CERTIFICATION BAN
Program Guidance #17-03
Issued and Effective Date: Oct 19, 2017

I. Purpose

This guidance summarizes the Certification Ban process finalized in the Enhanced Oversight and Accountability final rule (81 FR 72442-44; and 45 CFR 170.581), clarifies certain circumstances that could trigger a Certification Ban, and specifies responsibilities of ONC-Authorized Certification Bodies (ONC-ACBs) as part of the Certification Ban process.

II. Certification Ban

The certification of any of a health IT developer's health IT is prohibited when the certification of one or more of the health IT developer's Complete EHRs or Health IT Modules is:

(1) Terminated by ONC under the ONC Health IT Certification Program (Program);
(2) Withdrawn by an ONC-ACB because the health IT developer requested it to be withdrawn when the health IT developer's health IT was the subject of a potential non-conformity or non-conformity as determined by ONC;
(3) Withdrawn by an ONC-ACB because of a non-conformity with any of the certification criteria adopted by the Secretary under subpart C of part 170 (i.e., Certification Criteria for Health Information Technology); or
(4) Withdrawn by an ONC-ACB because the health IT developer requested it to be withdrawn when the health IT developer's health IT was the subject of surveillance for a certification criterion or criteria adopted by the Secretary under subpart C of part 170, including notice of pending surveillance.

See 45 CFR 170.581(a).

"Termination" means an ***ONC*** action to "terminate" or "revoke" the certification status of a Complete EHR or Health IT Module. An action by an ***ONC-ACB*** to "terminate," "remove," or "revoke" the certificate of a Complete EHR or Health IT Module is referred to as "withdrawal." International Organization for Standardization/International Electrotechnical Commission 17065:2012 Conformity assessment – Requirements for bodies certifying products, processes and services (ISO/IEC 17065) defines the requirements for conformity assessment by ONC-ACBs. ISO/IEC 17065 defines "withdrawal" (as also defined in ISO 17000) as a revocation or cancellation of the statement of conformity. This occurs in two situations: (1) when an ONC-ACB proactively removes a certification based on its own accord; or (2) when a health IT developer initiates the discontinuation of a product's certification and requests that the ONC-ACB remove the product's certificate. ONC makes the distinction between "termination" and "withdrawal" to conform with ISO's use of "withdrawal" throughout the ISO standards. However, ONC retains use of the term "termination" because it enforces Program requirements directly, not under delegated authority and not subject to ISO standards, as is the case for ONC-ACBs (see 81 FR 72443).

A. Withdrawals

A withdrawal as specified in (3) and (4) above focus on non-conformities with certification criteria, but **not** non-conformities arising from 45 CFR 170.523(k)(1) (disclosure of information about limitations and additional types of costs associated with certified health IT), 170.523(l) (compliance with rules governing the use of the ONC Certification and Design Mark), or 170.523(n) (health IT developer quarterly submission of user complaints to ONC-ACBs) (81 FR 72443).

If a withdrawal occurs as part of a completed corrective action plan approved by ONC or an ONC-ACB, then a Certification Ban would not be applicable.

B. Application to Health IT Developers

The Certification Ban affects health IT developers participating in the Program, their subsidiaries, and their successors (81 FR 72443).

III. Notification and ONC-ACB Responsibilities

In addition to posting corrective action plans, suspensions, withdrawals, and terminations of certified health IT to the Certified Health IT Product List (CHPL), Certification Bans will also be posted on the CHPL. ONC will also use, on a case by case basis, other forms of appropriate publication and dissemination, such as the ONC or Program listservs.

ONC will directly notify the ONC-Approved Accreditor, ONC-ACBs, and ONC-Authorized Testing Laboratories (ONC-ATLs) of a decision to terminate a Health IT Module or Complete EHR's certification under ONC direct review. The ONC-ACB that issued the certification must acknowledge receipt of the notification and immediately begin procedures for handling a certificate(s) terminated by ONC.

An ONC-ACB must immediately notify ONC when they have withdrawn a Health IT Module or Complete EHR's certification under the conditions set forth in 45 CFR 170.581(a)(2), (3), or (4). The ONC-ACB should include in its notification to ONC the following:

1. Product name and version
2. Developer name
3. Reason for withdrawal
4. Date of withdrawal
5. If the conditions of 45 CFR 170.581(a)(3) or (4) are met, then a summary of the potential non-conformity(ies) or non-conformity(ies).

ONC will notify other ONC-ACBs and ONC-ATLs should the ONC-ACB notification result in a health IT developer being placed under Certification Ban.[1]

ONC-ACBs and ONC-ATLs must initiate processes for tracking health IT developers (including their subsidiaries and successors) that have been placed under a Certification Ban.

IV. Reinstatement and Remediation

To have a Certification Ban lifted:

(1) A health IT developer must request in writing ONC's permission to participate in the Program;
(2) The request must demonstrate that the customers affected by the certification termination or withdrawal have been provided appropriate remediation; and
(3) ONC must be satisfied with the health IT developer's demonstration that all affected customers have been provided with appropriate remediation and grant reinstatement into the Program.

See 45 CFR 170.581(b).

A. Requests for Reinstatement

Requests for reinstatement must be submitted to ONC in writing to ONC.Certification@hhs.gov with "Certification Program Reinstatement Request" in the subject field.

B. Appropriate Remediation

Demonstration by a health IT developer that all affected customers have been provided with appropriate remediation includes listing the form of remediation (81 FR 72444).

ONC will require that the scope of certified health IT previously provided to the affected customers be maintained (*i.e.*, a health IT developer must demonstrate, and ONC is satisfied, that all the necessary certified health IT has been *made available* to affected customers) (81 FR 72444).

In providing appropriate remediation to affected customers, ONC acknowledges that there may be other ways for health IT developers to correct situations for customers short of correcting the certified version or providing a replacement certified version. Therefore, ONC provides that, as determined by ONC, other certified health IT may be *made available* by the health IT developer that would remedy the non-conformity for all affected customers. This certified health IT may be the health IT of another health IT developer (81 FR 72444). There also may be reasons why a customer does not implement the corrected certified version or other available certified health IT

[1] Note that under ONC direct review the certification of any health IT produced by a health IT developer that has the certification of one of its Complete EHRs or Health IT Modules **suspended** under the Program is prohibited, unless ONC cancels a suspension. 45 CFR 170.580(d)(5).

in a timely manner or at all. ONC will take into consideration customer responses (*e.g.*, the customer declines or postpones the correction or signs a release of obligation, which may be the result of a financial settlement) when ONC determines whether a health IT developer has demonstrated that appropriate remediation has been provided to all affected customers (81 FR 72444).

C. Determination

ONC makes determinations regarding the lifting of a Certification Ban in all circumstances. ONC may, as appropriate, work with ONC-ACBs and health IT developer customers to determine if the requirements of 45 CFR 170.581(b) have been met. For example, ONC may verify that appropriate remediation has been provided for all affected customers. ONC may also randomly or methodically verify information with affected customers (81 FR 72444).