

# What New CDS Regulation Means for You: Benefits for Clinicians Using Health IT Certified to the Decision Support Interventions (DSI) Certification Criterion

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Clinicians who interact with common [clinical decision support](#) (CDS) tools using their electronic health records (EHRs) readily understand their value to increase the quality of patient care, enhance population health outcomes, and avoid errors and adverse events. Thanks to [recent regulations](#), clinicians will soon have enhanced decision support capabilities and access to critical information about many of these CDS tools through their certified EHRs.

Starting January 1, 2025, ONC Health IT Certification Program requirements will enable clinicians' access to [enhanced capabilities](#), such as the ability to provide feedback to CDS alerts. It will also support clinician access to information on how these decision support tools are developed, tested, evaluated, and should be used.

The ONC Health IT Certification Program categorizes most rules-based CDS tools as evidence-based decision support interventions (evidence-based DSIs) and establishes a new definition for machine learning-based and artificial intelligence driven CDS tools as "predictive DSIs."



## Evidence-based decision support interventions

Evidence-based DSIs are rules-based decision support tools, rather than those based on relationships learned in data (i.e., predictive DSIs). These are often based on consensus clinical guidelines. For example, a decision support rule that recommends a follow-up appointment within 12 weeks according to United States Preventive Services Taskforce (USPSTF) recommendations would be considered an evidence-based DSI under ONC's regulation. Evidence-based DSIs 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 DSI in § 170.102 ([89 Fed. Reg. 1240-1241](#))

## Predictive decision support interventions

Predictive DSI means "technology that supports decision-making based on algorithms or models that derive relationships from training data and then produce an output that results in prediction, classification, recommendation, evaluation, or analysis." This definition includes large language models (LLMs) and other generative AI and is not constrained by specified use cases or intended uses. For example, this definition includes both clinical and administrative use cases, such as those that predict risk of sepsis, readmission, and patient no-shows, as well as technology that estimates glomerular filtration rate (eGFR) and generates clinical notes using large language models ([89 Fed. Reg. 1244-1245](#)).

The HHS Assistant Secretary for Technology Policy (ASTP) administers the [ONC Health IT Certification Program](#), which certifies Health IT Modules — including EHRs. The Certification Program adopts health IT standards, implementation specifications, and certification criteria on behalf of HHS.

The ONC Health IT Certification Program's new DSI requirements also include requirements for health IT developers to support clinicians' access to information that can help them comply with other HHS policies and programs, such as the [HIPAA Security Rule](#) and the Office of Civil Rights "[nondiscrimination in the use of patient care decision support tools](#)" requirements.

**Clinicians should ask their leadership and developers of their certified EHR to "show me the source attributes!"**

**All clinical users can have access to information on how certain decision support tools were developed, tested, evaluated, and should be used, known as source attribute information in the Certification Program.**

**Decisions about who, where, and when access to source attribute information occurs is a customer-level decision.**

**Make sure your organization gives you access!**

For example, Certified Health IT developers must identify when data elements salient to health equity, including race, sex, social determinants of health, and pregnancy or disability status data are used as inputs to evidence-based and predictive DSIs they supply as part of their products. Certified Health IT developers are also required to apply risk management practices to predictive DSIs they supply and publicly disclose summaries of such risk management practices. Given these Certification Program requirements, clinicians will be better positioned to identify when these tools employ such input variables and mitigate the risk of discrimination resulting from the use of these tools.

In addition, clinicians will be able to contribute to a growing information ecosystem regarding the performance and quality of predictive DSIs supplied by their Certified Health IT developer. Under existing Certification Program requirements, clinicians are able to [freely communicate publicly](#) about their experiences with certified health IT. This is also true of user-facing "source attribute" information, which includes information on how a predictive DSI was tested for fairness and validity.

These and other "Did you know...?" aspects of new ONC Health IT Certification Program requirements describe important benefits to clinical users and the clinical community. We encourage clinicians to check with their Certified Health IT developers to understand when and how these capabilities will be made available in 2025.

**User feedback on evidence-based DSIs: Clinicians, did you know...?**

- You will be able to provide feedback on evidence-based DSIs directly through your certified technology. These DSIs include alerts, warnings, and other types of decision support that are actively presented in your clinical workflow.
- You can get an export of the feedback data you provide, and this feedback data must be exportable in a computable format. Clinicians can work with their Certified Health IT developer to identify types of feedback data, which at minimum must include the intervention, action taken, user feedback provided, user, date, and location.
- You can work with your Certified Health IT developers to determine the range of actions that are appropriate as part of the feedback data. Potential actions may include whether the clinician viewed, accepted, declined, ignored, overrode, or modified the DSI.

**The ability to provide feedback and export feedback data will help support continuous improvement so that many common CDS tools can be monitored and made more effective. In addition to quality improvement, export of feedback data facilitates research, associating feedback data with other relevant data, and linking DSI to patient health outcomes, including identifying and reducing health disparities and possible discriminatory outcomes. (Note: The ONC Health IT Certification Program does not require users to provide feedback, only that their Certified Health IT supports such a capability.)**

## Selection of Predictive DSIs: Clinicians, did you know...?

- You already have the ability to select (or activate) evidence-based DSIs through your Certified Health IT. Beginning in 2025, you will also have the ability to select predictive DSIs using your Certified Health IT, regardless of whether your Certified Health IT developer supplies their own predictive DSIs.
- Your Certified EHR must support the selection (or activation) of predictive DSIs that use any data element listed in an active version of the [United States Core Data for Interoperability \(USCDI\)](#). These USCDI data elements include common demographic and vital signs data, such as sex, age, and weight, as well as specialized data, such as smoking status, medications, and immunizations.
- This means that if your organization self-develops a predictive DSI or your organization purchases a predictive DSI from a third-party, your Certified EHR must be capable of enabling you to select or activate that predictive DSI.

**The ability for clinicians to select predictive DSIs supports the widespread use of these tools and achieves a policy goal to ensure that users have equal technical capabilities.**

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## Access to DSI source attributes: Clinicians, did you know...?

- Your Certified Health IT must enable clinical users to access, record, and change "source attributes" – data points, measures, metrics, and descriptions – that include qualitative and quantitative information related to how DSIs are developed, tested, evaluated, and should be used.
- These include 13 source attribute fields for evidence-based DSIs and 31 source attribute fields for predictive DSIs. The complete list of source attributes required for Certified Health IT to support is available in the [DSI Resource Guide](#).
- Your Certified Health IT should have complete and up-to-date source attribute information for each DSI the developer supplies as part of its certified product. Some source attributes may be listed as "unknown," and clinicians should see the absence of information as a signal in itself regarding the quality of the DSI.
- Your Certified Health IT must provide source attribute fields for DSIs they supply, as well as for DSIs that their customers self-develop or purchase from third-parties.

**The capability to access, record, and change source attributes helps clinicians assess the fairness, appropriateness, validity, effectiveness, and safety (FAVES) of predictive DSIs. While there are no requirements in the Certification Program for clinical users to review source attributes, it is best practice for clinicians and end users to conduct such affirmative reviews in an effort to identify potentially discriminatory tools, as discriminatory outcomes could violate applicable civil rights law.**

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## Intervention Risk Management: Clinicians, did you know...?

- Every predictive DSI supplied by your Certified Health IT developer must have risks and adverse impacts analyzed and mitigated. Certified Health IT developers are required to cover the following risk "characteristics," aligned with the [National Institute for Standards and Technology AI Risk Management Framework](#):
- If your Certified Health IT developer supplies a predictive DSI as part of their product, they are required to establish policies and controls for governance, including for how data are acquired, managed, and used.
- Certified Health IT developers are required to publicly disclose their risk management practices. This public disclosure facilitates the availability of appropriate information to help assist in making medical decisions.

**Transparency provided through public disclosure helps ensure that the entities developing and supplying predictive DSIs identify, analyze, and mitigate specific kinds of risks known to cause harm or adverse impacts. This information can help clinicians comply with other HHS requirements, including HIPAA Security Rule requirements and requirements to identify and mitigate risks of discrimination through the use of predictive DSIs.**

### Characteristics

-  Validity
-  Reliability
-  Robustness
-  Fairness
-  Intelligibility
-  Safety
-  Security
-  Privacy

## Public communications of performance: Clinicians, did you know...?

- You have the right to publicly discuss various aspects of Certified Health IT performance. Specifically, you are allowed to share your experiences of using a Certified Health IT Module.
- Public communications, including research, regarding the output of an algorithm and how it is displayed in a health IT system cannot be restricted. This means that source attribute information, which is user-facing, can be freely discussed by customers.
- If an individual requests access to their health information as part of their HIPAA right of access from a HIPAA covered entity, that individual, generally, has the right to access underlying data and information used to generate healthcare recommendations about an individual's healthcare, such as information about the use of a predictive DSI in a healthcare decision and source attribute information associated with the use of a predictive DSI in a healthcare decision.

**The rights afforded to clinicians as part of the [Communications Condition and Maintenance of Certification](#) requirements in the [ONC Health IT Certification Program](#) allow you to openly discuss different aspects of Certified Health IT's performance and your personal experience with its user-facing features. In particular, you can publicly praise and publicly critique source attributes related to predictive DSIs. You can share these views with your colleagues and through publications.**