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About this guide
The purpose of this document is to successfully guide you through the process of working with ICSA Labs in certifying your healthcare IT solution for the ONC Health IT Certification Program. We enter this process as a partnership with our customers and strive to provide as much information as possible to make that partnership a success. This most recent version includes updates from the 2015 Edition Final Rule that impacts both 2014 and 2015 Edition Certified Health IT.

Look for the following icon which designates important changes and updates to the program based on the latest regulations.
ICSA Labs
ONC Health IT Certification Program Certification Manual

Background

About ICSA Labs
ICSA Labs is an ONC-Authorized Certification Body (ONC-ACB) under the Health IT Certification Program put into effect by the Office of the National Coordinator for Health Information Technology (ONC). Our scope of accreditation extends to certifying complete and modular health IT products that have been approved by the National Coordinator and are effective for use in the ONC Health IT Certification Program. The ONC of the U.S. Department of Health & Human Services issued this program through the Federal Register 45 CFR 170 Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology. See the ONC’s website at https://www.healthit.gov/topic/certification-ehrs/certification-health-it for more information.

ICSA Labs has proven itself to ONC to be a worthy Certification Body by demonstrating subject matter expertise and operating a Quality Management System within the constructs of ISO/IEC 17065. In addition, ICSA Labs is one of a select few entities that has achieved accreditation as an ONC Authorized Health IT Testing Laboratory by NVLAP (Lab Code 200697-0). This distinction allows ICSA Labs to test health IT modules to work as expected, and will include the capabilities needed to use the technology in a meaningful way to comply with federal requirements.

ICSA Labs is authorized by the ONC to test and certify both complete and modular health IT to the effective 2014 Edition, 2014 Edition Release 2, and 2015 Edition criteria published by the ONC.

ICSA Labs obtains financial support solely from the fees it charges for the testing and certification services it provides to developers and vendors who seek approval of their products in accordance with published ONC criteria.

About the ONC Health IT Certification Program
EHR certification provides assurance and confidence to healthcare providers that a product has been tested to work as expected, and will include the capabilities they need to use the technology in a meaningful way to improve the quality of care provided to their patients.

In the ONC Health IT Certification Program, certification and testing activities are performed by separate entities. Certification is completed by the ONC-Authorized Certification Body and testing is performed by the ONC-Authorized and NVLAP Accredited Testing Laboratory (ONC-ATL). Developers and vendors first test their product with the ATL, and if their product meets the baseline requirements, those results are submitted to the ONC-ACB for certification. Once the product is certified, the information is submitted to ONC for inclusion on the Certified Health IT Product List (CHPL).

• For more information about the federal testing and certification program, please visit https://www.healthit.gov/topic/certification-ehrs/certification-health-it.

Previously, ONC included policy that supported the EHR Incentive Programs in its previous Editions that:
• Defined the Certified EHR Technology (CEHRT) definition on behalf of CMS
• Required “meaningful use measurement” criteria
• Specified the minimum number of clinical quality measures developers must certify to in order to participate in the EHR Incentive Programs
• Specified criteria as “ambulatory” or “inpatient”
Per ONC, 2015 Edition and future editions no longer includes policy to support the EHR Incentive Programs.

- Each program sets its own requirements (e.g., CMS defines the CEHRT definition in its final rule)
- The ONC Health IT Certification Program is “agnostic” to settings and programs, but can support many different use cases and needs
- This allows the ONC Health IT Certification Program to support multiple program and setting needs, for example:
  - EHR Incentive Programs
  - Long-term and post-acute care
  - Chronic care management
  - Behavioral health
  - Other public and private programs

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Doing Business with ICSA Labs

Pre-Application

Information related to the ICSA Labs ONC Health IT certification program can be obtained by contacting ICSA Labs with general request for information including specific customer and product information and the type of certification requested. When an inquiry is received, ICSA Labs will initiate further discussion with regards to product, schedule, scope of services, pricing and other requirements. Your organization will work directly with ICSA Labs throughout the application process. ICSA Labs accepts test results directly from a lab which has a current NVLAP accreditation as a Health IT Testing Lab. ICSA Labs is also an NVLAP accredited Health IT Testing Lab, so customers may choose to both test and certify with ICSA Labs. Customers interested in testing services from ICSA Labs should refer to the ICSA Labs Healthcare Program Testing Manual for further information about the ICSA Labs Accredited Test Lab (ATL).

Application

Once the customer completes a healthcare registration form the Account Manager provides the customer with a contract. The contract describes the work that ICSA Labs will perform, based from the customer selections on the registration form, and includes terms and conditions and associated pricing. The customer may choose to pay with or without a purchase order (PO). The effective date and term of the engagement is defined within the contract. Note: registering for 2015 Edition Certification takes place through the ICSA Labs customer portal.

ONC Certification Designations

Testing and certification in the 2014 Edition program is specific to the Ambulatory (Eligible Providers) domain or the Inpatient (Eligible Hospitals) domain, and within those domains an EHR technology could obtain a Complete EHR or an EHR Modular certification. EHR technology can meet the requirements of criteria spanning both domains and in those cases may apply for both certifications.

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For 2015 Edition Certification, ONC has dropped the ‘complete’ certification designation, so all products certified will be called certified modules. ONC has also dropped the ‘ambulatory’ and ‘inpatient’ domain designations.
2014 Edition Certification

- A 2014 Edition Complete EHR must meet all of the required criteria required for a given domain (Ambulatory or Inpatient). Criteria labeled as “Optional” are not required for certification.
- A 2014 Edition EHR Module must meet at least one of the criteria for a given domain (Ambulatory or Inpatient).

Additional requirements and dependencies (see the program registration form for additional details):

- For products testing 170.314(c) – Clinical Quality Measures:
  - Ambulatory products certified must test at least 9 CQMs (6 must be Core) from a minimum of 3 domains identified by CMS (See ICSA Labs Healthcare Registration Form for more information)
  - Inpatient products certified must test at least 16 CQMs from a minimum of 3 domains identified by CMS (See ICSA Labs Healthcare Registration Form for more information)
- 170.314(g)(1) – “automated numerator recording” and 45 CFR 170.314(g)(2) – “automated measure calculation” are not required for measures that are no longer included in the meaningful use criteria for EHR reporting periods in 2015 through 2017 as a result of CMS’s recent final rule. See the following ONC FAQ for more information. [The measures that are no longer required include: Demographics, Vital signs, Smoking status, Clinical summaries, Incorporate lab results, Patient reminders, Electronic notes, Imaging, Family health history, Problem list, Medication list, Medication allergy list, Advance directives, Electronic medication administration record (eMAR), Send labs from EH to EP]
- 170.314(g)(2) Automated measure calculation is REQUIRED for Complete EHRs
- 170.314(g)(3) Safety-enhanced design [attestation only] is REQUIRED for either Complete EHRs or EHR Modules if also testing any of the following criteria: 170.314.a1-2, a6-8, a16, a18-20, b3-4, or b9
- 170.314(g)(4) Quality management system [attestation only] is REQUIRED for all systems

The 2014 Edition Base EHR is not an actual certification issued, but is defined by ONC as certified EHR technology products that meet the following certification criteria adopted by the Secretary:

- At least one of the four CPOE criteria from 170.314(a)(1), (a)(18), (a)(19), or (a)(20);
- Demographics - 170.314(a)(3);
- Problem, Medication, Medication Allergy Lists and Clinical Decision Support - 170.314(a)(5) through § 170.314(a)(8);
- Transitions of Care - Both 170.314(b)(1) and (2); or, both 170.314(b)(8) and 170.314(h)(1); or 170.314(b)(1) and (2) combined with either 170.314(b)(8) or 170.314(h)(1), or both 170.314(b)(8) and 170.314(h)(1);
- Data Portability - 170.314(b)(7);
- Clinical Quality Measures - 170.314(c)(1) through 170.314(c)(3);
  - Certified to the 170.314(c)(1) and (2):
    - (i) For no fewer than 9 clinical quality measures covering at least 3 domains from the set selected by CMS for eligible professionals, including at least 6 clinical quality measures from the recommended core set identified by CMS; or
    - (ii) For no fewer than 16 clinical quality measures covering at least 3 domains from the set selected by CMS for eligible hospitals and critical access hospitals.
Privacy and Security: 170.314(d)(1) through 170.314(d)(8)

Note the definition of Base EHR has been updated to reflect the 2014 Edition Release 2 criteria.

**2015 Edition Certification**


- A 2015 Edition Health IT Module must meet at least one of the applicable certification criteria.

Additional requirements and dependencies (see the healthcare program registration form for additional details):

<table>
<thead>
<tr>
<th>170.315(a) Clinical</th>
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<tbody>
<tr>
<td>[All criteria in this category also require testing of d1-7]</td>
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<tr>
<th>170.315(b) Care Coordination</th>
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<tr>
<td>[All criteria in this category also require testing of d1-3 and d5-8]</td>
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<thead>
<tr>
<th>170.315(c) Clinical Quality Measures</th>
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<tbody>
<tr>
<td>[All criteria in this category also require testing of d1-3 and d5]</td>
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<tr>
<th>170.314(d)(1) Authentication, access control, and authorization [Gap]</th>
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<tr>
<td>REQUIRED if also testing any of the following criteria:</td>
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<tr>
<td>170.315.a.1-15, 170.315.b.1-9, 170.315.c.1-4, 170.315.e.1-3, 170.315.f.7, 170.315.g.7-9, 170.315.h.1-2</td>
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<tr>
<th>170.315(d)(2) Auditable events and tamper-resistance</th>
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<tr>
<td>REQUIRED if also testing any of the following criteria:</td>
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<tr>
<td>170.315.g.7-9 requires testing of d2 or d10</td>
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<tr>
<th>170.315(d)(3) Audit report(s)</th>
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<tr>
<td>REQUIRED if also testing any of the following criteria:</td>
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<thead>
<tr>
<th>170.315(d)(4) Amendments [Gap]</th>
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<tr>
<td>REQUIRED if also testing any of the following criteria:</td>
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<tr>
<td>170.315.a.1-15</td>
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<tr>
<th>170.315(d)(5) Automatic access time-out [Gap]</th>
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<td>REQUIRED if also testing any of the following criteria:</td>
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<tr>
<th>170.315(d)(6) Emergency access [Gap]</th>
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<tr>
<td>REQUIRED if also testing any of the following criteria:</td>
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<td>170.315.a.1-15, 170.315.b.1-9</td>
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<tr>
<th>170.315(d)(7) End-user device encryption [Gap]</th>
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<td>REQUIRED if also testing any of the following criteria:</td>
</tr>
<tr>
<td>170.315.a.1-15, 170.315.b.1-9, 170.315.e.1, 170.315.f.7</td>
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<tr>
<th>170.315(d)(8) Integrity</th>
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<tr>
<td>REQUIRED if also testing any of the following criteria:</td>
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<td>170.315.b.1-9</td>
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<tr>
<th>170.315(d)(9) Trusted connection</th>
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<td>REQUIRED if also testing any of the following criteria:</td>
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<td>170.315.b.1-9</td>
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<td>Section</td>
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<tr>
<td>170.315.e-1</td>
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<tr>
<td>170.315(d)(10)</td>
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<td>170.315(e)</td>
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<td>170.315(f)</td>
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<td>170.315(g)(5)</td>
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<tr>
<td>170.315(g)(6)</td>
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<tr>
<td>170.315(h)</td>
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**Privacy and Security Requirements**

*ONC has introduced another significant change with the 2015 Edition as it relates to the testing of privacy and security certification criteria.*

A Health IT Module will need to meet applicable privacy and security certification criteria, which is based on the other capabilities included in the Health IT Module. This removes the responsibility from the provider to ensure that they possess technology certified to all the necessary privacy and security criteria. See the diagram below illustrating the final 2015 Edition Privacy and Security Certification Framework for more information.
Self-Declaration for 30 Criteria

ONC has introduced another significant change to the 2015 Edition.

On September 21, 2017 ONC announced updates to the 2015 Edition ONC Health IT certification program to support efficiency and reduce testing burdens on developers. As a result of this announcement, Health IT developers will now be able to certify to 30 of the 55 2015 Edition criteria through self-declaration as opposed to demonstration or attestation. The test procedures for these 30 criteria, found here, have been designated as developer self-declaration.

In order to qualify for these criteria, the developer is required to conduct their own testing and submit a form to their test lab to disclose pertinent information. Developers should retain evidence of the tests and their results in the event that an ONC-ACB is required to conduct surveillance of one of the self-declared criteria.

The 2015 Edition Base EHR: is not an actual certification issued, but is defined by ONC as certified EHR technologies products that meet the following certification criteria adopted by the Secretary:

- Demographics § 170.315(a)(5), Problem List § 170.315(a)(6), Medication List § 170.315(a)(7), Medication Allergy List § 170.315(a)(8), Smoking Status § 170.315(a)(11), Implantable Device List § 170.315(a)(14)
- Clinical Decision Support § 170.315(a)(9)
- Computerized Provider Order Entry § 170.315(a)(1), (2) or (3)
- Clinical Quality Measures—Record and Export § 170.315(c)(1)
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- Transitions of Care § 170.315(b)(1), Data Export § 170.315(b)(6), Application Access—Patient Selection § 170.315(g)(7), Application Access—Data Category Request § 170.315(g)(8), Application Access—All Data Request § 170.315(g)(9), Direct Project § 170.315(h)(1) or Direct Project, Edge Protocol, and XDR/XDM § 170.315(h)(2).

The requirements of the 2015 Edition Base EHR Definition can be met using one certified Health IT module or a combination of certified Health IT modules.

**Attestations and Disclosures Required for all ONC Certified Health IT (2014 and 2015 Edition)**

Certified health IT developers are required to conspicuously disclose in plain language on their website, in all marketing materials, communication statements, and other assertions related to certified health IT (regardless of whether the website refers to the certification or certified status of the developer's health IT):

- Additional types of costs users may incur to implement or use health IT for any purpose within the scope of its certification (not just for achieving MU objectives)
- Limitations (including contractual, technical, or other limitations) that are likely to limit a user's ability to implement or use health IT for any purpose within the scope of its certification

Additionally, all certified HIT developers must:

- Provide a hyperlink for all disclosures, which will be published via ONC's CHPL
- Make a transparency pledge indicating whether or not they will provide the required information to other persons and organizations (e.g., customers, prospective customers, and associations representing consumers or providers) upon request. The attestation template that ICSA Labs provides must indicate whether or not the developer voluntarily agrees to the pledge (or not), and must return it to ICSA Labs with a signature.
- Provide a complaints handling process for complaints from end-users.

**Pricing and Payment Terms**

ICSA Labs will provide pricing to interested parties upon request. ICSA Labs offers competitive pricing and payment terms.

**Submission of Materials**

When the registration form and executed contract documents are received, the customer must facilitate submission of all required test materials within ten (10) business days. If the customer has used a Test Lab other than ICSA Labs, a summary of the test results must be received directly from the Test Lab and must include, at a minimum, the information below. Accredited Test Labs may submit this information using their native documentation, or they may request a template from ICSA Labs to use for the purpose of providing the required information. Note that ICSA Labs has an approved test results summary template that ATL's can use to submit information for products tested to the 2014 Edition and 2015 Edition criteria. This template can be provided upon request. The test results information should include:

- ATL information
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- Name of Testing Lab
- NVLAP Lab ID
- Address
- Website URL
- Phone, email and point of contact information

- Developer Information
  - Developer name
  - Address
  - Website URL
  - Phone, email and point of contact information

- Product Information
  - Product name
  - Product version/release

- Start and end dates of testing period (does not have to include individual test event dates)
- Summary of results for all criteria tested
- Name and version of additional relied upon software used during testing to assist in complying with the certification requirements and which criteria they were used for

- Edition of ONC Certification Tested (e.g., 2014, 2015)
  - For 2014 Edition only:  
    - Certification Type (Complete/modular)
    - Domain tested (Ambulatory/Inpatient)

- List of all criteria tested and results
- Detailed test information per criterion
  - Version of Test Procedure used
  - Version of test tools used
  - Location of tool used, e.g., local or remote
  - Modifications, if any, to the Approved Test Methods
  - Modifications, if any, to the test tools used
    - NOTE: Sequencing of tests to achieve operational efficiencies is not considered modifications to either the approved test methods or tool and do not require capture and communication.

- Visual Verification (e.g., Screenshots, videos)
  - Tool test results output
  - For all criteria with no associated test tool, successful results should be captured by a form of visual verification with accompanying explanatory narrative/annotations.
    - NOTE: ATLS are required to capture visual verifications, and provide to ONC-ACB and/or ONC upon request.

- List of all clinical quality measures tested identified by criterion, including the CMS CQM #, and description and version as applicable.
- Manifest of output artifacts, e.g., filenames of C-CDA’s, etc., that accompany the report.
- Attestations, Self-declarations and Documentation
  - Provide all documentation to support a conformity decision for tests permitting developer documentation/attestation.
  - When there are options within the criteria against which to demonstrate conformance, the selected option(s) shall be recorded.
  - Opinions and interpretations where required.
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ICSA Labs reserves the right to request additional corroborating documentation such as recordings of tests or screen captures to substantiate the results of the test. In an effort to maintain the integrity of the certification process, ICSA Labs will not accept testing materials provided by the customer. All testing materials must be received directly from the Accredited Test Lab.

Previously Certified Product from another Accredited Certification Body

As an ONC-Authorized Certification Body (ONC-ACB) ICSA Labs can accept test results from any NVLAP Accredited IT Test Lab and can perform product updates for products certified by another ONC-ACB. At the time the product updates are submitted (also see Company Name Changes, Product Private-Labeling, and/or Product Name Changes section) the vendor will be required to authorize a Statement of Work and Service Order Form which describes the work that ICSA Labs will perform and the associated pricing. If the product update is approved, ICSA Labs will issue a certificate to the vendor and submit the certification information to the ONC. Should the vendor wish to certify new products they will be required to follow the standard application procedure (see Doing Business with ICSA Labs section).

Certification Process

Certification Body Review
The certification process includes an evaluation of the testing artifacts and a review to ensure all certification requirements have been met once all required contracts and testing materials have been received. These steps are conducted by qualified ICSA Labs Certification Body staff and may take up to ten (10) business days once all required documentation and contracts have been submitted. Should any deficiencies be identified, ICSA Labs will provide the customer and the Test Lab, as appropriate, the opportunity to submit clarification or additional information. Once the assessment is complete, and if there are no issues with the submitted materials, the certification is issued and the certification information will be published to the ONC’s Certified Health IT Product List (CHPL).

Gap Certification
Gap certification is the certification of a previously certified Complete EHR or EHR Module(s) to:

- All applicable new and/or revised certification criteria adopted by the Secretary based on the test results of an Accredited Testing Laboratory (ATL); and
- All other applicable certification criteria adopted by the Secretary based on the test results used to previously certify the Complete EHR or EHR Module(s).
- The ICSA Labs registration form denotes all gap eligible criteria

Certification to Newer Versions of Certain Standards
ONC-Authorized Certification Bodies (ONC-ACBs) may certify Complete EHRs and/or EHR Module(s) to a newer version of certain identified minimum standards as specified in the Final Rule and approved final test procedures if the Secretary has accepted a newer version of an adopted minimum standard.

Applicability of an accepted newer version of an adopted minimum standard is as follows:
1. ONC-ACBs are not required to certify Complete EHRs and/or EHR Module(s) according to newer versions of an adopted minimum standard accepted by the Secretary until the incorporation by reference provision of the adopted version is updated in the Federal Register with a newer version.

2. Certified EHR Technology may be upgraded to comply with newer versions of an adopted minimum standard accepted by the Secretary without adversely affecting the certification status of the Certified EHR Technology.

Certification Body Decision

Based on the Certification Body Evaluator and Reviewer’s input, the product may be granted certification based on the requirements found in ISO/IEC 17065:2012 and the rules and regulations required under that ONC Health IT Certification Program. If an adverse decision is reached by the certification body on one or more criteria, the customer is provided with a detailed report of their findings, including the justification for the certification decision. The customer may have one or more of the below options:

- The customer can contact an ONC Authorized, NVLAP-Accredited Test Lab to perform any required retesting. Customers that wish to use ICSA Labs as their test lab should contact their Account Manager.
- In scenarios where the certification body found required criteria to be satisfactory and where a non-conformity was found in non-required criteria, the customer can request the certification body to issue certification on those criteria that were found to be in compliance.
- The customer may agree to completion of the additional evaluation tasks or instead may halt evaluation tasks.
- The customer can appeal the certification body’s decision (see Appeals and Disputes).

If the ICSA Labs certification body grants certification, all ONC certifications will be transmitted to the ONC for listing on the Certified Health IT Product List (CHPL).

Certified Health IT Product List (CHPL)

The Certified Health IT Product List (CHPL) provides the authoritative, comprehensive listing of Complete EHRs and EHR Modules that have been tested and certified under the certification program maintained by the Office of the National Coordinator for Health IT (ONC Health IT). Each Complete EHR and EHR Module listed on the site has been certified by an ONC-authorized certification body. Only the product versions that are included on the CHPL are certified under the ONC certification program.

Notification of a granted certification will be provided by the ACB. Once a product successfully achieves certification through ICSA Labs, the information is transmitted to ONC for listing on the CHPL website. For each certified product, the CHPL lists the certification body responsible for granting certification, the Certified Product ID number, the specific criteria that each product tested against (including individual clinical quality measures), any 3rd party software used help meet the certification requirements, the Health IT developer’s response to the transparency pledge, and the public url where the developer posts the related certification disclosure information. The CHPL may also include a hyperlink to the publicly available test results summary document (for 2014 Edition certifications), safety enhanced design test results and any notice of nonconformity issued by the ACB and any subsequent corrective actions undertaken by the product developer.

Visit the ICSA Labs certification body’s page on the CHPL for the latest information with regards to any updates and additional guidance on generating certification IDs for CMS attestation purposes.
Certificate of Compliance
If certification is granted, ICSA Labs issues a Certificate of Compliance that documents the criteria and domain (for 2014 Edition products) in which the product is now certified.

Changes to Certification Scheme
When the certification scheme introduces new or revised requirements that affect the client, the ICSA Labs Certification Body will ensure these changes are communicated to all customers via email. ICSA Labs will verify the implementation of any related changes by its customers and will take actions required by the scheme.

Marketing
Once certified, ICSA Labs sends a congratulatory note to the customer, along with an electronic Certificate of Compliance, the ICSA Labs certification logos, the ONC Health IT certification logos and marketing and usage guidelines. Products certified under the ONC certification program must adhere to ONC certification guidelines to maintain their product certification (see Certification Guidelines).

ICSA Labs also maintains a website of certified products. After achieving certification, products are typically posted to the ICSA Labs website within five (5) business days. Products tested to the 2014 Edition criteria will also include a hyperlink to the test results summary used to grant the certification decision.

ICSA Labs can provide customers with a press release template for use in drafting their certification announcement if desired. ICSA Labs’ Public Relations and Legal teams must review and approve all press releases before an announcement may be made. This process typically takes 5 business days or longer depending on changes to the template.

Maintaining and Extending Certification

Adaptations
ONC permits adaptations (meaning software designed to run on a different medium such as a mobile device or tablet) of certified EHR Modules without additional certification requirements if the technology includes the full and exact same capabilities required by the certification criteria to which the EHR technology it is serving as an adaptation of was certified.

While adaptations may require user interface and other design feature changes, ONC focuses on the requirement that the capabilities in the adaptation area are a “one-for-one match” with the specific certification criteria adapted from the EHR Module, which may be less than the overall capabilities of all of the criteria tested in an EHR Module.

ONC expects developers to include the relevant privacy and security capabilities in the adaptations. For 2014 Edition certified products, developers do not need additional testing for an adaptation, but adaptations must conform to the certification provisions issued for the Complete EHR or Health IT Module.

ONC cautions that an adaptation would not be independently listed on the Certified Health IT Products List (CHPL) unless the developer seeks a separate certification for it; thus, as part of the attestation process, an EP, EH, or CAH would have to select the certified Complete EHR or EHR Module from which the adaptation was created.
Quarterly Reporting

Adaptations and Updates:
ICSA Labs is required to provide quarterly updates to ONC based on the ongoing product information that a certified health IT developer submits with regards to adaptations and product updates noted in 45 CFR 170.523(m)(1) and (m)(2). On a quarterly basis each calendar year, certified health IT developers must submit a record of:

1. All adaptations of certified Health IT Modules; and
2. All updates made to certified Complete EHRs and certified Health IT Modules affecting the capabilities in certification criteria to which the “safety-enhanced design” criteria apply.

Complaints:
ICSA Labs is required to submit a list of complaints received to the National Coordinator on a quarterly basis each calendar year that includes the number of complaints received, the nature/substance of each complaint, and the type of complainant for each complaint. ICSA Labs fields complaints directly, and additional complaints could be received from end-users and the ONC.

The reporting periods for adaptations and complaints are as follows:
- Q1: January 1 – March 31
- Q2: April 1 – June 30
- Q3: July 1 – September 30
- Q4: October 1 – December 31

A list of all adaptations and updates should be submitted to ICSA Labs no later than 5 business days after the close of the quarter.

Modifying Certified Products

Certification is granted to the specific product and version tested. Recent ONC guidance on product identification and versioning is available here (see guidance #17-05). It is normal for healthcare IT products to be updated during the software product’s life cycle, and it is possible for a product to be changed and still retain its certification provided the necessary steps are followed.

When a certified product is updated to include new features, or a new software version is released, the Authorized Certification Body must be contacted. ICSA Labs requests that a Product Update form and any additional documentation to help facilitate the review be submitted for any certified products that are updated or modified. ICSA Labs will review these modifications and determine whether a new version can inherit the original certification (no retesting required) or whether retesting and recertification must occur.

Products issued certification under the ONC certification program typically remain on the CHPL, unless the certification body has decertified the product due to non-compliance with specified terms and conditions, the product developer has withdrawn the certified product, or ONC has retired the certification edition. If a product is no longer maintained or needs to be withdrawn as a certified product on the CHPL, the system developer must contact ICSA Labs with the request.
Company Name Changes, Product Private-Labeling, and/or Product Name Changes

All company and/or product name changes must be reported to ICSA Labs following the designated process. ICSA Labs will only adjust company and product name changes after receiving the required documentation.

Company name changes and company headquarters address and billing changes must be submitted to ICSA Labs using the Product Update Form. The reason for the change must be noted. If the company name change has occurred due to an acquisition or a merger, ICSA Labs must be provided with the name, title, phone number and email address for the Primary Contact, Technical Contact and Marketing Contact for the new company. Company headquarters address and/or billing address changes may be submitted to ICSA Labs in writing and signed by an authorized official.

Rebranded or private-labeled product certifications must be submitted to ICSA Labs using the Product Private-Label Form. ICSA Labs must be provided with the name, title, phone number and email address for the Primary Contact, Technical Contact and Marketing Contact for the new company. The original manufacturer or company and the company rebranding the product must both sign the form as evidence that they are aware of the requested changes.

Product name changes must be submitted to ICSA Labs using the Product Update Form.

Private-Labeling

EHR technology developers may work with business partners/distributors and permit them to sell (unmodified) certified EHR systems under their own brand/name/label. Private-Labeling or rebranding a certified product for the use of marketing/selling it under a different name is permissible for unmodified products – meaning that there have been no changes to the product code, aside from those having to do with changing the name/brand/label of the product. These types of changes are allowable so long as they do not affect the product’s compliance with the certification criteria against which it was certified.

This practice is also specifically sanctioned under the ONC certification program (see ONC FAQs for more information).

Certifications are product and version specific. To extend certification to a private-labeled product, the customer and their business partner/distributor must:
- Complete and sign the Product Private-Labeling Form;
- Provide documentation of changes made to the product. For example, a screen capture of ‘before’ and ‘after’ displays, written summary of the changes, release notes, etc.;
- Submit a completed MSA and SoS form (business partner/distributor only); and
- Remit product rebranding fees.

Upon receipt of all required documentation and fees, ICSA Labs will make a determination on whether the private-labeled product may inherit the original product’s certification. This decision is communicated to all affected parties and if the certification is granted, information concerning the new certification, such as logos, is provided to the private-label and they are responsible for adhering to all marketing requirements. Products achieving certification under the Private-Label process may also release a press announcement of their achievement (see Press Releases). Note that if certification is suspended or withdrawn for the originally certified product, certification will also be suspended or withdrawn for the corresponding private-labeled product.
Value Added Resellers (VARs)

It is common practice for an EHR developer to increase the channels of marketing for their certified product by using value added resellers (VARs). VARs typically resell the original developers product using the original vendor’s company and product name, as well as its original version number. If you wish to use resellers to distribute your product, it is the original product developer’s responsibility to ensure that their business partners/distributors adhere to the terms and conditions of the certification issued, including ICSA Labs logo and usage guidelines, the ONC Health IT certification logos and usage guidelines and that their business partners/distributors understand and abide by the information specified at 45 CFR 170.523 (see ONC Guidelines).

Certification Guidelines

The following guidelines are important for products that wish to remain certified and in compliance with the ICSA Labs certification requirements and, if applicable, federal constraints.

Appeals and Disputes

If a product is found to be non-compliant with the certification criteria, a customer may submit an appeal and/or dispute to the Director of ICSA Labs for a Management Review. All appeals/disputes must be submitted in writing (mail, fax, email). When submitting an appeal/dispute to ICSA Labs for review, the following information should be included:

a) the reason(s) the customer believes that the denial or revocation of certification should be reversed, including any objections, corrections, and factual information the customer believes to be relevant to the appeal/dispute
b) the elements of the specific certification program the customer plans to address in the appeal/dispute
c) whether the customer prefers to be present during the review meeting with ICSA Labs personnel
d) the contact information of any person the customer plans to include in the meeting in order to present factual information relevant to the appeal/dispute, with a clear description of the factual information available from these persons; and
e) a list and copies of all relevant documents, exhibits, or other information the customer intends to submit in support of the appeal/dispute.

ICSALabs will acknowledge receipt of an appeal/dispute for review, notify the customer if it is incomplete, and permit the customer to provide any missing information within an agreed upon period of time after such notice. Complete appeals/disputes will be reviewed by the ICSA Labs Management Team, and an agreed upon timeframe will be established for a decision to be rendered by the ICSA Labs Management Team. ICSA Labs may require the customer to clarify, supplement, or amend an appeal/dispute under review. Also, where the customer has requested participation in the meeting, the customer may be required to provide additional presentation information prior to the meeting date. The appeal/dispute may be delayed if the customer does not provide necessary information for the appeal/dispute.

ICSALabs will request the customer to respond to the complaint and provide any clarification or supplemental information that the customer believes will assist ICSA Labs in its consideration of the appeal/dispute. Also, if the customer recommends the participation of other individuals in the investigation or meeting, ICSA Labs at its sole discretion, may include such individuals in the Management Team’s investigation or the meeting.

If a customer stipulates in its appeal/dispute that it desires to participate in the meeting of such appeal/dispute, it will be invited by ICSA Labs to attend the meeting. In the event that the customer does not request to participate in
the meeting, the appeal/dispute will be resolved and decided based on the appropriate information and review, which may include a recorded retest if determined appropriate by ICSA Labs.

Prior to the meeting, ICSA Labs will review the information submitted by the customer and, if applicable, any new test results. If the customer chooses to be present at the meeting, the customer will be given the opportunity to make a statement. ICSA Labs will resolve and decide the appeal/dispute based on the test results, including, if applicable, any new results that may be available from any retests, relevant and credible information presented by the customer, ICSA Labs policies and procedures, and, if applicable, the action or decision of the Managing Director of ICSA Labs. The ICSA Labs Management Team will issue a written decision to the customer within an agreed upon timeframe after the meeting stating that the customer’s product is ICSA Labs Certified or that certification has been denied.

**Surveillance Activities**

The following section provides a general overview of surveillance activities that are covered in greater detail in the yearly surveillance plan which is reviewed by the ONC. See ICSA Labs’ [CY2018 Surveillance Plan](#) for detailed information.

ICSA Labs conducts reactive and proactive surveillance on all certified products to ensure continued conformance to the standards and requirements under which the product was certified. Surveillance activities are tracked and documented as part of the ONC policy guidance and ISO/IEC 17065 requirements for an accredited certification body. Surveillance activities conducted by ICSA Labs include:

- Reactive surveillance based on complaints, repeated certification inheritance requests, information provided in transparency disclosures and attestations, etc.
- Proactive surveillance to verify information related to transparency and disclosure requirements. All certified HIT developers must ensure:
  1. Correct usage of the ICSA Labs logo and ONC Health IT Certified Logo as appropriate;
  2. Statements about ICSA Labs and the certification achieved must not be misleading or contain inaccuracies; and
  3. The name and version number of the product described as certified by the customer must match the certified product name and version on file at ICSA Labs (see Modifying Certified Products).

Additional requirements for products certified by ICSA Labs under the ONC certification program: the certified logo used must be from ICSA Labs and not from another authorized certification body, the required language in the Final Rule concerning marketing of the certified product must be used (see ONC Guidelines – Transparency and Disclosure Requirements) and the required transparency and disclosure requirements must be adhered to (see ONC Guidelines - Transparency and Disclosure Requirements).

All nonconformities identified during surveillance activities will be communicated to the customer and ONC, and will result in the customer submitting a Corrective Action Plan (CAP) (See Corrective Action Procedures in CY 2018 Surveillance Plan to ICSA Labs within 30 days of notification. Evidence of the non-conformity and associated CAP must be posted online to the CHPL web site per ONC.

A non-response may be grounds for further punitive action. Extensions may be granted on a case by case basis. ICSA Labs will review the CAP within 10 business days and make a determination as to whether the plan will be approved, needs any revisions, or is altogether rejected.
The determination will be based on a review of the thoroughness and completeness of the submitted CAP based on the CAP requirements outlined above, and whether the timelines and proposed corrective actions provide confidence to the certification body that the product is in conformance or will be by a certain target date. Depending on the degree and scope of the non-conformities, it is still possible that the certification may be suspended or withdrawn. See the section on Suspension and Withdrawal for more information.

A Corrective Action Plan is required any time an ACB finds that a product or a developer is non-compliant with any certification criterion or any other requirement of certification, including the transparency and disclosure requirements.

Complaints
ICSALabs adheres to ONC requirements regarding complaints related specifically to the scope of ONC certified Health IT and criteria tested and certified in the ONC Health IT Certification Program. As such, all product developers must:

- Provide ICSA Labs with information regarding their complaints resolution process;
- Maintain a record of all customer complaints related to a product’s compliance with the certification criteria against it was tested to be provided to ICSA Labs upon request for surveillance related activities; and
- Retain a log of actions taken in response to such complaints.

In the event ICSA Labs is contacted either by ONC or by a customer in possession of HIT certified by ICSA Labs with complaints about a product’s ability to comply with the certification criteria (“Complaints”), ICSA Labs will notify the customer and investigate the complaint to take appropriate action. A record of all complaints received, the action taken and its effectiveness will be maintained. Complaints and information related to such Complaint about an ICSA Labs’ client obtained from sources other than ICSA Labs’ client (e.g., from a complainant or from regulators) (“Information”) will be treated as confidential by ICSA Labs except for Information that:

- is made public by the sources or becomes public other than through an action by ICSA Labs or its employees;
- is already in the possession of ICSA Labs without obligation of confidentiality; or
- is disclosed pursuant to a valid order of a court or other governmental body.

Users or purchasers of ICSA Labs ONC-ACB Certified EHR products that have complaints or questions about the certified product functionality may submit complaints to ICSA Labs by completing the Certified Product Complaint form found on the ICSA Labs website. Any complaints from a user or purchaser will be qualified to determine whether the complaint is related to a specific product and version certified, and whether the complaint is within the scope of functionality tested and certified under the ONC Health IT Certification Program. A product’s certification may be suspended or withdrawn if a complaint has been received and after review by the ICSA Labs certification body, the complaint is found to be valid and compromises the integrity of the product’s certification. ICSA Labs will notify the customer, any associated Accredited Testing Lab and any affected federal entity (e.g., the ONC). See the following section for more information.

Suspension, Withdrawal, or Revocation of Certification

The status of certified products listed on the CHPL web site will be set to one of the following:
• **Active** – Certification was granted by the ONC-ACB and remains in good standing on the CHPL.

• **Retired** – The product’s certification has been retired as part of HHS policy. The product is no longer considered certified.

• **Suspended by ONC** – The certification of the product has been suspended by ONC because:
  1. ONC believes the product poses a potential risk to public health or safety
  2. The developer fails to respond in a timely manner to any communication to ONC, including, but not limited to:
     a. Fact-finding
     b. A notice of potential non-conformity
     c. A notice of conformity
  3. The developer fails to timely submit a proposed CAP that adequately addresses the elements required by ONC.
  4. The developer does not fulfill its obligations under the CAP. While the product remains certified, the developer will be unable to update or certify new products for the duration of the suspension.

• **Suspended by ONC-ACB** – Certification has been suspended by the ONC-ACB due to failure to submit or complete a corrective action plan in time. While the product remains certified, the ONC-ACB may withdraw its certification if the corrective action is not submitted within 30 days or completed in an agreed upon time.

• **Terminated by ONC** – Certification has been terminated by ONC. The product is no longer considered certified.

• **Withdrawn by Developer** – Certification was voluntarily withdrawn by the developer. This may be because the product is no longer supported by the developer or they choose to no longer support ongoing certification requirements. Developers may not choose this option in response to ONC-ACB surveillance, ONC direct review, or a finding of non-conformity. Once withdrawn, the product is no longer considered certified and cannot be reinstated without resubmitting for certification.

• **Withdrawn by Developer Under Surveillance/Review** – Certification was withdrawn by the developer while the product was under ONC-ACB surveillance or ONC direct review. The product is no longer considered certified.

• **Withdrawn by ONC-ACB** – Certification was withdrawn by the ONC-ACB. The product is no longer considered certified.

• **Certification Ban** - The certification of any of a health IT developer’s health IT is prohibited when the certification of one or more of the health IT developer’s Complete EHRs or Health IT Modules is:
  1. Terminated by ONC under the ONC Health IT Certification Program (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; and
  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.
ICSA Labs may suspend a previously granted certification if one of the following conditions is met:

- The developer is no longer actively supporting the product’s certification; or
- Notification by the Testing Lab that the test results have been recalled; or
- Failure to respond to ICSA Labs surveillance inquiries; inability to successfully complete surveillance re-testing; or
- The product does not adhere to the requirements enumerated in the “ONC Guidelines” section below; or
- There is a compliance discrepancy between the system that was certified and the system in use by clients. Applicants are given ten (10) business days after notice by ICSA Labs of the compliance discrepancy to provide a satisfactory explanation; or
- There is a breach in the contractual obligations and agreed upon terms and conditions of certification. Applicants are given ten (10) business days after notice by ICSA Labs of the breach to either resolve it or provide a reasonable explanation of why the breach cannot be corrected.

The developer will be notified via email prior to any certifications being suspended. If the reason for the suspension is not resolved within the required timeline communicated by ICSA Labs to the developer, ICSA Labs may change the status of the suspended certification to Withdrawn by ONC-ACB. Once a product is withdrawn it cannot be reinstated for any reason. If a developer wishes to restore a previously certified product they must resubmit the product for a new certification.

If certification is reinstated after suspension, ICSA Labs will make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure all appropriate indications exist that the product continues to be certified. If a decision to reduce the scope of certification is made as a condition of reinstatement, ICSA Labs will make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly specified in certification documentation and public information.

ONC reserves the right to suspend or terminate a certification at their discretion per the rules governed under the Enhanced Oversight and Accountability Rule. ICSA Labs cannot apply the ONC imposed product status. In the event that ONC exercises this option, it is ONC’s responsibility to notify ICSA Labs of the change. ICSA Labs will update the applicable record/s when notified.

Note: It is critical for all certified product developers to maintain at least one valid email address with ICSA Labs for communication purposes and keep ICSA Labs up to date with regards to certification contacts. Surveillance related requests, updates on certification requirements, and other important information is conveyed via email primarily.

ONC Guidelines - Transparency and Disclosure Requirements

Please note that the Department of Health and Human Services and the ONC maintain that companies must adhere to the following guidelines with regards to the certified product per the information specified at 45 CFR 170.523(k)(1).

All certifications must require that a Complete EHR or Health IT Module developer conspicuously include the following text on its website and in all marketing materials, communications statements, and other assertions related to the Complete EHR or EHR Module’s certification:

(i) “This [Complete EHR or EHR Module] is [specify Edition of EHR certification criteria] compliant and has been certified by ICSA Labs in accordance with the applicable certification criteria adopted by the
Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services.”

AND

a. The vendor name

b. The date certified

c. The product name and version

d. The unique certification number or other specific product identification

e. Where applicable, the certification criterion or criteria to which each EHR module has been tested and certified

f. The clinical quality measures to which a complete EHR or EHR module has been tested and certified

g. And where applicable, any additional software a complete EHR or EHR module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary

h. And where applicable, any additional types of costs that a user may be required to pay to implement or use the Complete EHR or Health IT Module’s capabilities, whether to meet meaningful use objectives and measures or to achieve any other use within the scope of the health IT’s certification. (Examples given include: fixed, recurring, transaction-based, or otherwise that are imposed by a health IT developer (or any third-party from whom the developer purchases, licenses, or obtains any technology, products, or services in connection with its certified health IT) to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of capabilities to which health IT is certified; or in connection with any data generated in the course of using any capability to which health IT is certified.)

i. And where applicable, any limitations (whether by contract or otherwise) that a user may encounter in the course of implementing and using the Complete EHR or Health IT Module’s capabilities, whether to meet meaningful use objectives and measures or to achieve any other use within the scope of the health IT’s certification. (Examples given include, but not limited to technical or practical limitations of technology or its capabilities, that could prevent or impair the successful implementation, configuration, customization, maintenance, support, or use of any capabilities to which technology is certified; or that could prevent or limit the use, exchange, or portability of any data generated in the course of using any capability to which technology is certified.)

A developer may satisfy the requirement to disclose the information required by § 170.523(k)(1) in its marketing materials, communications statements, and other assertions related to a Complete EHR or Health IT Module’s certification by providing an abbreviated disclaimer, appropriate to the material and medium, provided the disclaimer is accompanied by a hyperlink to the complete disclosure on the developer’s website.

Where a hyperlink is not feasible (for example, in non-visual media), the developer may use another appropriate method to direct the recipient of the marketing material, communication, or assertion to the complete disclosure on its website.
Attestation Requirement

As a condition of certification, health IT developers must make one of the following attestations:

In the affirmative:
In support of enhanced marketplace transparency and visibility into the costs and performance of certified health IT products and services, and the business practices of health IT developers, [Developer Name] hereby attests that it will provide in a timely manner, in plain writing, and in a manner calculated to inform, any part (including all) of the information required to be disclosed under 45 CFR §170.523(k)(1) under the following circumstances:

- To all persons who request such information.
- To all persons who request or receive a quotation, estimate, description of services, or other assertion or information from [Developer Name] in connection with any certified health IT or any capabilities thereof.
- To all customers prior to providing or entering into any agreement to provide any certified health IT or related product or service (including subsequent updates, add-ons, or additional products or services during the course of an ongoing agreement).

-OR–

In the negative:
[Developer Name] hereby attests that it has been asked to make the voluntary attestation described by 45 CFR §170.523(k)(2) in support of enhanced marketplace transparency and visibility into the costs and performances of certified health IT products and services, and the business practices of health IT developers and [Developer Name] hereby declines to make such attestation at this time.

-OR–

Self-developer exclusion:
[Developer Name] hereby attests that it is a self-developer exempt from the disclosure requirements at 45 CFR §170.523(k)(1)(iii) and 170.523(k)(2). [Developer Name] further attests that as a self-developer it does not and will not market, sell or license its certified Health IT Module(s).

The failure of a health IT developer to disclose the required information is a violation of an explicit certification program requirement and thus constitutes a non-conformity.

A developers' adherence to their attestations is voluntary, however ICSA Labs is required to include the developers’ attestations in the hyperlink submitted to the National Coordinator for inclusion in the CHPL so that the public can determine which developers have attested to taking the additional actions to promote transparency of their technologies and business practices. ONC notes that a developer’s attestation under 45 CFR § 170.523(k)(2) does not broaden or change the scope of the information a developer is required to disclose under 45 CFR § 170.523(k)(1).

ICSA Labs administers the transparency attestation requirement by including it as part of new 2015 Edition certification registrations, the update process for previously certified products, and as part of the follow up that is required for quarterly reporting information.
Developer Complaints Processes

Vendors and product developers are required to provide details of their complaint handling process for complaints relating to the scope of functionality certified in the ONC Health IT Certification Program. These processes may be reviewed and verified by ICSA Labs as part of ongoing post-certification surveillance procedures.

The complaint handling process will include details as to how customers can report defects or make complaints about the product including:

- Methods customers can use to report the issue
- The process used to track the issue
- The process used to analyze the issue
- How issues are resolved
- How customers are subsequently notified

All product developers must also:

- Provide ICSA Labs with documentation outlining internal complaint handling processes;
- Maintain a record of all customer complaints related to a product's compliance with the ONC Health IT Certification criteria against which it was tested; and
- Retain a log of actions taken in response to such complaints.

The complaint handling processes of any developer whose technology was subject to surveillance during the applicable calendar year will be reviewed by ICSA Labs to determine whether the appropriate actions were taken as reported in their complaint handling processes. If the issues were not properly addressed, ICSA Labs will follow up, as necessary with the vendor/developer and end user as a next step and report to ONC.

ICSA Labs and ONC Health IT Certified Logos and Usage Guidelines

Once the customer has been notified by ICSA Labs that certification has been granted, the applicant may begin using the ICSA Labs and the ONC Health IT Certified logos. Use of both logos is optional; however, they must be used in accordance with their respective Usage Guidelines and Terms and Conditions. These guidelines and terms and conditions are provided to the customer in electronic format after certification is granted.

As a reminder, your ONC Health IT Certified status applies specifically to your technology, not your company as a whole. For this reason, use of these logos must be clearly attributed to the product that received certification. Any use of these logos must include your product name, version number and all marketing details required by the final rule (see 45 CFR 170.523(k)(1) under ONC Guidelines above), including any additional types of costs that a customer is required to incur to implement a certified Complete or certified EHR module and attempt to meet MU objectives and measures for attestation.

Press Releases

All marketing materials related to certified products must adhere to the guidelines posted in the “ONC Guidelines” section above. Any press release that includes information about ICSA Labs must undergo a review and approval process by the ICSA Labs Public Relations (PR) department. Please be advised that this process can take 5 business days or longer. Applicants are encouraged to begin the draft press release approval process as early as possible to
ensure that there are no delays in announcing a newly certified product. ICSA Labs can provide a template for the press release that may expedite the approval process and provide additional direction based on internal PR guidelines.

Additional Resources
Please review the following sources for additional information for more information:

- ICSA Labs Website – Certification
- ONC Regulation FAQs on the Health IT Certification Program
- Additional information about the ONC’s Certified Health IT Product List (CHPL)
- 2014 Edition Test Methods
- 2015 Edition Test Methods
- Criteria and Terms of Usage for the ONC Health IT Certification Mark
- ONC Regulations Related to the Health IT Certification Program
- ONC Program Guidance on Product Surveillance
- ONC Policy Guidance on Product Identification and Versioning
- ONC Policy Guidance on Self-Declaration Approach for ONC-Approved Test Procedure
- ONC Policy Guidance on the Certification Ban

NOTE: Hyperlinks followed by this symbol may download documents automatically or may open in a new site where a file is automatically downloaded, as determined by the user’s browser settings.

Contact
For more information about ICSA Labs’ ONC Health IT Certification Program, contact us at EHR@icsalabs.com.

ICSA Labs
1000 Bent Creek Blvd, Suite 200
Mechanicsburg, PA 17050
www.icsalabs.com