



Office of the National Coordinator
for Health Information Technology

HTI-1 Proposed Rule

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

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

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Today's Topics

1. Background: Predictive Algorithms in Health Care and Role of Certified Health IT
2. Overview and Proposed Requirements for All Decision Support Interventions (DSIs)
3. Predictive DSI Definition and Attestation
4. Source Attributes for Predictive DSIs
5. Intervention Risk Management for Predictive DSIs
6. Oversight and Implementation



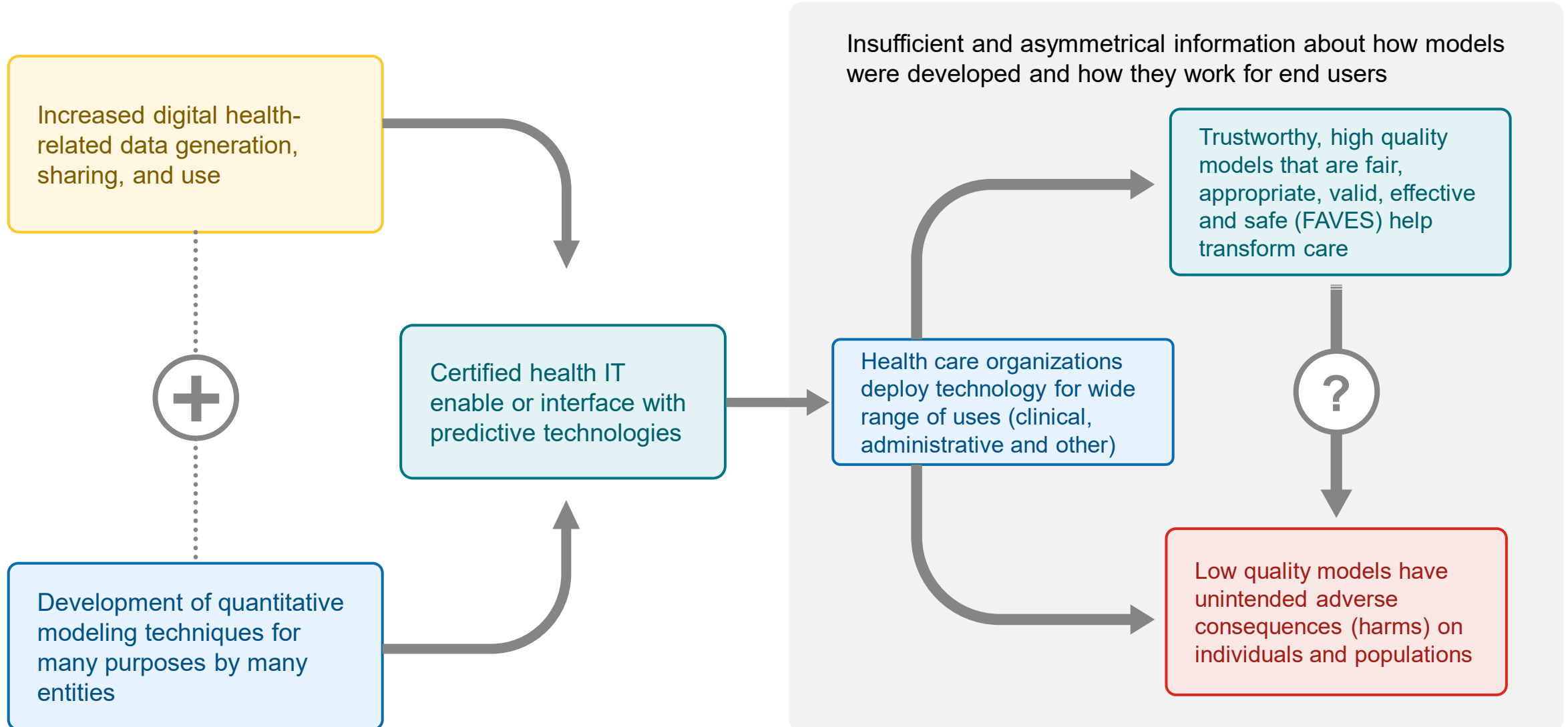
Background for DSI and Predictive Model Proposals



Predictive Models and Machine Learning in Health Care

- Long history of using predictive models in health care
 - Ranson (1974): Objective correlation between tabulated score and mortality¹
 - Apache III (1991): Logistic regression²
 - Epic's Sepsis Model (2019): Penalized logistic regression³
- Machine learning and language models have many similarities with predictive models
 - Learn from relationships and patterns in historical data
 - Predict unknown information based on those relationships
 - For instance, a patient's readmission risk based on demographic, diagnosis and other factors
 - Or the next word based on a prompt

Tech View: Current State of Predictive Models in Health Care



Predictive Models and Machine Learning (ML) in Health Care: Unintended Consequences

- Amid excitement about predictive models / ML, there has been recent evidence of unintended consequences from their use:
 - A population health management model was discovered to have unintended racial bias implications causing re-release of the model^{1,2}
 - A sepsis prediction model fielded in a number of medical facilities was found to have low validity and subsequently updated and re-released^{3,4}
 - A model developed to estimate glomerular filtration rates has been recommended to be replaced by the National Kidney Foundation and American Society of Nephrology amid concerns that its use of race as a key variable was widening health disparities for black patients^{5,6,7}
- These instances highlight the value of transparent information for improving predictive models in health care



Role of Certified Health IT in Predictive Models and Machine Learning

- The existing scope and structure of the ONC Health IT Certification Program are fit to enhance transparency around predictive decision support
- The Program has existing requirements to make transparent information regarding the authorship, bibliographic, and other kinds of “source attribute” information for evidence-based decision support and linked referential interventions.
- ML / AI in health care is often best considered a form of decision support or ‘augmented intelligence’
- ONC is proposing to update the existing decision support criterion to directly include predictive decision support, inclusive of ML technologies





Proposed Revised Criterion: § 170.315(a)(9) – Clinical Decision Support: Objective, Benefits, and Impact

Objective: Enable improved information transparency on the trustworthiness of predictive DSIs to support their widespread use in health care.

Benefits:

- Improve transparency on how the predictive DSI was designed, developed, trained, evaluated, and should be used, addressing fundamental information asymmetries in the marketplace for predictive DSIs.
- Enable the public to understand how developers of certified health IT with Health IT Modules that enable or interface with predictive DSIs manage risks related to fairness, validity, safety, security, and privacy.
- Support consistent availability of predictive DSI information, including information salient to health equity by design.

Impact: With the availability of this information, users of certified health IT would be able to determine the DSI's quality and whether its recommendations are fair, appropriate, valid, effective, and safe (FAVES)

Transparency & Trustworthiness in DSI Proposals

Transparency

Information about the.....

(1) use of data related to health equity in predictive DSIs,

(2) technical and performance aspects of predictive DSIs, and

(3) organizational competencies employed to manage risks for predictive DSIs.

Transparency would provide essential information needed to determine whether and how to use the predictive model's outputs.

Trustworthiness

- ONC frames “trustworthy” or “high quality” predictive DSIs as Fair, Appropriate, Valid, Effective, and Safe (FAVES)

Fair	Model does not exhibit prejudice or favoritism toward an individual or group based on their inherent or acquired characteristics.
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.



Overview and Proposed Requirements for All DSIs

Proposed Revised Criterion: § 170.315(a)(9) - Clinical Decision Support

Proposal:

Revise and rename existing clinical decision support (CDS) criterion to reflect contemporary and emerging functions, uses and data elements.

This revision includes:

Additional requirements for all decision support

A definition for “predictive decision support intervention”

Requirements for Health IT Modules that enable or interface with predictive decision support interventions

Requirements for developers of health IT that certify such Health IT Modules



Transparency Is a Prerequisite for Trustworthy AI

Updating Decision Support

Proposed requirement to enable decision support based on new data elements

Proposed feedback requirement

Proposed requirement to support authoring and revising source attributes

Data Transparency

Proposed source attributes requirement 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

Performance Transparency for Predictive DSI

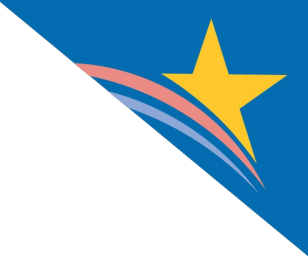
Proposed source attributes would enable consistent and routine electronic access to technical and performance information on predictive DSIs

- Spanning intended use, training data descriptions, measures of fairness, and ongoing maintenance

Organizational Transparency for Predictive DSI

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



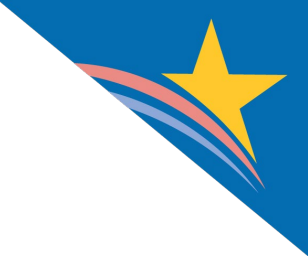
Proposed Requirements for § 170.315(b)(11) – Decision Support Interventions

Much of the proposed structure and requirements of the CDS (a)(9) criterion are duplicated across the proposed DSI (b)(11) criterion

Reflect capabilities with which participants have years of familiarity

Health IT Modules must configure Evidence-based DSIs and Linked referential DSIs based on a defined set of data elements including

- Problems, medications, allergies and intolerances, demographics, laboratory, vital signs
- Propose to reference related USCDI v3 data elements and classes
- **NEW:** Procedures and Unique Identifier(s)



Proposed Requirements for § 170.315(b)(11) – Decision Support Interventions

Health IT Modules would be 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 information 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 a DSI is developed by a developer of certified health IT, information for all attributes are required, unless otherwise noted in proposed regulation as “if available”



For DSIs that are developed by other parties, health IT modules must 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.

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



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



Enable end users to provide feedback based on information displayed through the intervention and

- Make available such feedback data for export, in a computable format,
- Data includes but not limited to 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 Attestation

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 prior data
 - Contrast with evidence-based DSI which supports decision-making by relying on pre-defined rules based on expert consensus or from expert recommendation (e.g., computable clinical guidelines).
- Predictive DSIs include those based on:
 - Simple statistics or regression model → risk calculator
 - Machine learning models (e.g., predicting healthcare costs; sepsis onset; no-show)
 - From widely used ASCVD and APACHE IV models, to bespoke machine learning models used to predict opioid overdose, hospital bed capacity, and other emerging use cases^{11,12}
 - Natural language processing (NLP) and large language models (LLMs) (sometimes referred to as generative AI)
- DSI may be presented in a broad array of forms (e.g., alerts, order sets, flowsheets)
- Proposed definition is
 - **Not** tied to a specific purpose or intended use.
 - **Not** dependent on who developed the algorithm or model (can be someone other than a developer of certified health IT)
 - **Not** based on a level of risk associated with the technology’s purpose.

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, or
 - Other technologies
 - Are there prominent models (e.g., simulation models, unsupervised learning models) used to support decision-making in health care that are not effectively captured under the proposed definition of a predictive DSI?
 - If so, is it feasible and appropriate to include such models in the scope of this rule?



Predictive DSI Attestation



Health IT Modules certified to 170.315(b)(11) would **not** be 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

Developers of certified health IT and its certified Health IT Module are subject to applicable predictive DSI requirements

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

Subject to applicable general DSI requirements (described on previous slides)

“Enables or Interfaces with”

“Enables or interfaces with” encompasses a broad set of ways the health IT module might make it possible to use predictive DSI.

- Includes applications developed by
 - Developers of certified health IT,
 - Their users, or
 - Other parties (e.g., third-party software developers)

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

- Standalone applications used within or as a part of a Health IT Module
- Includes instances where predictive DSIs are enabled by default and instances where they can be enabled by users

Example: Calculations for a predictive DSI occur within the Health IT Module, either 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



“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

“Enables or Interfaces with”

Interfaces with: The Health IT Module facilitates either the

- 1) Launch of a predictive model or DSI or
- 2) 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

Examples:

- 1) 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)
- 2) A predictive DSI application is launched from a certified Health IT Module, including through the use of a single sign-on functionality



“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



Proposed Scope of Covered Technologies

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

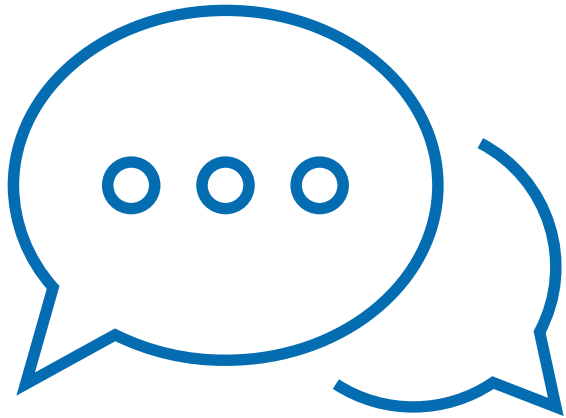
- Developer self-develops predictive DSIs for use in their certified Health IT Module; **or**
- Developer’s Health IT Module enables or interfaces with predictive DSIs developed by its users or customers, such as a health care organization or medical center; **or**
- Developer’s Health IT Module enables 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)



Request for Comment for Enabled by or Interfaced with



Are “enable,” and “interface with,” appropriately scoped to reflect the design, development, and use of these emerging technologies in healthcare?

Three thick, parallel blue lines slanting upwards from the bottom left towards the top right, partially overlapping the yellow title box.

Source Attributes for Predictive DSIs

Overview of Proposals to Improve Transparent & Trustworthy DSIs Through the ONC Health IT Certification Program

Technical & Performance

- Information about how the predictive DSI “works” made available to users, in plain language and via direct display, drill down, or link out:
 - Output and intended use, out of scope use(s), description of training data, external validation, update schedule, etc.
 - Like a “nutrition label”; leverage existing “source attributes” certification requirement
- Supportive of health equity by design:
 - Identification of REL, SOGI, SDOH, & Health Status data elements used
 - Information on validity and fairness of prediction in test and local data (if available)
- Additional enhancements that enable:
 - Authoring and revision capability for users
 - User feedback capabilities and feedback exports for quality improvement of DSIs

Governance

- Public disclosure regarding how certified health IT developer manages risks and governs predictive DSIs:
 - Risk analysis (8 risk types): validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy
 - Risk mitigation of those risks
 - Governance processes, including data management
- Summary documentation must be:
 - Publicly accessible through hyperlink without precondition
 - Reviewed annually for updates
- Detailed documentation must be:
 - Available to ONC upon request from ONC for each predictive DSI the certified health IT enables or interfaces with
 - Reviewed annually for updates

Oversight

- Conformance to proposed requirements through Real World Testing (RWT) Program:
 - RWT for all DSI types (predictive, evidence-based, and linked referential) beginning for 2024 plans
 - Annual cycle of RWT plans and results publicly available via the Certified Health IT Product List (CHPL)
 - Measures demonstrating conformance to requirements, self-identified by developer

Overview of Proposed Source Attribute Requirements

If a Health IT Module enables or interfaces with predictive DSIs, we are proposing that the module must make information about additional Source Attributes available to provide users transparency on how the predictive DSI was designed, developed, trained, evaluated, and should be employed.

Technical & Performance

- Information about how the predictive DSI “works” made available to users, in plain language and via direct display, drill down, or link out:
 - Output and intended use, out of scope use(s), description of training data, external validation, update schedule, etc.
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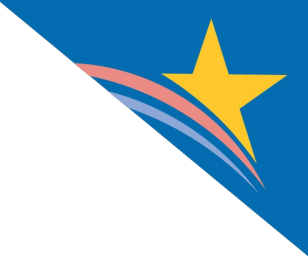
Sources of Source Attributes

We emphasized source attribute information that

1. Were most commonly included in existing, reviewed reporting guidelines¹³⁻²²
2. Would be most meaningful and interpretable in the context of health IT users and developers
3. Were focused on health equity, fairness, and identifying issues of bias
4. Were intended to show that the model would perform effectively outside of the specific context in which it was developed

Goals

- Identify minimum necessary attributes
- Based on existing model reporting guidelines¹³⁻²²
- Balance prescriptiveness and flexibility to accommodate varied applications, contexts, and use cases
- Align with existing reference material (e.g., NIST AI Risk Management Framework, White House Blueprint for an AI Bill of Rights)
- Support emerging industry-led efforts



Predictive Decision Support Intervention – Source Attributes

Intervention Details (3)

- Output
- Intended use
- Cautioned out of scope use(s)

Intervention Development (3)

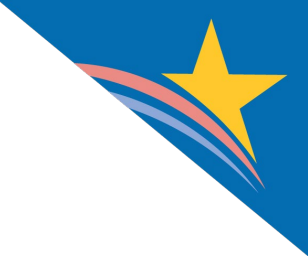
- Input features including description of training and test data
- Process used to ensure fairness in development
- External validation process, if available

Quantitative Performance Measures (5)

- Validity and Fairness of prediction in test data
- Validity and Fairness of prediction in external data, if available
- References to evaluation of use of the model on outcomes, if available

Ongoing Maintenance & Intervention Use (3)

- Update and continued validation or fairness schedule
- Validity of prediction in local data, if available
- Fairness of prediction in local data, if available



Example Source Attribute Description

Output of the intervention

- The value that the model produces as an output, including whether the output is a prediction, classification, or other type of output.
- Allows users to determine if the output is appropriate or may inherently reflect low validity or bias because of concerns about the process that produces an output in the training data.

Fairness of prediction in external data, if available

- The measure or set of measures related to the model's fairness in terms of the accuracy of its output across certain groups in external data (i.e., data from a different source than the primary training data).
- It is important for users to be able to view measures related to model performance from outside the development environment or to be informed when the model has not been evaluated in external data.

RFC: Source Attributes

- We request comment on whether there are items contained within the proposed source attributes that we should explicitly require as elements of source attributes information.
 - Specific attention to three Source Attributes with multiple “should” components:
 - “Intended use of the intervention,”
 - “Input features of the intervention including description of training and test data”
 - “External validation process, if available”



RFC: Input Features Example

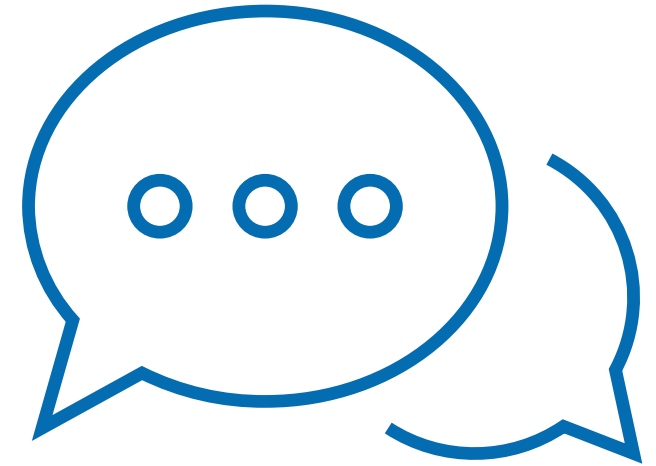


Input features of the intervention including description of training and test data

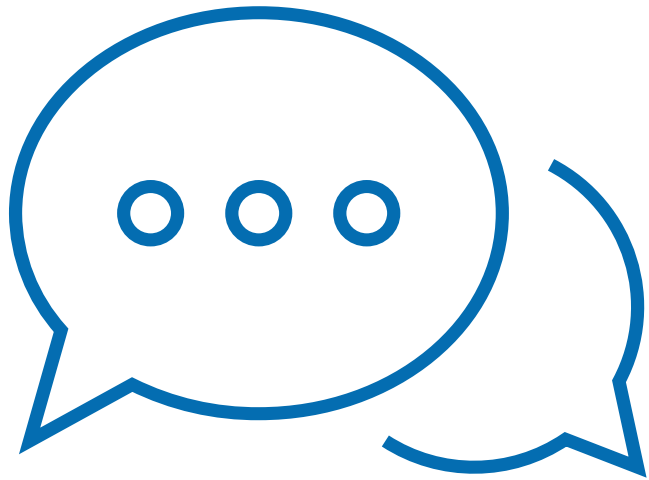
- A description of the data on which the model learned relationships and the data on which the model was tested during development.
- This description should include:
 - 1) exclusion and inclusion criteria;
 - 2) statistical characteristics of the demographic and other key variables;
 - 3) the source and clinical setting from which the data was generated,
 - 4) the extent of missing values in the training and testing data sets; and
 - 5) other attributes related to data quality, such as the comprehensiveness of the data and the process of collecting the data.

RFC: Additional Source Attributes Example

- **Intervention Details**
 - Information on explainability and interpretability
 - Whether a DSI meets the definition of a medical device under the FDA definition
- **Intervention Development**
 - Details on how model prediction and classification cut-points were selected
 - Security and privacy-preserving approaches included in model development
- **Quantitative Measures of Intervention Performance**
 - Model calibration or calibration curve
 - Confidence or prediction intervals or other measures of uncertainty
- **Ongoing Maintenance of Intervention Implementation and Use**
 - Whether the model is 'online' or 'unlocked'
 - Any additional organizational or technical controls in place to evaluate the impact of the online or unlocked updating and results of that evaluation.
 - The controls in place to update the descriptions of source data to reflect the changing composition of the data.



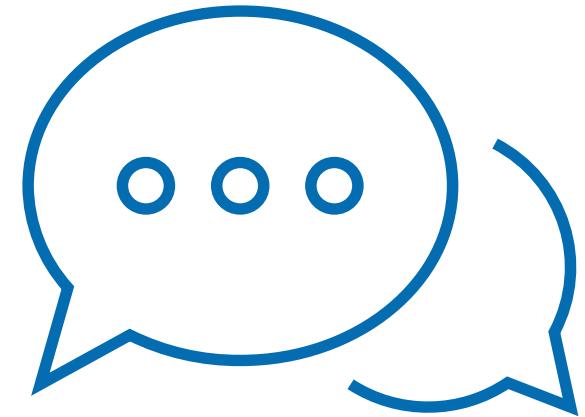
RFC: Source Attributes Public Availability



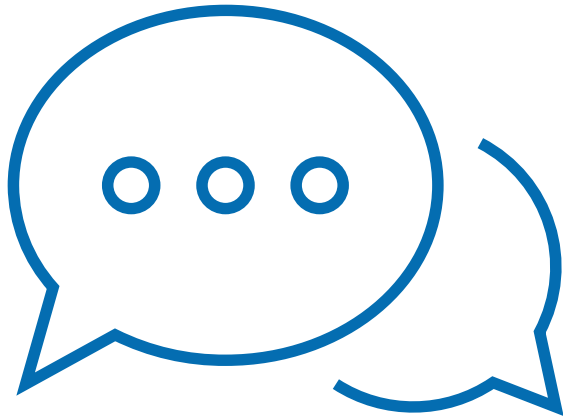
- Whether we should require developers of certified health IT with Health IT Modules certified to proposed § 170.315(b)(11) to make all source attributes information in the proposed § 170.315(b)(11)(vi) publicly available or accessible.
- Is public availability of this information necessary to effectively improve the emerging market for predictive DSIs or to ensure public confidence in predictive DSIs by enabling research use of source attribute information?

RFC: Source Attributes Information Available to Patient

- Are existing Program requirements in the Communications condition and maintenance of certification requirements sufficient to ensure open and transparent discussion regarding the use of predictive DSIs in patient care – including discussion between users of certified health IT and patients?
- Should we require developers of certified health IT to provide the technical capability for users to support patients electronically accessing underlying source attribute information (e.g., through a patient portal or otherwise indicate to a patient when a predictive DSI was used to make decisions about the patient in the course of the patient's care)?
- We also are interested in learning more about how to incorporate the patient perspective and overall engagement meaningfully and sustainably.



RFC: Other Parties



- When predictive DSI are developed by other parties, we anticipate that developers of certified health IT would obtain information from the model developers, owners, or creators.
- We propose to allow developers of certified health IT with Health IT Modules that enable or interface with predictive DSIs that are developed by other parties to clearly indicate when any source attribute information is not available for user review.
- We seek comment on whether we should require developers of certified health IT to display source attribute information for other parties with which the developer of certified health IT has a contractual relationship.



Consensus Metrics and Standards

- We also solicit comment on testing or assessment tools that might further support transparency and trustworthiness including
 - Consensus metrics and technical standards for evaluating fairness (assessing for bias) and validating performance (including testing performance in different populations and evaluating applicability or generalizability) of predictive models that are enabled by or interface with Health IT Module(s) prior to and during deployment
 - Development and engineering of algorithmic impact assessments (AIAs)
 - Development of documentation of datasets used, such as datasheets for datasets and data cards as well as tools that could be useful in these areas so that Health IT Modules certified to §170.315(b)(11) can demonstrate it meets a given requirement on an ongoing basis



Intervention Risk Management for Predictive DSIs

Overview of Proposals to Improve Transparent & Trustworthy DSIs Through the ONC Health IT Certification Program

Technical & Performance

- Information about how the predictive DSI “works” made available to users, in plain language and via direct display, drill down, or link out:
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- Additional enhancements that enable:
 - Authoring and revision capability for users
 - User feedback capabilities and feedback exports for quality improvement of DSIs

Governance

- Public disclosure regarding how certified health IT developer manages risks and governs predictive DSIs:
 - Risk analysis (8 risk types): validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy
 - Risk mitigation of those risks
 - Governance processes, including data management
- Summary documentation must be:
 - Publicly accessible through hyperlink without precondition
 - Reviewed annually for updates
- Detailed documentation must be:
 - Available to ONC upon request from ONC for each predictive DSI the certified health IT enables or interfaces with
 - Reviewed annually for updates

Oversight

- Conformance to proposed requirements through ONC’s Real World Testing (RWT) Program:
 - RWT for all DSI types (predictive, evidence-based, and linked referential) beginning for 2024 plans
 - Annual cycle of RWT plans and results publicly available via the Certified Health IT Product List (CHPL)
 - Measures demonstrating conformance to requirements, self-identified by developer

Overview of Proposed Intervention Risk Management (IRM) Requirements

If a Health IT Module enables or interfaces with predictive DSIs, a health IT developer must employ or engage in “intervention risk management practices” and make summary information of those practices publicly accessible

Governance

- Public disclosure regarding how certified health IT developer manages risks and governs predictive DSIs:
 - Risk analysis (8 risk types): validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy
 - Risk mitigation of those risks
 - Governance processes, including data management
- Summary documentation must be:
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Pillars IRM Practices

Risk Analysis

- Analyze potential risk(s) and adverse impact(s) associated with the predictive DSI, including but not limited to:
 - Validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy

Risk Mitigation

- Implement practices to minimize or mitigate risk(s) identified in the Risk Analysis associated with the predictive DSI
 - For example, developers include participants with diverse expertise, including patients, in designing and testing predictive models.

Governance

- Establish policies and implement controls for predictive DSI, including how data are acquired, managed, and used in the predictive DSI

Note: Generally, many of the proposed terms and concepts in the IRM proposal rely on the National Institute of Standards and Technology (NIST) [AI Risk Management Framework](#) and U.S. Department of the Treasury's Office of the Comptroller of the Currency (OCC) [Model Risk Management Guidance & Handbook](#).

Characteristics for Risk Analysis & Mitigation for Predictive DSIs



Propose to require certified health IT developers employ or engage in risk analysis and mitigation practices for 8 characteristics:

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

- Proposal includes definitions and descriptions of each characteristic and approaches that should be taken to assess and mitigate risks.
- Request comment on whether these proposed requirements should include more specificity, including on approaches to assess and mitigate risks.
- Request comment on best practices or other items contained within the risk analysis proposal that should be explicitly required.

Areas to Include 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); and
- 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; and
- Approaches to include SMEs in measuring/validating performance

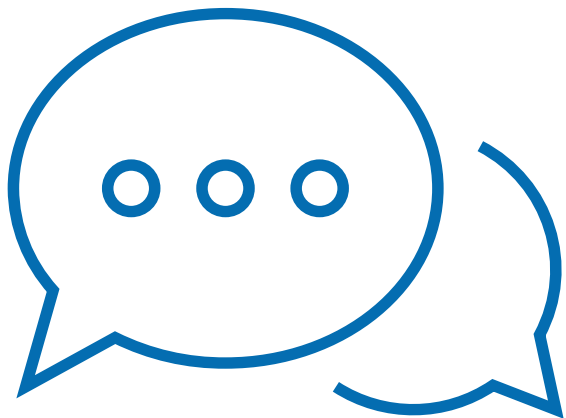
Governance

Should include:

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

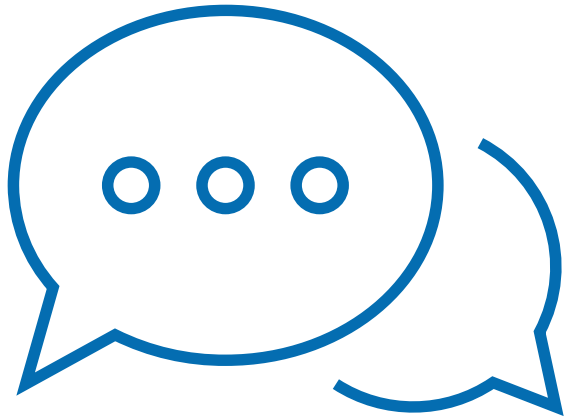


RFC: Intervention Risk Management and Other Parties



- We expect other parties to provide the developer of certified health IT with relevant intervention risk management information so that such information may be available for both detailed and summary documentation.
- Similar to how the source attributes proposals treat other parties, we expect other parties to provide the developer of certified health IT with relevant intervention risk management information so that such information may be available for both detailed and summary documentation.
- We seek input on ways in which developers of certified health IT can best determine that intervention risk management practices have been conducted for all predictive DSIs that their Health IT Module enables or interfaces with.

Additional Requests for Comment



- Users of Certified Health IT and Predictive Decision Support Intervention Management
- Data Practices and Governance: Ethical, Legal, and Social Implications (ELSI) of Data Collection and Use
- Technical Data Standards and Data Management: Electronic Data Source, Capture, and Use



Oversight & Implementation

Snapshot of Proposals to Improve Transparent & Trustworthy DSIs Through the ONC Health IT Certification Program

Technical & Performance

- Information about how the predictive DSI “works” made available to users, in plain language and via direct display, drill down, or link out:
 - Output and intended use, out of scope use(s), description of training data, external validation, update schedule, etc.
 - Like a “nutrition label”; leverage existing “source attributes” certification requirement
- Supportive of health equity by design:
 - Identification of REL, SOGI, SDOH, & Health Status data elements used
 - Information on validity and fairness of prediction in test and local data (if available)
- Additional enhancements that enable:
 - Authoring and revision capability for users
 - User feedback capabilities and feedback exports for quality improvement of DSIs

Governance

- Public disclosure regarding how certified health IT developer manages risks and govern predictive DSIs:
 - Risk analysis (8 risk types): validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy
 - Risk mitigation of those risks
 - Governance processes, including data management
- Summary documentation must be:
 - Publicly accessible through hyperlink without precondition
 - Reviewed annually for updates
- Detailed documentation must be:
 - Available to ONC upon request from ONC for each predictive DSI the certified health IT enables or interfaces with
 - Reviewed annually for updates

Oversight

- Conformance to proposed requirements through Real World Testing (RWT) Program:
 - RWT for all DSI types (predictive, evidence-based, and linked referential) beginning for 2024 plans
 - Annual cycle of RWT plans and results publicly available via the Certified Health IT Product List (CHPL)
 - Measures demonstrating conformance to requirements, self-identified by developer

Overview of Proposed Oversight Requirements

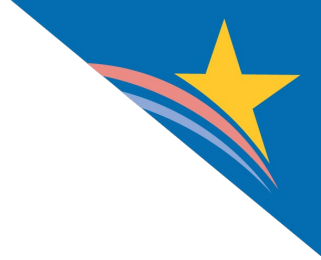
Oversight

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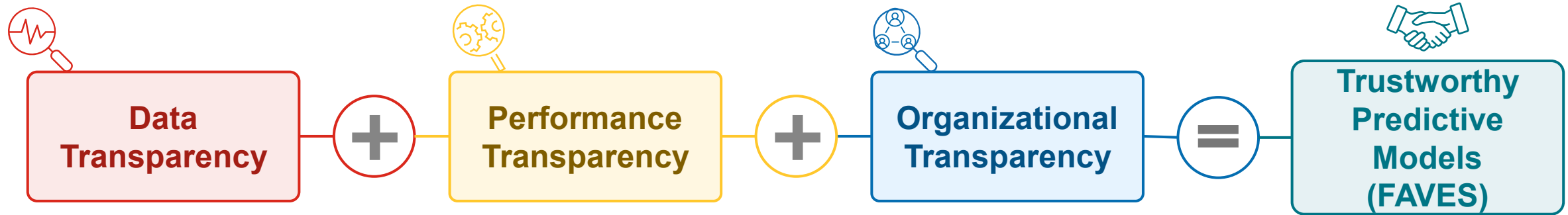
Proposed Implementation Timeline and RWT Implications

- 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
- Propose to add (a)(9) to the list of applicable criteria for Real World Testing



Wrap Up

Transparency Is a Prerequisite for Trustworthy AI



Data Transparency

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

Performance Transparency

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

Organizational Transparency

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



Source Attributes and *IRM Information* Help Users Determine the FAVES of a Predictive DSI

Fair	Appropriate	Valid	Effective	Safe
<p>Process used to ensure fairness in development of the intervention</p> <p>Fairness of prediction in test data</p> <p>Fairness of prediction in external data, if available</p> <p>Fairness of prediction in local data, if available</p> <p><i>Risks to fairness are managed</i></p>	<p>Output of the intervention</p> <p>Intended use of the intervention</p> <p>Cautioned out-of-scope use of the intervention</p> <p><i>Risks to intelligibility are managed</i></p>	<p>Input features of the intervention including description of training and test data</p> <p>External validation process, if available</p> <p>Validity of prediction in test data</p> <p>Validity of prediction in external data, if available</p> <p>Validity of prediction in local data, if available</p> <p><i>Risks to Validity, Robustness, and Reliability are managed</i></p>	<p>References to evaluation of use of the model on outcomes, if available</p> <p>Update and continued validation/fairness schedule</p>	<p><i>Risks to safety are managed</i></p> <p><i>Risk to security are managed</i></p> <p><i>Risks to privacy are managed</i></p>

Intended Impact Statements

Enable patients to benefit from health care provider's use of trustworthy predictive models for decisions related to their care

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 their certified Health IT Modules enable or interface with

Support 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, potentially propagated by predictive DSIs, to expand the use of these technologies in safer, more appropriate, and more equitable ways



Opportunities to Comment and to Learn More

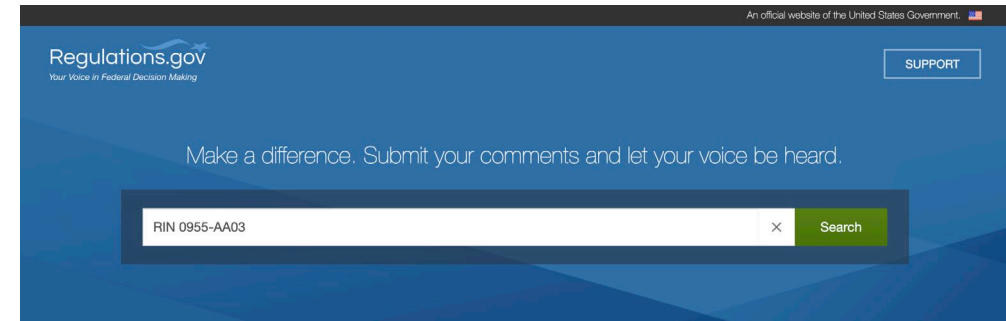
How to Submit a Comment

Federal eRulemaking Portal

You may submit comments, identified by RIN 0955-AA03, through <http://www.regulations.gov>. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word.

Public Comment Template

We will provide a template following publication of the proposed rule in the Federal Register for the public to use, if they so choose, when submitting their comments.



What's New on Regulations.gov

New features include the ability to download Agency, Docket, and Public Submission Document metadata in bulk. See [FAQs](#) for more detail.



Explore

Comments Due Soon

Today	78
Next 3 Days	108
Next 7 Days	149



Resources Available on HealthIT.gov!

Visit <https://healthIT.gov/proposedrule> for additional information. More updates will be added over time.

Fact Sheets

- General Overview
- At-a-Glance
- Decision Support Interventions and Predictive Models
- Insights Condition
- Information Blocking (upcoming release)

Measurement Spec Sheets

- One for each of the 9 proposed Insights Condition measures

The image displays two screenshots of the HealthIT.gov website. The top screenshot is an 'AT-A-GLANCE' page titled 'Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule' dated April 2023. It lists 'Standards and Certification Criteria Proposals' and 'Certification Program Proposals'. The bottom screenshot is a 'GENERAL OVERVIEW' page for the same proposed rule, dated April 2023. It includes a 'Proposal Highlights' section with four main points: implementing the 'eHR Reporting Program', providing enhancements to information blocking regulations, proposing adoption of USCDI Version 3, and updating certification standards. It also features a 'Discontinuing Year-Themed Editions for Health IT Certification Criteria' section.

HITAC HTI-1 Proposed Rule Task Force



Overarching Charge:

The HTI-1 Proposed Rule Task Force 2023 will evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule.

- All Task Force meetings are open to the public
- Registration and meeting materials can be found at:
<https://www.healthit.gov/topic/federal-advisory-committees/hitac-calendar>

Don't Miss Our Upcoming Webinars

Visit <https://healthIT.gov/proposedrule> for additional information.
More updates will be added over time.

Upcoming Webinars



Insights Condition Proposals

May 11, 1:00 PM ET



Information Blocking Proposals

May 18, 1:00 PM ET



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for Health Information Technology

Contact ONC



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<https://www.youtube.com/user/HHSONC>

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Endnotes

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