ONC Health IT Certification Program
The Office of the National Coordinator for Health Information Technology

What is Direct Review?

Direct Review is the process established by ONC to determine if Certified Health IT Developers and their Certified Health IT meet the requirements of the ONC Health IT Certification Program (Certification Program). When ONC believes that Certified Health IT may not conform to the requirements of the Certification Program or that a developer has not complied with a Condition or Maintenance of Certification requirement, ONC may initiate the Direct Review process to assess the situation and, if necessary, ensure Certified Health IT Developers remedy the issue and bring their product(s) back into compliance with the Certification Program requirements in a timely manner.

The Direct Review process promotes accountability, ensuring Certified Health IT conforms to Certification Program requirements when it is implemented and used in real world settings.

When Is Direct Review Initiated?

ONC may elect to initiate Direct Review if it has a reasonable belief:

- That the Certified Health IT may be causing or contributing to conditions that present a serious risk to public health or safety;

- That the Certified Health IT Developer is not compliant with a Condition or Maintenance of Certification requirement; or

- That suspected non-conformities, while in the scope of an ONC-Authorized Certification Body's (ONC-ACB) oversight, may present challenges that prevent the ONC-ACB's effective investigation, and that ONC is better situated to review the Certified Health IT.

ONC obtains information on the performance of Certified Health IT and compliance to Certification Program requirements from numerous sources including, but not limited to, ONC-ACB quarterly surveillance reports, questions submitted and issues raised by ONC-ACBs and ONC-Authorized Testing Laboratories (ONC-ATLs), issues submitted directly to ONC from users, and referrals from other government agencies. ONC continuously analyzes information from these sources to identify cases that may warrant the initiation of a Direct Review. ONC may coordinate and share information with other agencies and may engage other persons and entities, as appropriate, to effectively respond to suspected problems with Certified Health IT.

ONC encourages users to follow the Certified Health IT Complaint Process if they encounter any problems related to Certification Program requirements.

What Happens During Direct Review?

During a Direct Review, if ONC determines there is a potential non-conformity, it may send a notice of potential non-conformity to the Certified Health IT Developer. If ONC determines that the product or developer's actions or practices do not conform with the Certification Program, a notice of non-conformity may be sent to the Certified Health IT Developer. In response to a notice from ONC, a Certified Health IT Developers must respond with information identified in the notice and should respond promptly. If ONC determines a Certified Health IT Developer has an non-conformity, ONC requires the Certified Health IT Developer to correct it by way of a Corrective Action Plan (CAP). ONC could take the more serious step of suspending or terminating the affected certification(s), and/or issuing a certification ban to the Certified Health IT Developer if identified issues are not corrected.

What Is a CAP?

The goal of the Direct Review process is to remedy any identified non-conformities or non-compliance with Certification Program requirements in a timely manner. ONC has established the CAP to resolve these types of issues. CAPs must contain a comprehensive plan of action, including a timeline, to bring their product(s) back into full compliance with the Certification Program requirements. ONC may seek specific information or ask for additional information to be included in the CAP, but the Certified Health IT Developer is ultimately responsible for ensuring the CAP identifies the appropriate steps for compliance.

For a CAP to be approved by ONC, the Certified Health IT Developer must include:

- an assessment and description of the nature, severity, and extent of the non-conformity;

- a detailed description of how the Certified Health IT Developer will resolve the identified issues, notify affected customers, and ensure all issues are resolved;

- the timeframe under which all elements of the CAP will be completed; and

- other elements as described in 45 CFR 170.580(c)(2).

Can ONC Determinations Be Appealed?

It is important to note that ONC may suspend the certification of a health IT product at any time if ONC has a reasonable belief that the Certified Health IT may present a serious risk to public health or safety. ONC may also elect to terminate the certification issued to a health IT product. The Direct Review process includes opportunities for Certified Health IT Developers to appeal a suspension, termination, or certification ban determination made by ONC regarding a specific Certified Health IT Product. Once an appeal request is received by ONC, a hearing officer will be assigned by the National Coordinator to adjudicate the appeal on their behalf. Unless ONC cancels the suspension or rescinds the termination determination, the National Coordinator's determination on appeal, as issued by the hearing officer, is final.

Making Direct Reviews Public

To facilitate public transparency, information about a Direct Review that results in a CAP will be publicly displayed on a Certified Health IT product's listing within ONC's Certified Health IT Product List (CHPL). Users can check the CHPL to identify any changes in the status of the Certified Health IT. ONC's goal is to ensure Certified Health IT Developers remedy any identified non-conformities in a timely manner.
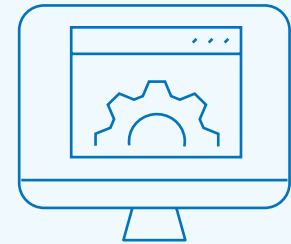
If there are concerns regarding compliance with Certification Program requirements, there is a complaint process to reach an appropriate resolution. As a first step, ONC urges users to work directly with the Certified Health IT Developer to resolve any issues, as this will likely be the quickest and most efficient means of having concerns recognized, addressed, and resolved. If efforts between a user and the Certified Health IT Developer fail to resolve the concern, the ONC-ACB that certified the health IT may be able to provide further assistance. The appropriate ONC-ACB and its contact information can be found under the Certified Health IT product's listing on the CHPL. If neither step successfully addresses the concerns, customers and users of Certified Health IT can submit a complaint directly to ONC through the Health IT Feedback and Inquiry Portal.