Attestations Resource Guide

(Last updated: February 28, 2023)

How to Use This Resource Guide

This resource guide describes the Attestations requirements for health IT developers participating in the ONC Health IT Certification Program (Certification Program). This resource will assist health IT developers of certified health IT (hereinafter "Certified Health IT developers") to understand their responsibilities under the Attestations Condition and Maintenance of Certification requirements.

While every effort has been made to ensure the accuracy of restatements of 45 CFR Part 170, this resource is not a legal document. The official requirements are contained in the relevant laws and regulations.

ONC has incorporated a limited number of scenarios and use cases for illustrative purposes only. These scenarios are based on stakeholder feedback and inquiries received in ONC's Health IT Feedback and Inquiry Portal. The scenarios and other information presented in this guide may not be universally applicable to every Certified Health IT developer or their individual circumstances, nor is it intended to be. The information is meant to be illustrative in nature only.

AFTER REVIEWING THIS RESOURCE GUIDE, CERTIFIED HEALTH IT DEVELOPERS WILL KNOW:

- What are Attestations
- Who is required to submit Attestations
- Deadlines for Attestations
- How to submit Attestations
- Scenarios and use case examples for Attestations
- Where to find additional Attestations information

Table of Contents

What are Attestations?

The Conditions and Maintenance of Certification are initial and ongoing requirements that must be met or adhered to by Certified Health IT developers under the Certification Program.

Attestations are an indication of compliance, noncompliance, or inapplicability provided to the Secretary of Health and Human Services (HHS) as they apply to Certified Health IT developers for the following Conditions and Maintenance of Certification requirements:

- Information Blocking
- Assurances
- Communications
- Application Programming Interfaces (APIs)
- Real World Testing

Attestations hold Certified Health IT developers accountable on an ongoing basis and encourage continued compliance with the Conditions and Maintenance of Certification requirements. ONC can review potential or known instances where a Condition or Maintenance of Certification requirement under the Certification Program has not been met or is not being met by a Certified Health IT developer, in accordance with the corrective action process in 45 CFR 170.580. Specifically, if ONC has a reasonable belief that a Certified Health IT developer has not complied with a Condition or Maintenance of Certification requirement, then it may initiate Direct Review.

Who is Required to Submit Attestations?

Attestations are a Condition of Certification and include an ongoing Maintenance of Certification requirement in the Certification Program. As part of the Condition of Certification, a Certified Health IT developer, or its authorized representative, must provide an attestation of compliance with the specified Conditions and Maintenance of Certification requirements.

In order to maintain their certification(s), the ongoing Maintenance of Certification requires Certified Health IT developers that have or have had an active certification under the Certification Program at any time during the attestation period to provide on a semiannual cycle the attestations specified in 45 CFR 170.406(a).

Certified Health IT developers provide their attestation of compliance based on the Conditions and Maintenance of Certification that apply to them for all their active certification(s) during a specified attestation period.

Deadlines for Attestations

Certified Health IT developers submit their attestations of compliance for past actions under the Certification Program within a designated 30-day window every 6 months (i.e., semiannually).

Table 1: Deadlines for Attestation

Attestation Window Opens	Attestation Window Closes	Attestation Period
April 1	April 30	October 1 – March 31
October 1	October 31	April 1 – September 30

Note, the first attestation window that opened on April 1, 2022, covered an irregular attestation period due to the publication dates of the ONC Cures Act Final and Interim Final Rules. A regular 6-month attestation period commences with the attestation window opening on October 1, 2022, and continues every 6 months thereafter. Also, ONC will extend the October attestation window to allow developers to submit their attestations through October 31st.

Submitting Attestations

CERTIFIED HEALTH IT PRODUCT LIST ACCESS

During the attestation window, Certified Health IT developers submit their attestations to ONC-Authorized Certification Bodies (ONC-ACBs) for review using the Certified Health IT Product List (CHPL).

To register on the CHPL, Certified Health IT developers should contact their respective ONC-ACB to request initial access or to update existing accesses. Registered users can invite others within their developer organization to create a CHPL account as needed.

The CHPL Developer User Guide is available as a resource to registered users by logging into the CHPL and navigating to the "CHPL Resources" tab. The guide contains detailed information on accessing and completing the submission process.

AUTHORIZED SUBMITTERS

All attestations must be approved and submitted by an officer, employee, or other representative authorized by the Certified Health IT developer to make binding attestations on its behalf, as users are required to attest they are capable of binding the Certified Health IT developer to its attestations. If an individual with a developer organization has been identified to serve in that capacity, that person will need their own CHPL account to complete and submit the attestations.

ATTESTATIONS SUBMISSION LANGUAGE

Below is a copy of the official attestations submission language with accompanying explanation to help Certified Health IT developers understand the attestation process. Please note that this copy of the official attestations submission language with annotations is provided for informational and planning purposes. This should be read and understood in conjunction with the relevant companion resources included here as reference.

As a health IT developer of certified health IT that had an active certification under the ONC Health IT Certification Program at any time during the Attestation Period, please indicate your compliance, noncompliance, or the inapplicability of each Condition and Maintenance of Certification requirement for the portion of the Attestation Period you had an active certification.

Select only one response for each statement.

If "Noncompliant" is selected, you may, but are not required to, indicate the status of a Corrective Action Plan (CAP) under the Certification Program.

Note: Certified Health IT developers provide their attestation based on the Conditions and Maintenance of Certification that apply to them for all their active certification(s) during the specified attestation period. A requirement is either applicable to the Certified Health IT developer for one or more of its active certification(s), or it is not.

Certified Health IT developers must select "Noncompliant" for a Condition and Maintenance of Certification requirement if they were not compliant with the requirement at any point during the specified attestation period, regardless of the status of a corrective action plan (CAP) under the Certification Program. This is true even if the issue that resulted in the noncompliance has already been resolved by the time of attestation.

If "Noncompliant" is selected, a Certified Health IT developer may, but is not required to, indicate the status of one or more CAPs under the Certification Program. Also, they may be provided the opportunity to submit additional information as needed either during the ONC-ACB completeness review or during ONC's Direct Review process, should ONC choose to initiate Direct Review.

Certified Health IT developers who have completed or are undergoing corrective actions are unlikely to trigger ONC Direct Review for a noncompliance selection if it has already been fully addressed through corrective actions to regain Certification Program compliance.

Companion Resources:

Attestations Certification Companion Guide
Direct Review Fact Sheet

Information Blocking

We attest to compliance with the Information Blocking Condition of Certification requirement described in 45 CFR 170.401.

- ○ Compliant
- ○ Noncompliant

For a selection of "Noncompliant," please indicate the status of a Corrective Action Plan (CAP) under the Certification Program. **(optional – check all that apply)**

- ☐ Not under a CAP
- ☐ Under an open CAP
- ☐ Completed a CAP during the specified Attestation Period

Note: The Information Blocking Condition of Certification requirement applies to all Certified Health IT developers.

Companion Resources:

Information Blocking Certification Companion Guide

Information Blocking Fact Sheet

Assurances

We attest to compliance with the Assurances Condition and Maintenance of Certification requirements described in 45 CFR 170.402.

- ○ Compliant with the requirements of 45 CFR 170.402; 45 CFR 170.402(a)(4) is applicable because we are a developer of a Certified Health IT Module that is part of a health IT product which electronically stores EHI and therefore must certify to the certification criterion in § 170.315(b)(10).
- ○ Compliant with the requirements of 45 CFR 170.402; 45 CFR 170.402(a)(4) is not applicable because we are not a developer of a Certified Health IT Module that is part of a health IT product which electronically stores EHI.
- ○ Noncompliant

For a selection of "Noncompliant," please indicate the status of a Corrective Action Plan (CAP) under the Certification Program. (**optional – check all that apply**)

- ☐ Not under a CAP
- ☐ Under an open CAP
- ☐ Completed a CAP during the specified Attestation Period

Note: The Assurances Condition and Maintenance of Certification requirements apply to <u>all</u> Certified Health IT developers. However, there are two compliance options to distinguish whether the condition of 45 CFR 170.402(a)(4) was also applicable. If during the Attestation period the developer had at least one Certified Health IT Module that was part of a health IT product which electronically stores EHI, then certification to the § 170.315(b)(10) Electronic Health Information (EHI) Export criterion would also be applicable, and the developer should select the first option indicating that the condition of 45 CFR 170.402(a)(4) was applicable.

If the condition of 45 CFR 170.402(a)(4) was applicable, a Certified Health IT developer should attest to compliance even if they had not yet certified to the certification criterion in § 170.315(b)(10) because the permissible certification and deadline for compliance by December 31, 2023, has not yet expired.

If the developer did not have at least one Certified Health IT Module that was part of a health IT product which electronically stores EHI, then the developer should select the second option indicating that the condition of 45 CFR 170.402(a)(4) was <u>not</u> applicable.

Companion Resources:

Assurances Certification Companion Guide

§170.315(b)(10) Electronic Health Information export

Communications

We attest to compliance with the Communications Condition and Maintenance of Certification requirements described in 45 CFR 170.403.

- ○ Compliant
- ○ Noncompliant

For a selection of "Noncompliant," please indicate the status of a Corrective Action Plan (CAP) under the Certification Program. **(optional – check all that apply)**

- ☐ Not under a CAP
- ☐ Under an open CAP
- ☐ Completed a CAP during the specified Attestation Period

Note: The Communications Condition and Maintenance of Certification requirements apply to <u>all</u> Certified Health IT developers.

Companion Resources:

Communications Certification Companion Guide

Application Programming Interfaces

We attest to compliance with the Application Programming Interfaces (APIs) Condition and Maintenance of Certification requirements described in 45 CFR 170.404.

- ○ Compliant
- ○ Noncompliant
- ○ Not Applicable

For a selection of "Noncompliant," please indicate the status of a Corrective Action Plan (CAP) under the Certification Program. **(optional – check all that apply)**

- ☐ Not under a CAP
- ☐ Under an open CAP
- ☐ Completed a CAP during the specified Attestation Period

Note: The Application Programming Interfaces (APIs) Condition and Maintenance of Certification requirements apply to Certified Health IT developers certified to any of the certification criteria adopted in § 170.315(g)(7) through (g)(10).

The ONC Cures Act Final Rule requires updates to many of the certification criteria adopted in § 170.315(g)(7) through (g)(10). Assuming they are compliant with the other applicable API Condition and Maintenance of Certification requirements, a developer with health IT modules certified to any of these certification criteria should attest to compliance even if they have not yet met the Cures Update requirements for these criteria because the deadline for compliance by December 31, 2022, has not yet expired.

Companion Resources:

API Certification Companion Guide

API Resource Guide

Real World Testing

We attest to compliance with the Real World Testing Condition and Maintenance of Certification requirements described in 45 CFR 170.405.

- ○ Compliant
- ○ Noncompliant
- ○ Not Applicable

For a selection of "Noncompliant," please indicate the status of a Corrective Action Plan (CAP) under the Certification Program. **(optional – check all that apply)**

- ☐ Not under a CAP
- ☐ Under an open CAP
- ☐ Completed a CAP during the specified Attestation Period

> **Note:** The Real World Testing Condition and Maintenance of Certification requirements apply to Certified Health IT developers certified to any of the certification criteria outlined in § 170.405(a).
>
> **Companion Resources:**
> Real World Testing Certification Companion Guide
> Real World Testing Fact Sheet

SUBMISSION CONFIRMATION

Attestations are submitted to ONC-ACBs for completeness review and subsequent submission to ONC. If accepted for submission to ONC, the "Attestations" status on the Certified Health IT developer's CHPL page will update to publicly indicate "Attestations submitted" for the relevant attestation period. Please note the contents of individual developer attestation submissions are not publicly available on the CHPL, only an indication that the attestation has been submitted.

Once a submission is accepted, a Certified Health IT developer has met the requirements of the Attestations Condition and Maintenance of Certification. If there are issues with an attestation submission that prevent its acceptance, either the ONC-ACB or ONC will contact the developer to resolve the situation.

NONCOMPLIANT ATTESTATIONS

An attestation of noncompliance does not prevent a submission from being accepted. As a reminder, the attestations are required by law and are solely an indication of compliance, noncompliance, or inapplicability to the Conditions and Maintenance of Certification for a specified period.

Certified Health IT developers must select "Noncompliant" for a Condition and Maintenance of Certification requirement if they were not compliant with the requirement at any point during the specified attestation period, regardless of the status of a corrective action plan (CAP) under the Certification Program. This is true even if the issue that resulted in the noncompliance has already been resolved by the time of attestation. However, if "Noncompliant" is selected, they may, but are not required to, indicate the status of one or more CAPs under the Certification Program.

Furthermore, if a Certified Health IT developer submits an attestation of noncompliance to a Condition and Maintenance of Certification requirement, they may submit additional information as needed either during the ONC-ACB completeness review or during ONC's Direct Review process, should ONC choose to initiate Direct Review.

ONC's goal is always to work with Certified Health IT developers to remedy any noncompliance through corrective action in a timely manner. Certified Health IT developers who have completed or are undergoing corrective actions are unlikely to trigger Direct Review for a noncompliance if it has already been fully addressed through corrective actions to regain Certification Program compliance.

Certified Health IT developers should direct any inquiries regarding their submitted attestations to their respective ONC-ACB.

Attestations Scenarios and Use Case Examples

Please note that these scenarios are for illustrative purposes only. The information presented here is intended to provide stakeholders with examples only and may not be universally applicable to every Certified Health IT developer or their individual circumstances, nor is it intended to be.

All scenarios assume any Certified Health IT Modules were active at some point during a specified attestation period, unless otherwise noted.

ATTESTATIONS: SCENARIO 1 – APPLICABILITY OF REQUIREMENT

Scenario 1, Use Case 1: Multiple Certified Health IT Modules
Overview: You are a Certified Health IT developer with three active Certified Health IT Modules. Only Health IT Module #1 was certified to any of the API certification criteria adopted in § 170.315(g)(7) through (g)(10). Health IT Modules #2 and #3 were not. Is the API Condition and Maintenance of Certification applicable to you?

Outcome: Yes. You are required to attest to either compliance or noncompliance because you have at least one active certification that was applicable for the APIs Condition and Maintenance of Certification. Certified Health IT developers provide their attestation based on the Conditions and Maintenance of Certification that apply to them for all their active certification(s) during a specified attestation period. A requirement is either applicable to the Certified Health IT developer for one or more of its active certification(s), or it is not.

Scenario 1, Use Case 2: Compliance Deadline
Overview: You are a Certified Health IT developer with an active Certified Health IT Module that is part of a health IT product which electronically stores electronic health information (EHI) and therefore must certify to the § 170.315(b)(10) EHI Export criterion. You were compliant with all the other applicable Assurances requirements but had not yet certified to the (b)(10) criterion because the compliance deadline is not until December 31, 2023. Is the Assurances Condition and Maintenance of Certification applicable to you?

Outcome: Yes. You should attest to compliance with the Assurances Condition and Maintenance of Certification. Note there are two compliance options to distinguish whether the condition of 45 CFR 170.402(a)(4) requiring certification to the § 170.315(b)(10) Electronic Health Information (EHI) Export criterion was also applicable because at least one Certified Health IT Module was part of a health IT product which electronically stores EHI.

If the condition of 45 CFR 170.402(a)(4) was applicable, a Certified Health IT developer should attest to compliance even if they had not yet certified to the certification criterion in § 170.315(b)(10) because the permissible certification and deadline for compliance by December 31, 2023, has not yet expired.

For any applicable Condition or Maintenance of Certification requirement with a specified compliance deadline, a Certified Health IT developer should attest to compliance even if they have not yet met the requirement providing the deadline for compliance has not yet expired, and they are also compliant with all other applicable requirements.

ATTESTATIONS: SCENARIO 2 – NONCOMPLIANT ATTESTATION

Scenario 2, Use Case 1: Nondisclosure of a Known Issue
Overview: You are a Certified Health IT developer with an active Certified Health Module certified to at least one of the API criteria adopted in § 170.315(g)(7) through (10) requiring you to publish complete business and technical documentation via a publicly accessible hyperlink to meet the API condition at 45 CFR 170.404(a)(2)(i). You became aware the hyperlink was broken and did not fix it, making the documentation no longer publicly accessible. You also did not disclose the issue to your ONC-Authorized Certification Body (ONC-ACB). Should you attest "Noncompliant" to the APIs Condition and Maintenance of Certification?

Outcome: Yes, you should attest "Noncompliant" to the APIs Condition and Maintenance of Certification. Certified Health IT developers must select "Noncompliant" for a Condition and Maintenance of Certification requirement if they were not compliant with the requirement at any point during the specified attestation period, regardless of whether it was a disclosed instance of non-compliance in the Certification Program. This is true even if the broken hyperlink that resulted in the noncompliance has already been fixed by the time of your attestation.

You may submit additional information as needed either during the ONC-ACB completeness review or during ONC's Direct Review process, should ONC choose to initiate Direct Review.

ONC's goal is always to work with Certified Health IT developers to remedy any noncompliance through corrective action in a timely manner. Certified Health IT developers who have completed or are undergoing corrective actions are unlikely to trigger Direct Review for a noncompliance if it has already been fully addressed through corrective actions to regain Certification Program compliance.

Scenario 2, Use Case 2: Resolution of a Known Issue Prior to Disclosure
Overview: You are a Certified Health IT developer that discovered an issue with an active Certified Health IT Module and its certified capability with the §170.315(e)(3). Patient Health Information Capture criterion. You fixed the issue prior to informing your ONC-Authorized Certification Body (ONC-ACB). When the ONC-ACB conducted surveillance, there was a finding of no non-conformity because the issue had already been resolved, so no corrective action plan (CAP) was issued. Should you attest "Noncompliant" to the Assurances Condition and Maintenance of Certification?

Outcome: Yes, you should attest "Noncompliant" to the Assurances Condition and Maintenance of Certification as you did not meet the requirement at 45 CFR 170.402(a)(2) regarding conformance to the full scope of the certification criteria. A noncompliance to a Condition or Maintenance of Certification

requirement is not limited to a finding of a surveillance non-conformity in the Certification Program that resulted in a corrective action plan (CAP). A Certified Health IT developer must select "Noncompliant" if they were not compliant with a requirement at any point during the specified attestation period, regardless of whether or not the noncompliance was part of a CAP or a surveillance activity. You may submit additional information as needed either during the ONC-ACB completeness review or during ONC's Direct Review process, should ONC choose to initiate Direct Review.

As part of their process, ONC-ACBs also review their compliance records to verify a Certified Health IT developer has attested within the scope of their certification, which includes any known instances on their end where a Condition or Maintenance of Certification requirement under the Certification Program was not met—even if the compliance activity resulted in no CAP being issued because the potential non-conformity had already been resolved by the time it was disclosed.

Scenario 2, Use Case 3: Resolution of a Corrective Action Plan (CAP)
Overview: You are a Certified Health IT developer with at least one active Certified Health IT Module certified to any of the certification criteria requiring a Real World Testing Plan to meet the Real World Testing maintenance at 45 CFR 170.405(b)(1). You missed submitting your Real World Testing Plan by the date determined by your ONC-Authorized Certification Body (ONC-ACB). The ONC-ACB opened a surveillance activity with a finding of a non-conformity and issued a corrective action plan (CAP). You submitted your plan according to the terms of the CAP, and the CAP is considered completed. Should you attest "Noncompliant" to the Real World Testing Condition and Maintenance of Certification?

Outcome: Yes, you should attest "Noncompliant" to the Real World Testing Condition and Maintenance of Certification. Certified Health IT developers must select "Noncompliant" for a Condition and Maintenance of Certification requirement if they were not compliant with the requirement at any point during the specified attestation period, and regardless of the status of a corrective action plan (CAP) under the Certification Program.

Please note ONC's goal is always to work with Certified Health IT developers to remedy any noncompliance through corrective action in a timely manner. Certified Health IT developers who have completed or are undergoing corrective actions are unlikely to trigger Direct Review for a noncompliance if it has already been fully addressed through corrective actions to regain Certification Program compliance.

Additional Resources

ONC 21st Century Cures Act Final Rule Overview
https://www.healthit.gov/curesrule/

ONC 21st Century Cures Act Final Rule (Federal Register)
Federal Register page

ONC Certification Program Resources
https://www.healthit.gov/topic/certification-ehrs/certification-resources

Conditions and Maintenance of Certification
https://www.healthit.gov/topic/certification-ehrs/conditions-maintenance-certification

Certified Health IT Product List (CHPL)
https://chpl.healthit.gov/#/resources/overview

2015 Edition Cures Update Certification Criteria
https://www.healthit.gov/topic/certification-ehrs/2015-edition-cures-update-test-method