Office of the National Coordinator for Health Information Technology

# ONC Health IT Certification Program Developer Roundtable

June 20, 2024

# Please Note:

- The materials contained in this presentation are based on the provisions contained in 45 C.F.R. Parts 170 and 171. While every effort has been made to ensure the accuracy of this restatement of those provisions, this presentation is not a legal document. The official program requirements are contained in the relevant laws and regulations. Please note that other Federal, state and local laws may also apply.

- This communication is produced and disseminated at U.S. taxpayer expense.

# Agenda

1. Opening Remarks
2. Standards Version Advancement Process (SVAP)
3. Requirements for Decision Support Interventions and Predictive Models

# Today's Speakers

1. Robert Anthony, Director, Certification and Testing
2. Shawn Spurlock, Public Health Analyst, Certification and Testing
3. Liz Turi, Branch Chief, Standards
4. Jeff Smith, Deputy Director, Certification and Testing
5. Nikki Hayes, Public Health Analyst, Certification and Testing

# Standards Version Advancement Process (SVAP)

Shawn Spurlock, Certification and Testing

# Standards Version Advancement Process (SVAP)

The SVAP allows health IT developers participating in ONC's Health IT Certification Program to voluntarily update their Health IT Modules to use newer versions of standards than are adopted in regulation so long as certain conditions are met.

## Why Is This Important?

- Provides flexibility to approve newer versions of adopted standards without rulemaking.
- Institutes a predictable and timely approach within the Certification Program to keep pace with the industry's standards development efforts.
- Supports interoperability in the real world as updated versions of standards reflect insights gained from real-world implementation and use.

**ONC established the voluntary SVAP flexibility as part of the "Real World Testing" Condition and Maintenance of Certification requirement of the 21st Century Cures Act.**

# SVAP and Certification

- Limited to standards adopted in the certification criteria to meet the Real World Testing Condition of Certification.
- Increased flexibility when seeking initial certification or to maintain certification of a Health IT Module.
- Ensure standards version updates are effectively implemented.
- Address standards version updates in annual Real World Testing plans and results.

**SVAP Certification**

https://www.healthit.gov/topic/standards-version-advancement-process-svap

# Applicable Real World Testing Certification Criteria

## Care Coordination

§ 170.315(b)(1) Transitions of care

§ 170.315(b)(2) Clinical information reconciliation and incorporation

§ 170.315(b)(3) Electronic prescribing

§ 170.315(b)(6) Data export

§ 170.315(b)(7) Security tags - summary of care - send

§ 170.315(b)(8) Security tags - summary of care - receive

§ 170.315(b)(9) Care plan

§ 170.315(b)(10) Electronic Health Information export

## ★★★ Clinical Quality Measures

§ 170.315(c)(1)—record and export

§ 170.315(c)(2)—import and calculate

§ 170.315(c)(3)—report

## Patient Engagement

§ 170.315(e)(1) View, download, and transmit to 3rd party

## Electronic Exchange

§ 170.315(h)(1) Direct Project

§ 170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM

## Public Health

§ 170.315(f)(1) Transmission to immunization registries

§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance

§ 170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results

§ 170.315(f)(4) Transmission to cancer registries

§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting

§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting

§ 170.315(f)(7) Transmission to public health agencies — health care surveys

## Application Programming Interfaces

§ 170.315(g)(7) Application access—patient selection

§ 170.315(g)(8) Application access—data category request

§ 170.315(g)(9) Application access—all data request

§ 170.315(g)(10) Standardized API for patient and population services

# How to use SVAP

- For the approved SVAP versions, Certified Health IT developers choosing to leverage the SVAP flexibility can do so on initial certification of their Health IT Module or to maintain certification for their Module. To take advantage of the flexibility to update to newer approved versions, a Certified Health IT developer will need to:
  - For existing certifications only, provide advance notice to all affected customers and their ONC-Authorized Certification Body (ONC-ACB), expressing
    - intent to update to the more advanced version of the standard;
    - expectations for how the update will affect interoperability of each affected Health IT Module; and
    - whether they intend to continue to support the certificate(s) for the existing Certified Health IT Module(s) version.
  - Successfully demonstrate conformance with approved more recent versions of the standard(s) included in each updated certification criterion to confirm they meet the updated requirements.
  - Maintain the updated Certified Health IT Module(s) in full conformance with all applicable Certification Program requirements, which includes ensuring their Real World Testing plans and results address the updated standards.

# The SVAP Cycle

- To keep pace with the industry's standards development efforts, the process to identify, approve, and make available newer versions of standards takes place on an annual cycle
- The cycle commences each with the opening of the Public Comment Period and concludes when the Approved SVAP Standards become effective.

# 2024 SVAP Timeline

- 2024 SVAP Public Comment Period
  - Opened: January 16, 2024
  - Closed: May 21, 2024
- 2024 SVAP Announcement
  - June 20, 2024
- 2023 SVAP Effective (60-Day Delay)
  - August 19, 2024
- 2025 SVAP Public Comment Period
  - Opens: January 2025
  - Closes May 2025

**SVAP Annual Process**
https://www.healthit.gov/SVAP

# Previously Approved SVAP Standards

- A version of an adopted standard approved for use during any SVAP cycle remains available for certification until a newer SVAP version of that standard is approved.

- If a newer SVAP version is approved, the previously approved SVAP version will be replaced and no longer available for use in the Certification Program.
  - Certified Health IT developers **do not** need to keep advancing to newer SVAP versions once they choose to use SVAP.
  - No new certifications can be made to the replaced SVAP version once the newer version goes into effect in the Certification Program.
  - Any certifications to the replaced SVAP version will still be valid.

**SVAP Certification Complete List:**
https://www.healthit.gov/topic/standards-version-advancement-process-svap

# SVAP Resources

- **2024 SVAP Fact Sheet:** https://www.healthit.gov/sites/default/files/2024-06/2024_SVAP_Fact_Sheet_508.pdf
- **SVAP Certification Page**: https://www.healthit.gov/topic/standards-version-advancement-process-svap
  - Obtain the list of approved SVAP versions and operational information for certification
- **SVAP Process Page**: https://www.healthit.gov/svap
  - View information on the annual process, including the list of eligible standards and their versions for consideration
- **ONC Standards Bulletin**: https://www.healthit.gov/topic/standards-technology/onc-standards-bulletin
  - View and sign up for healthcare stakeholder alerts that include updates about ONC health IT standards initiatives such as the SVAP
- **Certification Program Resources**: https://www.healthit.gov/topic/certification-ehrs/certification-resources
  - Access reference documents and other resources related to ONC's Health IT Certification Program

# Approved Standards for 2024

Liz Turi, Standards

# Approved Standards (9)

1. United States Core Data for Interoperability (USCDI), Version 4, October 2023 Errata
2. HL7® FHIR® US Core Implementation Guide STU 7.0.0, May 8, 2024
3. HL7® CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes, Edition 3 – US Realm
4. CMS QRDA I Implementation Guide for Hospital Quality Reporting (Updated August 2023) & CMS QRDA III Implementation Guide for Eligible Clinicians (Updated November 2023)
5. HL7® Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 2018 Update
6. HL7® Version 2.5.1 Implementation Guide: Syndromic Surveillance, Release 1 - US Realm Standard for Trial Use, July 2019
7. HL7® CDA R2 Implementation Guide: National Health Care Surveys (NHCS), R1 STU Release 3.1 - US Realm
8. HL7® FHIR® SMART Application Launch Framework Implementation Guide v2.2.0, April 30, 2024
9. Web Content Accessibility Guidelines (WCAG) 2.2, October 5, 2023

# Annual Updates (4)

| REGULATORY STANDARD VERSION | 2024 APPROVED STANDARDS VERSION | CERTIFICATION CRITERIA(ON) |
|---|---|---|
| United States Core Data for Interoperability (USCDI), Version 1, July 2020 Errata<br>(Adoption of this standard expires on January 1, 2026)<br><br>USCDI, Version 3, October 2022 Errata<br>(This standard is required by December 31, 2025) | **USCDI, Version 4, October 2023 Errata** | § 170.315(b)(1);(b)(2); (e)(1);(f)(5); (g)(9); (g)(10) |
| Health Level 7 (HL7®) FHIR® US Core Implementation Guide STU 3.1.1 (Adoption of this standard expires on January 1, 2026)<br><br>HL7® FHIR® US Core Implementation Guide STU 6.1.0<br>(This standard is required by December 31, 2025) | **HL7® FHIR® US Core Implementation Guide STU 7.0.0, May 8, 2024** | § 170.315(g)(10) |
| HL7® Implementation Guide for CDA® Release 2: Consolidated CDA Templates (C-CDA) for Clinical Notes (US Realm), Draft Standard for Trial Use, August 2015, June 2019 (with Errata)<br><br>HL7® CDA® R2 Implementation Guide: C- CDA® Templates for Clinical Notes R2.1 Companion Guide, Release 2 - US Realm, October 2019 (Adoption of this standard expires on January 1, 2026)<br><br>HL7® CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 - US Realm, June 2023<br>(This standard is required by December 31, 2025) | **HL7® CDA® R2 Implementation Guide: Consolidated CDA® Templates for Clinical Notes, Edition 3.0 - US Realm, May 2024** | § 170.315(b)(1); (b)(2); (b)(7), (b)(8), (b)(9); (e)(1); (g)(9) |
| CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2020 (December 2019)<br><br>CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2020 (April 2020) | **CMS QRDA I Implementation Guide for Hospital Quality Reporting (Updated August 2023)**<br><br>**CMS QRDA III Implementation Guide for Eligible Clinicians (Updated November 2023)** | § 170.315(c)(3) |

# Standards Related to Public Health Criteria (3)

| REGULATORY STANDARD VERSION | 2024 APPROVED STANDARDS VERSION | CERTIFICATION CRITERIA(ON) |
|---|---|---|
| HL7® 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, October 1, 2014 | **HL7® Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 2018 Update** | § 170.315(f)(1) - Transmission to immunization registries |
| CDC PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0, April 21, 2015 & Erratum | **HL7® Version 2.5.1 Implementation Guide: Syndromic Surveillance, Release 1 - US Realm Standard for Trial Use, July 2019** | § 170.315(f)(2) - Transmission to public health agencies — syndromic surveillance |
| HL7® Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1 - US Realm, HL7® Draft Standard for Trial Use, December 2014 | **HL7® CDA® R2 Implementation Guide: National Health Care Surveys (NHCS), R1 STU Release 3.1 - US Realm** | § 170.315(f)(7) - Transmission to public health agencies — health care surveys |

# Interoperability and Accessibility Standards (2)

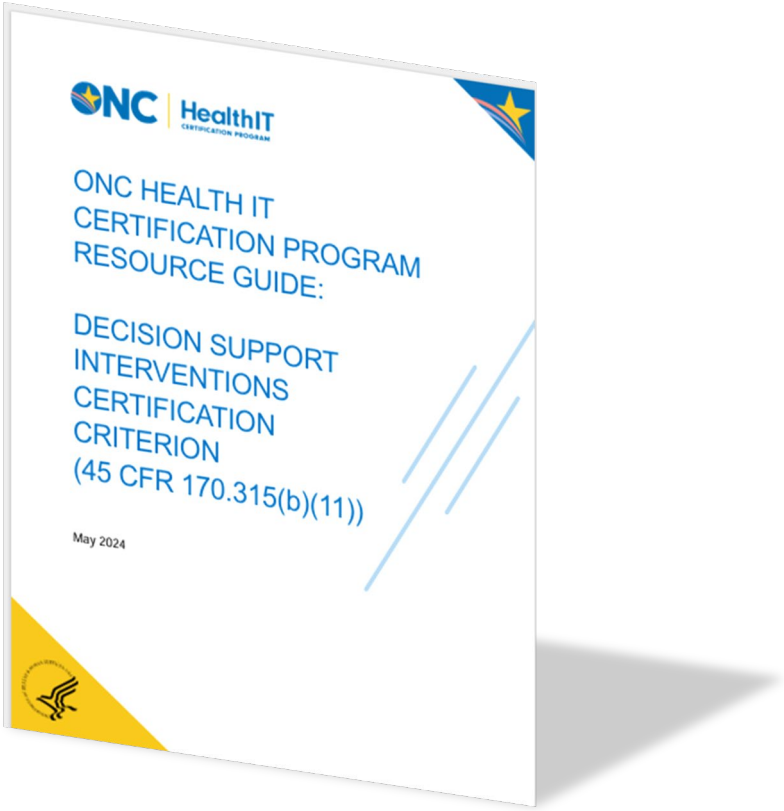
| REGULATORY STANDARD VERSION | 2024 APPROVED STANDARDS VERSION | CERTIFICATION CRITERIA(ON) |
|---|---|---|
| HL7® FHIR® SMART Application Launch Framework Implementation Guide Release 1.0.0, November 13, 2018 (Adoption of this standard expires on January 1, 2026)<br><br>HL7® FHIR® SMART Application Launch Framework Implementation Guide Release 2.0.0, November 26, 2021 (This standard is required by December 31, 2025) | **HL7® FHIR® SMART Application Launch Framework Implementation Guide v2.2.0, April 30, 2024** | § 170.315(g)(10) - Standardized API for patient and population services |
| Web Content Accessibility Guidelines (WCAG) 2.0, December 11, 2008 | **Web Content Accessibility Guidelines (WCAG) 2.2, October 5, 2023** | § 170.315(e)(1) - View, download, and transmit to 3rd party |

# Requirements for Decision Support Interventions and Predictive Models

Jeff Smith, Certification and Testing
Nikki Hayes, Certification and Testing

# DSI Resource Guide v1.0

- Distills proposed rule and final rule preamble into plain language explanations
- Includes clarifications made since final rule release (thanks to industry inquiries)
- Provides a walk-through of requirements for the (b)(11) DSI criterion, including:
  - Key definitions and dates
  - Examples of likely Predictive DSIs
  - Highlights important functionalities
- DSI Resource Guide available here



# Agenda

1. Key Definitions & Concepts
2. Overview of required capabilities in § 170.315(b)(11)
3. Timelines
4. Q&A

# Key Definitions & Concepts

# 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

# Key Concepts

- **Evidence-based DSIs** are only those DSIs that are actively presented to users in clinical workflow to enhance, inform, or influence decision-making related to the care a patient receives and that do not meet the definition for Predictive Decision Support Intervention at § 170.102.
  - Actively presented stands in contrast to decision support that initiates an action without a user's knowledge or occurs outside a user's normal workflow.

- **Source attributes** are categories of technical performance and quality information related to how evidence-based DSIs and Predictive DSIs were designed, developed, tested, evaluated, and should be used.

- **FAVES** is a conceptual model for DSI quality. Each source attribute and risk management requirement contributes to a better understanding of whether a Predictive DSI is Fair, Appropriate, Valid, Effective, and Safe (FAVES).

- **Intervention Risk Management**, or IRM, practices are a set of activities used to analyze and mitigate different kinds of risks associated with Predictive DSIs. IRM practices also include policies and controls for governance and data management related to Predictive DSIs.

# Key Concepts Continued

- The “Supplied By” Configuration Nexus
  - A key phrase included in 45 CFR 170.315(b)(11) regulation text is: “supplied by the health IT developer as a part of its Health IT Module.”
    - Certified Health IT Developers can supply evidence-based and Predictive DSIs they create themselves and they can supply DSIs created by other parties
  - “Supplied by” means that the Certified Health IT Developer takes stewardship and accountability for that specific evidence-based or Predictive DSI within its Health IT Module (89 FR 1253)
  - We interpret “as part of its Health IT Module” to mean that the developer of certified health IT has explicitly offered or provided its customers the technical capability to use or support a Predictive DSI, regardless of whether the Predictive DSI was developed by the developer of certified health IT or by other parties (89 FR 1253)
  - Supplied DSIs can comprise clinical, administrative, operational, and use cases

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

# Decision Support Configuration

- This requirement establishes that Health IT Modules certified to § 170.315(b)(11) enable:
  - A limited set of identified users to configure both evidence-based and predictive DSIs based on user's role;
  - Interventions based on the reconciliation of a patient's medications, allergies and intolerance, and problems as part of a transition of care or referral summary; and
  - Users of the Health IT Module to provide electronic feedback data for evidence-based DSIs.
    - The Health IT Module must support (at a minimum) feedback data regarding the intervention, action taken, user feedback provided, user, date, and location
    - The Health IT Module must subsequently make such feedback data available to a limited set of identified users for export in a computable format.

# Additional Clarifications: Feedback Loops

- Only evidence-based DSIs that are actively presented to users in a clinical workflow to enhance, inform, or influence decision-making related to the care a patient receives must be supported by "feedback loop" functionality in § 170.315(b)(11)(ii)(C).

- The § 170.315(b)(11) certification requirements do not specify when or how feedback should be gathered. Real-time workflows, where user feedback is provided immediately, and post hoc workflows, where user feedback is provided afterwards or through a separate application are acceptable. Our requirements are intended to be flexible to enable a user to provide feedback in a manner appropriate to their workflow. Further, nothing in the Certification Program requires users to provide electronic feedback.

- Developers of a Health IT Module certified to § 170.315(b)(11) must allow a specific group of users, as determined by the user organization, to access and export feedback data in a computable format. The developer of the Health IT Module is not required to export this feedback data to all users. Instead, the option to export of feedback data must be available to a specific group of users identified by the customer.

# DSI Selection

- Health IT Modules certified to the § 170.315(b)(11) DSI criterion must enable a limited set of identified users to select (i.e., activate) electronic decision support interventions that are evidence-based and Predictive.
- Rather than establish a list of evidence-based DSI and Predictive DSI use cases that Certified Health IT developers must support, the Certification Program establishes a scope of DSIs that must be supported based on data elements found in the US Core Data for Interoperability.
- Evidence-based DSIs within scope of the Certification Program that must be supported include those that use any of the following USCDI-based data elements: problems; medications; allergies and intolerances; at least one demographic specified in paragraph § 170.315(a)(5)(i); laboratory; vital signs; unique device identifier(s) for patient implantable device(s); and procedures.
  - Conversely, evidence-based DSIs that do not use any of these data elements do not need to be supported and are not subject to other § 170.315((b)(11) requirements, such as the “feedback loops” functionality in § 170.315(b)(11)(ii)(C).
- Predictive DSIs within scope of the Certification Program that must be supported include those that use any USCDI data element.

# Additional Clarifications: Selection

- We did not specify a standardized mechanism or configuration to "enable selection" of evidence-based and Predictive DSIs
- Developers of Certified Health IT must support some mechanism for customers to select Predictive DSIs, whether those Predictive DSIs are self-developed by the customer or developed by other parties
- Evidence-based DSIs that include any of the demographic data elements at § 170.315(a)(5)(i) must be supported
  - These data elements are different in scope and may require use of different vocabulary standards than the USCDI data elements listed under the "Patient Demographics/Information" data class versions of these data concepts
  - Health IT Modules must support evidence-based DSIs that use the data concepts at § 170.315(a)(5)(i) and should adhere to standards and requirements in § 170.315(a)(5)(i)
- Please see "Appendix A: Scope of USCDI-based data elements that § 170.315(b)(11) certified Health IT Modules must support for use in evidence-based DSIs" for more information

# Source Attribute Support

- All Health IT Modules certified to § 170.315(b)(11) must support 13 source attribute fields for evidence-based DSIs and 31 source attribute fields for Predictive DSIs used by their customers.
  - The requirement to support source attribute fields for evidence-based and Predictive DSI does not necessarily mean the Certified Health IT developer is responsible for the content of these source attribute fields.
  - The determination of whether a Certified Health IT developer is responsible for the content of source attribute fields depends on whether the DSI is supplied by the Certified Health IT developer as part of its Health IT Module.
- Certification Program does not prescribe a best-practices format in which source attribute information should be displayed. Certified Health IT developers should work with their customers to determine the best format and structure of source attribute information.

# 13 Source Attributes for Evidence-based DSIs

Already required as part of CDS criterion

1. Bibliographic Information
2. Developer of the intervention
3. Funding source of the technical implementation for the intervention's development
4. Release, an if applicable, revision date(s) of the intervention

**Use of data elements salient to health equity**

5. Use of race in the intervention
6. Use of ethnicity in the intervention
7. Use of language in the intervention
8. Use of sexual orientation in the intervention
9. Use of gender identity in the intervention
10. Use of sex in the in the intervention
11. Use of age (date of birth) in the intervention
12. Use of social determinants of health in the intervention
13. Use of health status assessments data in the intervention

# Additional Clarifications: Developer-Supplied Evidence-based DSI Source Attributes

- In cases where a DSI is not based on published clinical guideline but local needs, the bibliographic citation § 170.315(b)(11)(iv)(A)(1) and the developer of the intervention § 170.315(b)(11)(iv)(A)(2) may be the same.
- In cases where information is only available through published literature, developers may provide information for these source attributes that indicate that the relevant information is not available and that it cannot be replicated.
- For source attributes in § 170.315(b)(11)(iv)(A)(5)-(13), use of the data element is required to be disclosed. Identifying that one of those data elements is not used, is not required.
- The Certification Program requires that developers indicate when an evidence-based DSI uses patient demographic, social determinants of health (SDOH), and health status assessment data elements in § 170.315(b)(11)(iv)(A)(5) through (13). Consistent with the dates established in § 170.213, Health IT Modules must indicate when USCDI v1 data elements are used in evidence based DSIs up to and including December 31, 2025. Beginning January 1, 2026, Health IT Modules must indicate when USCDI v3 data elements are used according to § 170.315(b)(11)(11)(iv)(A)(5)-(13).

# Nine Predictive DSI Source Attribute Categories

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

# Thirty-One Predictive DSI Source Attributes

## 1 General Description and Outputs

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

## 2 Purpose

5) Intended use of the intervention;
6) Intended patient population(s) for the intervention's use;
7) Intended user(s); and
8) Intended decision-making role for which the intervention was designed to be used/for.

## 3 Cautioned Out-of-Scope Use

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

## 4 Development and Input Features

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

## 5 Process used to ensure fairness

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

## 6 External Validation Process

17) 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
18) Party that conducted the external testing;
19) Description of demographic representativeness of external data including, at a minimum, those used as input features in the intervention;
20) Description of external validation process.

## 7 Quantitative Measures of Performance

21) Validity of intervention in test data derived from the same source as the initial training data;
22) Fairness of intervention in test data derived from the same source as the initial training data;
23) Validity of intervention in data external to or from a different source than the initial training data;
24) Fairness of intervention in data external to or from a different source than the initial training data;
25) 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

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

## 9 Validation or Fairness Schedule

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

# Thirty-One Predictive DSI Source Attributes

## 1 General Description and Outputs

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

## 2 Purpose

5) Intended use of the intervention;
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8) Intended decision-making role for which the intervention was designed to be used/for.

## 3 Cautioned Out-of-Scope Use

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20) Description of external validation process.

## 7 Quantitative Measures of Performance

21) Validity of intervention in test data derived from the same source as the initial training data;
22) Fairness of intervention in test data derived from the same source as the initial training data;
23) Validity of intervention in data external to or from a different source than the initial training data;
24) Fairness of intervention in data external to or from a different source than the initial training data;
25) 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

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

## 9 Validation or Fairness Schedule*

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

# Additional Clarifications: Developer-Supplied Predictive DSI Source Attributes

- While the Certification Program identified defined input fields for Predictive DSI source attributes, it did not establish requirements for specific measures, baselines, or identified specific thresholds for content that is related to those categories.
- The Certification Program has not established requirements for specific measures of validity or fairness.
- Developers may indicate that the relevant information for specific source attributes is not available nor re-creatable.
  - For example, Predictive DSIs that use models provided through peer-reviewed literature, such as Atherosclerotic Cardiovascular Disease (ASCVD), estimated glomerular filtration rate (eGFR), acute physiology and chronic health evaluation IV (APACHE IV), may not have access to training data that would allow them to provide a description of demographic representativeness. In such scenarios, developers may indicate the that the relevant information is not available and cannot be replicated.
  - For LLMs that only use free text as inputs, rather than structured data of the kind we list at § 170.315 (b)(11)(iv)(B)(4)(ii) and (iii), Certified Health IT developers may indicate that variables related to race, ethnicity, language, sexual orientation, gender identity, social determinants of health, and health status assessments were not included in the Predictive DSI's training data.

# When is a developer responsible for source attribute content?

NES EHR


NES-developed Hypertension Predictive Model

NES EHR *Now With*: Zelda's Hypertension Predictive Model


What about Konami's Contra-indications Model?

Predictive DSIs authored, developed, or supplied by a certified health IT developer are subject to ONC requirements

Made by third-party for NES EHR

# 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

# Access & Modification of Source Attribute Information

- The Certification Program establishes a set of 4 capabilities that Health IT Modules must support related to the source attribute content associated with evidence-based and Predictive DSIs.
  - Health IT Modules must enable a limited set of identified users to access complete and up-to-date plain language descriptions of source attributes.
  - Health IT Modules must enable a limited set of identified users to record source attribute information.
  - Health IT Modules must enable a limited set of identified users to change source attribute information.
  - Health IT Modules must indicate when source attribute information is not available for some source attributes related to external validation, local testing for validity and fairness, and continued assessments of validity and fairness.

- Certified Health IT developers are responsible for updating information related to these source attributes if it is generated or becomes available with the Certified Health IT developer's knowledge. For example, if the Certified Health IT developer's supplied Predictive DSIs is tested for fairness in local data with the help of the Certified Health IT developer following deployment at a customer's site, that information must be made available as source attribute information to reflect the up-to-date requirement for source attributes at § 170.315(b)(11)(v)(A)(1).

# Additional Clarifications: Access & Modification

- For purposes of requirements in § 170.315(b)(11) a subsidiary of a Certified Health IT developer that develops a Predictive DSI would be considered the same as if the subsidiary were the developer of Certified Health IT, subjecting Predictive DSIs developed by the subsidiary to the same requirements as a Predictive DSI supplied by a developer of Certified Health IT as part of its Health IT Module.

- Certified Health IT developers must provide the functionality to enable access and modification to source attributes but are not responsible for the content that may be recorded, changed, or accessed by these users.

- The Health IT Module is required to enable users the capability to populate source attributes for Predictive DSIs that self-developed by customers as well as the capability to populate source attributes for Predictive DSIs developed by other parties.

- Certified Health IT developers are not responsible for the accuracy or use of source attribute information that is modified by their users. Rather, Certified Health IT developers are required to have Health IT Modules that support the capability for their users to author or revise source attribute information.

# Organizational transparency on risk management of Predictive DSIs

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
- Summary information of risk management and governance to be publicly available

# Additional Clarifications: Intervention Risk Management

- The Certification Program requirements are not prescriptive about the use of a particular framework, standard, guideline, or best-practice for risk management and governance.
  - The Program provides Certified Health IT developers with substantial flexibility in the risk management practices they choose to apply to Predictive DSIs they supply as part of their Health IT Modules.
  - Developers may therefore choose to apply different levels of rigor to the risk analysis, risk mitigation, and governance of different Predictive DSIs.
- Developers are not required to review risk management information from other parties nor include the risk management information from other parties as part of the IRM documentation requirement.
- Certified Health IT developers are encouraged to review the NIST AI RMF Govern Section 6 as this section provides several suggested actions and documentation questions that may be informative towards meeting governance requirements as it relates to AI risks and benefits arising from third party software.

# Principles of Proper Conduct for ONC-ACBs to Ensure IRM Documentation Compliance

- Summary information for the IRM documentation needs to be submitted to Certified Health IT developer's ONC-ACB and the ONC-ACB must review this information before issuing a certification to § 170.315(b)(11). The ONC-ACB must post this information to the CHPL for Health IT Modules certified to the § 170.315(b)(11) DSI criterion.
  - Summary information for the IRM documentation needs to be submitted to the ONC-ACB for review before issuing a certification.
  - Summary information of IRM practices does not need to include public disclosure of specific information on code, model tuning, parameter or hyperparameter selection, or details on how individual input or output variables were selected or operationalized, which we understand to form the underpinnings of developers concerns related to intellectual property.
- This requirement aligns with the existing guidelines for API documentation in section § 170.315(g)(10)(viii)(B). The API documentation requirements were first proposed in the Cures Act Proposed Rule (84 FR 7484) and finalized in the ONC Cures Act Final Rule (88 FR 25748).
- Our final policy gives Certified Health IT developers flexibility to determine the information and the level of detail that would be useful to inform potential users of whether a model is FAVES without providing information at the level of detail that might constitute proprietary information.

# Safety-Enhanced Design and the (b)(11) DSI criterion

- Certified Health IT developers must assess user-facing functionality gaps between the requirements of § 170.315(a)(9) CDS and § 170.315(b)(11) DSI and as necessary update their safety-enhanced design (SED) testing.
  - User-centered design process(es) must have been applied to each capability of technology associated with the certification criterion.
  - SED testing should be updated when there is a user interface / functionality change to the criterion

Examples of new functionality that *may* require updated SED testing

- Functionality new to the § 170.315(b)(11) DSI criterion, such as a user's ability to modify source attributes and source attribute information at § 170.315(b)(11)(v)(B)
- Functionality to enable users to provide feedback to evidence-based DSIs at § 170.315(b)(11)(ii)(C)

# Assurances Maintenance of Certification Requirements

- Certified Health IT developers with Health IT Modules certified to § 170.315(b)(11) must ensure that their Health IT Modules have complete and up-to-date descriptions of source attribute information, both at the time of certification and on an ongoing basis while their Health IT Modules are certified to § 170.315(b)(11).
    - If Certified Health IT developers do not continue to keep associated attribute information up to date, this could have adverse impacts on user trust, accuracy, usage, and safety. Hence, this Maintenance of Certification requires them to keep such information updated to better maintain the integrity of DSIs.

- This Maintenance of Certification also requires that intervention risk management practices are updated as needed and those updates are reflected in summary information provided to ONC-ACBs for public availability.

# Implementation Timeline & requirements

**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

**Providers**

As of their 2025 performance period for CMS payment policy, certified health IT will support providers' ability to select both evidence-based and Predictive DSIs, as well as 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

# Q&A

Health IT Feedback & Inquiry Portal available at:
https://inquiry.healthit.gov/

# Thank you!

**Please submit questions, concerns, or feedback to**
**https://inquiry.healthit.gov/**