



“ONC Health IT Certification Program: Enhanced Oversight and Accountability”

Final Rule Fact Sheet

The Office of the National Coordinator for Health Information Technology (ONC) issued the “ONC Health IT Certification Program: Enhanced Oversight and Accountability” final rule on October 14, 2016. The final rule is available at <http://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations>.

The final rule updates the ONC Health IT Certification Program (Program) to provide enhanced oversight and health information technology (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 Bodies (ONC-ACBs), and makes a more comprehensive set of ONC-ACB surveillance results publicly available. These three areas are discussed further below.

ONC Direct Review of Certified Health IT

The final rule 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. More specifically, the final rule:

- **Supports Provider Confidence in Certified Health IT through a Direct Review Process.** Through this final rule, ONC articulates a regulatory framework for directly reviewing certified health IT to determine if non-conformities with certified health IT exist in the circumstances listed above. ONC’s review will focus on capabilities and aspects of health IT that are certified under the Program, including whether the capabilities of certified health IT perform properly when they interact with other capabilities or products. The review of those other capabilities or products would be limited to the extent necessary to determine whether the certified capabilities are functioning in a manner consistent with Program requirements.



- **Facilitates ONC and Health IT Developers Working Together to Create Corrective Action Plans to Address Problems.** ONC will provide direction and approve comprehensive corrective action plans for health IT developers to address non-conformities, including notifying affected customers. As highlighted in the final rule, ONC's intent is to help health IT developers identify and address non-conformities in the health IT that providers use to support patient care. Corrective action plans will support that intent, and ONC intends to work with health IT developers to remedy any non-conformities in a timely manner and across all customers. When necessary, ONC may suspend and/or terminate a certification issued to certified health IT and—in such situations—a health IT developer would be provided an opportunity to appeal ONC's determination. In cases of termination, ONC will coordinate with other Department of Health and Human Services programs, such as the Medicare and Medicaid Electronic Health Record Incentive Programs, to help identify and make available appropriate remedies to users of terminated certified health IT.

ONC-Accredited Testing Labs (ONC-ATLs)

The final rule puts in place processes for ONC to have more direct oversight of testing labs under the Program. The finalized approach and processes will create an authorization and oversight paradigm for ONC-ATLs similar to the processes that exist today for ONC-ACBs.

ONC will now authorize testing labs to become ONC-ATLs through a formal application process. The final rule also specifies the means for retaining and, when necessary, suspending and revoking ONC-ATL status under the Program. These updates to the testing lab process support ONC's commitment to overseeing and addressing testing and certification performance issues throughout the continuum of the Program.

Transparency and Availability of Surveillance Results

The final rule will require ONC-ACBs to make identifiable surveillance results publicly available on the web-based [Certified Health IT Product List \(CHPL\)](#) 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.

This information will also benefit health IT developers that perform well. To date, ONC only lists corrective action plans for non-conformities on the CHPL. Through this final rule, ONC will provide more complete information that illuminates good performance and continued conformity with Program requirements for certified health IT.