ONC Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

CERTIFICATION BAN

PROGRAM GUIDANCE #17-03

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I. PURPOSE

The Office of the National Coordinator (ONC) Certification Program (Certification Program) provides this updated guidance as a summary of the Certification Ban process, which was finalized under the Enhanced Oversight and Accountability Final Rule (81 FR 72442-44; and 45 CFR 170.581) and the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule) (85 FR 25786). It clarifies the circumstancesthat may trigger a Certification Ban, defines the responsibilities of ONC-Authorized Certification Bodies (ONC-ACBs) as part of the Certification Ban process, and outlines conditions for potential reinstatement and remediation of a banned health IT developer.

II. CIRCUMSTANCES THAT MAY TRIGGER A CERTIFICATION BAN

According to 45 CFR 170.581(a), a certification ban may be imposed on a developer's health IT when:

(1) The certification of one or more of the health IT developer's Health IT Modules is:
  (i) Terminated by ONC under the ONC Health IT Certification Program;
  (ii) Withdrawn from the ONC Health IT Certification Program by an ONC-ACB because the health IT developer requested it to be withdrawn (for reasons other than to comply with Program requirements) when the health IT developer's health IT was the subject of a potentialnon-conformity or non-conformity as determined by ONC;
  (iii) Withdrawn by an ONC-ACB because of a non-conformity with any of the certification criteria adopted by the Secretary under subpart C of part 170;
  (iv) Withdrawn by an ONC-ACB because the health IT developer requested it to be withdrawn (for reasons other than to comply with Program requirements) when the health IT developer's health IT was the subject of surveillance for a certification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 part170, including notice of pending surveillance; or

(2) ONC determines a certification ban is appropriate per its review under § 170.580(a)(2)(iii).

See 45 CFR 170.581(a).

A. Terminations and Withdrawals leading to Certification Ban

Termination refers to an ONC action to end or revoke the certification status of a Health IT Module while a **withdrawal refers to an ONC-ACB action** to terminate, remove, or revoke the certificate of a Health IT Module.

While a termination or withdrawal refers to the revocation of a health IT developer's certification of a Health IT Module, a **Certification Ban applies to the health IT developer, its subsidiaries, and successors, and prohibits future health IT by that developer from being certified** (81 FR 72443).

ISO/IEC 17065[1] 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 the use of the term "termination" because it enforces Certification Program requirements directly, not under delegated authority, and not subject to ISO standards, as is the case for ONC-ACBs (see 81 FR 72443).

[1] 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.

A withdrawal as specified in 45 CFR 170.581(a)(1)(iii) and (iv) focuses on non-conformities with certification criteria, but not non-conformities arising from:

- 45 CFR 170.523(k)(1), disclosure of all known material information concerning additional types of costs or fees 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), ONC-ACB quarterly submission of complaints to ONC.

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.[2]

B. Certification Ban Determination as a result of Direct Review for Noncompliance with a Condition and Maintenance of Certification Requirement

Per 45 CFR 170.580(a)(2)(iii), ONC may initiate Direct Review if it has reasonable belief that a Health IT Developer has not complied with a Condition or Maintenance of Certification requirement. ONC may determine a Certification Ban is appropriate if the developer fails to work with ONC or their ONC-ACB to address the noncompliance, or if the developer is non-compliant with the requirements of the established corrective action plan.

As ONC considers a Certification Ban or termination of a Health IT Module's certificate, several factors may influence its decision, including but not limited to:

- whether the Health IT Developer has previously been found in noncompliance with the Conditions and Maintenance of Certification requirements or other Certification Program requirements;
- the severity and pervasiveness of the noncompliance;
- cooperation on the part of the Health IT Developer during ONC review;
- potential negative impact on providers participating in Centers for Medicare & Medicaid Services (CMS) programs; and
- whether termination and/or a Certification Ban is necessary to ensure the integrity of the certification process (85 FR 25787)

C. Certification Ban Notification and ONC-ACB Responsibilities

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

ONC will directly notify ONC-ACBs and ONC-Authorized Testing Laboratories (ONC-ATLs) of a decision to terminate a Health IT Module under ONC Direct Review or of a decision to issue a Certification Ban for a health IT developer. ONC-ACBs should acknowledge receipt of the Certification Ban notification to demonstrate that they are aware that they should not explore future certifications with the banned developer. The ONC-ACB that issued the certification must 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 under the conditions set forth in 45 CFR 170.581(a)(1)(ii), (iii), or (iv).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)(1)(iii) or (iv) are met, then a summary of the potential non-conformity(ies) or non-conformity(ies).

[2] ISO/IEC 17065:2012 § 7.11 Termination, reduction, suspension, or withdrawal of certification

ONC will notify other ONC-ACBs and ONC-ATLs should the ONC-ACB notification result in a Health IT Developer being placed under a Certification Ban.[3]

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.

D. Effects of Terminations and Bans on Current and Future Health IT Products

Once a Certification Ban is placed on a Health IT Developer, the certified health IT products under them would still be considered certified, unless a product's certificate was terminated. This means that those products would still be available for use by providers participating in programs that require the use of certified health IT. However, while under a Certification Ban, a Health IT Developer could not make updates to the certification of those products. This means that access to new certified functionalities within a product would be limited (85 FR 25786).

If a product's certification status impacts healthcare providers that use the product for participation in programs of the Department of Health and Human Services (HHS), ONC would continue to support HHS and other federal and state partners, such as CMS, to help identify and make available appropriate remedies for users of terminated certified health IT. This would include supporting policies to mitigate negative impacts on providers, such as the availability of hardship exceptions for the Promoting Interoperability (PI) Programs for hospitals as mandated by section 4002(b)(1)(A) and (b)(2) of the 21st Century Cures Act and finalized by CMS in the FY 2018 Inpatient Prospective Payment System final rule (82 FR 38488 through 38490 and 85 FR 25786).

III. REINSTATEMENT AND REMEDIATION

Banned developers may be eligible for reinstatement into the program if certain conditions are met, as outlined in 45 CFR 170.581(d). To be considered for reinstatement:

(1) A health IT developer must request in writing ONC's permission to participate in the Certification Program;
(2) The request must demonstrate that the customers affected by the certificate termination, withdrawal, or noncompliance with a Condition or Maintenance of Certification requirement have been provided appropriate remediation.
(3) For noncompliance with a Condition and Maintenance of Certification requirement, the noncompliance must be resolved.
(4) If ONC is satisfied with the Health IT Developer's demonstration that all affected customers have been provided with appropriate remediation, ONC may grant reinstatement into the Certification Program.

A. Requests for Reinstatement

Requests for reinstatement must be submitted to ONC in writing to the Health IT Feedback and Inquiry Portal using the "ONC Health IT Certification" icon.

B. Appropriate Remediation

The request for reinstatement submitted by a Health IT Developer must demonstrate that the customers affected by the certificate ban have been provided with appropriate remediation, which includes maintaining the scope of the certified health IT it previously provided. In other words, Health IT Developers must demonstrate that all necessary certified Health IT has been made available to affected customers and that the affected customers have the option to choose alternative means of remediation.

ONC acknowledges that there may be other ways for Health IT Developers to provide remediation for affected

[3] Note that under ONC Direct Review the certification of any health IT produced by a developer that has the certification of one of its Health IT Modules **suspended** under the Certification Program is prohibited, unless ONC cancels a suspension. 45 CFR 170.580(d)(5).

customers other than 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 developer. If a customer declines or postpones the correction or signs a release of obligation, ONC will take into consideration their response when deciding if appropriate remediation has been provided to all affected customers.

ONC may also require the Health IT Developer to provide their customer list to ONC to verify that the correction has been completed for a random selection of users. For additional information on the reinstatement and remediation of a certification ban, please refer to 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(d) 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). ONC may consider any and all factors, including past bans, in its decision to grant reinstatement into the Certification Program (85 FR 25786).