ONC HealthIT CERTIFICATION PROGRAM

9 Key Functionalities and Requirements of the New (b)(11) DSI Criterion

July 2024

To be conformant with the new requirements at 45 CFR 170.315(b)(11) Decision Support Interventions (DSI), a Certified Health IT Module must support 9 key functionalities that are different from what is currently required under the § 170.315(a)(9) Clinical Decision Support (CDS) certification criterion. This explainer describes these key functionalities and provides tips and resources for Certified Health IT developers to learn more.

1 Enable a user to provide electronic feedback data for evidence-based DSIs, including at a minimum the intervention, action taken, user feedback provided (if applicable), user, date, and location.

- Make available such feedback data to a limited set of identified users for export, in a computable format.

QUICK TIP

We note that the "action taken" by a user likely will be specific to the intended use of the evidence-based DSI. Actions could include whether the user viewed, accepted, declined, ignored, overrode, or modified the DSI in some way. For more information, please reference the DSI Resource Guide here.

2 Enable a limited set of identified users to select (i.e., activate) DSIs that are:

- **Evidence-based** and use any of the following data: (1) Problems, (2) Medications, (3) Allergies and Intolerances, (4) At least one demographic specified in § 170.315(a)(5)(i), (5) Laboratory, (6) Vital Signs, (7) Unique Device Identifier(s) for a Patient's Implantable Device(s), (8) Procedures
- **Predictive** and use any data expressed in USCDI v1 (and beginning January 1, 2026, USCDI v3)

The Certification Program requires Health IT Modules certified to § 170.315(b)(11) to enable users to select (i.e., activate) both evidence-based and Predictive DSIs, but it does not require a developer of certified health IT to author, develop, or supply a Predictive DSI through its Health IT Module to be certified to § 170.315(b)(11).

QUICK TIP

The Certification Program provides flexibility to Certified Health IT developers to customize or limit user access to specific functions base on their clients' preferences. This means that certain features such as the ability to record, change, and access source attributes, may only be accessible to a select group of users. However, the decision to restrict access lies with the clients, not the developers. Readers should reference the table, "Scope of USCDI-based data elements that § 170.315(b)(11) certified Health IT Modules must support for use in evidence-based DSIs," here in the DSI Resource Guide. Evidence-based DSIs that do not use any of the data elements listed in the hyperlinked table 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).

3 Support 13 source attribute "fields" listed in paragraphs (b)(11)(iv)(A) for evidence-based DSIs and support 31 source attribute "fields" in paragraph (b)(11)(iv)(B) for Predictive DSIs.

QUICK TIP Certified Health IT developers are not responsible for populating source attribute information (e.g., the content for source attributes) for Predictive DSIs developed by their customers or for third-party technology companies chosen by their customers. This applies even if the customer leverages data from the Certified Health IT developer's Health IT Module or if the output from the third-party technology company's Predictive DSI is integrated into a customer's clinical workflow through a Health IT Module. For a list of all source attribute "fields" required for support as part the (b)(11) DSI criterion, see the DSI Resource Guide here for evidence-based DSIs and here for Predictive DSIs. Also, see page 6 of this document for a table of Predictive DSI source attributes.

If the Certified Health IT developer supplies an evidence-based or Predictive DSI as part of its Health IT Module, the requirements in Key Functionality #4 apply. If the Certified Health IT developer does not supply any DSI, requirements for source attribute information (i.e., the content for source attributes) do not apply.

4 Enable a limited set of identified users to access complete and up-to-date plain language descriptions of source attribute information for "supplied" evidence-based and Predictive DSIs.

QUICK TIP Supplied DSIs are those that are authored, developed, or explicitly offered by a Certified Health IT developer to its customers. A supplied DSI is considered part of the Health IT Module if the DSI is part of a product that has been listed on the Certified Health IT Product List (CHPL) and the listed product is certified to § 170.315(b)(11). This means that if a Certified Health IT Developer supplies a DSI as part of a CHPL-listed product certified to § 170.315(b)(11), then the Certified Health IT Developer is responsible for all associated source attribute information (or content) requirements for those DSIs and the Certified Health IT developer must keep such source attribute information complete and up-to-date. Learn more here in the DSI Resource Guide.

5 Enable a limited set of identified users to:

- Record, change, and access source attributes in paragraphs (b)(11)(iv)(A) and (b)(11)(iv)(B).
- Record, change, and access additional source attributes not specified in paragraph (b)(11)(iv)(B).

QUICK TIP Certified Health IT developers must provide the functionality to enable access and modification to source attributes but are not responsible for the content that is recorded, changed, or accessed by users. The Health IT Module is required to enable users the capability to populate source attributes for Predictive DSIs 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. For more information, please review the DSI Resource Guide here.

6 **Apply intervention risk management (IRM) practices to each Predictive DSI supplied by the health IT developer as part of its Health IT Module.**

- Risk analysis
- Risk mitigation
- Governance, including how data are acquired, management, and used

QUICK TIP Certified Health IT developers do not need to adhere to IRM practice requirements in § 170.315(b)(11)(vi) if they do not supply any Predictive DSIs as part of their Health IT Module. However, if after certification to § 170.315(b)(11), a Certified Health IT developer starts to supply Predictive DSIs as part of their certified Health IT Module, they must comply with all relevant requirements in § 170.315(b)(11), including those related to IRM practice requirements.

In addition to the above Key Functionalities, Health IT Modules certified to the (b)(11) DSI Criterion and their Certified Health IT developers must:

7 **Publish risk management summaries for the public.** Submit summary information of intervention risk management practices via publicly accessible hyperlink to ONC-Authorized Certification Body (ONC-ACB) that allows any person to access the summary information directly without any preconditions or additional steps. (For more information, please review: 89 FR 1279)

QUICK TIP Certified Health IT developers are not required to publicly share specific code, model tuning, parameter or hyperparameter selection, or details on how individual input or output variables were operationalized. However, they are encouraged to provide information that they believe would be helpful in informing potential users about whether a model is FAVES (fair, appropriate, valid, effective, and safe). For more information, please review the DSI Resource Guide here.

8 **Review and update source attribute and risk management information.** Starting January 1, 2025, and on an ongoing basis thereafter, review and update as necessary source attribute information in § 170.315(b)(11)(iv)(A) and (b)(11)(iv)(B), intervention risk management practices described in § 170.315(b)(11)(vi), and intervention risk management summary information.

QUICK TIP The source attributes that may be indicated as unavailable or left blank include those related to "external validation" source attributes, attributes related to "fairness and validity in data other than testing data," two of the source attributes within the "ongoing maintenance of intervention," and all source attributes in the "update and continued validation or fairness assessment schedule" section. Additionally, Certified Health IT developers should be aware that they are responsible for updating information related to these source attributes if it is generated or becomes available with their knowledge. For more information, please review the DSI Resource Guide here.

9 **Assess gaps in functionality for SED testing.** Certified Health IT developers must assess user-facing functionality gaps between the requirements of § 170.315(a)(9) and § 170.315(b)(11) and, as necessary update, their safety-enhanced design (SED) testing. This means that functionality new to the (b)(11) DSI criterion, such as the functionality to modify source attributes and source attribute information at § 170.315(b)(11)(v)(B) and the functionality to enable users to provide feedback to evidence-based DSIs at § 170.315(b)(11)(ii)(C), would likely require user-centered design processes applied during development of those functionalities and included as part of summative testing. For more information, please review the DSI Resource Guide here.

QUICK TIP

Just like the § 170.315(a)(9) CDS criterion, the § 170.315(b)(11) criterion is subject to safety-enhanced design requirements. SED should be updated when there is a UI/functionality change. In theory, a new version of USCDI may or may not give rise to or result in updating SED. The Certified Health IT developer will need to make that determination when evaluating whether to conduct additional SED testing.

§ 170.315(g)(3) requires Certified Health IT developers to assess user-facing functionality gaps between the requirements of § 170.315(a)(9) and § 170.315(b)(11) and as necessary update their SED testing. For more information, please review the SED Certification Companion Guide (CCG).

For more information, please find a few helpful links, such as the **Certification Companion Guide (CCG)** and the **DSI Resource Guide**.

Additionally, please refer to the **final rule** as well as a direct link to the **DSI regulation text**.

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(b)(11)(iv)(B)(1)

Details and output of the intervention

- 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.

(b)(11)(iv)(B)(2)

Purpose of the intervention

- 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).

(b)(11)(iv)(B)(3)

Cautioned out-of-scope use of the intervention

- 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.

(b)(11)(iv)(B)(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.

(b)(11)(iv)(B)(5)

Process used to ensure fairness in development of the intervention

- 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.

(b)(11)(iv)(B)(6)

External validation process

- 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.**

(b)(11)(iv)(B)(7)

Quantitative measures of performance

- 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.**

(b)(11)(iv)(B)(8)

Ongoing maintenance of intervention implementation and use

- 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.**

(b)(11)(iv)(B)(9)

Update and continued validation or fairness assessment schedule

- 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.

Source attributes followed by ** must indicate when information is not available for review. Otherwise, content for all source attributes listed must be complete and up-to-date for Predictive DSIs supplied by the Certified Health IT Developer (See § 170.315(b)(11)(v)(A)(2))