ONC HEALTH IT CERTIFICATION PROGRAM RESOURCE GUIDE:

DECISION SUPPORT INTERVENTIONS CERTIFICATION CRITERION (45 CFR 170.315(b)(11))

May 2024

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Introduction:

On January 9, 2024, ONC finalized the adoption of the "decision support intervention," or DSI, certification criterion in at 45 CFR 170.315(b)(11). The § 170.315(b)(11) DSI criterion is a revision of the "clinical decision support (CDS)" criterion in 45 CFR 170.315(a)(9) and directly responds to the emergence of artificial intelligence- and machine learning-based predictive algorithms used to aid decision-making in healthcare. Our policies at § 170.315(b)(11) are intended to introduce much-needed information to evaluate the quality of Predictive DSIs so that users of Certified Health IT have sufficient information to determine whether a Predictive DSI is trustworthy.

Our requirements apply to Predictive DSIs that are supplied by Certified Health IT developers. Predictive DSIs that are developed by a health system, or a third-party technology company are not subject to the requirements at § 170.315(b)(11) unless or until a Certified Health IT developer supplies a Predictive DSI as part of a Health IT Module that is certified to § 170.315(b)(11). Our requirements are also not aimed at approving or guaranteeing the quality of Predictive DSIs or the models they are based on. Instead, our requirements are intended to provide users and the public greater information on whether a Predictive DSI is fair, appropriate, valid, effective, and safe (what we refer to as the FAVES quality framework).

The anticipated outcome of such transparency will increase public trust and confidence in Predictive DSIs, allowing users including healthcare systems, clinicians, and patients, to expand the use of these technologies in safer, more appropriate, and more equitable ways. The information this requirement makes available will support users in navigating the market for predictive and generative AI in healthcare. It will also help address numerous challenges, including risks of bias and harm, that such tools can present. This set of information will become a consistently available, industry-wide baseline upon which others can build, standardize, and enhance.

While transparency on the technical and performance dimensions of a Predictive DSI is necessary, alone it is insufficient. The transparency about the organizational and socio-technical competencies employed by those who develop Predictive DSIs is necessary for users to determine whether their Predictive DSI is FAVES. Therefore, we also require that Certified Health IT developers apply intervention risk management practices to Predictive DSIs they supply as part of their Health IT Module, and subsequently make summary information about these practices available publicly. We finalized three intervention risk management practices including (1) risk analysis, (2) risk mitigation, and (3) governance, including establishment of policies and controls for how data are acquired, managed, and used in Predictive DSIs.

We anticipate that our requirements for transparency about how a Predictive DSI is designed, developed, trained, evaluated, and managed for risk will lead to more deliberate practices to improve the quality and performance of Predictive DSIs, such as more frequent and better documented evaluations for how a Predictive DSI is validated and monitored in local settings.

Purpose and Disclaimer

This informative resource supplements other public documentation on the ONC Health IT Certification Program (Certification Program) website and is intended to help developers of certified health IT with Health IT Modules certified to § 170.315(b)(11) understand their requirements and obligations. While every effort has been made to ensure the accuracy of restatements of 45 CFR Part 170, this guide is not a legal document. The official requirements are contained in the relevant laws and regulations. This resource should be read and understood in conjunction with the following companion resources:

- § 170.315(b)(11) DSI Certification Companion Guide
- Regulation text at 45 CFR 170.315(b)(11)
- Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule

Terminology

To make this resource more accessible, some plain language terms are used for certain regulatory concepts. The use of these terms is strictly for convenience and does not impose any new requirements or alter the interpretation of existing requirements under the Certification Program. When encountering any of the following terms noted in the table below, the reader should associate the following definitions:

Term	Definition
Predictive DSIs	§ 170.102 "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" (89 FR 1244). Predictive DSIs support decision-making by learning or deriving relationships to produce an output, rather than those that rely on pre-defined rules to support decision-making (89 FR 1243).
Evidence-based DSIs	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. (89 FR 1240)
FAVES	FAVES is a conceptual model for Predictive 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). (89 FR 1233)

Term	Definition
Intervention Risk Management (IRM)	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.
Source attributes	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. The Certification Program includes 13 source attributes for evidence-based DSI and 31 source attributes for Predictive DSI.
Other party	Any party that develops a DSI, a model, or an algorithm that is used by a DSI, and is not the developer of certified health IT or a subsidiary of the developer of certified health IT. (89 FR 1253)
"Supplied by"	The term 'supplied by' is an important connection for various requirements related to evidence-based and Predictive DSIs in § 170.315(b)(11). Certified Health IT Developers can supply evidence-based and Predictive DSIs they create themselves, and they can supply DSIs created by other parties and included as a part of their Health IT Module. A phrase included in (b)(11) regulation text is: "supplied by the health IT developer as a part of its Health IT Module," which 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).

Key Dates

December 31, 2024:

- Developers of Health IT Modules that are currently certified to CDS criterion §170.315(a)(9) must update their health IT and provide the § 170.315(b)(11) DSI criterion to their customers by December 31, 2024, to remain compliant with the Base EHR definition.
- A developer of Certified Health IT with a module certified to §170.315(b)(11) must apply IRM practices for each Predictive DSI it supplies as part of its Health IT Module and submit summary information to its ONC-ACB via publicly accessible hyperlink according to §170.523(f)(1)(xxi) before December 31, 2024.

January 1, 2025:

- §107.315(a)(9) CDS criterion expires from the ONC Health IT Certification Program on January 1, 2025.
- Certified Health IT developers certified to § 170.315(b)(11) must comply with the Maintenance of Certification requirement adopted at §170.402(b)(4).

Decision Support Interventions Certification Criterion at § 170.315(b)(11)

The HTI-1 final rule establishes a new definition for "Predictive Decision Support Intervention," in § 170.102 which serves as the scope for technologies subject to requirements in § 170.315(b)(11). This definition includes a wide range of AI- and ML-based techniques, from large language models (LLMs) and other generative AI to simpler risk calculators. The definition is not constrained by specified use cases, perceived level of risk, or intended uses (e.g., it includes models that predict risk of sepsis, readmission, estimated glomerular filtration rate, and risk of suicide attempt).

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). This requirement ensures that customers of Health IT Modules certified to § 170.315(b)(11) can leverage Certified Health IT to deploy self-developed Predictive DSIs or Predictive DSIs developed by third-parties if they so choose.

Health IT Modules must support "source attributes" for both evidence-based and Predictive DSIs listed in § 170.315(b)(11)(iv) as well as support access and modification functionality described in § 170.315(b)(11)(v). Per requirements at § 170.315(b)(11)(iv), Health IT Modules must support the source attribute categories listed at § 170.315(b)(11)(iv)(A) for evidence-based DSIs and at § 170.315(b)(11)(iv)(B) for Predictive DSIs. However, only developers of Certified Health IT that supply evidence-based or Predictive DSIs as part of their Health IT Module are required to provide the content related to source attributes in § 170.315(b)(11)(iv)(A) and § 170.315(b)(11)(iv)(B). In other words, health IT developers are responsible for only the DSIs that they supply as part of their Certified Health IT.

Per requirements at § 170.315(b)(11)(v)(A) and (B), the Certification Program requires that Health IT Modules must enable a limited set of identified users to access complete and up-to-date descriptions of source attributes related to evidence-based DSIs and Predictive DSIs that are supplied by the developer of Certified Health IT as part of its Health IT Module, and Health IT Modules must enable a limited set of identified users to record and change source attributes listed in paragraphs § 170.315(b)(11)(iv)(A) and (B). In addition, § 170.315(b)(11)(v)(B) ensures that users of Health IT Modules can record, change, and access source attributes for DSIs developed by other parties, including DSIs self-developed by a health system or purchased by a health system from a third-party technology firm. Further, requirements in § 170.315(b)(11)(v)(B)(2) will support the ongoing evolution of source attributes for emerging Predictive DSIs by giving users the ability to record, change, and access additional source attributes not specified in regulation text.

These requirements ensure that users have access to and can modify source attribute information regarding the performance and quality of Predictive DSIs, including how the model or algorithm behind the prediction was designed, developed, tested, and evaluated. Once implemented, users of Certified Health IT with Predictive DSIs supplied by their developer will have access to more than thirty data points, metrics, and descriptions to help determine whether

the Predictive DSI they are using is fair, appropriate, valid, effective, and safe (FAVES). Users will also have capabilities to modify and customize source attributes related to any DSI, not just those that are supplied by the Certified Health IT developer, to account for local validation and the development of more fit-for-purpose source attributes. Near-term, this set of Predictive DSI source attributes will help create a consistent, industry-wide baseline upon which public-private collaboratives can build as they advance structured "model cards" and other related initiatives.

Health IT Modules certified to § 170.315(b)(11) must also apply intervention risk management (IRM) practices to each Predictive DSI supplied by the health IT developer as part of its Health IT Module. These IRM practices include risk analysis, risk mitigation, and governance. The Certification Program specifies that risk analysis and risk mitigation should cover topics identified in the NIST Artificial Intelligence Risk Management Framework, including validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy. For governance practices, the Certification Program requires developers of Certified Health IT to establish policies and implement controls regarding how data is acquired, managed, and used for all Predictive DSIs supplied by the health IT developer as part of its Health IT Module. The Certification Program requires that summary information regarding these IRM practices be made available publicly. This will support broad transparency so that users, patients, researchers, and other interested parties can understand steps developers of Certified Health IT take to identify and mitigate risks related to Predictive DSIs they supply as part of their Health IT Modules.

Beyond the requirements in § 170.315(b)(11), the Certification Program also includes ongoing requirements under § 170.402(b)(4) Assurances Condition and Maintenance of Certification requirements that reinforce a health IT developer's responsibility to review and update transparency information as necessary. Health IT developers must review and update descriptions of DSI source attributes listed in § 170.315(b)(11)(iv)(A) and (B) as applicable. The requirements in § 170.402(b)(4) also include reviewing and updating IRM practices for all Predictive DSIs supplied by the Health IT Module. Additionally, the Certified Health IT developer must ensure that summary IRM practice information is publicly available and submitted via hyperlink to its ONC-ACB. Developers with products certified to § 170.315(b)(11) must comply with this ongoing Maintenance of Certification requirement starting January 1, 2025.

Finally, the Certification Program has time-limited the CDS criterion at § 170.315(a)(9) by revising the Base EHR definition in § 170.102 to include an option for a Health IT Module to meet the definition by either being certified to the existing § 170.315(a)(9) CDS certification criterion or being certified to the § 170.315(b)(11) DSI criterion for the period up to, and including, December 31, 2024. On and after January 1, 2025, only the § 170.315(b)(11) DSI criterion will be included in the Base EHR definition and the adoption of the § 170.315(a)(9) CDS criterion in will expire from the Certification Program on January 1, 2025.

Developers certifying to the (b)(11) DSI criterion must attest directly to the ONC-ACB to conformance with § 170.315(b)(11). Currently, there is no test tool, test procedure, or any requirements for testing to certify to § 170.315(b)(11)

The conformance method for the § 170.315(b)(11) DSI criterion is through an attestation to the Certified Health IT developer's ONC-ACB. While an ONC-ACB may have additional documentation requirements to support this attestation, this conformance method is the same as that of the § 170.315(a)(9) CDS criterion.

Predictive DSI examples

The following are examples of technologies and functions that would and would not likely meet the definition of Predictive DSIs. These can be found at (89 FR 1245).

Likely Predictive DSI Examples	Non-Predictive DSI Examples
Models that **predict whether a given image contains a malignant tumor** or that predict patient reported pain based on an image, **trained based on relationships observed in large data sets** often using neural networks, would **likely** be considered Predictive DSIs.	**Indices and classification systems developed by expert consensus rather than in empirical data**, such as the SOFA index and NYHA Heart Failure classification, would likely **not** be considered Predictive DSIs but are likely evidence-based DSI because the score is based on pre-defined rules and not relationships learned in training data.
Models that pre-selected or highlighted a default order from an **order set based on relationships in training data** indicating that order was most likely to be selected would **likely** be considered Predictive DSIs.	Growth charts, for instance percentile calculations **based on a lambda-mu-sigma transformation** of similar age children's weights, with parameters learned in training data from a national sample of children, would likely **not** be considered Predictive DSIs because the underlying model is based on the distribution of a single variable (*e.g.,* weight**) rather than a prediction based on relationships between variables**.
Models that **predict risk** of sepsis, readmission (*e.g.,* LACE+), estimated glomerular filtration rate (eGFR), or risk of suicide attempt, which have been **trained based on relationships observed in large data sets**, often using logistic regression and machine learning techniques, and are used to support decision making, would **likely** be considered Predictive DSIs.	A calculation for BMI would likely **not** be considered a Predictive DSI because the calculation (weight divided by height squared) is **not based on relationships in training data**.

Likely Predictive DSI Examples	Non-Predictive DSI Examples
Models that generate clinical notes or draft clinical notes and **that were trained based on relationships in large data sets of free text, including large language models**, and support decision making about what to document in the clinical note, would **likely** be considered Predictive DSIs.	Patient matching algorithms **based on indices of similarities, rather than by relationships in training data** where an outcome is known, would likely **not** be Predictive DSIs. Many of these technologies are most similar to unsupervised machine learning, which we described previously in this section and in the HTI–1 Proposed Rule at 88 FR 23786 as out of scope of the current definition of Predictive DSI.
Models that use natural language processing to route secure messages, which were **trained based on the relationship between message contents** and the individual who responded to similar messages in the past would **likely** be considered Predictive DSIs.	Rules-based algorithms for routing secure messages **based on the type of message, rather than relationships in training data**, would likely **not** be considered Predictive DSIs.
	Optical character recognition, used simply to make a PDF readable or searchable to end users, would likely **not** be considered Predictive DSI **because it does not support decision-making**.
	Unsupervised learning models would likely **not** be considered a Predictive DSI **insofar as such models are trained in data without labels**. This exclusion reflected our understanding that it is not feasible to produce descriptions for many of the source attributes we are requiring for Predictive DSI (see also 89 FR 1244). These unsupervised models contrast with LLMs and other forms of generative AI, which often leverage self-supervised learning wherein the data itself provides a label (*e.g.,* the next word in a string of text) and the model returns a predicted value of that label as output, in which case the accuracy, validity and fairness of a prediction can readily be assessed (although additional use-case specific evaluation may also be beneficial).

Select details, context, and clarifications related to the DSI criterion at § 170.315(b)(11)

The following section describes the requirements for Health IT Modules certified to § 170.315(b)(11) as described in the regulation text and HTI-1 preamble. Some clarifications provide additional context based on CCGs available here.

Paragraph § 170.315(b)(11)(i) Decision support intervention interaction.

Regulation text: Interventions provided to a user must occur when a user is interacting with technology.

What it means: This requirement is unchanged from the § 170.315(a)(9) CDS at § 170.315(a)(9)(i) and was initially established in 2012 to ensure that interventions can be integrated with the Health IT Module (*i.e.,* not standalone).

Paragraph § 170.315(b)(11)(ii) Decision support configuration.

Regulation text: § 170.315(b)(11)(ii) Decision support configuration.

A. Enable interventions specified in paragraphs (b)(11)(iii) of this section to be configured by a limited set of identified users based on a user's role.
B. Enable interventions when a patient's medications, allergies and intolerance, and problems are incorporated from a transition of care of referral summary received and pursuant to paragraph (b)(2)(iii)(D) of this section.
C. Enable a user to provide electronic feedback data for evidence-based decision support interventions selected via the capability provided in paragraph (b)(11)(iii)(A) of this section and make available such feedback data to a limited set of identified users for export, in a computable format, including at a minimum the intervention, action taken, user feedback provided (if applicable), user, date, and location.

What it means: This requirement establishes that Health IT Modules certified to § 170.315(b)(11) enable:

- A limited set of identified users must be able 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 must be able 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; and the Health IT Module must subsequently make such feedback data available to a limited set of identified users for export in a computable format.

Clarifications:

- The Certification Program provides flexibility to Certified Health IT developers and their clients to determine which users have access to certain functions. The concept of "limited set of identified users" may restrict certain functionalities to a smaller group of users that are specifically identified and granted the necessary privileges to use the capabilities in § 170.315(b)(11). This flexibility supports any number and configuration of users that may enable interventions—such as administrators and select front-line clinician users—as determined by the organization using the certified health IT.
- 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).
    - Actively presented evidence-based DSIs include, but are not limited to, interruptive alerts. Medication alerts, order sets, icons, and clinical calculators may also be considered "actively presented," and subject to feedback loop requirements if these are presented to users in a clinical workflow to enhance, inform, or influence decision-making related to the care a patient receives. These actively presented interventions stand in contrast to back-end systems rules that are not presented to users and are not related to care an individual patient receives, such as those used for resource management or back-end logic that may support an organization's business rules but are not part of a user's workflow.
- 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.
- Developers of Certified Health IT and their customers are in the best position to determine the range of actions that are appropriate as part of feedback data. Possible actions may include viewing, accepting, declining, ignoring, overriding, or modifying the DSI. We do not mandate a predefined list of supported actions taken. We believe developers of Certified Health IT and their customers are better equipped to determine the appropriate range of actions that should be included in feedback data.
- See also additional information and clarifications beginning 89 FR 1239

Paragraph § 170.315(b)(11)(iii) Decision support intervention selection

Regulation text: § 170.315(b)(11)(iii) Decision support intervention selection. Enable a limited set of identified users to select (i.e., activate) electronic decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) that are:

A. Evidence-based DSIs and use data identified in § 170.315(b)(11)(iii)(A) which include problems; medications; allergies and intolerances; at least one demographic specified in paragraph (a)(5)(i); laboratory; vital signs; Unique Device Identifier(s) for patient implantable device(s); and procedures.
B. Predictive DSIs and use any data expressed in the standards at § 170.213

What that means: Health IT Modules must enable users to select both evidence-based DSIs and Predictive DSIs. 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. Readers should review Appendix A for a list of USCDI Version 1 and, as of January 1, 2026, USCDI Version 3 data elements, that must be supported for evidence-based DSIs.

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.

Clarifications:

- We did not specify a standardized mechanism or configuration to “enable selection” of evidence-based and Predictive DSIs. The conformance requirement is a functional requirement and parallels the “selection” function that is part of the certification criterion at § 170.315(a)(9)(iii) for evidence-based 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.
- Some data elements listed in § 170.315(b)(11)(iii)(A) are not part of USCDI v1 and are only included in USCDI v3. Until the expiration date of USCDI v1, Health IT Modules are not required to support evidence-based DSIs that solely rely on data elements from USCDI v3. However, starting from January 1, 2026, Health IT Modules must support DSIs based on all the data elements listed in § 170.315(b)(11)(iii)(A) of USCDI v3.
- Similarly, the scope of Predictive DSIs selection that a Health IT Module must support will expand with the regulatory requirements of the USCDI.

Paragraph § 170.315(b)(11)(iv) Source attributes

Regulation Text: § 170.315(b)(11)(iv) Source attributes. Source attributes listed in paragraphs (b)(11)(iv)(A) and (B) of this section must be supported.

What it means: 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. This determination depends on whether the DSI is supplied by the Certified Health IT developer. See the section "Source Attribute Access and Modification" for more details on source attribute content-related requirements.

Clarifications:

- The 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.

Source attribute categories at § 170.315(b)(11)(iv)(A)-(B) and select clarifications

Below are the thirteen source attributes for evidence-based DSIs and thirty-one source attributes Predictive DSIs. Following these lists are clarifications intended to provide Certified Health IT developers direction regarding the information intended to be captured or included by select source attributes.

Evidence-based DSI source attributes at § 170.315(b)(11)(iv)(A)(1)-(13)
1) Bibliographic citation of the intervention (clinical research or guideline)
2) Developer of the intervention (translation from clinical research or guideline)
3) Funding source of the technical implementation for the intervention(s) development
4) Release and, if applicable, revision dates of the intervention or reference source
5) Use of race as expressed in the standards in § 170.213
6) Use of ethnicity as expressed in the standards in § 170.213
7) Use of language as expressed in the standards in § 170.213
8) Use of sexual orientation as expressed in the standards in § 170.213
9) Use of gender identity as expressed in the standards in § 170.213
10) Use of sex as expressed in the standards in § 170.213
11) Use of date of birth as expressed in the standards in § 170.213
12) Use of social determinants of health data as expressed in the standards in § 170.213

13) Use of health status assessments data as expressed in the standards in § 170.213

Clarifications:

- 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).

(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))

Clarifications:

- 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. Rather, the defined input fields enable consistent and routine access to technical and performance information, which is intended to assist users in determining whether a Predictive DSI is fair, appropriate, valid, effective, and safe. These source attributes will help establish a consistent transparency baseline, or foundation, especially given that we have not established requirements for specific measures. Rather than be prescriptive, we encourage industry, academic, professional associations, and other interested parties to determine which information best fits each use case. For a full discussion of Predictive DSI source attributes, Certified Health IT developers should consult 89 FR 1259.
- The Certification Program has not established requirements for specific measures of validity or fairness. Nor has the Certification Program established baseline expectations for any descriptions identified in the source attributes related to Predictive DSIs.
- 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), and the LACE+ models measuring hospital length of stay (L), admission acuity (A), comorbid conditions (C), emergency department utilization within six months before the admission (E) as well as sex, age and hospital, 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 (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.

Paragraph § 170.315(b)(11)(v) Source Attribute Access and Modification

Regulation Text: § 170.315(b)(11)(v) Source Attribute Access and Modification.

A. *Access.*
1. For evidence-based decision support interventions and Predictive Decision Support Interventions supplied by the health IT developer as part of its Health IT Module, the Health IT Module must enable a limited set of identified users to access complete and up-to-date plain language descriptions of source attribute information specified in paragraphs (b)(11)(iv)(A) and (B) of this section.
2. For Predictive Decision Support Interventions supplied by the health IT developer as part of its Health IT Module, the Health IT Module must indicate when information is not available for review for source attributes in paragraphs (b)(11)(iv)(B)(6); (b)(11)(iv)(B)(7)(iii), (iv), and (v); (b)(11)(iv)(B)(8)(ii) and (iv); and (b)(11)(iv)(B)(9) of this section.

B. *Modify:*
1. For evidence-based decision support interventions and Predictive Decision Support Interventions, the Health IT Module must enable a limited set of identified users to record, change, and access source attributes in paragraphs (b)(11)(iv)(A) and (B) of this section.
2. For Predictive Decision Support Interventions, the Health IT Module must enable a limited set of identified users to record, change, and access additional source attributes not specified in paragraph (b)(11)(iv)(B) of this section.

What it means: 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. Two of these capabilities establish expectations for the provision of content related to source attribute "categories" for DSIs that are supplied by the health IT developer as part of its Health IT Module. Specifically, unless otherwise indicated, all other source attributes related to evidence based and Predictive DSIs that are supplied by the health IT developer as part of its Health IT Module must be complete and up-to-date.

This means that Certified Health IT developers are not accountable for populating source attribute information for Predictive DSIs developed by their customers or for populating source attribute information for third-party technology companies their customers choose to deploy. This is true even if the customer leverages data from the Certified Health IT developer's Health IT Module and even if the output from a third-party technology firm's Predictive DSI is delivered to or through a Health IT Module into a customer's clinical workflow.

Certified Health IT developers are not required to receive, acquire, or otherwise obtain source attribute information for an other party's evidence-based or Predictive DSI unless such DSI is supplied by the developer of certified health IT as part of its Health IT Module.

WHAT ONC MEANS WHEN IT SAYS...

"OTHER PARTY"

Means any entity that develops a DSI, a model, or an algorithm that is used by a DSI that is not the Certified Health IT developer or a subsidiary of the Certified Health IT developer.

These other parties include hospitals, clinics, health systems, third-party technology companies, and research organizations, among others.

"AS PART OF ITS HEALTH IT MODULE"

This means that the Certified Health IT developer has explicitly offered or provided its customers the technical capability to use or support a Predictive DSI. This includes both clinical and non-clinical Predictive DSIs that are supplied by the Certified Health IT developer.

"SUPPLIED BY THE HEALTH IT DEVELOPER"

Are those DSIs authored or developed by the Certified Health IT developer as well as those interventions authored or developed by an other party that the Certified Health IT developer includes as part of its Health IT Module.

For example, this concept includes scenarios where a Certified Health IT developer has contracts specifically covering the enablement and use of an other party Predictive DSI. The concept of supplied by also means that the Certified Health IT developer has taken on stewardship and accountability for that Predictive DSI.

"HEALTH IT MODULE"

Takes its meaning from 45 CFR 170.102 and means any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary.

A Certified Health IT developer is only responsible for source attribute content for those DSIs that it has knowledge of, accountability for, and technical capability to support as part of its Health IT Module. Given the definition of Predictive DSI, the range of Predictive DSIs that are subject to the requirements of the § 170.315(b)(11) DSI criterion includes both clinical and non-clinical technologies that are integrated with or affect certified functionalities.

There are 4 capabilities that Health IT Modules must support related to the source attribute content associated with evidence-based and Predictive DSIs.

NOTE: These capabilities apply to both DSIs supplied by the health IT developer as part of its Health IT Module as well as those DSIs that are developed by other parties, such as DSIs self-developed by a health system or purchased by a health system from a third-party technology firm.

1) **Health IT Modules must enable a limited set of identified users to access complete and up-to-date plain language descriptions of source attributes.** The concept of "plain language description," means language that the intended audience can readily understand and use because that language is clear, concise, well-organized, accurately describes the information, and follows other best practices of plain language writing.

2) **Health IT Modules must enable a limited set of identified users to record source attribute information.** Recall that the Certification Program provides flexibility in defining which users have access to certain functions, including this one to record source attributes. This flexibility is such that any number and configuration of users may have the capability to record as determined by the organization using the Certified Health IT, such as administrators and select front-line clinician users. This function is important for users who may be using a self-developed Predictive DSI to add their own source attribute information.
3) **Health IT Modules must enable a limited set of identified users to change source attribute information.** This functionality is important for users who may perform re-validation of a deployed Predictive DSI that has been supplied by a developer of Certified Health IT as part of its Health IT Module. Consider the scenario where there is an existing value of validation in a local setting (source attribute at § 170.315(b)(11)(iv)(8)(ii)) because local validation of the Predictive DSI was done during deployment, but the Certified Health IT developer doesn't know the client re-validated the model after 3 months of use. In this scenario, the functionality to enable a user to change the source attribute is necessary.
4) **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.** Specifically, Certified Health IT developers are permitted to leave the following source attribute fields blank for Predictive DSIs they supply:
    - All source attributes at § 170.315(b)(11)(iv)(B)(6), External validation process, including:
        - Description of the data source, clinical setting, or environment where an intervention's validity and fairness has been assessed, other than the source of training and testing data
        - Party that conducted the external testing
        - Description of demographic representativeness of external data according to variables in paragraph §170.315 (b)(11)(iv)(A)(5)–(13) including, at a minimum, those used as input features in the intervention
        - Description of external validation process
    - Source attributes at § 170.315(b)(11)(iv)(B)(7) Quantitative measures of performance, including:
        - 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
    - Source attributes at § 170.315(b)(11)(iv)(B)(8)(ii) and (iv) Ongoing maintenance of intervention implementation and use, including:
        - Validity of intervention in local data
        - Fairness of intervention in local data

- All source attributes at § 170.315(b)(11)(iv)(B)(9) Update and continued validation or fairness assessment schedule, including:
  - Description of process and frequency by which the intervention is updated
  - Description of frequency by which the intervention's performance is corrected when risks related to validity and fairness are identified.

When these source attributes are not complete and up-to-date, a Health IT Module must indicate when such information is not available for review. Meanwhile, all other source attributes must have information that is complete and up-to-date. Further, Certified Health IT developers should note that they 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 Predictive DSIs is tested for fairness in external data (i.e., consistent with the source attribute at § 170.315(b)(11)(iv)(B)(7)(ii)) 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).

Clarifications:

- 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 are responsible to 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. [see also 89 FR 1271]
- 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. [see also 89 FR 1271]

Paragraph § 170.315(b)(11)(vi) Intervention Risk Management

Regulation Text: Intervention Risk Management practices must be applied for each Predictive DSI supplied by the health IT developer as part of its Health IT module.

- **A.** Risk Analysis: Predictive DSI(s) must be subject to analysis of potential risks and adverse impacts associated with the following characteristics: validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy.
- **B.** Risk Mitigation: Predictive DSI(s) must be subject to practices to mitigate identified risks.
- **C.** Governance: Predictive DSI(s) must be subject to policies and implemented controls for governance, including how data are acquired, managed, and used.

What it means: Every Predictive DSI that a Certified Health IT developer supplies as part of its Health IT Module must manage risks and adverse impacts related to (1) validity; (2) reliability; (3) robustness; (4) fairness; (5) intelligibility; (6) safety; (7) security; and (8) privacy. This risk management must include risk analysis and risk mitigation of these topics. Additionally, Certified Health IT developers must institute policies and controls for governance, including how data are acquired, managed, and used.

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. Similarly, Certified Health IT developers may choose to apply different levels of detail describing their approaches to risk management practices as part of the summary information that must be submitted per requirements in § 170.523(f)(1)(xxi). The public disclosure of IRM practices employed by the developer of certified health IT provides transparency to purchasers (potential users), users, and other interested parties, and contributes to appropriate information to help guide medical decisions.

Clarifications:

- 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.
- Activities related to risk management could include estimates of the likelihood and magnitude or 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 activities to consider 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 subject matter experts (SMEs) in measuring/validating performance.
- Governance activities to consider 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.
- Developers are encouraged to implement policies and controls to evaluate whether risk analysis and risk mitigation practices are being carried out as specified; to consider how policies and controls are monitored and updated; and to plan a schedule for updating those policies and controls. Policies and controls should include details on roles, responsibilities, staff expertise, authority, reporting lines, and continuity.
- Developers are encouraged to have accountability and escalation policies and controls related to how management oversees the development, deployment, and management of Predictive DSIs.
- 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.
- Developers of Certified Health IT may also review The Office of the Comptroller of Currency for guidance on best practices related to risk management of models developed by third parties.

IRM practice resources and frameworks

- The Program encourages developers of Certified Health IT to examine industry resources, such as the National Institutes for Standards and Technology Artificial Intelligence Risk Management Framework (NIST AI RMF) or the ISO/IEC standard for Information Technology – Artificial Intelligence – Risk management for guides non-specific to healthcare to help developers structure their IRM practices while addressing several of the identified risks in § 170.315(b)(11)(vi)(A).
- Additionally, developers could use healthcare-specific guides such as the Application of ISO 14971 To Machine Learning In Artificial Intelligence developed by AAMI and the British Standards Institution and the Health Equity Across the AI Lifecycle (HEAAL) framework, which could help mitigate specific risks, such as those to fairness.

Paragraph § 170.315(g)(3) Safety Enhanced Design and associated requirements

Regulation text: User-centered design processes must be applied to each capability technology includes that is specified in the following certification criteria: paragraphs (a)(1) through (5), (9) until the criterion's expiration date, and (14), and (b)(2), (3), and (11) of this section.

What it means: The Certification Program has modified the §170.315 (g)(3) Safety Enhanced Design certification criterion to reference the new certification criterion in § 170.315(b)(11). 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. It should be noted existing clarifications regarding SED that require user-centered design process(es) to be applied to each capability of technology that is associated with the certification criteria named in this certification criterion [see 77 FR 54188]. This means that functionality new to the § 170.315(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)(iii)(C), would likely require additional user-centered design processes applied during development of those functionalities and included as part of summative testing.

Clarifications:

- The § 170.315(b)(11) DSI criterion is a revision of §170.315(a)(9) CDS criterion and there are a number of parallel functions between (a)(9) and (b)(11). Given this, the Program expects that developers may use/resubmit SED testing from § 170.315(a)(9) for § 170.315(b)(11) and that an entirely new SED may not be necessary in all circumstances. We recommend that Certified Health IT developers assess user-facing functionality gaps between § 170.315(a)(9) and § 170.315(b)(11) and as necessary update their SED.
- Certified Health IT developers will need to publish updated SED information to the CHPL to incorporate § 170.315(b)(11) when the developer of the Health IT Module seeks certification to § 170.315(b)(11).
- We note existing clarifications regarding SED that to demonstrate compliance with the criterion at § 170.315(g)(3), user-centered design process(es) must have been applied to each capability of technology that is associated with the certification criteria named in this certification criterion. [77 FR 54188]

Paragraph § 170.402(b)(4) Assurances Condition and Maintenance of Certification Requirements for Developers with Health IT Modules Certified to § 170.315(b)(11)

Regulation text: For developers of Health IT Modules certified to § 170.315(b)(11), 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), intervention risk management practices described in § 170.315(b)(11)(vi), and summary information provided through § 170.523(f)(1)(xxi).

What it means: 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). 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.

Several source attributes are intended to provide users information on how the intervention performs in local data. This is both because models and data used to drive Predictive DSIs will change over time and because bias and inaccuracies are likely to appear after a predictive algorithm is deployed. 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.

Paragraph § 170.523(f)(1)(xxi) Principles of Proper Conduct for ONC-ACBs to Ensure IRM Documentation Compliance

Regulation text: Where applicable, summary information of the intervention risk management practices listed in § 170.315(b)(11)(vi) is submitted by the health IT developer via publicly accessible hyperlink that allows any person to access the summary information directly without any preconditions or additional steps.

What it means: 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.

Clarifications:

- Summary information for the IRM documentation needs to be submitted to the ONC-ACB for review before issuing a certification.
- 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.
- 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.
- For more information, please review: 89 FR 1280

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.

(b)(11)(ii)(A) data	USCDI Version 1 data elements	USCDI Version 3 data elements
(1) Problems	1. Problems	1. Problems
		2. SDOH problems/health concerns
		3. Date of diagnosis
		4. Date of resolution
(2) Medications	1. Medications	1. Medications
		2. Dose
		3. Dose Unit of Measure
		4. Indication
		5. Fill Status
(3) Allergies and Intolerances	1. Substance (Medication)	1. Substance (Medication)
	2. Substance (Drug Class)	2. Substance (Drug Class)
	3. Reaction	3. Reaction
(4) At least one demographic specified in § 170.315(a)(5)(i)	**Note:** Demographic data element requirements are available and located in § 170.315(a)(5)(i). The USCDI versions of these data concepts do not apply. Rather, the data concepts at § 170.315 (a)(5)(i) should adhere to standards and requirements in § 170.315(a)(5)(i)	
	1. Race and Ethnicity	1. Race
	2. Preferred Language	2. Ethnicity
	3. Sex	3. Preferred Language
	4. Sexual Orientation	4. Sex
	5. Gender Identity	5. Sexual Orientation
		6. Gender Identity
(5) Laboratory	1. Tests	1. Tests
	2. Values/Results	2. Values/Results
		3. Specimen Type
		4. Result Status

(b)(11)(ii)(A) data	USCDI Version 1 data elements	USCDI Version 3 data elements
(6) Vital Signs	1. Systolic Blood Pressure	1. Systolic Blood Pressure
	2. Diastolic Blood Pressure	2. Diastolic Blood Pressure
	3. Heart Rate	3. Heart Rate
	4. Respiratory Rate	4. Respiratory Rate
	5. Body Temperature	5. Body Temperature
	6. Body Height	6. Body Height
	7. Body Weight	7. Body Weight
	8. Pulse Oximetry	8. Pulse Oximetry
	9. Inhaled Oxygen Concentration	9. Inhaled Oxygen Concentration
	10. BMI Percentile (2 - 20 years)	10. BMI Percentile (2 - 20 Years)
	11. Weight-for-length Percentile (Birth - 36 Months)	11. Weight-for-length Percentile (Birth - 24 Months)
	12. Head Occipital-frontal Circumference Percentile (Birth - 36 Months)	12. Head Occipital-frontal Circumference Percentile (Birth - 36 Months)
(7) Unique Device IDs	1. Unique Device Identifier(s) for a Patient's Implantable Device(s)	1. Unique Device Identifier(s) for a Patient's Implantable Device(s)
(8) Procedures	1. Procedures	1. Procedures
		2. SDOH Interventions
		3. Reason for Referral

Appendix B: Detailed Source Attributes

For evidence-based DSIs:

- § 170.315(b)(11)(iv)(A)(1) – Bibliographic citation of the intervention (clinical research or guideline)
- § 170.315(b)(11)(iv)(A)(2) – Developer of the intervention (translation from clinical research or guideline)
- § 170.315(b)(11)(iv)(A)(3) - Funding source of the technical implementation for the intervention(s) development
- § 170.315(b)(11)(iv)(A)(4) - Release, an if applicable, revision date(s) of the intervention
- § 170.315(b)(11)(iv)(A)(5) - Use of race as expressed in the standards in § 170.213
- § 170.315(b)(11)(iv)(A)(6) - Use of ethnicity as expressed in the standards in § 170.213
- § 170.315(b)(11)(iv)(A)(7) - Use of language as expressed in the standards in § 170.213
- § 170.315(b)(11)(iv)(A)(8) - Use of sexual orientation as expressed in the standards in § 170.213
- § 170.315(b)(11)(iv)(A)(9) - Use of gender identity as expressed in the standards in § 170.213
- § 170.315(b)(11)(iv)(A)(10) - Use of sex as expressed in the standards in § 170.213
- § 170.315(b)(11)(iv)(A)(11) - Use of date of birth as expressed in the standards in § 170.213
- § 170.315(b)(11)(iv)(A)(12) - Use of social determinants of health data
- § 170.315(b)(11)(iv)(A)(13) - Use of health status assessments as expressed in the standards in § 170.213

For Predictive DSIs:

1) **Details and output of the intervention,** including § 170.315(b)(11)(iv)(B)(1):
   - § 170.315(b)(11)(iv)(B)(1)(i) - Name and contact information for the intervention developer
   - § 170.315(b)(11)(iv)(B)(1)(ii) - Funding source of the technical implementation for the intervention(s) development
   - § 170.315(b)(11)(iv)(B)(1)(iii) - Description of value that the intervention produces as an output
   - § 170.315(b)(11)(iv)(B)(1)(iv) - Whether the intervention output is a prediction, classification, recommendation, evaluation, analysis, or other type of output
2) **Purpose of the intervention,** including § 170.315(b)(11)(iv)(B)(2):
   - § 170.315(b)(11)(iv)(B)(2)(i) - Intended use of the intervention§
   - 170.315(b)(11)(iv)(B)(2)(ii) - Intended patient population(s) for the intervention's use
   - § 170.315(b)(11)(iv)(B)(2)(iii) - Intended user(s)
   - § 170.315(b)(11)(iv)(B)(2)(iv) - Intended decision-making role for which the intervention was designed to be used/for (e.g., informs, augments, replaces clinical management)

3) **Cautioned Out-of-Scope Use of the intervention,** including § 170.315(b)(11)(iv)(3):
   - § 170.315(b)(11)(iv)(3)(i) - Description of tasks, situations, or populations where a user is cautioned against applying the intervention
   - § 170.315(b)(11)(iv)(3)(ii) - Known risks, inappropriate settings, inappropriate uses, or known limitations
4) **Intervention Development Details and Input features**, including at a minimum§ 170.315(b)(11)(iv)(4):
   - § 170.315(b)(11)(iv)(4)(i) - Exclusion and inclusion criteria that influenced the training data set
   - § 170.315(b)(11)(iv)(4)(ii) - Use of variables in paragraph (b)(11)(iv)(A)(5)-(13) as input features
   - § 170.315(b)(11)(iv)(4)(iii) - Description of demographic representativeness according to variables in paragraphs (b)(11)(iv)(A)(*5*) through (13) of this section including, at a minimum, those used as input features in the intervention
   - § 170.315(b)(11)(iv)(4)(iv) - Description of relevance of training data to intended deployed setting
5) **Process used to ensure fairness** in development of intervention, including § 170.315(b)(11)(iv)(5):
   - § 170.315(b)(11)(iv)(5)(i) - Description of the approach the intervention developer has taken to ensure that the intervention's output is fair
   - § 170.315(b)(11)(iv)(5)(ii) - Description of approaches to manage, reduce, or eliminate bias
6) **External Validation Process**, including § 170.315(b)(11)(iv)(6):
   - § 170.315(b)(11)(iv)(6)(i) - 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
   - § 170.315(b)(11)(iv)(6)(ii) - Party that conducted the external testing
   - § 170.315(b)(11)(iv)(6)(iii) - 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
   - § 170.315(b)(11)(iv)(6)(iv) - Description of external validation process

7) **Quantitative measures of performance**, including § 170.315(b)(11)(iv)(7):
   - § 170.315(b)(11)(iv)(7)(i) - Validity of intervention in test data derived from the same source as the initial training data;
   - § 170.315(b)(11)(iv)(7)(ii) - Fairness of intervention in test data derived from the same source as the initial training data;
   - § 170.315(b)(11)(iv)(7)(iii) - Validity of intervention in data external to or from a different source than the initial training data;
   - § 170.315(b)(11)(iv)(7)(iv) - Fairness of intervention in data external to or from a different source than the initial training data;
   - § 170.315(b)(11)(iv)(7)(v) - References to evaluation of use of the intervention on outcomes, including, bibliographic citations or hyperlinks to evaluations of how well the intervention reduced morbidity, mortality, length of stay, or other outcomes
8) **Ongoing Maintenance of Intervention Implementation and use**, including § 170.315(b)(11)(iv)(8):
   - § 170.315(b)(11)(iv)(8)(i) - Description of process and frequency by which the intervention's validity is monitored over time
   - § 170.315(b)(11)(iv)(8)(ii) - Validity of intervention in local data
   - § 170.315(b)(11)(iv)(8)(iii) - Description of the process and frequency by which the intervention's fairness is monitored over time
   - § 170.315(b)(11)(iv)(8)(iv) - Fairness of intervention in local data
9) **Update and Continued Validation or Fairness assessment schedule**, including § 170.315(b)(11)(iv)(9):
   - § 170.315(b)(11)(iv)(9)(i) - Description of process and frequency by which the intervention is updated and
   - § 170.315(b)(11)(iv)(9)(ii) - Description of frequency by which the intervention's performance is corrected when risks related to validity and fieriness are identified