ONC Health IT Certification Program Developer Roundtable Question & Answers

Q: Requirement where users must have the ability to edit the source attributes- does this create a conflict with the Maintenance of Certification requirement?

No, the requirements to enable a user to modify source attributes do not conflict with the Maintenance of Certification requirements to "review and update as necessary" source attribute information because any modifications made by a user to a source attribute for a Certified Health IT developer's supplied DSI is not the responsibility of the Certified Health IT developer. However, if Certified Health IT developer determines that a source attribute should be updated (per requirements in the Maintenance of Certification requirements) the Certified Health IT developer is obligated to communicate these updates to the appropriate clients and users.

Q: For PDSI, many of the examples describe "likely" included in scope for PDSI to be certified. Can you clarify if something is "likely" in scope for certification; are there any issue/ramifications with not certifying something that is "likely" in scope given the changing material available for certification and the significant amount of work involved to meet the certification requirements?

The examples listed in the HTI-1 preamble and the DSI Resource Guide are meant to help readers understand which types of functionalities would likely meet the definition of "Predictive DSI." The question of whether these sorts of examples would be subject to ONC requirements is dependent on a range of other factors (like whether a certified developer supplies the Predictive DSI as part of its Health IT Module).

Predictive DSI

Q: Any thoughts on using FHIR® EHR Launch for Predictive DSI?

ONC did not specify how a certified developer should support a user to select a Predictive DSI. Developers have 1lexibility in determining how to support selection capabilities, which could include the use of SMART App Launch.

Q: What if there are no 3rd party apps yet that support the requirements of Predictive DSI but my EHR still supports EHR Launch for 3rd party apps, is that sufficient for attesting to (b)(11) for Predictive DSI until a 3rd party app becomes available?

ONC did not specify how a certified developer should support a user to select a Predictive DSI. Developers have flexibility in determining how to support selection capabilities, which could include the use of SMART App Launch.

Q: Would AI and Large Language Model used for ambient listening and generate a clinical note but not used to "predict" or "suggest" care be considered Predictive DSI?

This use case was explicitly mentioned in the HTI-1 final rule as an example of a functionality that would likely be considered a Predictive DSI. It is highly likely that such a model was trained on data and resulted in an output that predicts the most likely next word in a string (if it is a LLM for example). A key dimension in this kind of example is whether the functionality also "supports decision-making."

Q: Do the rules in DSI need to be specific to the client? I have sites that don't do PCP related items and I have yet to create rules for other specialty, so the concept is enabled but not yet helpful. I don't see any guidance on what is required by specialty, will this be the case later?

The ONC Certification Program requirements do not identify specific DSIs that must be supported beyond drug-drug / drug-allergy contraindication checking. Certified developers must enable users to select DSIs based on whether the DSI uses data listed here: https://www.ecfr.gov/current/title-45/part-170/section-170.315#p-170.315(b)(11)(iii).

Q: Can you clarify what "export" means for the feedback?

Export means that a user must be able to download and compute feedback data as specified in https://www.ecfr.gov/current/title-45/part-170/section-170.315#p-170.315(b)(11)(ii)(C)

Q: If a developer develops predictive DSI, is it still mandatory to support third party PDSI?

Yes, Certified Health IT developers that supply a Predictive DSI to their customers must also support their customers' selection of third party PDSI. How a Certified Health IT developer supports their customers' selection of third party PDSI is not specified in the regulations, so certified developers have flexibility in determining how to support customers' selection of third party PDSI.

Q: Many (if not all) health equity attributes are self-reported. Is that part of what is reflected for source attribute?

The requirement is that if any of those data concepts listed at 45 CFR 170.315(b)(11)(iv)(A) were included as part of the evidence-based DSI input variables, that those are identified so users know that race, for example, was part of the rules-based logic of the evidence-based DSI.

Q: For the 13 attributes, is the expectation to support each source attribute individually OR in combination?

Both. Each source attribute field must be supported and source attribute information must be complete and up-to-date for evidence-based DSI that are supplied by the Certified Health IT developer. However, if an evidence-based DSI does not 2nclude "ethnicity" for example, the source attribute at § 170.315(b)(11)(iv)(A)(6) does not need to indicate that "ethnicity" was not included as an input variable. Identifying that one of those data elements in § 170.315(b)(11)(iv)(A)(5)-(13) is not used, is not required.

Q: When ONC says: "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." Does this mean that if a customer has a Predictive DSI and tells the developer they want to use it with the developer's EHR that the developer must offer integration with the customer's Predictive DSI?

This is correct. The Certified Health IT developer must offer some way for the customer to use their self-developed or purchased-from-a-third party PDSI. However, this does not mean that a Certified Health IT developer must support bespoke integrations. Stated differently, a Certified Health IT developer must have some way for customers to user other party-developed DSIs, but a Certified Health IT developer is not required to support all the ways a customer might want to select/integrate a third-party PDSI.

Q: That graphic/animation was kind of confusing. Maybe simplifying the terms and display names (Example EHR, Example Predictive DSI #1, etc).

Is it saying that the 3rd party app that was not developed by the EHR (the 3rd graphic at the bottom) is not required to meet Predictive DSI requirements?

The 3rd graphic at the bottom was meant to convey a PDSI that a Certified Health IT developer is not supplying so the Certified Health IT developer is not responsible for the source attribute content. The Certified Health IT developer is still required to support source attribute fields for these "non-supplied" other party PDSIs.

Q: What is your recommendation for SED testing for PDSI functionality where a developer does not supply any PDSI? Is it sufficient to show EHR launch functionality would support a PDSI if selected by a customer?

Generally, yes. But recall that supporting selection of a PDSI is not the only difference between § 170.315(a)(9) and § 170.315(b)(11). It is likely that SED testing would also be needed for "feedback" related functionality.

Q: Did I understand that USCDI v1 has to be included in the Evidence based data elements?

Not all USCDI v1 data elements must be supported for use in evidence-based DSIs. Evidence-based DSIs that 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 must be supported. Please note that demographic data in #4 include those data concepts and standards listed in 170.315(a)(5)(i), not USCDI demographics data class and elements.

Q: Does b(11) make it mandatory for vendors to support both evidence-based DSIs and predictive DSIs? Or can a vendor qualify for certification to the b(11) requirement if they only support predictive DSI?

A developer may certify to § 170.315(b)(11) without supplying any Predictive DSI and the only evidence-based DSI that a developer must support (but not necessarily supply) is drug-drug and drug-allergy contraindication checking per requirements at § 170.315(b)(11)(iii). Please see 89 FR 1241 for more.

Q: If the vendor needs to support evidence-based DSI in addition to predictive DSI, does the evidence-based DSI need to be supplied by the vendor? Or can the vendor simply provide the functionality for customers to integrate and enable evidence-based DSIs that are developed by external developers?

Generally, a developer must only provide the functionality for a customer to select (i.e., activate) an evidence-based DSI and these DSIs may be developed by external third-parties or the users themselves. Given the requirements at § 170.315(b)(11)(iii) drug-drug and drug-allergy contraindication checking in some form is the only specified DSI required of Health IT Modules certified to § 170.315(b)(11) to support. All other use cases are at the discretion of the user as long as they are within the scope of data identified at (b)(11)(iii)(A) and (B). Please see 89 FR 1241.