The ONC Health IT Certification Program

Certifying systems for electronic health records

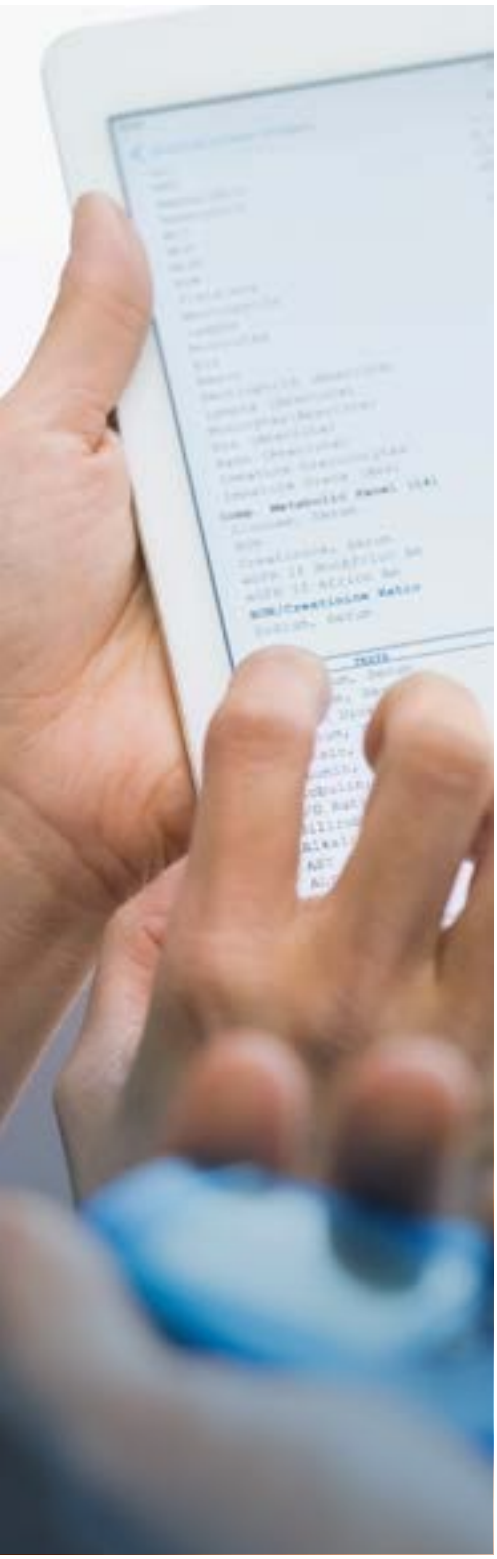
Empowering Trust™

Executive summary

The increased use of electronic health records (EHRs) is helping to transform patient healthcare in the U.S. and around the world. As the healthcare industry strives to implement the most advanced health information technologies available, EHR systems are facilitating the efficient exchange of vital patient information between providers while also speeding up insurance reimbursements and helping control costs. At the same time, the confidentiality of vital patient information is paramount, making the integrity and security of EHR systems a key requirement.

In the U.S., the Office of the National Coordinator for Health Information Technology (ONC Health IT) within the Department of Health and Human Services (HHS) has established minimum requirements for IT systems that store and process EHRs. As part of the agency's overall effort to promote the adoption and use of secure EHR systems, healthcare providers that use systems certified to ONC Health IT requirements are eligible to receive incentive payments and are not subject to Medicare or Medicaid program payment penalties. As a result, the ONC Health IT Certification Program is making an important contribution to ensuring timely and effective access to accurate patient healthcare information.

This UL white paper discusses the ONC Health IT Certification Program for developers of EHR software systems and modules, and details specific aspects of the system certification process. The paper also provides information on UL's ONC Health IT certification services.



About the ONC Health IT Certification Program

The ONC Health IT Certification Program is an essential aspect of efforts by the U.S. Centers for Medicare and Medicaid (CMS) to control healthcare costs and improve treatment outcomes. Under the CMS's Electronic Health Record Incentive Programs, Medicare and Medicaid payments to clinicians, health clinics and hospitals can be adjusted to reflect the implementation and use of qualified EHR modules and systems designed to make healthcare administrative processes more efficient. These incentive programs are expected to drive improvements in administrative efficiencies and to increase clinical effectiveness, thereby helping to ensure better outcomes for patients while also controlling the overall cost of care.

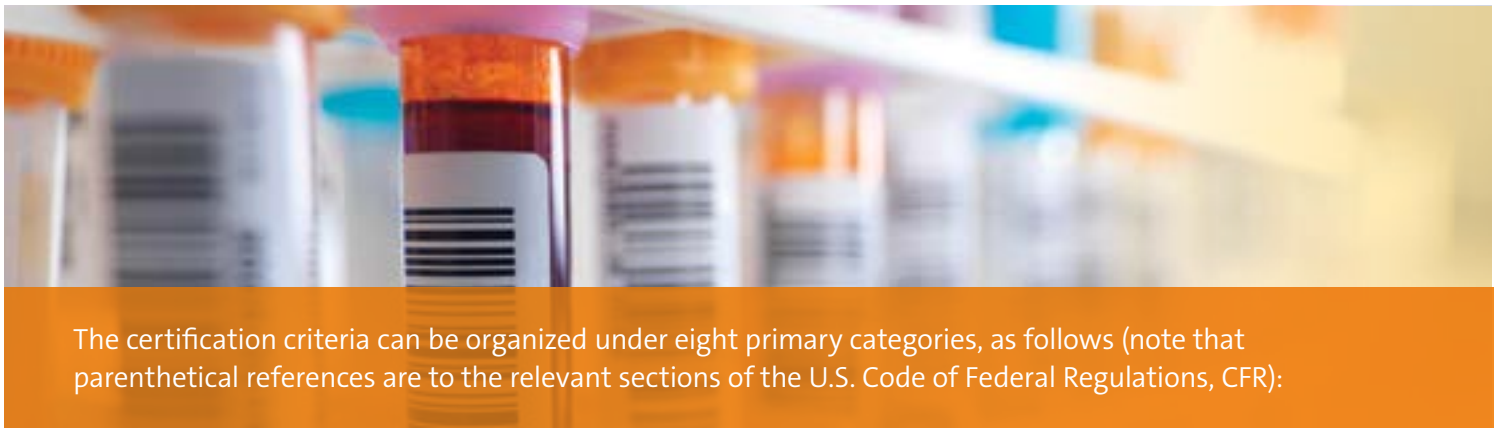
To qualify under any of the CMS Incentive Programs, an EHR software module or system must conform with specific, CMS-defined requirements. These requirements have been codified by the ONC in its "Health Information Technology (Health IT) Certification Criteria.[1]" Originally published in 2014, the Certification Criteria were last updated in October 2015 to better reflect advances in IT technologies, and to increase the minimum level of functionality for EHR modules and systems established under the CMS's Stage 3 implementation of its requirements.

ONC Health IT Certification assessments are conducted by independent testing laboratories that have been authorized under the National Voluntary Laboratory Accreditation Program (NVLAP) and administered by the National Institute of Standards and Technology (NIST). These authorized testing laboratories (ATLs) conduct health IT conformity testing in accordance with the requirements set forth in the ONC's Health Information Certification Criteria. ATL test results are then submitted to an ONC-approved certification body (ACB), which verifies compliance with ONC requirements and issues the actual EHR module or system certification.

ACBs are also responsible for conducting post-certification surveillance activities to help ensure ongoing compliance with ONC requirements in the field under actual use conditions. Surveillance of certified EHR modules and systems can include both random assessments and testing, as well as assessments conducted in response to a specific, identified concern or complaint. When such an assessment identifies a module or system that does not comply with the original certification requirements, the developer or manufacturer of that product must work with the ONC to develop a corrective action plan to bring it back into compliance.

An overview of ONC Health IT Certification requirements

The CMS's criteria under its Stage 3 implementation can now be applied to all EHR modules and systems seeking ONC Health IT certification. Initially implemented in 2017, specific requirements under Stage 3 are detailed in the 2015 Edition of the ONC's Certification Criteria. The 2015 Edition retains 16 separate certification criteria from the 2014 Edition, and adopts 19 new criteria intended to align with the key objectives that healthcare service providers must meet to comply with the Stage 3 requirements. As a result, there are 60 separate criteria applicable to the certification of EHR modules and systems under the ONC Health IT certification program.



The certification criteria can be organized under eight primary categories, as follows (note that parenthetical references are to the relevant sections of the U.S. Code of Federal Regulations, CFR):

Clinical criteria

Criteria under this category include:

- Computerized provider order entry (CPOE) for medications, laboratory tests and diagnostic imaging (170.315(a)(1-3))
- Drug-drug and drug-allergy interactions (170.315(a)(4))
- Drug formulary and preferred drug list check (170.315(a)(10))
- Clinical decision support (170.315(a)(9))
- Patient information, including: demographics (170.315(a)(5)); family health history (170.315(a)(12)); smoking status (170.315(a)(11)); and patient-specific education resources (170.315(a)13))
- Lists, including: problems (170.315(a)(6)); medications (170.315(a)(7)); and medication allergies (170.315(a)(8))
- Implantable devices (170.315(a)(14))
- Social, psychological and behavioral data (170.315(a)(15))

Care coordination

Criteria under this category include:

- Transitions of care documents (170.315(b)(1))
- Clinical information reconciliation and incorporation (170.315(b)(2))
- Electronic prescribing (170.315(b)(3))
- Common Clinical Data Set summary record—create (170.315(b)(4)), and receive (170.315(b)(5))
- Data export (170.315(b)(6))
- Data segmentation for privacy—send (170.315(b)(7)) and receive (170.315(b)(8))
- Care plan (170.315(b)(9))

Certification criteria continued:

Clinical quality measures (CQMs)

Criteria under this category include:

- Record and export (170.315(c)(1))
- Import and calculate (170.315(c)(2))
- Report (170.315(c)(3))
- Filter (170.315(c)(4))

Privacy and security

Criteria under this category include:

- Authentication, access control, authorization (170.315(d)(1))
- Auditable events and tamper-resistance (170.315(d)(2))
- Audit reports (170.315(d)(3))
- Amendments (170.315(d)(4))
- Automatic access time-out (170.315(d)(5))
- Emergency access (170.315(d)(6))
- End-user device encryption (170.315(d)(7))
- Integrity (170.315(d)(8))
- Trusted connection (170.315(d)(9))

Patient engagement

Criteria under this category include:

- View, download and transmit to third parties (170.315(e)(1))
- Secure messaging (170.315(e)(2))
- Patient health information capture (170.315(e)(3))

Public health

Criteria under this category include:

- Transmission to immunization registries (170.315(f)(1))
- Transmission to public health agencies—syndromic surveillance (170.315(f)(2))
- Transmission to public health agencies—reportable lab tests and values/results (170.315(f)(3))
- Transmission to cancer registries (170.315(f)(4))
- Transmission to public health agencies—electronic case reporting (170.315(f)(5))
- Transmission to public health agencies—antimicrobial use and resistance reporting (170.315(f)(6))
- Transmission to public health agencies—health care surveys (170.315(f)(7))

Design and performance

Criteria under this category include:

- Automated numerator recording (170.315(g)(1)) and automated measure calculation (170.315(g)(2))
- Safety enhanced design (170.315(g)(3))
- Quality management system (170.315(g)(4))
- Accessibility-centered design (170.315(g)(5))
- Consolidated CDA creation performance (170.315(g)(6))
- Application access, including: patient selection (170.315(g)(7)); data category request (170.315(g)(8)); and all data request (170.315(g)(9))

Transport methods

Criteria under this category include:

- Direct Project (170.315(h)(1))
- Direct Project, Edge Protocol and XDR/XDM (170.315(h)(2))

The ONC has published certification companion guides and test procedures for each of the 60 specified criteria.[2] These guides and test procedures provide detailed information that can be extremely useful to EHR developers seeking to achieving compliance with the certification requirements.

The certification process

For developers of EHR software modules and systems, the process of achieving and maintaining ONC Health IT certification typically involves four separate steps, as follows:

Pre-testing

Given the scope and complexity of the requirements with which EHR software modules and systems must comply, developers often request pre-testing in advance of the actual testing by an ATL. Pre-testing can provide important insights into how a product will fare in the formal evaluation against the applicable certification criteria, and help to identify those areas where a product is not compliant. With this information, developers can then work to address and correct any non-conforming aspects of their product ahead of testing, thereby increasing the likelihood of a successful testing outcome and reducing the time and costs required for retesting.

Testing by an authorized testing laboratory

During the formal testing process, personnel at the ATL will conduct a full-scale evaluation of the EHR software module or system against all of the applicable criteria, either at the ATL's testing location or at the developer's facility. In both cases, the EHR module or system to be tested is set up to function as intended, using any supplementary software as required. Actual testing is conducted by ATL personnel, who then evaluate the results of each test to determine whether the product meets the requirements of each criterion. In some cases, there may be an opportunity within the time allotted to address problems or non-compliances to help facilitate a successful outcome. Upon completion of the formal testing, the ATL will prepare a comprehensive report of the testing conducted and results.

Review and certification by an approved certification body (ACB)

The test report and certification application are then forwarded to the designated ACB for review. First, an ACB reviewer evaluates the certification application and compares it with the marketing material associated with the EHR module or system being submitted to verify consistency between the submitted product and the product's stated application or use. Then, personnel reviews the ATL's test report and any supplemental materials submitted with the certification application to verify the product's compliance with the applicable requirements, and then forwards the certification application and ATL test report to the ACB certifier with their recommendation for certification.

Once an EHR software module or system has been approved for certification, the ACB forwards the relevant product information to the ONC for posting on its publicly-available Certified Health IT Product List (CHPL) where interested parties can verify the certification status of any certified product. The product is permitted to bear the ONC Certified Health IT Certification and Design mark as evidence of its compliance with the standards and certification criteria of the ONC Certified Health IT Program.

Post-certification assessments and responsibilities

All health IT-certified EHR modules and systems are subject to surveillance activities conducted by the ACB as a condition of their certification. As previously noted, this surveillance can consist of random checks of post-market software modules and systems, as well as reviews prompted by a specific, identified concern or complaint. In addition to surveillance initiated by the ACB, the ONC itself can conduct a review of certified modules and systems in specified instances, such as when there is a reasonable belief that the product may present a serious risk to public health or safety.

Developers of software modules and systems certified under the ONC Health IT Certification Program are also required to submit each calendar quarter an attestation of any changes or adaptations of a certified product that may affect aspects essential to the initial certification. Developers are also obligated to maintain records of any complaints received, to take appropriate steps to address those complaints and to document the actions that were taken.

Finally, developers seeking to maintain certification of EHR modules and systems that have been subsequently modified must contact their ATL to determine whether the modifications affect any of the product's previously certified capabilities, and the extent to which retesting may be required. Retesting and recertification are also required in cases where new features or capabilities are added to meet additional ONC Health IT certification criteria.

UL's role in the ONC Health IT Certification Program

Through its InfoGard subsidiary, UL has participated in the ONC Health IT Certification Program since its inception in 2010, and is both an ATL and an ACB under the program. EHR testing services can be performed either on-site at the developer's facility, on-site at UL or remotely. The testing process and procedures are based on the specific needs of the certification applicant, and are designed to support a successful testing outcome. Pre-testing consultation is also available, which can help to reduce testing time by identifying potential issues in advance.

As an ACB, UL can also conduct a review of test reports prepared by NVLAP-authorized testing laboratories to determine if an EHR software module or system qualifies for certification. If additional testing is required, UL works with the testing laboratory to address issues that require further clarification. Once all testing has been successfully completed and all requirements have been met, UL certifies the module or system and forwards the relevant product information to the ONC for posting on its CHPL website.

UL-certified products are also approved to bear the ONC Certified Health IT Mark, as well as UL's Certified EHR Logo, signifying that the product meets the ONC's requirements. Finally, UL-tested and certified EHR modules and systems are listed on UL's own EHR Certified Product List at **https://industries.ul.com/medical-and-laboratory/healthcare-it-security/ehr-certificate-list.**

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Summary + conclusion

The ONC's Health IT Certification Program is a vital tool in efforts to help ensure the quality and security of EHR software modules and systems, and directly supports the work necessary to achieve a more efficient and cost-effective healthcare system in the U.S. However, for EHR developers, achieving Health IT certification for their products can be a lengthy and complex process that, if not managed properly, can delay the introduction of new and innovative EHR technologies. A thorough understanding of the ONC's requirements and the criteria for certification under the Health IT Certification Program can help streamline the testing and certification process, and increase the likelihood of achieving certification.

As both an ATL and an ACB under the ONC Health IT Certification Program, UL has an in-depth understanding of the testing and certification requirements applicable to EHR software modules and systems. UL is also intimately familiar with the various Medicare and Medicaid incentive programs for healthcare providers, and can assist EHR developers in understanding the requirements of the incentive programs of greatest importance to their current and prospective target markets.

For further information about UL's testing, certification and advisory services in support of the ONC's Certified Health IT Program, or to learn more about UL's other Healthcare IT and security offerings, visit https://industries.ul.com/medical-and-laboratory/healthcare-it-security/onc-hit-certification or contact Milton Padilla at milton.padilla@ul.com.

End notes

1. "2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (HER) Definition, and ONC Health IT Certification Program Modifications," U.S. Department of Health and Human Services, published in the U.S. Federal Register, October 16, 2015. Web. 11 February 2018. https://www.federalregister.gov/documents/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base.

2. "Testing and Test Methods: 2015 Edition Test Method," at the HealthIT.gov website. Web. 11 February 2018. https://www.healthit.gov/policy-researchers-implementers/2015-edition-test-method.