

# CERTIFICATION PROGRAM ENFORCEMENT AND OVERSIGHT

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Compliance with ONC Health IT Certification Program (Certification Program) requirements is managed collaboratively by ASTP/ONC and ONC-Authorized Certification Bodies (ONC-ACBs) to foster a culture of continued conformance of certified health information technology (health IT) through a variety of oversight and enforcement activities. For more information regarding ASTP/ONC oversight and enforcement, review [45 CFR 170.580](#), [§170.581](#), and preamble discussions of these provisions in the ONC Health IT Certification Program: Enhanced Oversight and Accountability Final Rule (EOA Final Rule) ([81 FR 72404](#)) 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 25642](#)).

**This Resource Guide outlines the potential outcomes that a developer of Certified Health IT might face if they are unable to maintain compliance with the Certification Program requirements.**

## OVERSIGHT: DIRECT REVIEW, AND SURVEILLANCE

In relation to the Certification Program, oversight refers to ASTP/ONC's authority to monitor and seek assurances that Certified Health IT and developers' practices continue to adhere to all applicable certification requirements.

Through the [EOA Final Rule](#), ASTP/ONC established a regulatory framework for [direct review](#) of Certified Health IT products and their developers' satisfaction of applicable Certification Program requirements. The [ONC Cures Act Final Rule](#) updated the framework to accommodate Conditions and Maintenance of Certification requirements applicable to Certification Program-participating developers as required by the [21st Century Cures Act](#) (Pub. L. 114-255). ASTP/ONC may initiate direct review of Certified Health IT or its developer's actions or practices to determine whether either conform to the Certification Program requirements.

Additionally, under the Certification Program, ONC-ACBs are required to perform surveillance of the 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 goal of the Certification Program oversight and enforcement is to uphold ongoing compliance and foster sustained accountability among Certified Health IT developers concerning the performance, reliability, and safety of their Certified Health IT. The objective is to confirm consistent, continuous compliance by Certified Health IT developers and the persistent conformance of their Certified Health IT. While mechanisms exist to address non-compliance, including potential penalties and sanctions, ASTP/ONC prioritizes encouraging collaborative solutions among developers of Certified Health IT and ONC-ACBs to ensure steadfast adherence to Certification Program requirements and maintain public confidence.

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

- Self-reporting of non-conformity by the developer;
- ONC-ACB surveillance activities;
- Complaints from providers, patients, 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.

In complement to the standards, certification criteria, and other Program requirements established by ASTP/ONC regulations, developers participating in the Certification Program may also be required to meet additional obligations under the terms of their agreements with their ONC-ACBs in order to maintain certification. (Contact your ONC-ACB for more information about additional requirements.)

If a non-conformity is identified in a Certified Health IT Module or a Certified Health IT developer's actions or practices, it is always the primary goal of the Certification Program to foster timely correction of the non-conformity. The objective of the oversight processes is to encourage developers to prevent or identify and address non-compliance to Conditions and Maintenance of Certification requirements and non-conformities in Certified Health IT. ASTP/ONC and ONC-ACBs will work with developers as the developers strive to remedy any non-conformities in a timely manner 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 with a Condition and Maintenance of Certification requirement, or a matter of public health or safety.

## ENFORCEMENT

The enforcement processes are designed to encourage and assist developers in fulfilling Certification Program requirements. As a result of a direct review or ONC-ACB surveillance, corrective action for non-conformities may be required. Depending on the case, other types of enforcement action also may be indicated, such as a withdrawal, suspension or termination of a certification.

### Types of Enforcement

Aside from notifying the developer of a non-conformity and requiring they submit and successfully complete a corrective action plan (CAP), other types of enforcement under the Program include:

- Suspension of the affected certification(s) pending remedial action by the developer.
- Removal of the affected certification(s) from the Certification Program, through withdrawal or termination.
- Banning certification of a developer's health IT until the conditions established in [45 CFR 170.581\(d\)](#) are met.

## Suspension

The certification of a product can be suspended by ASTP/ONC, the ONC-ACB that supports the certification, or both. Although the developer's product(s) remain certified during a suspension, the developer is prohibited from marketing, licensing, and selling their affected Certified Health IT Module(s) as certified for the time period during which it is under suspension.

As outlined in [45 CFR 170.580\(d\)](#), the National Coordinator may suspend a Health IT Module's certification at any time if ASTP/ONC 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 ASTP/ONC no longer believes the product presents said risk.

As outlined in [45 CFR 170.556\(d\)\(5\)](#), an ONC-ACB shall initiate suspension procedures for a Health IT Module if:

- A developer does not submit a proposed CAP in the allotted time
- A developer does not make requested revisions to a CAP
- A developer fails to complete corrective actions within the specified timeframe and manner outlined in the CAP
- A developer fails to pay for the fees associated with the testing, certification and surveillance services ONC-ACBs provide
- A developer fails to provide informational updates about changes to the Certified Health IT Module
- A developer fails to provide access to Certified Health IT products for surveillance activities
- A developer fails to maintain records of certification, testing, and surveillance activities

## 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 scope of certification for criteria being supported in its 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. 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 developer has not completed the actions necessary to reinstate the suspended certification as outlined in [45 CFR 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

In the context of the Certification Program enforcement, “termination” refers to an ASTP/ONC action to “terminate” or “revoke” the certification status of a Health IT Module. The National Coordinator may terminate a Health IT Module’s certification if:

- It is determined to be appropriate based on information provided by the developer in response to ASTP/ONC’s notice of proposed termination;
- The developer does not respond in writing to the proposed termination notice in the timeframe specified in [45 CFR 170.580\(e\)\(3\)](#);
- It is determined that the developer is noncompliant with a Condition or Maintenance of Certification requirement; or
- The circumstances outlined in [45 CFR 170.580\(f\)\(1\)\(iii\)\(A\)-\(G\)](#) occur during a direct review.

## Certification Ban

To protect the integrity of the Certification Program and users of Certified Health IT products, ASTP/ONC has a process to impose a ban on future certification of a developer’s products when certification of any of the developer’s health IT has been terminated by ASTP/ONC or withdrawn while in a status of non-conformity, potential non-conformity, or during a surveillance action, or if the National Coordinator determines a Certification Ban is appropriate per ASTP/ONC direct review initiated based on reasonable belief that the developer has not complied with a Condition and Maintenance of Certification requirement. Generally a termination or a withdrawal of a Certified Health IT Module, while it is the subject of ONC-ACB surveillance or of a potential non-conformity or non-conformity as determined by the National Coordinator, will trigger a Certification Ban on all current and future products of a developer. However, this ban does not apply if a product is withdrawn as part of a completed CAP approved by ASTP/ONC or an ONC-ACB.

In the process of determining whether to issue a Certification Ban or a termination of a Health IT Module’s certificate under 45 CFR 170.581(a), ASTP/ONC may consider whether the Certified Health IT developer has previously been found in non-compliance with any applicable requirements of the ONC Health IT Certification Program. This may include violations to the Conditions and Maintenance of Certification requirements or other Certification Program requirements. Additional considerations include the severity and pervasiveness of the non-compliance; the developer’s cooperation during direct review; impact on health care providers; and whether the termination and/or Certification Ban is necessary to ensure the integrity of the certification process.

## IMPLICATIONS OF SUSPENSIONS, TERMINATIONS AND CERTIFICATION BANS ON CURRENT AND FUTURE CERTIFIED HEALTH IT PRODUCTS

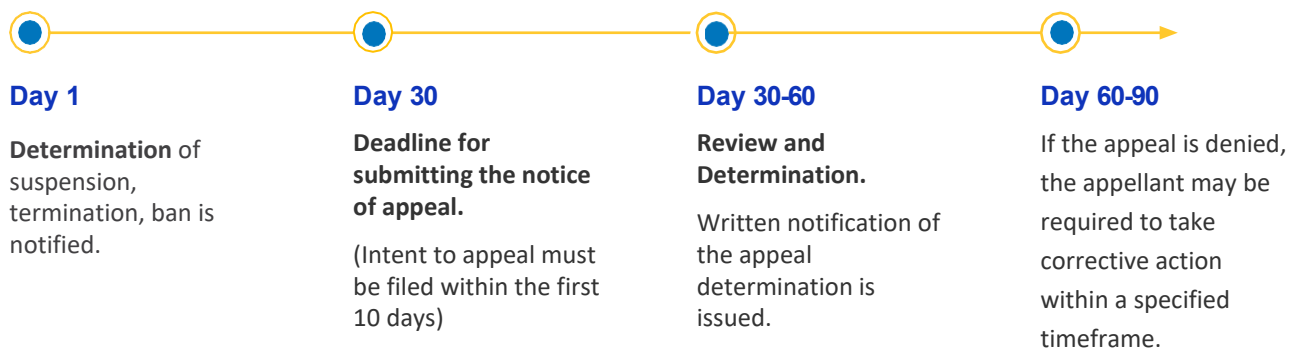
If the Certified Health IT product does not meet the applicable Certification Program requirements and a termination goes into effect, the health IT developer must notify all potentially affected customers of the identified non-conformities and termination of certification in a timely manner. Once a product’s certification is terminated, it cannot be updated and the product will no longer meet the requirements of any Medicare incentive programs requiring use of Certified Health IT. In an effort to reduce the negative impact of a termination on end users, ASTP/ONC would help identify mitigating strategies for providers using this product.

On the other hand, while a health IT product’s certification is suspended, that health IT product remains certified. Thus, the suspended health IT would still be available for use by providers participating in Medicare (or other) programs that require the use of Certified Health IT. However, while any Health IT Module’s certification is suspended, the developer must cease and desist from any marketing, licensing, or sale of the Health IT Module as “certified” under the ONC Health IT Certification Program until the suspension is canceled in accordance with 45 CFR 170.580(d)(6). Also, the certification of any other health IT by a health IT developer that has the certification of one of its products suspended is prohibited unless or until ASTP/ONC cancels the suspension (45 CFR 170.580(d)(5)).

Once a Certification Ban goes into effect, any Certified Health IT Module(s) of that developer for which certification had not been withdrawn or terminated would still be considered certified. This means that those products for which certification had not been terminated or withdrawn would still be available for use by providers participating in Medicare (or other) programs that require the use of Certified Health IT. However, while a health IT developer is subject to a ban, that developer cannot not make updates to the certification of those products still certified ([85 FR 25786](#)), and the certification of any other health IT by that developer is prohibited, unless or until the developer achieves reinstatement under 45 CFR 170.581(d).

## OPPORTUNITY TO APPEAL

Once the National Coordinator or an ONC-ACB has made enforcement determinations, developers will be notified and have an opportunity to appeal the decision. For terminations of certification by the National Coordinator, the developer may appeal before the termination becomes effective ([45 CFR 170.580\(f\)\(2\)\(ii\)](#)). A Certification Ban is effective immediately for any bans made as a result of a certificate termination or withdrawal from the Certification Program ([45 CFR 170.581\(c\)](#)). See the timeline below for when developers can appeal.



## Remediation and Reinstatement

A suspension can be ended at any time, if the National Coordinator determines ASTP/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](#)).

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. While termination decisions that take effect are permanent and cannot be reversed, developers do have the opportunity to request reinstatement following a Certification Ban if the circumstances that triggered the ban are remedied. To have a Certification Ban lifted, the following conditions must be met as outlined in [45 CFR 170.581\(d\)](#):

1. A health IT developer requests in writing permission to participate in the Certification Program;
2. The request demonstrates that the customers affected by the certificate termination, withdrawal, or non-compliance with a Condition or Maintenance of Certification requirement have been provided appropriate remediation;
3. For non-compliance with a Condition and Maintenance of Certification requirement, the non-compliance is resolved; and
4. The National Coordinator 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 do not involve correcting the certified version or providing a replacement certified version of their product. As determined by the National Coordinator, 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.

The National Coordinator makes the determination regarding the lifting of a Certification Ban in all circumstances. However, ASTP/ONC may engage in fact-finding and other communications with ONC-ACBs and a health IT developer's customers to inform the National Coordinator's determination as to whether the conditions for lifting the ban have been met.