

## Certification Program Enforcement Outcomes

Conformance to the ONC Health IT Certification Program (Certification Program) is managed collaboratively by ONC and ONC-Authorized Certification Bodies (ONC-ACBs) to foster a culture of continued compliance through a variety of oversight and enforcement activities<sup>1</sup>. **This Resource Guide outlines the potential outcomes that a developer may face if they are unable to maintain their adherence to the Certification Program requirements.**

### Oversight and Surveillance: Precursors for Enforcement

In relation to the Certification Program, oversight refers to ONC's authority to seek assurances that Certified Health IT developers and their products continue to be compliant to all applicable certification requirements.

Through the [Enhanced Oversight and Accountability Final Rule](#) (EOA) and the [ONC Cures Act Final Rule](#), ONC has established a regulatory framework to conduct [Direct Review](#) of Certified Health IT developers and their products. ONC could initiate direct review whenever it becomes aware of potential non-conformity or non-compliance to the Certification Program requirements, or the developer is non-compliant with a Condition or Maintenance of Certification requirement.

Additionally, under the Certification Program, ONC-ACBs are required to perform surveillance of the health information technology (health IT) they have certified ([45 CFR 170.556](#) and [§ 170.523\(i\)](#)) to determine if a certified health IT product continues to function as required by its certification.

The objective of oversight and surveillance is to continue to promote developer accountability for the performance, reliability, and safety of health IT. The primary object of ONC oversight is to ensure continued compliance and conformance by Certified Health IT developers, not to penalize them.

ONC and ONC-ACBs may become aware of a possible violation of Certification Program requirements through:

- Self-reported non-conformities by the Certified Health IT developer
- ONC-ACB surveillance activities;
- Complaints from providers, patients, other developers or others that may interact with the product;
- Issues raised by ONC-ACBs or ONC-Authorized Testing Laboratories (ONC-ATLs); and/or
- Referrals from other government agencies.

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1. For more information regarding ONC oversight and enforcement, review the language outlined in the Enhanced Oversight and Accountability Final Rule ([81 FR 72442-44](#); [45 CFR 170.580](#); [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](#)).

## Oversight and Surveillance: Precursors for Enforcement (Cont.)

If a non-conformity is identified in a developer's Certified Health IT Module, it is always the goal of the Certification Program to work with developers first to correct these non-conformities. With ONC's oversight and surveillance processes, the objective is always to help developers identify and address non-compliance to Conditions and Maintenance of Certification requirements and non-conformities in certified health IT that providers use to support patient care. ONC and ONC-ACBs will work with Certified Health IT Developers to remedy any non-conformities in a timely manner and for all potentially impacted customers.

However, scenarios may arise where further enforcement is needed. The enforcement actions that may be taken differ depending on whether the non-conformity is to a certification criterion, a non-compliance to a Condition and Maintenance of Certification requirement, or a matter of public health or safety.

## Enforcement

Enforcement encompasses the processes of compelling the developers to fulfill those requirements. As a result of a direct review, ONC may require the corrective action for found non-conformities, and, when necessary, may include a suspension or termination of a certification, or the issuance of a certification ban on a developer. ONC-ACBs may also require the corrective action to remedy non-conformities, but if further enforcement is necessary an ONC-ACB may impose a suspension, withdrawal or termination of a developer's certification.



## Types of Enforcement:

### Suspension

The certification of a product can be suspended by ONC and ONC-ACBs as they both have the authority to do so and it prohibits a developer the marketing, licensing, and sale of their affected Certified Health IT Module as certified for the time period for which it is under suspension.

While the product remains certified, ONC outlines in [§ 170.580\(d\)](#) it may suspend a Health IT Module's certification if it has a reasonable belief that the certified health IT presents a serious risk to public health or safety and may also cancel the suspension if it no longer believes the product presents said risk. As outlined in [§ 170.556\(d\)\(5\)](#), an ONC-ACB may initiate suspension procedures for a Health IT Module if:

- A developer does not submit a proposed corrective action plan in the allotted time;
- A developer does not make requested revisions to a correct action plan; and
- If the developer does not complete corrective actions in the specified timeframe.

### Withdrawal

Typically, the withdrawal of a health IT product's certification is done per the request of its developer when there is an intent to reduce the criteria being supported in said product. If the Certified Health IT developer no longer supports the product with the criteria to be removed, then it should be withdrawn from certification.

## Types of Enforcement (Cont.):

### Withdrawal (Cont.)

However, in the context of enforcement, a withdrawal refers to an ONC-ACB action to revoke or cancel the certificate of a Health IT Module. If a Health IT Module's certification has been suspended, an ONC-ACB is permitted to initiate certification withdrawal procedures when the health IT developer has not completed the actions necessary to reinstate the suspended certification as outlined in [§ 170.556\(d\)\(6\)](#). A withdrawal may also occur if the developer and ONC-ACB agree that withdrawing the certificate is the appropriate action to correct the non-conformity.

### Termination

A termination refers to an ONC action to terminate or revoke the certification status of a Health IT Module. A Health IT Module's certification may be terminated if:

- It is determined as appropriate based on information provided by the health IT developer in response to ONC's notice of proposed termination;
- The developer does not respond in writing to the proposed termination notice in the timeframe specified;
- ONC determines that the developer is noncompliant with a Condition or Maintenance of Certification requirement; or
- Under certain circumstances as outlined in [§ 170.580\(f\)\(1\)\(iii\)\(A\)-\(G\)](#), if the health IT fails to communicate, cooperate and/or fulfill its obligations during a direct review.

### Certification Ban

To protect the integrity of the Certification Program and users of certified health IT products, ONC has a process of imposing a certification ban on the future certification of a Certified Health IT developer's products that have been terminated by ONC or withdrawn<sup>2</sup> while in a status of non-conformity, potential non-conformity, or during a surveillance action, or if ONC determines a certification ban is appropriate per its review for a potential noncompliance with a Condition and Maintenance of Certification requirement. ([§ 170.581](#))

In the process of making the determination if a certification ban and/or a termination of a Health IT Module's certificate is warranted, ONC would consider if the Certified Health IT Developer has previously been found in non-compliance with the Conditions and Maintenance of Certification requirements or other Certification Program requirements; the severity and pervasiveness of the noncompliance; the developer's cooperation during the direct review; impact on providers; and whether this termination and/or certification ban is necessary. ([85 FR 25787](#))

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2. Generally, a termination or withdrawal of a Certified Health IT Module may trigger a certification ban on all current and future products of a Certified Health IT developer. However, if a product is withdrawn as part of a completed CAP approved by ONC or an ONC-ACB, a certification ban would not be applicable. See [45 CFR 170.581\(a\)\(1\)\(ii\)](#)

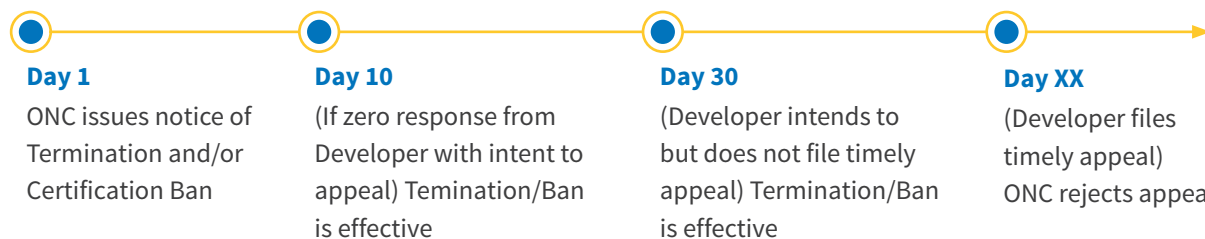
## Impact of Suspensions, Terminations and Certification Bans on Current and Future Certified Health IT Products

If the Certified Health IT Product does not continue to meet the Certification Program requirements and a termination goes into effect, the health IT developer must notify all potentially affected customers of the identified non-conformity(ies) and termination of certification in a timely manner. This product could not be updated and would no longer meet the requirements of the Medicare and Medicaid electronic health record (EHR) Incentive Program. In an effort to reduce the negative impact of a termination on end users, ONC would help identify mitigating strategies for providers using this product.

On the other hand, once a certification ban, suspension, or withdrawal is made effective, the health IT products under that developer would still be considered certified. This means that those products would still be available for use by providers participating in programs that require the use of certified health IT. Notably, a banned health IT developer could not make updates to the certification of those products ([85 FR 25786](#)), and the certification of any health IT produced by a health IT developer that has the certification of one of its products suspended is prohibited unless ONC cancels the suspension (45 CFR 170.580(d)(5))

### Opportunity to Appeal

Once ONC or ONC-ACB has made enforcement determinations, Certified Health IT developers will still have an opportunity to appeal the decision. For terminations of a certification or certification bans issued in relation to a nonconformity with a Condition and Maintenance of Certification requirement, there is an opportunity for the developer to appeal before the termination becomes effective <sup>3</sup>. A certification ban will be effective immediately for any bans that are determined in relation to a certificate termination or Withdrawal from the Certification Program ([§ 170.581\(c\)](#)). See the below timeline for when developers can appeal.



3. For terminations, the effective date is as outlined in 45 CFR 170.580(f)(2)(ii). For certification bans, the effective date is as outlined in 45 CFR 170.581(c).

## Reinstatement and Remediation

In the case of certification that is voluntarily withdrawn by the developer and for those that are withdrawn by the ONC-ACB, the product is no longer considered certified and cannot be reinstated without resubmitting for certification.

A suspension can be canceled at any time, if ONC no longer has a reasonable belief that the certified health IT presents a serious risk to public health or safety. This decision may be based on information provided by the health IT developer, such as completing corrective actions, or other reasons ([81 FR 72437](#)).

While termination decisions are permanent and cannot be reversed, developers do have the opportunity to request reinstatement following a certification ban. To have a certification ban lifted, the following conditions must be met as outlined in [§ 170.581\(d\)](#):

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 remediated.
3. For noncompliance with a Condition and Maintenance of Certification requirement, the noncompliance must be resolved.
4. ONC is satisfied with the written reinstatement request and information on remediation measures made available to all affected customers and grants reinstatement in the Certification Program.

It is important to highlight that there may be other ways for Certified Health IT developers to correct situations for customers that does not involve correcting the certified version or providing a replacement certified version of their product. As determined by ONC, other Certified Health IT product(s), from another Certified Health IT developer, may be made available by the implicated health IT developer, to remedy the non-conformity.

ONC makes the final determinations regarding the lifting of a certification ban in all circumstances. However, ONC may work with ONC-ACBs and health IT developer customers to determine if the conditions for lifting the ban have been met.