# Attestations What It Means for Health IT Developers

A Practical Overview of the Attestations Condition and Maintenance of Certification Requirements

This fact sheet 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 <u>45 CFR Part 170</u>, this resource is not a legal document. The official requirements are contained in the relevant laws and regulations.

# After reviewing this fact sheet, developers will know:

April 2022

- What are Attestations
- Who is required to submit Attestations
- Deadlines for Attestations
- How to submit Attestations
- Where to find additional Attestations information

This document touches on aspects of the ONC-Authorized Certification Body (ONC-ACB) role. However, the primary purpose is to **assist Certified Health IT Developers in understanding what is required to meet the Attestations Condition and Maintenance of Certification requirements.** 

## 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
- Application Programming Interfaces (APIs)
- Assurances
- 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 <u>45 CFR 170.580</u>. 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 <u>Direct Review</u>.



Communications

## 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 <u>45 CFR 170.406(a)</u>.

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).

Note, the first attestation window opening on April 1, 2022, covers an irregular attestation period due to the publication dates of the ONC Cures Act Final and Interim Final Rules.

Attestation Window Opens	Attestation Window Closes	Attestation Period
April 1, 2022	April 30, 2022	June 30, 2020 – March 31, 2022
October 1, 2022	October 30, 2022	April 1, 2022 – September 30, 2022

A regular 6-month attestation period commences with the attestation window opening on October 1, 2022, and continues every 6 months thereafter.

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

## **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 <u>Certified Health IT Product List (CHPL)</u>.

To register on the CHPL, Certified Health IT Developers should contact their respective ONC-ACB to request access. 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. As of the first attestation window, the guide will contain 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 the Certified Health IT Developer has authorized to make binding attestations on its behalf.

The registered CHPL user submitting the attestations of compliance should be authorized to do so, as users are required to attest they are capable of binding the Certified Health IT Developer to their 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.



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## Attestations Submission Language

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.



#### **Attestation Period:** [Dates of Attestation Period]

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.

**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 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.

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.

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

#### 1) Information Blocking

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

- Compliant
- Noncompliant

**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** 



HealthIT.gov/condition-ccg/attestations

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#### 2) Assurances

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

- Compliant with the requirements of 45 CFR 170.402; certifies to the criterion at 45 CFR 170.315(b)(10) and provides all of its customers of certified health IT with health IT certified to the certification criterion in 45 CFR 170.315(b)(10).
- Compliant with the requirements of 45 CFR 170.402; does not certify to the criterion at 45 CFR 170.315(b)(10) or does not provide all of its customers of certified health IT with health IT certified to the certification criterion in 45 CFR 170.315(b)(10).
- Noncompliant

**Note:** The Assurances Condition and Maintenance of Certification requirements apply to all Certified Health IT Developers. There are two compliance options to distinguish between Certified Health IT Developers that meet the condition of § 170.402(a)(4) and must also meet the maintenance requirements of § 170.402(b)(2), and those Certified Health IT Developers who do not.

If the condition of § 170.402(a)(4) and the maintenance requirements of § 170.402(b)(2) are applicable, a Certified Health IT Developer can attest to compliance even if they have not yet certified to the certification criterion at 45 CFR 170.315(b)(10) because the permissible certification and deadline for compliance has not yet expired.

#### Companion Resource

Assurances Certification Companion Guide

#### 3) Communications

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

- Compliant
- Noncompliant

**Note:** The Communications Condition and Maintenance of Certification requirements apply to all Certified Health IT Developers.

#### **Companion Resource** Communications Certification Companion Guide

#### 4) Application Programming Interfaces

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

- Compliant
- Noncompliant
- Not Applicable

**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).

#### **Companion Resources**

<u>API Certification Companion Guide</u> <u>API Resource Guide</u>



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## Attestations What It Means for Health IT Developers

#### 5) Real World Testing

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

- Compliant
- Noncompliant
- Not Applicable

**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 the submission are not publicly available on the CHPL.

If a Certified Health IT Developer submits an attestation of noncompliance to a Condition and Maintenance of Certification requirement, 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.

ONC's goal is 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.

## **Additional Resources**

**ONC 21st Century Cures Act Final Rule** 

ONC 21st Century Cures Act Final Rule Resources

**ONC Certification Program Resources** 

**Conditions and Maintenance of Certification** 

Certified Health IT Product List (CHPL)

2015 Edition Cures Update Certification Criteria

