# Fact Sheet

## "ONC Health IT Certification Program: Enhanced Oversight and Accountability" Proposed Rule

The Office of the National Coordinator for Health Information Technology (ONC) issued the "ONC Health IT Certification Program: Enhanced Oversight and Accountability" proposed rule ("proposed rule") on March 1, 2016. The proposed rule is open for public comment from March 2 until May 2, 2016 and is available at http://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations.

The proposed rule would modify the ONC Health IT Certification Program ("Program") and focuses on three areas:

ONC Direct Review of Certified Health IT

At present, review of certified health IT occurs through ONC-Authorized Certification Bodies (ONC-ACBs). We are now proposing that, in addition to such review, ONC would be able to directly review certified health IT ("direct review") and take actions when necessary that would promote health IT developer accountability for the performance, reliability, and safety of health IT. ONC's first and foremost goal will be to work with health IT developers to remedy any non-conformities with certified health IT in a timely manner and across all customers, potentially eliminating the need for suspension and/or termination processes. These provisions are a complement to the current paths of review for certified health IT through ONC-ACBs and provide an additional tool to address public health and safety issues that may arise.

The proposed rule includes provisions to:

- Directly review health IT certified under the Program, independent of and in addition to an ONC-ACB's role,;

- Enable ONC to assess non-conformities, including those that pose a risk to public health and safety, which may be caused by the interaction of certified and uncertified capabilities within certified health IT;

- Prescribe comprehensive corrective actions for health IT developers to address non-conformities, including notifying affected customers;

- Enable ONC to suspend and/or terminate a certification issued to a Complete Electronic Health Record (EHR) or Health IT Module;

- Institute processes for prohibiting further testing and certification of any health IT that a health IT developer brings to ONC if a found non-conformity is not first corrected or will be corrected through the release of new certified health IT.

## Oversight of ONC-Authorized Testing Laboratories

The proposed rule includes provisions that would enable ONC to conduct direct oversight of National Voluntary Laboratory Accreditation Program-accredited testing laboratories (labs) by proposing that they apply to become ONC-Authorized Testing Labs (ONC-ATLs). ONC is also proposing to establish processes for authorizing, retaining, suspending, and revoking ONC-ATL status under the Program.

The proposed approach and processes would create an authorization and oversight paradigm for testing labs that is similar and comparableto  to the paradigm that currently exists for ONC-ACBs. This approach would enable ONC to oversee and address testing and certification performance issues throughout the entire continuum of the Program in an immediate, direct, and precise manner.

## Transparency and Availability of Surveillance Results

The proposed rule includes provisions that would require ONC-ACBs to make identifiable surveillance results publicly available on their websites quarterly. This would enhance the transparency and accountability of health IT for customers and users by providing valuable information about the continued performance of certified health IT. The public availability of identifiable surveillance results would also provide a more complete context of surveillance by making more information about certified products available to purchasers and enabling health IT developers to note their continued compliance with Program requirements.