market competition, and vastly improve care for patients and populations. However, like any new health IT, it requires examination and inquiry to establish an evidence-base of benefits and risks.

" While predictive decision support interventions (DSIs) have enormous potential to improve many aspects of health care, they also present several potential risks that could lead to adverse impacts or outcomes. These risks may be magnified because of their potential to "learn" rapidly and produce predictions across many hundreds or thousands of patients.

Blog Series: Artificial Intelligence & Machine Learning Archives - Health IT Buzz Health IT Buzz

Common Terminology Around Key Concepts

Term	Description
Predictive decision support (*Model*)	Technology intended to support decision-making based on algorithms that derive relationships from training or example data and then are used to produce an output or outputs.
Transparency	Sufficient information provided on the model, including input data, validation of performance, and intended use.
Trustworthiness	Model risks identified, mitigated, managed, and evaluated to provide confidence in the positive impact of using the model, and information about steps taken to govern the model and address negative impacts and/or reduce bias or harm are documented.
Fair (*Unbiased, Equitable*)	Model does not exhibit prejudice or favoritism toward an individual or group based on their inherent or acquired characteristics. The impact of using the model is similar across same or different populations or groups.
Appropriate	Model is well matched to specific contexts and populations to which it is applied.
Valid	Model has been shown to estimate targeted values accurately and as expected in both internal and external data.
Effective	Model has demonstrated benefit in real-world conditions.
Safe	Model is free from any unacceptable risks and for which the probable benefits outweigh any probable risk.

What's Hindering the Use of AI/ML In Health Care?

During a June 2022 Health Information Technology Advisory Committee hearing on "health equity by design," **we heard that clinicians have unmet needs for information and transparency, and that until these needs are met, they are unlikely to use ML-driven tools or risk misapplying them to their patients.**

- Clinicians need to know that an AI product has been evaluated in their setting of care, that the technology was trained on data that reflects their practice population, and that the product will be continuously monitored.

- Clinicians want to be able to communicate back to developers of such AI products when a predictive recommendation did not work well for a patient.

- General concern that ML-driven technology does not create or recreate systemic inequalities that come with the lack of access to quality health insurance and quality care.

HealthITbuzz
THE LATEST ON HEALTH IT FROM ONC
Minimizing Risks and Maximizing Rewards from Machine Learning
Kathryn Marchesini; Jeff Smith and Jordan Everson | SEPTEMBER 7, 2022

Blog 4: Information Asymmetry & Predictive Models

" We see [a] lack of consistent information availability (or information asymmetry) as a defining challenge inhibiting the optimization of predictive decision support interventions (DSIs) in health care. For students of economics, this type of insufficient information or "quality uncertainty" is one of the most famous forms of market failures, often colloquially called a "market for lemons"—as in the ancient slang for malfunctioning used cars.

HealthITbuzz
THE LATEST ON HEALTH IT FROM ONC
Back to the Future: What Predictive Decision Support Can Learn from DeLoreans and The Big Short

Signs that you have a market for lemons

1. Purchasers or Users Complain About Real Lemons
2. Information Asymmetry Abounds, Leading to An Inability to Determine the "Good" from the "Bad"
3. Producers or Suppliers of Quality Products Exit the Market

DeLoreans and The Big Short

- There are two classic things that can be done about a "market for lemons"
  - Create quality certification, so purchasers have some trust in the underlying quality of what they're buying
    - Medical licensing boards, skills credentialing, organization accreditation, product approvals
  - Require transparency to make it easier for potential users to ascertain the quality or appropriateness of a product
    - CARFAX Vehicle History reports, food nutrition labels, drug facts labels

- However, the experience of the financial services industry highlights that validation information may not be sufficient to ensure models are high quality and used appropriately on its own.
  - Organizational competencies and practices in managing risk for models and AI/ML-related technologies matter
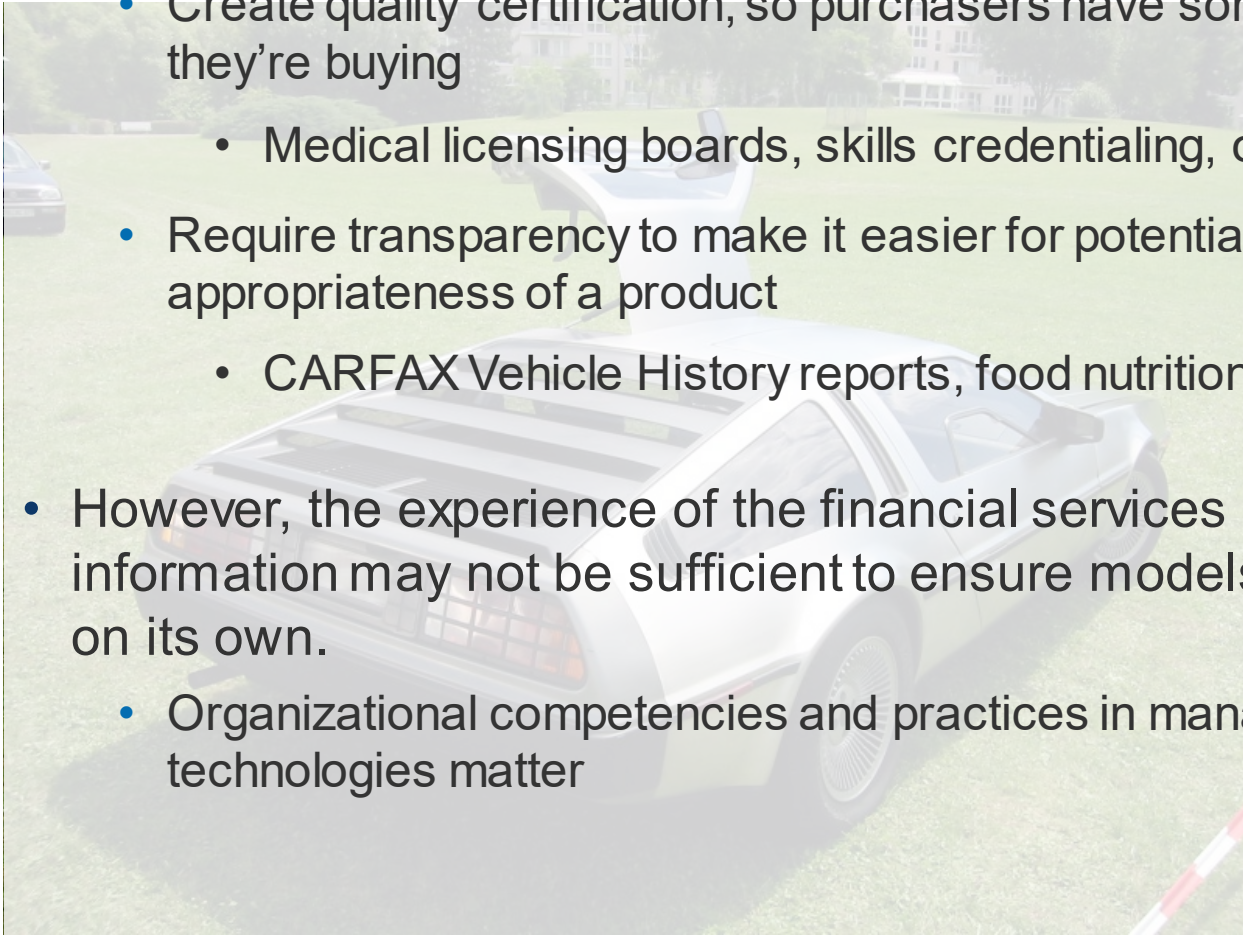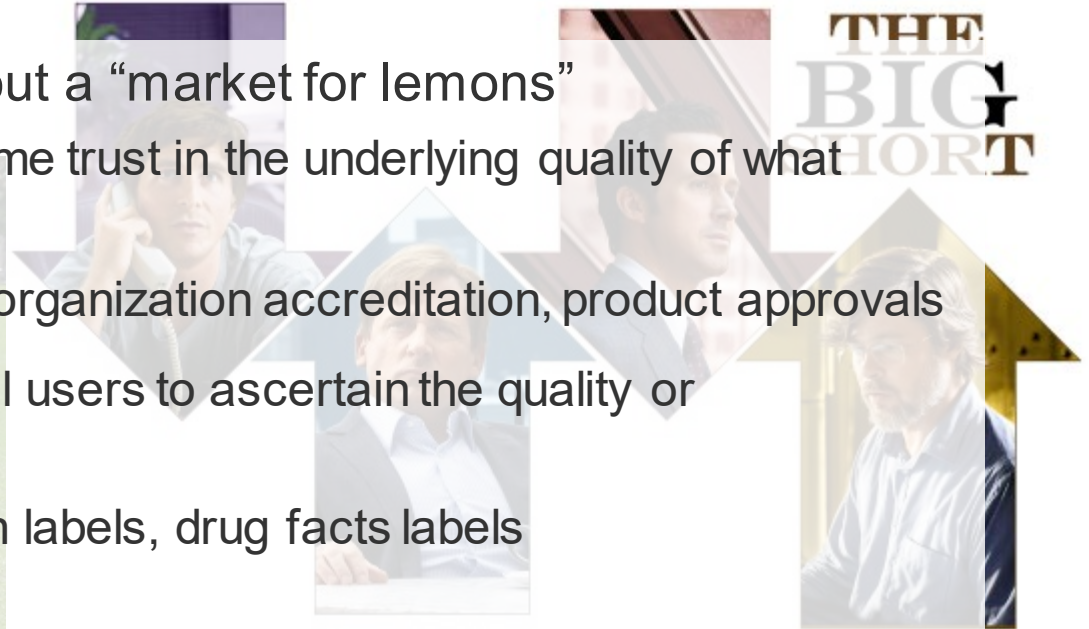
Decision Support And Certified Health IT

- Since 2010, the Program has maintained a CDS certification criterion, consistent with the "qualified electronic health record" definition in section 3000(13) of the PHSA,
  - An electronic record of health-related information on an individual that has the capacity to "provide clinical decision support" (42 U.S.C. § 300jj(13)(B)(i)).

- The initial CDS criterion required that a Health IT Module could:

- Implement rules, "according to specialty or clinical priorities;"
  - "Automatically and electronically generate and indicate in real-time, alerts and care suggestions based upon clinical decision support rules and evidence grade;" and
  - Track, record, and generate reports on the number of alerts responded to by a user (75 FR 2046)

- HITPC recommendations in 2012 provided the framework for our current CDS criterion, including requirements that Health IT Modules support CDS that :
  - Displays source or citation of CDS
  - Is configurable based on patient context (e.g., inpatient, outpatient, problems, meds, allergies, lab results)
  - Is presented at a relevant point in clinical workflow
  - Includes alerts presented to users who can act on alerts (e.g., licensed professionals);
  - Is integrated with the EHR (i.e., not standalone)

The Landscape for CDS has evolved since 2012

- Predictive models are increasingly being used and relied upon to inform an array of decision-makers, including clinicians, payers, researchers, and individuals

- Certified health IT is a central component and data source of these predictive models
  - Power the training and real-world use of predictive models as testing data or real-time inputs into deployed predictive models
  - Create and deploy predictive algorithms or models for use in production environments through their Health IT Modules
  - Enable other parties, including third-party developers and customers of the developer of certified health IT, to create and deploy predictive models through the developer's Health IT Modules
  - Are often the vehicle or delivery mechanism for predictive model outputs to reach users, such as clinicians, through decision support

Proposed Revisions

CDS versus DSI

- Clinical Decision Support (CDS)
  - CDS encompasses a variety of tools to enhance decision-making in the clinical workflow
  - These tools include computerized alerts and reminders to care providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support, and contextually relevant reference information, among other tools

- Decision Support Intervention (DSI)
  - DSI expand on the concept of CDS to reflect the various and expanding forms of decision support that certified Health IT Modules enable or interface with
  - Increasingly, DSIs include use cases or are intended to support decision-making across all areas of health care, not just clinical workflow, including early detection of disease, automating billing procedures, facilitating scheduling, supporting public health disease surveillance, and other uses beyond traditional CDS
  - We intend for the DSI criterion to be inclusive of the wide variety of use cases that Health IT Modules may support moving forward
  - DSIs covered by our proposed requirements include existing DSI types, evidence-based and linked referential, and the proposed predictive DSI type

§ 170.315(a)(9) to § 170.315(b)(11)

- Much of the proposed structure and requirements are duplicated across the CDS § 170.315(a)(9) criterion for the proposed DSI § 170.315(b)(11) criterion and reflect the capabilities included in the CDS criterion
  - Health IT Modules must enable Evidence-based DSIs and Linked referential DSIs based on a defined set of data elements
    - Problems, medications, allergies and intolerances, demographics, laboratory, vital signs
    - NEW: Procedures and Unique Identifier(s)
  - Health IT Modules are required to enable a user to review "source attributes" information
    - 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: Use in the intervention of specific demographic data
    - NEW: Use of social determinants of health data
    - NEW: Use of health status/assessment data

Proposed New Requirements for All Health IT Modules Certified to the DSI Criterion

- Source Attributes must be available as a "plain language description" to users "via direct display, drill down, or link out from a Health IT Module"
  - This would make a historic expectation explicitly required

- If DSI is developed by a developer of certified health IT, all attributes are required, unless otherwise noted as "if available"

- For DSIs that are developed by other parties, clearly indicate when any attribute is not available for the user to review
  - Other parties include health systems, third-party software developers, medical education publishers, etc.

- Health IT Modules must enable users to "author and revise source attributes and information" beyond source attributes listed
  - This would provide flexibility for users to design DSI information unique to their circumstances

- Enable end users to provide feedback regarding the intervention and make available such feedback data for export, in a computable format, including the intervention, action taken, user feedback provided (if applicable), user, date, and location
  - This would support quality improvement for all DSIs

Predictive DSI Definition and Related Request for Comment

Predictive Decision Support Intervention Means:

"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."

- Request for comment:
  - Predictive DSI definition would not include
    - Simulation models that use modeler-provided parameters rather than training data
    - Unsupervised machine learning techniques that do not predict an unknown value among other technologies.
  - Are there prominent models (e.g., simulation models, unsupervised learning models) used to support decision-making in healthcare that are not effectively captured under the proposed definition of a predictive DSI?
  - If so, is it is feasible and appropriate to include such models in the scope of this proposed rule?

Proposed Predictive DSI Attestation

- Health IT Modules certified to § 170.315(b)(11) **are not required to enable or interface** with predictive DSIs, but developers of certified health IT must make one of the following attestations:
  - Yes – the Health IT Module enables or interfaces with a predictive decision support intervention(s) based on any of the data expressed in the USCDI
  - No – the Health IT Module does not enable or interface with a predictive decision support intervention(s) based on any of the data expressed in the USCDI

- If the developer attests "yes," to this statement, the developer and its certified Health IT Module are subject to applicable predictive DSI requirements

- If the developer attests "no" to this statement, the developer would be subject to applicable general DSI requirements

Proposed Scope of Covered Technologies

Developers of certified health IT should attest "yes," if any of the following are true:

- Developer self-develops predictive DSIs for use in their certified Health IT Module; or

- Developer's Health IT Module enables or interfaces with predictive DSIs developed by its users or customers, such as a health care organization or medical center; or

- Developer's Health IT Module enables or interfaces with predictive DSIs developed by an "other party," such as a separate software developer(s)

AND

- Predictive decision support intervention is based on any of the data expressed in the USCDI standards (§ 170.213)

"Enabled by or Interfaced with"

- Enables = The developer of certified health IT has the technical capability to support a predictive model or DSI within the developer's Health IT Module
  - User-, third-party, and self-developed applications
  - Standalone applications used within or as a part of a Health IT Module
    - For example, if the calculations for a predictive DSI occur within the Health IT Module, either to or through a standalone app used within a Health IT Module or an app developed by a developer of certified health IT for use within a Health IT Module, we would consider this "enabling"
  - Includes instances where predictive DSIs are enabled by default and instances where they can be enabled by users

- Interfaces with = The Health IT Module facilitates either (1) the launch of a predictive model or DSI or (2) the delivery of a predictive model or DSI output(s) to users when such a predictive model or DSI resides outside of the Health IT Module
  - For example, scenarios where the calculations for a predictive DSI occur outside the Health IT Module, and the predicted value or output gets sent to or through a Health IT Module (or to or through an app used within or as part of a Health IT Module) would be considered to "interface with"
  - A Health IT Module would also "interface with," a predictive DSI in scenarios where an application is launched from a certified Health IT Module, including through the use of a single sign-on functionality
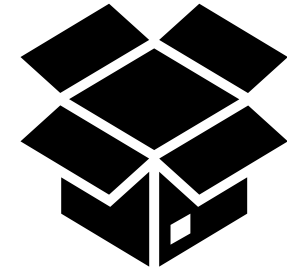
"enables" is about the certified health IT being a container within which a predictive model or DSI can be used (either as an app or as part of the Health IT Module)
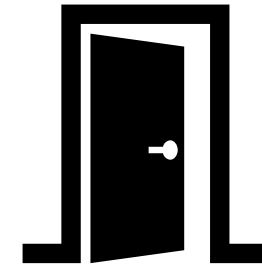
"interface with" is about the certified health IT being a door, through which actions can be taken to launch or deliver a predictive model or DSI

Proposed Implementation Timeline and RWT Implications

- Health IT Modules certified to § 170.315(a)(9) would need to update and provide their customers with technology certified to § 170.315(b)(11) and comply with these new requirements by December 31, 2024
  - Health IT Modules may be certified to (a)(9) and/or (b)(11) until December 31, 2024

- Propose to modify the Base EHR definition in § 170.102 to include § 170.315(b)(11)
  - (a)(9) will expire January 1, 2025, and (b)(11) will replace (a)(9) in the Base on and after January 1, 2025

- Developers of certified health IT with Health IT Module(s) certified to § 170.315(b)(11) would be required to submit real world testing plans and corresponding real world testing results, consistent with other "(b)-criteria" in § 170.405(a)
  - RWT for all DSI types (predictive, evidence-based, and linked referential) beginning for 2023 plans
  - Measures demonstrating conformance to requirements, self-identified by developer
  - Annual cycle of RWT plans and results publicly available via CHPL

- Propose to add (a)(9) to the list of applicable criteria for Real World Testing, effective as of a final rule until it expires

ONC
Office of the National Coordinator
for Health Information Technology

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