The Office of the National Coordinator for Health Information Technology

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

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Agenda

- ONC Direct Review of Certified Health IT
- ONC-Authorized Testing Laboratories (ONC-ATLs)
- Transparency and Availability of Identifiable Surveillance Results

The Final Rule…

- **Does not** create new certification criteria; or requirements for health IT developers not under direct review
- **Does not** create new certification/health IT requirements for providers participating in HHS programs
- **Does not** establish a means for ONC to directly test and certify health IT (ONC-ACBs will continue to test and certify)
- **Does not** establish regular or routine auditing of certified health IT by ONC

- **Does** establish a regulatory framework for ONC to directly review already certified health IT products
- **Does** increase ONC oversight of health IT testing bodies
- **Does** increase transparency and accountability by making identifiable surveillance results of certified health IT publicly available

ONC Direct Review of Certified Health IT

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- Support greater accountability for health IT developers under the Program
- Provide greater confidence to purchasers and users that health IT conforms to Program requirements when it is implemented, maintained, and used
- Sets up a process for ONC to work with health IT developers to remedy any identified non-conformities of certified health IT in a timely manner

ONC Direct Review of Certified Health IT

With the vast majority of physicians and hospitals now using certified health IT, ONC plays an important role in helping ensure that these products operate safely and reliably in the field.

- ONC direct review will:
  - **Be independent of (and may be in addition to) ONC-ACBs' surveillance** and other functions under the Program
  - **Focus on capabilities and aspects of health IT that are certified under the Program** (i.e., "**certified capabilities**"), taking into consideration other relevant functionalities or products to the extent necessary to determine whether certified health IT is functioning in a manner consistent with Program requirements
  - **Focus on circumstances involving:**
    1. **Potential risks to public health or safety; or**
    2. **Practical challenges that may prevent ONC-ACBs from carrying out their surveillance responsibilities**

ONC Direct Review of Certified Health IT

- **Serious Risk to Public Health or Safety**
  - ONC may initiate direct review if it has a reasonable belief that certified health IT may not conform to Program requirements because the certified health IT may be causing or contributing to conditions that present a serious risk to public health or safety
  - ONC will consider:
    - The potential nature, severity, and extent of the suspected conditions;
    - The need for an immediate or coordinated government response; and
    - If applicable, information that calls into question the validity of the health IT's certification or maintenance thereof under the Program.
- **Impediments to ONC-ACB Oversight**

  ONC may initiate direct review if it has a reasonable belief that certified health IT may not conform to Program requirements **and** the suspected non-conformity presents issues that:
  - May require access to confidential or other information that is unavailable to an ONC-ACB;
  - May require concurrent or overlapping reviews by multiple ONC-ACBs; or
  - May exceed an ONC-ACB's resources or expertise.
- **Examples – Six examples in the final rule (A through F (3-part example)) (81 FR 72420-25)**

Notice of Potential Non-Conformity & Notice of Non-Conformity

Notice of Potential Non-Conformity

- There **may be** a non-conformity with the certified health IT
- Developer must respond to ONC and/or third-party acting on behalf of ONC by (1) cooperating, (2) providing access to the certified health IT under review, and (3) providing a written explanation, within 30 days, unless adjusted by ONC, addressing the potential non-conformity

Notice of Non-Conformity

- There **is an actual** non-conformity with the certified health IT
- Must respond in the same fashion as for a notice of potential non-conformity and must submit a proposed corrective action plan (CAP)

Focusing on the Fix – Corrective Action Plan (CAP)

- The CAP process allows ONC to work with developers to address issues that arise.
- CAPs require health IT developers to:
  - Notify all potentially affected customers of the non-conformity and plan for resolution;
  - Attest and provide documentation that the non-conformity and all issues were resolved in the specified timeframe; and
  - Explain, and agree to execute, the steps that will prevent the non-conformity from re-occurring.

Focusing on the Fix - Communicate with Health IT Developers

- Communication with developers to successfully address any non-conformities is a key component of the process
- The direct review process includes opportunities for developers to respond to ONC concerns, and to appeal suspension and termination determinations made by ONC. For example:
  - Respond to a notice of potential non-conformity
  - Respond to a notice of non-conformity
  - Develop a CAP based on instruction and feedback from ONC (as discussed in the previous slide)

Keeps Clinicians and Users Informed Throughout the Process

- Developers are required to notify all potentially affected customers of the non-conformity and the plan for a resolution as part of CAPs that may result from direct review
- Developers must notify customers when the certification of their health IT is suspended or terminated, which ONC will also post on the ONC Certified Health IT Products List
- ONC will coordinate with other Department of Health and Human Services programs, such as the Advancing Care Information/Medicare and Medicaid Electronic Health Record Incentive Programs, to help identify and make available appropriate remedies to users of terminated certified health IT

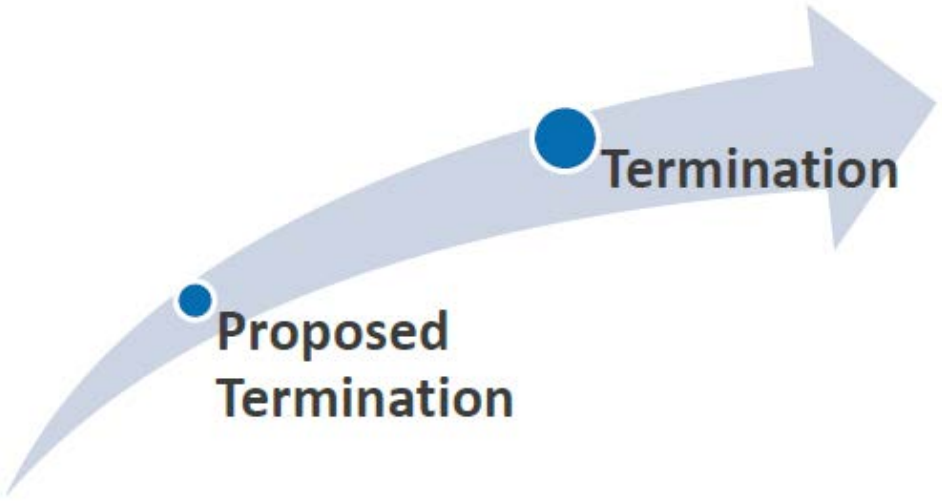
Suspension

- Limited the scope for suspension of certified health IT to when ONC has a reasonable belief that the certified health IT **may present a serious risk to public health or safety**

  - ONC would consider the nature, extent, and severity of the risk and the conditions giving rise to it, in light of the information available to ONC at the time
  - Separately, ONC could conclude that certified health IT poses a serious risk to public health or safety were it aware of information calling into question the validity of the health IT's certification

Proposed Termination

- Added a step to the direct review process, called **"proposed termination**," which calls on ONC to propose to terminate a certification issued to a Complete EHR or Health IT Module **before** an actual termination can occur
  - » Provides developers with additional opportunities to correct non-conformities, and work with and engage with ONC during direct review



Appeal

- Finalized a two-step process for filing a statement of intent to appeal and then filing the appeal and supporting documentation:

  - **Statement of intent to appeal** must be filed within 10 days of receipt of the notice of suspension or notice of termination

  - **Appeal**, including all supporting documentation, must be filed within 30 days of the filing of the intent to appeal

- Any ONC written statement must be provided to the health IT developer **within 15 days** of the health IT developer's filing of an intent to appeal.

Certification Ban

- Prohibits the certification of health IT, unless it serves to correct the non-conformity. This may incentivize a health IT developer to cure non-conformities and remedy the situation for affected customers.
  - » Health IT is tested and certified to meet adopted certification criteria and requirements and should continue to meet those certification criteria and requirements when implemented
  - » ONC intends to work with health IT developers to correct non-conformities

- We have provided additional clarity and flexibility for health IT developers to meet the requirements for lifting a Certification Ban.
  - » ONC makes determinations regarding the lifting of a Certification Ban in **all** circumstances
  - » Health IT developers must demonstrate, and ONC is satisfied, that all non-conformities have been addressed and the correction is made available for all affected customers w/appropriate remediation
  - » Appropriate remediation can be achieved through various means (e.g., make a replacement version available, obtaining a customer release, or obtaining an alternative health IT developer's certified product)

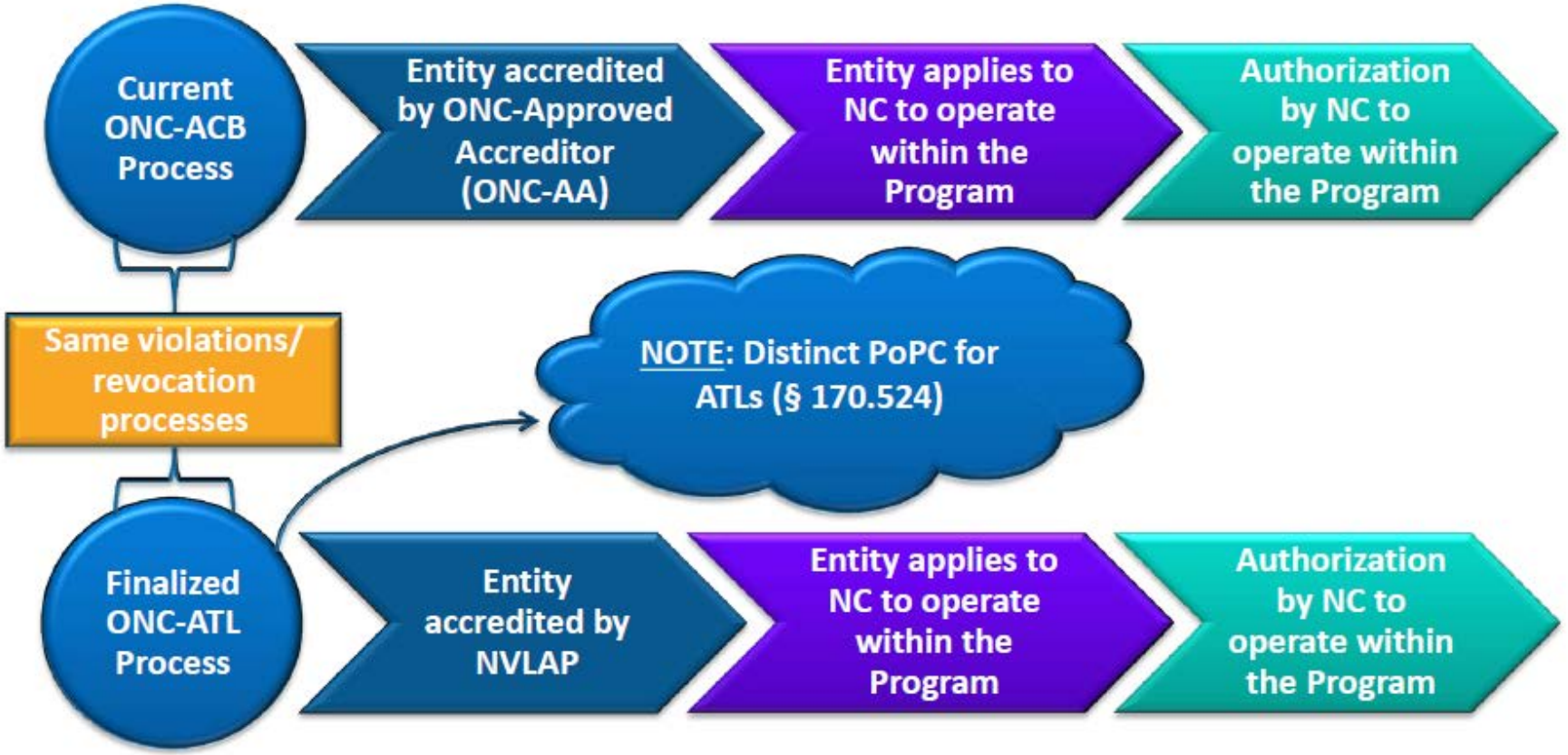
Note: Provisions of the Certification Ban are not effective until the final rule is effective on December 19, 2016.

ONC-Authorized Testing Laboratories (ONC-ATLs)

ONC-ATLs

- Establishes regulatory processes for ONC to have more direct oversight of testing labs under the Program. These processes are similar to the ONC-ACB processes.
- Provision enables ONC to oversee and address testing and certification performance issues throughout the entire continuum of the Program in an immediate, direct, and precise manner, including by:
  - Authorizing testing labs as ONC-ATLs.
    - Does not require labs applying for ONC-ATL status to obtain additional accreditation beyond NVLAP accreditation for health IT testing
  - Specifying requirements for retaining ONC-ATL status and means for ONC to suspend and revoke ONC-ATL status under the Program.

Comparison of ONC-ATL and ONC-ACB Processes



Transparency and Availability of Identifiable Surveillance Results

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- Requires ONC-ACBs to make identifiable surveillance results publicly available on the web-based Certified Health IT Product List (CHPL) on a quarterly basis.
- The information will include:
  - The names of health IT developers;
  - Names of products and versions;
  - Certification criteria and Program requirements surveilled;
  - Identification of the type of surveillance (i.e., reactive and randomized);
  - The dates of surveillance was initiated and completed;
  - The number of sites that were used in randomized surveillance; and
  - The results of surveillance.
- Results will first be posted no later than early April 2017.
- Further enhances transparency and provide customers and users of certified health IT with valuable information about the overall conformity of certified health IT to Program requirements.