

ONC Health IT Certification Program Overview

Introduction

The Office of the National Coordinator for Health Information Technology (ONC) operates the [ONC Health IT Certification Program \(Program\)](#) under the authority granted by section 3001(c)(5) of the Public Health Service Act (PHSA) and as defined in the Health Information Technology for Economic and Clinical Health (HITECH) Act. The voluntary Program is a third-party conformity assessment program for health information technology (health IT) based on the principles within the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) framework. ONC does not directly perform conformance testing or issue certifications itself. Rather, ONC collaborates with other organizations that it evaluates and authorizes to perform these functions on its behalf. The Program defines the requirements for health IT and the process by which health IT may become evaluated, tested (if required), certified, and maintain its certification.

Launched in 2010, the Program supports the [Promoting Interoperability Programs](#) (previously Medicare and Medicaid EHR Incentive Programs) administered by the Centers for Medicare & Medicaid Services (CMS). While the Promoting Interoperability Programs continue to require the use of certified health IT, the use of certified health IT has expanded to other [government and non-government programs](#). The Program has released multiple editions of certification criteria and regulations for new/expanded Program requirements.

The ONC Health IT Certification Program: Enhanced Oversight and Accountability Final Rule (Enhanced Oversight and Accountability Final Rule) ([81 FR 72404](#)) permits the Program to provide enhanced oversight for safety and health IT developer accountability. Specifically, the final rule stands up a focused ONC direct review regulatory framework, aligns the testing lab oversight with the existing processes for ONC Authorized Certification Body(ies) (ONC-ACBs), and makes a more comprehensive set of ONC-ACB surveillance results publicly available. The rule emphasizes the importance of protecting public health and safety while also strengthening transparency and accountability in the Program. It also enables the Program to better support providers and hospitals – the vast majority of whom use health IT.

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](#)) made several changes to the existing 2015 Edition Health IT Certification Criteria and adopted new Program requirements from the 21st Century Cures Act. The Final Rule introduced a small number of new certification criteria, revised several existing certification criteria, and removed several certification criteria. These changes constitute the “2015 Edition Cures Update.” The Program's Conditions and Maintenance of Certification requirements express initial requirements for health IT developers and their certified Health IT Module(s) as well as ongoing requirements that must be met by both health IT developers and their certified Health IT Module(s) under the Program.



Program Participants

ONC works with the following agencies and entities as part of Program operations:

National Institute of Standards and Technology (NIST): Per the HITECH Act, NIST, a federal agency within the Department of Commerce, and ONC collaborated to establish the voluntary certification program and continue to work together to develop the necessary functional and conformance testing requirements, test cases, and test tools in support of the Program.

National Voluntary Laboratory Accreditation Program (NVLAP): Administered by NIST, , accredits testing laboratories as a requirement for ONC-authorization to perform testing under the Program

ONC-Authorized Testing Laboratory (ONC-ATL): A NVLAP-accredited testing laboratory that has been authorized by ONC to perform health IT testing to determine conformance with ONC’s standards and certification criteria according to the [ONC-approved test method](#). Successfully tested products can be submitted to an ONC-ACB for certification.

Accreditation Body: Accredits certification bodies as a requirement for ONC-authorization to perform certification activities under the Program. Certification Bodies may choose any Accreditation Body, with an appropriate scope, that is a signatory of the Multilateral Recognition Arrangement (MLA) with the International Accreditation Forum (IAF) to become accredited.

ONC Authorized Certification Body (ONC-ACB): Certify health IT based on test results supplied by ONC-ATLs; post results on the [Certified Health IT Product List \(CHPL\)](#); and are responsible for conducting surveillance of certified health IT.

Health IT Developer: Presents health IT to ONC-ATL to be tested. Once the health IT developer’s product is determined to satisfy all applicable certification criteria, the developer then contacts an ONC-ACB to have their product certified.

Policy Making, Certification Criteria, and Standards Adoption

ONC manages the rulemaking process for the development and issuance of policy and regulations for the Program. Through the rulemaking process, ONC establishes the Program requirements, capabilities, standards, and interoperability requirements for certified health IT. This process includes review and input from within the federal government, as well as public and private stakeholders.

The most common rulemaking process begins with ONC issuing a notice of proposed rulemaking (NPRM) and requesting public comments on the NPRM, which is followed by a review of the comments. ONC then drafts the final rule with consideration of public comment and issues a final rule on behalf of the Department of Health and Human Services (HHS) Secretary. Through this rulemaking process, ONC establishes Program requirements as well as requirements for health IT developers and health IT, the latter which are referred to as “certification criteria.” Based on these certification criteria, ONC develops a test method (to include test procedures and test tools (including associated test data)) that is approved by the National Coordinator for Health Information Technology (National Coordinator). Draft test methods are available for





public feedback simultaneously with the NPRM. Only test procedures, test tools, and conformance methods approved by the National Coordinator may be used to test and evaluate health IT under the Program for the purposes of certification. Test procedures and test tools developed outside ONC may be submitted to the National Coordinator, as outlined in [75 FR 36168](#), for [review and approval](#).

Standards Version Advancement Process

The Standards Version Advancement Process (SVAP) provides health IT developers the option to use more advanced version(s) of the adopted standard(s) or implementation specification(s) included in the criteria the product is certifying to or is certified to, provided such versions are approved by the National Coordinator for use in health IT certified under the Program. All health IT developers voluntarily opting to avail themselves of the SVAP flexibility must ensure that their annual real world testing plans and real world testing results submissions address all the versions of all the standards and implementation specifications to which each Health IT Module is certified.

In addition to the SVAP, the Program address situations when a voluntary consensus standards organization issues a correction to a standard or implementation specification included in the Program. In the event that the adopted version of the standard or implementation specification is corrected by a voluntary consensus standards organization (or steward) after it has been adopted by ONC in a final rule, ONC follows a specific approach to determine whether, even if not yet formally adopted by the Secretary, the correction(s) should be incorporated into the testing, certification, and surveillance of health information technology (health IT) to the adopted standard or implementation specification.

In general, we review corrections to the length, data type, data type descriptions, usage, cardinality and/or value sets for various message elements, as well as corrections to conformance statements where they were mistakenly omitted or not clearly specified by the author of the standard or implementation specification. Each of these examples of corrections, if not implemented by the health IT industry, could lead to interoperability errors as well as the inconsistent implementation of the standard or implementation specification, which may impede electronic health information exchange.

If ONC determines that a correction(s) creates the concern described above, we will update the appropriate Certification Companion Guide(s) (CCG) to incorporate the correction and provide an interpretative explanation. These CCG notations will include a 90-day delayed effective date for the use of the correction(s) in testing and certification. We expect already certified health IT to include any such identified correction(s) without the need for further testing and certification under the Program. For the purposes of surveillance, there will be an 18-month delayed effective date from the CCG notations before a finding of an identified correction's absence during surveillance would constitute a non-conformity under the Program.





Operations

Program Structure

The Program's operational structure is informed by [ISO/IEC 17067](#) and operated within the ISO framework and concepts for third-party conformity assessment programs. The requirements defined in the adopted regulations are built on these concepts and are implemented as described in this section.

ONC has collaborated with NVLAP to develop and maintain the Healthcare Information Technology Testing Laboratory Accreditation Program. NVLAP, in accordance with [ISO/IEC 17025](#), [Handbook 150](#) and [150-31](#), and other requirement documents, accredits and oversees testing laboratories that perform functional and conformance testing. Once NVLAP accredits a testing laboratory, the testing laboratory must submit to ONC an application to become an ONC-ATL to begin testing health IT in the Program. ONC specifies the processes and requirements for retaining, suspending, or revoking ONC-ATL status under the Program. ONC-ATLs operate under a three-year authorization cycle and must remain in good standing by adhering to the [Principles of Proper Conduct](#) and requirements under [subpart E of Part 170](#).

For certification of health IT under the Program, similar to testing laboratory requirements, certification bodies must provide documentation, with an appropriate scope, that confirms that the applicant has been accredited to ISO/IEC 17065 by any accreditation body that is a signatory to the Multilateral Recognition Arrangement (MLA) with the International Accreditation Forum (IAF). The certification body provides this documentation when it submits an application to ONC to become an ONC-ACB to begin certifying health IT under the Program. ONC-ACBs operate under a three-year authorization cycle and must remain in good standing by adhering to the [Principles of Proper Conduct](#) and other requirements under [subpart E of Part 170](#). To renew its status, an ONC-ACB is required to submit a renewal request, which contains any updates to the information requested in the initial application to the National Coordinator, 60 days prior to the expiration of its status.

Surveillance of Certified Health IT

Health IT certified under the Program is subject to surveillance activities carried out by ONC-ACBs. Surveillance of certified health IT ensures the continued conformance of the functionalities and standards specifications required by certification. Surveillance is also a requirement set forth in ISO/IEC 17065 and must be performed by ONC-ACBs to maintain their accreditation and ONC authorization. The purpose of surveillance is to ensure that certified health IT capabilities meet certification requirements, not just in a controlled testing environment, but also when they are used in a clinician's office or a hospital. [Surveillance activities](#) can include randomized and reactive complaint-based surveillance.

When an ONC-ACB determines that a health IT module does not comply with certification requirements, the health IT module is considered non-conformant. Developers must work with their ONC-ACB on an appropriate corrective action plan (CAP) to correct the identified deficiency(ies) that led to the finding(s) of non-conformity and bring the certified health IT module(s) back into compliance. All CAPs must include certain required elements per [45 CFR § 170.556\(d\)\(3\)](#), including:

- A description of the non-conformities or deficiencies;
- How widespread the problem may be across the developer's other customers and users;





- How the developer will address the problem for all potentially affected customers and users;
- How the developer will ensure that all potentially affected customers and users are alerted and that their issues are resolved;
- The timeframe in which all corrective action will be completed; and
- An attestation by the developer that it has completed all elements of the approved CAP.

Under ONC's 2015 Edition Final Rule ([80 FR 62601](#)), ONC posts an initial finding of a non-conformity and updated aspects of CAPs on the CHPL **weekly**—including the date and a description of how the non-conformity was resolved. If the developer does not resolve the non-conformity(ies) and fulfill the terms of the CAP, an ONC-ACB will follow its procedures to suspend and withdraw the certification, which may include a [Certification Ban](#). Note that not all certified health IT modules have been surveilled. Thus, it is important for all stakeholders to **immediately report any potential issues that may warrant surveillance to an ONC-ACB or to ONC's [Health IT Feedback Form](#) and to check the CHPL regularly for the latest information**. Users of certified health IT should be familiar with the ONC [recommended process](#) for filing complaints concerning certified health IT.

To provide more complete information that illuminates whether certified health IT has been surveilled and continues to conform with Program requirements, ONC-ACBs are required to make “identifiable surveillance results” (those NOT resulting in a non-conformity) publicly available on the CHPL on a quarterly basis. This will further enhance transparency and provide customers and users of certified health IT with valuable information about the overall conformity of certified health IT to Program requirements.

ONC Direct Review of Certified Health IT

The Enhanced Oversight and Accountability Final Rule ([81 FR 72404](#)) articulates a regulatory framework for ONC to [directly review certified health IT](#) if there is a reasonable belief that: (1) the certified health IT may present a serious risk to public health or safety; or (2) a review of certified health IT could present practical challenges for ONC-ACBs, such as when a suspected non-conformity presents issues that may require access to certain confidential or other information that is unavailable to an ONC-ACB; may require concurrent or overlapping reviews by multiple ONC-ACBs; or may exceed the scope of an ONC-ACB's resources or expertise. This review will be complementary to surveillance conducted by ONC-ACBs and will promote health IT developer accountability for the performance, reliability, and safety of health IT.

Certification Ban

A developer of certified health IT may be prohibited from certification of health IT when one or more of the developer's certified health IT modules is:

- 1) Terminated by ONC under the Program;
- 2) Withdrawn by an ONC-ACB because the health IT developer requested it to be withdrawn when the health IT developer's health IT was the subject of a potential non-conformity or non-conformity as determined by ONC;
- 3) 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 (i.e., Certification Criteria for Health Information Technology); or





- 4) Withdrawn by an ONC-ACB because the health IT developer requested it to be withdrawn 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 part 170, including notice of pending surveillance.

A list of current banned developers is available on the [CHPL](#). A health IT developer may request in writing to have a certification ban lifted. In order to do this, the developer will need to demonstrate that appropriate remediation has occurred. Further details can be found under our [Certification Ban Program Guidance](#).

Certified Health IT Product List

The CHPL provides an authoritative, comprehensive listing of health IT modules that have been tested and certified through the Program. The CHPL is updated, at minimum, once per week.

Each certified Health IT Module on the CHPL has a "CHPL Product Number" assigned to it by the ONC-ACB that certified the product. The CHPL also generates the CMS EHR Certification Identification Number that represents a Health IT Module or combination of Health IT Modules, which are used for reporting to the Promoting Interoperability Programs. [Step-by-step instructions](#) for navigating CHPL and obtaining a CMS EHR Certification ID are available on the [CHPL website](#).

Real World Testing

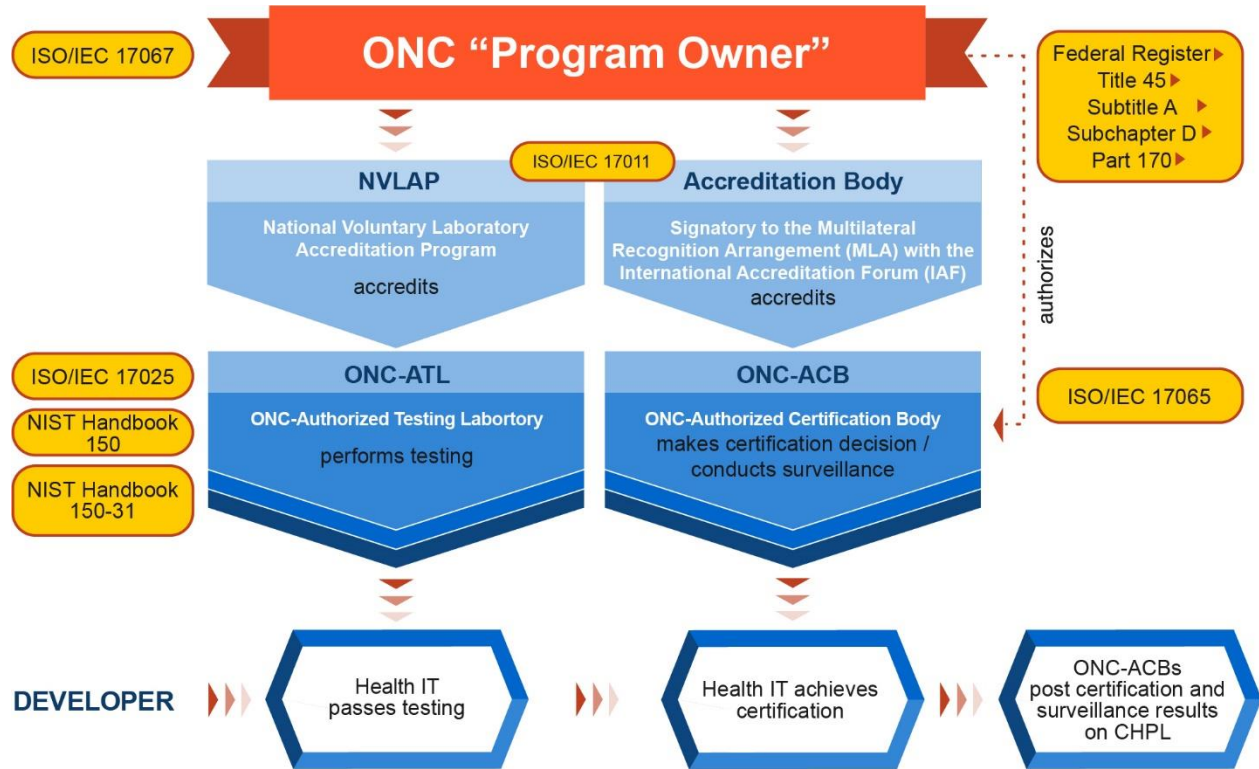
As a Condition and Maintenance of Certification requirement, health IT developers must successfully test the real world use of health IT for interoperability in the type(s) of setting(s) in which such technology would be marketed. To meet the requirements, health IT developers must submit publicly available annual real world testing plans, as well as annual real world testing results for health IT certified to certain criteria. All health IT developers voluntarily opting to use the SVAP flexibility must ensure that their annual real world testing plans and real world testing results submissions address all the versions of all the standards and implementation specifications to which each Health IT Module is certified.

ONC-ACBs must review and confirm that each health IT developer with one or more Health IT Module(s) certified to any of the required criteria submits real world testing plans and real world results on a timeframe that allows for the ONC-ACB to confirm completeness of all plans and results by the applicable annual due dates.





Program Structure



The labels alongside each entity are the ISO/IEC specifications to which that entity must be accredited. The Federal Register reference is the adopted regulation to which ONC operates the Program. Operation of the Program incorporates concepts within ISO/IEC 17067.

