Office of the National Coordinator for Health Information Technology

Requirements for Decision Support Interventions and Predictive Models (Algorithmic Transparency)

HTI-1 Final Rule

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

1/18/2024

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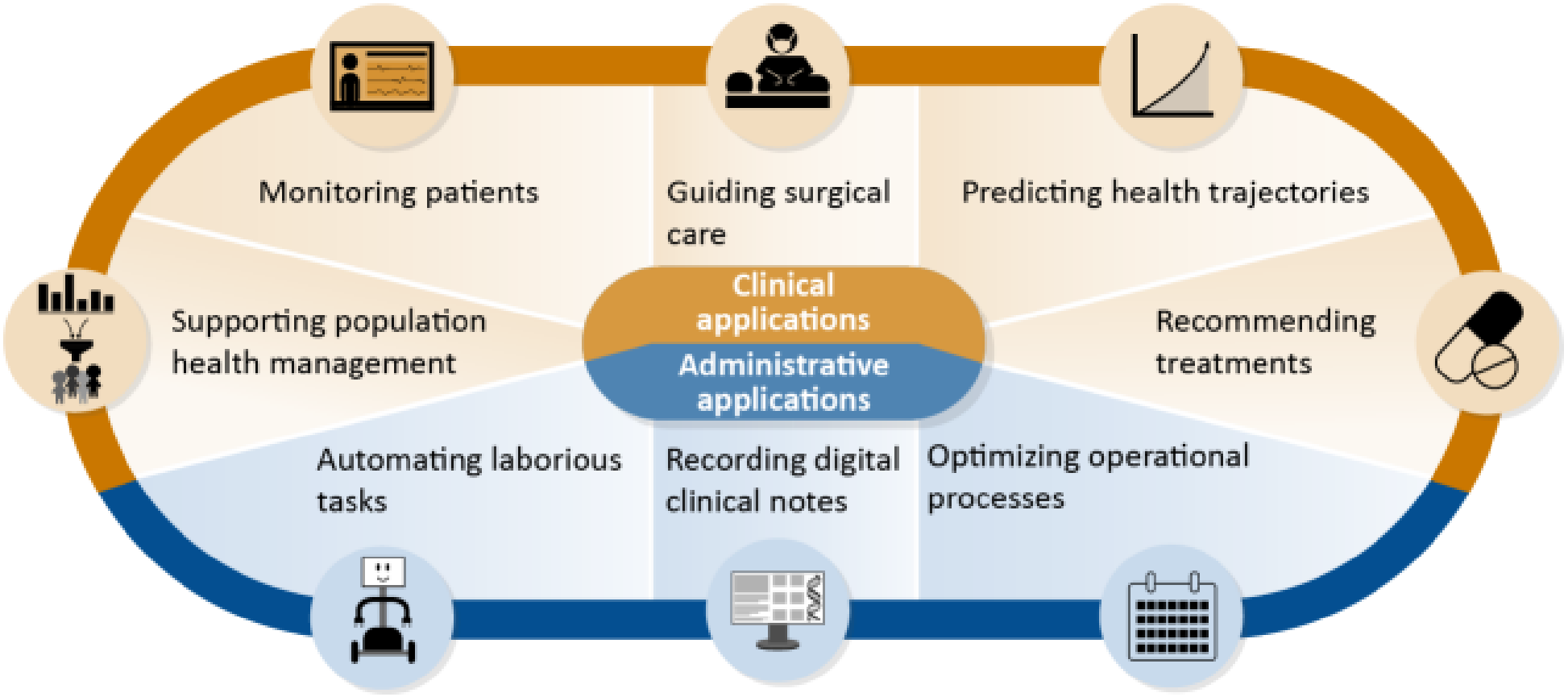
Agenda

1. Background and policy objectives for Predictive DSIs
2. Framing requirements for Health IT Modules certified to the DSI certification criterion (170.315(b)(11))
   - Predictive DSI definition
   - The “configuration nexus” for Predictive DSIs & Health IT Modules
   - Assurances Maintenance of Certification
3. Overview of required capabilities in 170.315(b)(11)
   - DSI selection and feedback loops
   - Source attributes for evidence-based and Predictive DSIs
   - Intervention risk management for Predictive DSIs
4. ONC-ACB Principle of Proper Conduct and implementation timelines
5. Policy impact and Health AI HHS regulatory snapshot

Background & Policy Objectives for Predictive DSIs

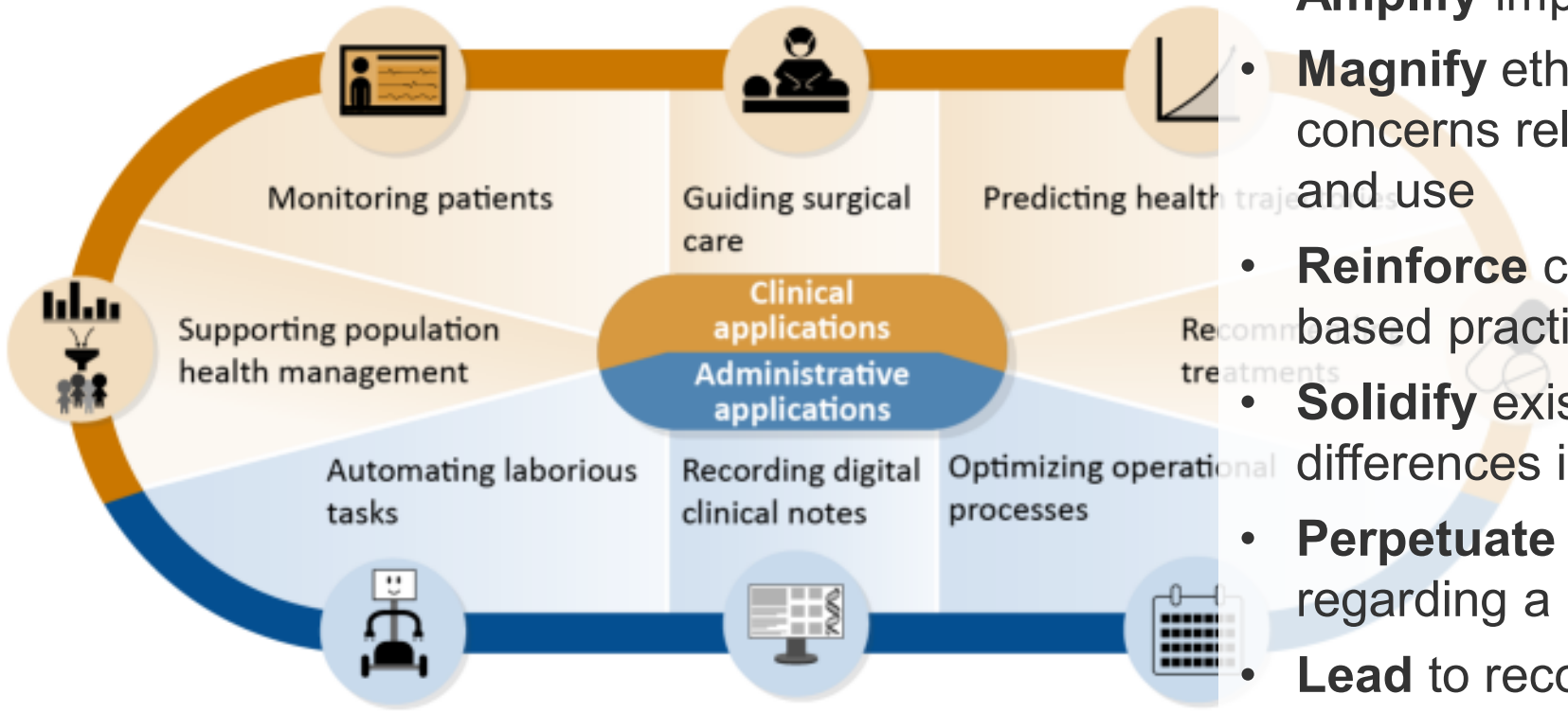
How can AI be used in healthcare?



: GAO. | GAO-21-7SP

https://www.gao.gov/assets/gao-21-7sp.pdf

What are the challenges?



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- **Amplify** implicit and structural biases
- **Magnify** ethical, legal, and social concerns related to data collection and use
- **Reinforce** common, non-evidence-based practices
- **Solidify** existing inexplicable differences in health outcomes
- **Perpetuate** information asymmetries regarding a model's quality
- **Lead** to recommendations that are ineffective or unsafe

Source: *"Getting the Best out of Algorithms in Health Care." Health IT Buzz blog. June 15, 2022*

An inclusive framing of how to address challenges

FAVES is our quality framework describing the characteristics of “high-quality” algorithms and communicates how we may get the best out of predictive models in health care.

Fair (unbiased, equitable)

Model does not exhibit biased performance, 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.

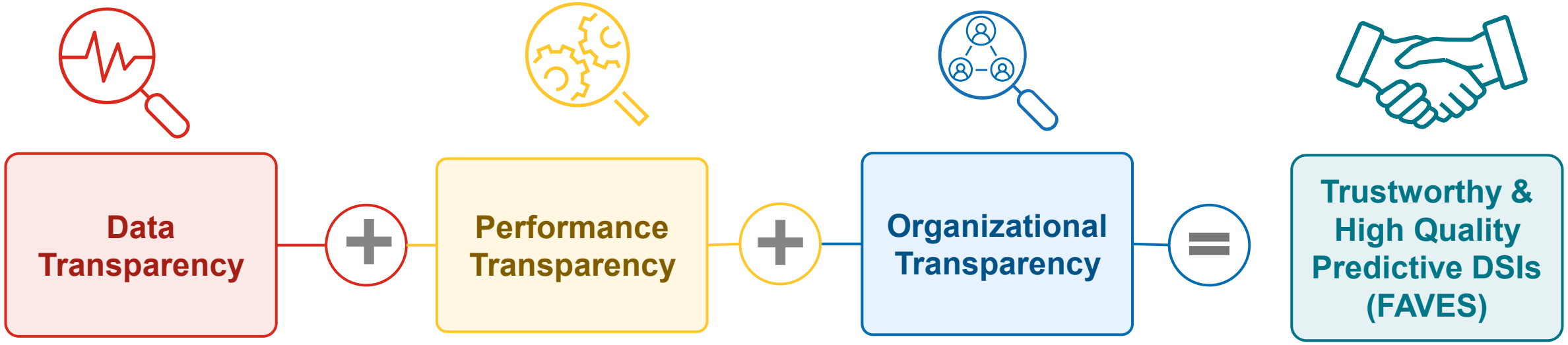
Effective

Model has demonstrated benefit and significant results in real-world conditions.

Safe

Model use has probable benefits that outweigh any probable risk.

Transparency Is a Prerequisite for Trustworthy AI



Data Transparency

Requirements enable users to know when a DSI uses specific data elements relevant to health equity

Performance Transparency

Enable users to have consistent and routine electronic access to technical, and performance information on Predictive DSIs

Organizational Transparency

Requirement for Certified Health IT developers to apply intervention risk management for each Predictive DSI they supply as part of their Health IT Module

Scoping requirements for Health IT Modules certified to the DSI certification criterion (§ 170.315(b)(11))

Predictive Decision Support Interventions

- ***Predictive Decision Support Intervention or Predictive DSI*** means technology that:
  1. Supports decision-making based on algorithms or models that
  2. Derive relationships from training data and then
  3. Produces an output that results in prediction, classification, recommendation, evaluation, or analysis

- The ONC Definition for Predictive DSI is
  - **Broad in scope:** includes a variety of techniques from algebraic equations to machine learning from relatively simple risk calculators (ASCVD or APACHE IV) to deep neural networks and LLMs
  - **Use case inclusive:** clinical, payer, research, administrative use cases
  - **Risk independent:** high-risk, low-risk, unknown risk
  - **Developer agnostic:** certified EHR company, health system, academic research lab, consumer technology firm

Configuration nexus for Predictive DSIs & Health IT Modules

- The “configuration nexus” for Predictive DSIs & Health IT Modules was proposed as a combination of three questions:
  - Does the technology in question meet the definition of Predictive DSI?
  - Does the Health IT Module enable or interface with one or more Predictive DSIs?
  - Does the Predictive DSI use any data based on the USCDI standard(s)?

- This configuration nexus was intended to maximize transparency for Predictive DSIs that:
  - Were natively integrated with and executable within a Health IT Module
  - Could be launched from a Health IT Module
  - Delivered outputs from an *other party*’s Predictive DSI to users through a Health IT Module

“enables”

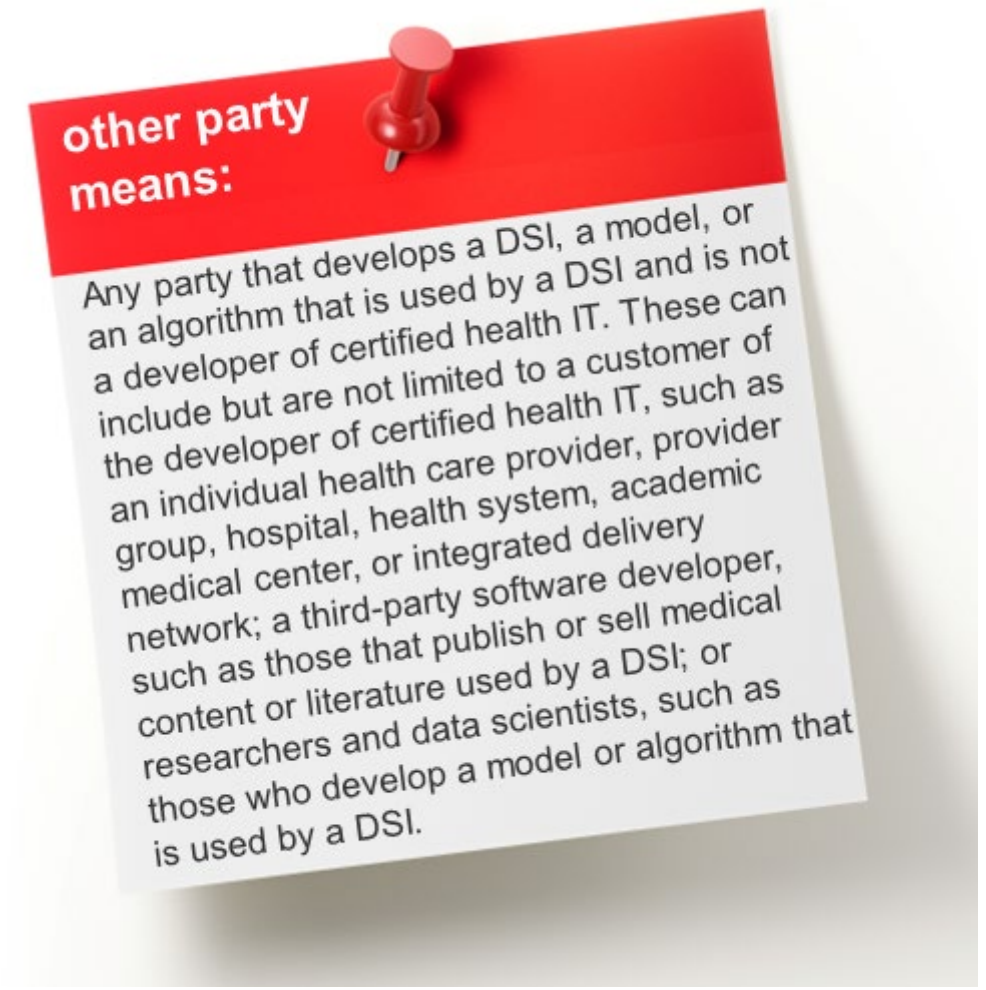
“enables” is about the Certified Health IT being a container within which a predictive model or DSI can be used (either as an app or as part of the Health IT Module)

“interfaces with”

"interfaces 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

Why the configuration nexus matters

- Established the contours of the “predictive DSI attestatio
- A “yes” for the attestation statement would mean that a H
  - Enable review of Predictive DSI-specific source attributes
  - Employ or engage in intervention risk management practi
  - Make detailed information of those risk management prac summary information available for public review
- A “yes” for the attestation statement would also mean tha
  - A Health IT Module would need to enable users to review Predictive DSIs, or clearly indicate when such information
  - A certified health IT developer would need to include infor *parties*
  - Review annually and update detailed and summary documentation from *other parties*



Survey Says?!

Reduced configuration nexus for Predictive DSIs & Health IT Modules

Proposed Configuration Nexus

Enables or interfaces with

- Commenters noted that
  - These terms and the resulting scope was vague, ambiguous, too broad, and problematic
  - Difficult to know whether a customer was enabling or interfacing with a Predictive DSI
  - Would require developers to meet transparency requirements for all third-party apps that customers use
  - Position certified health IT developers to be regulators

Finalized Configuration Nexus

Supplied by the health IT developer as part of its Health IT Module

- Includes Predictive DSIs that are authored or developed by the certified health IT developer
- Includes Predictive DSIs that are authored or developed by *other parties* if those Predictive DSIs are sold, marketed, or otherwise explicitly included as part of a Health IT Module
- Supplied by means that
  - Certified health IT developer has taken on stewardship and accountability for that Predictive DSI for the purposes of the Health IT Module
  - Knowledge of its use is known by the certified Health IT developer

Examples of “supplied by” configurations

- “Supplied by the health IT developer as part of its Health IT Module” would likely include:
  - When a developer of certified health IT certifying to 170.315(b)(11) offers customers (i.e., they can purchase or use) a hypertension model as part of its Health IT Module
  - When a developer of certified health IT includes a publicly available predictive model, like LACE+, or APACHE IV as part of its certified health IT product
  - When a developer incorporates an *other party’s* LLM, or other generative AI, that meets the definition of Predictive DSI and is part of what the developer offers its customers

- "Supplied by" **does not likely include** apps available through a certified health IT developer's app store

- From a conformance perspective, “supplied by the health IT developer as part of its Health IT Module” means:
  - Developers of certified health IT are not accountable for populating source attribute information for or applying IRM practices to Predictive DSIs in instances where their customers choose to deploy a self-developed Predictive DSI or an *other party*-developed Predictive DSI for use within their certified health IT
    - This is true even if the customer leverages data from the developer of certified health IT’s Health IT Module and even if the output from an *other party’s* Predictive DSI is delivered to or through a Health IT Module into a customer’s clinical workflow

Implications of this finalized configuration nexus

- Reduces the overall scope of technologies subject to final § 170.315(b)(11) requirements
- Maintains the intent of the attestation statement
  - Ensures Modules can certify to § 170.315(b)(11) without requiring them to author, revise, or otherwise supply a Predictive DSI
  - Instead of attesting "yes," a developer must enable access to complete and up-to-date source attribute information and apply specific IRM practices for each Predictive DSI it supplies as part of its Health IT Module
  - Instead of attesting "no," a health IT developer that does not supply any Predictive DSIs will not need to provide access to complete and up-to-date source attribute information or apply IRM practices, regardless of whether the developer's customers self-develop or use Predictive DSIs from *other parties*
- We note that if, after certification to § 170.315(b)(11), a developer begins to supply Predictive DSIs as part of its certified Health IT Module, it would need to comply with all applicable requirements in § 170.315(b)(11)

Assurances Maintenance of Certification Requirements

- Finalized a DSI criterion-specific instantiation of general Certification Program expectations as new Maintenance of Certification Requirements
- Builds on three specific existing Assurances Condition of Certification requirements
- Establishes ongoing obligations for developers of certified health IT that supply Predictive DSIs as part of their Health IT Modules to
  - Enable user access to updated descriptions of source attribute information
  - Review and update as necessary IRM practices that must be applied for each Predictive DSI the health IT developer supplies as part of its Health IT Module
  - Ensure the ongoing public accessibility of updated summary IRM practice information as submitted to their ONC-ACB via hyperlink
- Recognizes that such ongoing requirements would best fit under the Program as a developer-level responsibility, rather than a product-level responsibility

Overview of required capabilities in 170.315(b)(11)

At-A-Glance: DSI certification criterion

Final Rule:

- Revises existing CDS certification criterion by building on existing capabilities
- Streamlines and simplifies requirements for all Health IT Modules, while maintaining conditional requirements for Predictive DSIs
- Narrows the scope of impacted Predictive DSIs from what was proposed by constraining requirements to only those Predictive DSIs that are *supplied by a developer of certified health IT as part of its Health IT Module*

The DSI certification criterion includes:

A definition for “predictive decision support intervention”

Requirements for Health IT Modules to enable users to:

- Provide electronic feedback data for evidence-based DSIs and export such feedback data
- Select both evidence-based and Predictive DSIs
- Access complete and up-to-date source attribute information for evidence-based and Predictive DSIs
- Record, change, and access source attributes for evidence-based and Predictive DSIs

Requirements for risk management practices to be applied for Predictive DSIs

Establishes new Assurances Maintenance of Certification requirement to review and update DSI-related information on an ongoing basis

DSI Selection

- Finalized that all Health IT Modules certified to the DSI criterion must enable a limited set of identified users to select (i.e., activate) electronic decision support interventions that are
  - Evidence-based decision support interventions and use data identified in § 170.315(b)(11)(iii)(A)
  - Predictive decision support interventions and use any data expressed in the standards in § 170.213
- Ensures that users of Health IT Modules certified to the DSI criterion can select either evidence-based or Predictive DSIs
- Does not require a Health IT Module to author, develop, or otherwise supply a Predictive DSI
- Builds on existing technical capability to select (i.e. activate) DSIs chosen by users
- Represents a minimal level of effort beyond and is a slight modification to what we proposed if we had finalized the “no,” attestation.

Feedback Loops

Proposed Feedback Loops Requirement

Enable end users to provide electronic feedback data based on information displayed through the intervention and make available such feedback data for export, in a computable format, including but not limited to the intervention, action taken, user feedback provided (if applicable), user, date, and location.

Finalized Feedback Loops Requirement

Enable a user to provide electronic feedback data for **evidence-based decision support interventions** selected via the capability provided in paragraph (b)(11)(iii)(A) of this section and make available such feedback data to a limited set of identified users for export, in a computable format, including at a minimum the intervention, action taken, user feedback provided (if applicable), user, date, and location.

Scope of DSIs considered evidence-based for purposes of the Program

- Many commenters were concerned that our scope of evidence-based DSIs was too broad and that associated requirements (for source attributes and feedback loops) were unworkable
- For purposes of requirements in § 170.315(b)(11), we finalized that evidence-based DSIs 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

- This has implications for DSIs that Health IT Modules must
  - Enable selection (i.e. activation) of
  - Enable users to access source attributes for
  - Support “feedback loop” functionality for

DSI Source Attributes

Proposed Source Attribute Requirements

- We proposed to require all Health IT Modules to support source attributes for evidence-based and linked referential DSI types
- If developer attested “yes” as part of the predictive DSI attestation statement, then the Module must enable users to review source attributes for Predictive DSIs as well

- As proposed, source attributes combined capabilities to support “categories” and requirements to enable review of “content”
  - i.e., fields for source attribute information as well as the information itself

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

Finalized Source Attribute Requirements

- We have finalized separate requirements for Health IT Modules to support source attribute categories and source attribute content
  - Uniform requirements for all Health IT Modules certified to 170.315(b)(11) to
    - Support source attribute categories, or “fields,” for evidence-based and Predictive DSIs
    - Enable users to record, change, and access source attribute categories for evidence-based DSIs and Predictive DSIs
    - Enable users to record, change, and access additional source attributes not specified for Predictive DSIs
  - Conditional requirements for Health IT Module to enable
    - Access to complete and up-to-date plain language descriptions of source attribute information for evidence-based DSIs and Predictive DSIs supplied by the health IT developer as part of its Health IT Module

- This ensures that users have unform capabilities regardless of whether a health IT developer supplies a Predictive DSI

- Supports users who want to identify source attribute categories for self-developed Predictive DSIs or Predictive DSIs developed by *other parties,* and record, change, and access those source attributes

- Maintains intent of attestation to make source attribute information (content) conditional based on the “supplied by” configuration nexus

Evidence-based DSI Source Attributes

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 of race, ethnicity, language, sexual orientation, gender identity, sex, age
- NEW: Use of social determinants of health data
- NEW: Use of health status assessment data

Final Source Attribute Categories for Predictive DSIs

1. Details and output of the intervention
2. Purpose of the intervention
3. Cautioned Out-of-Scope Use of the intervention
4. Intervention development details and input features
5. Process used to ensure fairness in development of the intervention
6. External validation process
7. Quantitative measures of performance
8. Ongoing maintenance of intervention implementation and use
9. Update and continued validation or fairness assessment schedule

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.

Fostering an information ecosystem

- Source attribute categories expanded in regulation text to clarify numerous “shoulds” that were described in proposed rule preamble
  - Though more numerous, this explicitly states the limited type of information that must be available
    - E.g., proposed “Input features including description of training and test data” versus finalized “Use of variables in paragraph (b)(11)(iv)(A)(5)-(13) as input features”

- Emphasized source attribute information that are:
  - Most frequently included in existing, reviewed reporting guidelines
  - Meaningful and interpretable in the context of health IT users and developers
  - Focused on health equity, fairness, and identifying issues of bias
  - Intended to show that the model would perform effectively outside of the specific context in which it was developed

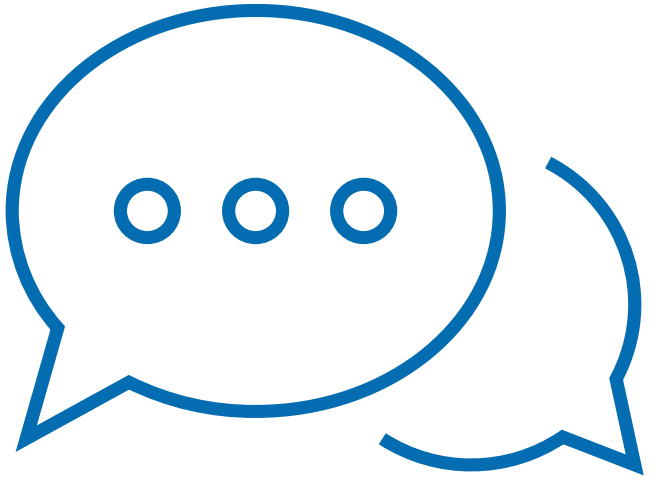
- Finalized source attribute information that:
  - Establishes a consistent, industry-wide foundation upon which others may standardize, customize, and enhance as they advance initiatives to structure “model cards” and initiate a wide range of evaluations / quality improvement
  - Balances prescriptiveness and flexibility to accommodate varied applications, contexts, and use cases
  - Aligns with existing reference material (e.g., NIST AI Risk Management Framework, White House Blueprint for an AI Bill of Rights, White House Executive Orders)
  - Supports emerging industry and academia-led efforts (CHAI, Health AI Partnership, VALID AI)

DSI source attribute modification

- Proposed “author and revise” capabilities, finalized “modify” capabilities
- For evidence-based and Predictive DSIs, the Health IT Module must enable a limited set of identified users to record, change, and access, related source attributes
- For Predictive DSIs, the Health IT Module must enable a limited set of identified users to record, change, and access additional source attributes not specified
  - Supports information related to local settings and post-deployment performance information
  - Supports customer users that self-develop Predictive DSIs or use *other party*-developed Predictive DSIs
  - Supports “independent review” for CDS that maybe relevant to FDA authority
  - Supports ongoing standardization, customization, and enhancements to source attributes
    - Accommodates emerging source attributes that may be more fit-for-purpose for specific uses (e.g., stratification), settings (e.g., oncology), and Predictive DSI types (e.g., LLMs and generative AI)

RFC: Should all source attributes information be publicly available or accessible?

- We declined to require public disclosure of source attribute information at this time
- As the industry gains experience with making source attributes available to users of Predictive DSIs, we may consider broader and public availability of source attribute information in future rulemakings



- Remind interested parties that under current Program requirements users have explicit rights to discuss publicly various aspects regarding the performance of certified health IT.
  - Specifically, we note that according to the Communications Condition and Maintenance of Certification requirements in § 170.403(a)(1)(iv) users have the right to describe relevant information regarding their experiences when using a Health IT Module
  - We note that source attribute information is among the kinds of information that customers may freely discuss publicly

Intervention Risk Management for Predictive DSIs

Proposed IRM practice requirements

- We proposed to require that by December 31, 2024, a developer of certified health IT that attested “yes” in the predictive DSI attestation statement would need to:
  - Employ or engage in IRM practices for all Predictive DSIs
  - Compile detailed documentation of IRM practices
  - Submit summary information to their ONC-ACB regarding IRM practices listed via a publicly accessible hyperlink
  - Review annually and, as necessary, update both detailed documentation and summary information
- We proposed that this work would need to include risk management information related to *other parties’* Predictive DSIs
- Commenters expressed significant concerns that our requirements would require disclosing IP or proprietary information, could compromise patient privacy, and increase administrative burdens

Final requirements for IRM practices

Intervention risk management practices must be applied for each Predictive DSI supplied by the health IT developer as part of its Health IT Module

1. Validity
2. Reliability
3. Robustness
4. Fairness
5. Intelligibility
6. Safety
7. Security
8. Privacy

- Predictive DSI(s) must be subject to
  - Analysis of potential risks and adverse impacts
  - Practices to mitigate identified risks
  - Policies and implemented controls for governance, including how data are acquired, managed, and used
- Final Rule preamble describes each characteristic and associated approaches that can be taken to assess and mitigate risks
  - Note: many of the terms and concepts in the IRM requirements rely on the National Institute of Standards and Technology (NIST) AI Risk Management Framework

Specifically, we have not finalized that developers review risk management information from *other parties* nor that developers include risk management information from *other parties* as part of documentation requirements

Activities to consider as part of IRM Practices

Risk Analysis

Should include:

- Estimates of the likelihood and magnitude of the negative impact (harm), or consequences, of each risk characteristic
- To whom each risk applies (including, for example, individual, group, and societal harm)
- Source of each risk

Risk Mitigation

Should include:

- Practices used to prioritize or establish different levels of risk
- Practices to mitigate or minimize identified risks
- Change control plans or ongoing validation and updating processes
- Processes to supersede, disengage, or deactivate deviations from intended use
- Approaches to include SMEs in measuring/validating performance

Governance

Should include:

- Setting an effective framework for risk management, with defined roles and responsibilities for clear communication of predictive DSI limitations and assumptions
- Setting and enforcing priorities for managing and using data as a strategic asset

ONC-ACB related requirements and implementation timeline

Health IT Developers	• Will have one year to update their certified health IT to support capabilities in 170.315(b)(11) • Will need to provide updated technology to their customers by December 31, 2024 • Will need to provide summary IRM practice information to their ONC-ACB before December 31, 2024 • Will need to keep source attribute information and risk management information up-to-date as an ongoing maintenance of certification requirement • Will need to include as part of Real World Testing Plans and Results
ONC-ACBs	• Will need to post a hyperlink to summary IRM practice information to CHPL by December 31, 2024
Providers	• As of their 2025 performance period for CMS payment policy, certified health IT will support providers' ability to access and modify detailed source attribute information for evidence-based and predictive DSIs they use
Industry	• The 31 source attributes finalized offers an industry-wide baseline from which more detailed "model cards" and other industry consensus can be formed • Transparency provisions are likely to incentivize the creation and support of fairer, better validated algorithms in healthcare

Wrap Up

Policy Impact of DSI Certification Criterion

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 potential risks and govern predictive DSIs that are supplied by the health IT developer as part of its Health IT Module

Foster an information ecosystem

Necessary to help healthcare organizations and users of these tools better determine whether their Predictive DSIs are fair, appropriate, valid, effective, and safe (FAVES)

Advance Health Equity by Design

By addressing bias and health disparities, potentially propagated by predictive DSIs, to expand the use of these technologies in safer, more appropriate, and more equitable ways for patients and individuals

How ONC fits into the broader Health AI HHS Regulatory Picture

Health AI Areas of HHS Activity

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Office for Civil Rights	FDA	ONC
Applicable Federal Policies		
Nondiscrimination in Health Programs and Activities Proposed Rule (Section 1557 of the Affordable Care Act)	**CDS and Device Software Function-related Guidance Documents**	**ONC Health IT Certification Program *(HTI-1 rulemaking)***
Who Must Comply?		
Health care provider, health plan, or recipients of financial assistance from HHS using AI to support decision-making in covered health programs and activities	*Manufacturer of device software functions (e.g., AI-enabled software that meets the definition of medical device)*	*Developers of certified health IT that supply a predictive DSI as part of its Health IT Module*
What Must Be Done?		
Not use clinical algorithms in discriminatory ways (proposed rule)	Receive FDA-approval for demonstrating the device software function's safety and effectiveness	Enable user access to predictive DSI performance information, apply risk management practices, keep information and practices up-to-date

Office of the National Coordinator for Health Information Technology

Phone: 202-690-7151

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