The Office of the National Coordinator for
Health Information Technology

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

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Agenda

✓ ONC Direct Review of Certified Health IT

 » Authority and Scope

 » ONC-Authorized Certification Bodies' (ONC-ACBs') Role

 » Review Processes

 » Consequences of Certification Termination

✓ ONC-Authorized Testing Laboratories (ONC-ATLs)

✓ Public Availability of Identifiable Surveillance Results

✓ Public Comment

✓ Additional Information and Resources

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The Proposed Rule...

- **Would not** create new certification requirements for health IT developers

- **Would not** create new certification/health IT requirements for providers participating in HHS programs

- **Would not** establish a means for ONC to directly test and certify health IT (ONC-ACBs will continue to test and certify)

- **Would not** establish regular or routine auditing of certified health IT by ONC

- **Would enable** ONC to directly review already certified health IT products

- **Would enable** increased ONC oversight of health IT testing bodies

- **Would enable** increased transparency and accountability by making identifiable surveillance results of certified health IT publicly available

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ONC Direct Review of Certified Health IT – Proposal

- Proposal (§ 170.580): Expand ONC's role in the ONC Health IT Certification Program ("Program") to encompass the ability to directly review health IT certified under the Program and when necessary, take corrective action, including the suspension and termination of certified health IT

- ONC Direct review would:

  - » Be independent of, and may be in addition to, reviews conducted by ONC-ACBs

  - » Extend beyond the continued conformance of the certified health IT's capabilities with the specific certification criteria, test procedures, and specific certification requirements

  - » Extend to the interaction of all capabilities within the certified health IT with certified capabilities and the interaction of all capabilities with other products

  - » Focus on situations that pose a **risk to public health or safety** and other exigencies

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ONC Direct Review of Certified Health IT – Goals

- Carry out the National Coordinator's responsibilities under Section 3001 of the Public Health Service Act (PHSA)

- Support greater accountability for health IT developers under the Program

- Provide greater confidence that health IT conforms to Program requirements

- Work with health IT developers to remedy any identified non-conformities of certified health IT in a timely manner
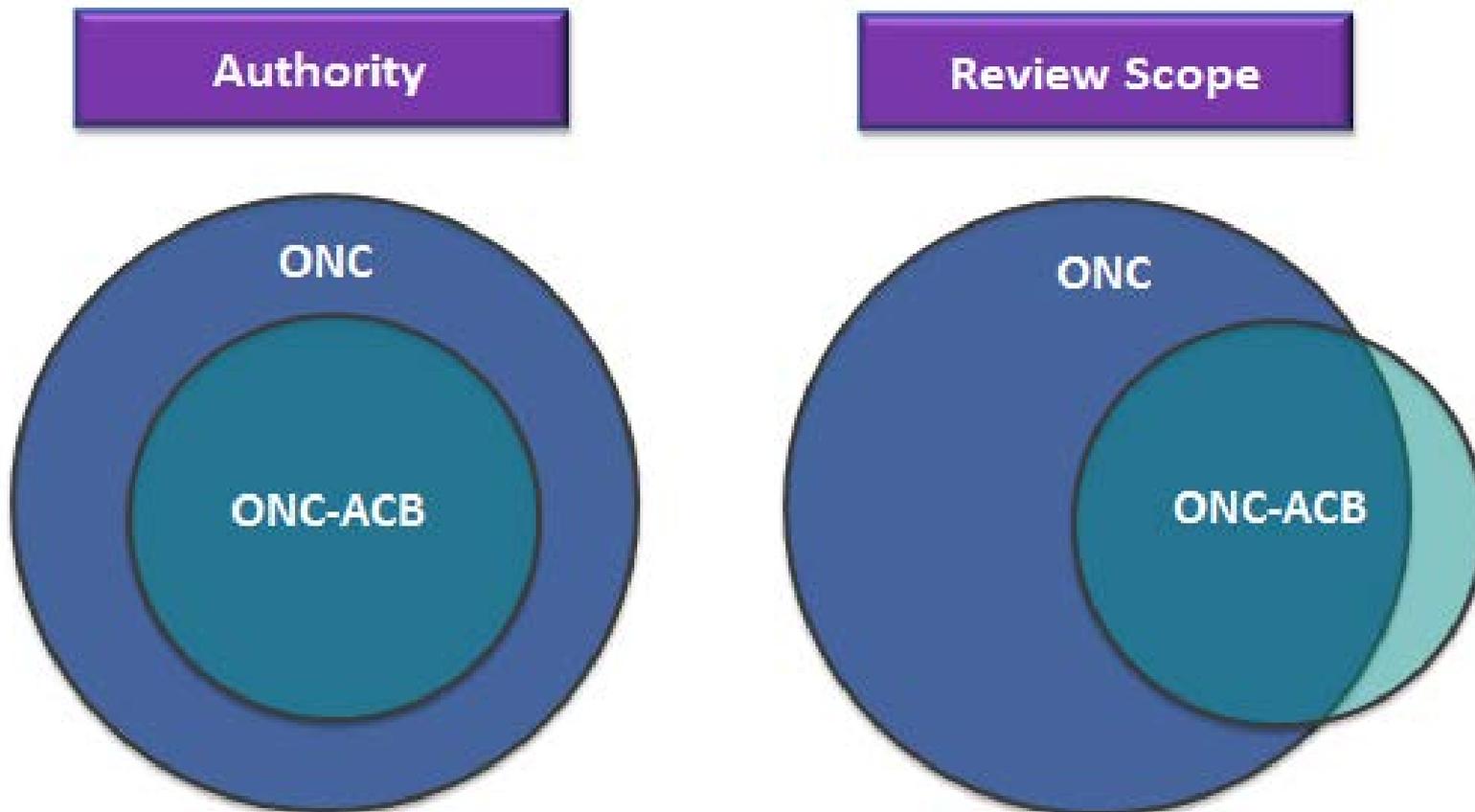
ONC Direct Review of Certified Health IT – An ONC-ACB's Role

3 Types of Review

ONC Only Review	ONC-ACB Only Review	Both
• **Examples**: Risk to public health or safety and other exigencies	• **Examples**: Developer does not follow ONC-ACB direction; certain ONC-ACB terminations	• **Examples**: Issues partially within ONC-ACB's purview that present special challenges or considerations

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Non-Conformity: Certified health IT that does not conform to the requirements of its certification or is, for example, leading to medical errors, breaches in the security of a patient's health information, or other outcomes that are in direct opposition to the National Coordinator's responsibilities under section 3001 of the PHSA.


One capability negatively impacts the functioning of the certified health IT

Examples of Non-Conformities That Could Warrant ONC Direct Review

» Developer has **products certified by 2 different ONC-ACBs** and a potential non-conformity w/certified capability may extend across all developers' certified health IT

» **Systemic, widespread, or complex issues** (e.g., certain fraudulent activities) that could be difficult for an ONC-ACB to investigate or address in a timely, effective manner

» **Risk to public health or safety**, including, for example, capabilities (certified or uncertified) of health IT directly contributing to or causing medical errors

» **Other exigencies** such as a non-conformity that could compromise the security or protection of patients' health information in accordance w/applicable law or that could lead to inaccurate or incomplete documentation and resulting inappropriate or duplicative care under federal health care programs

» **Issues w/confidential information** or information that cannot be shared w/ONC-ACB

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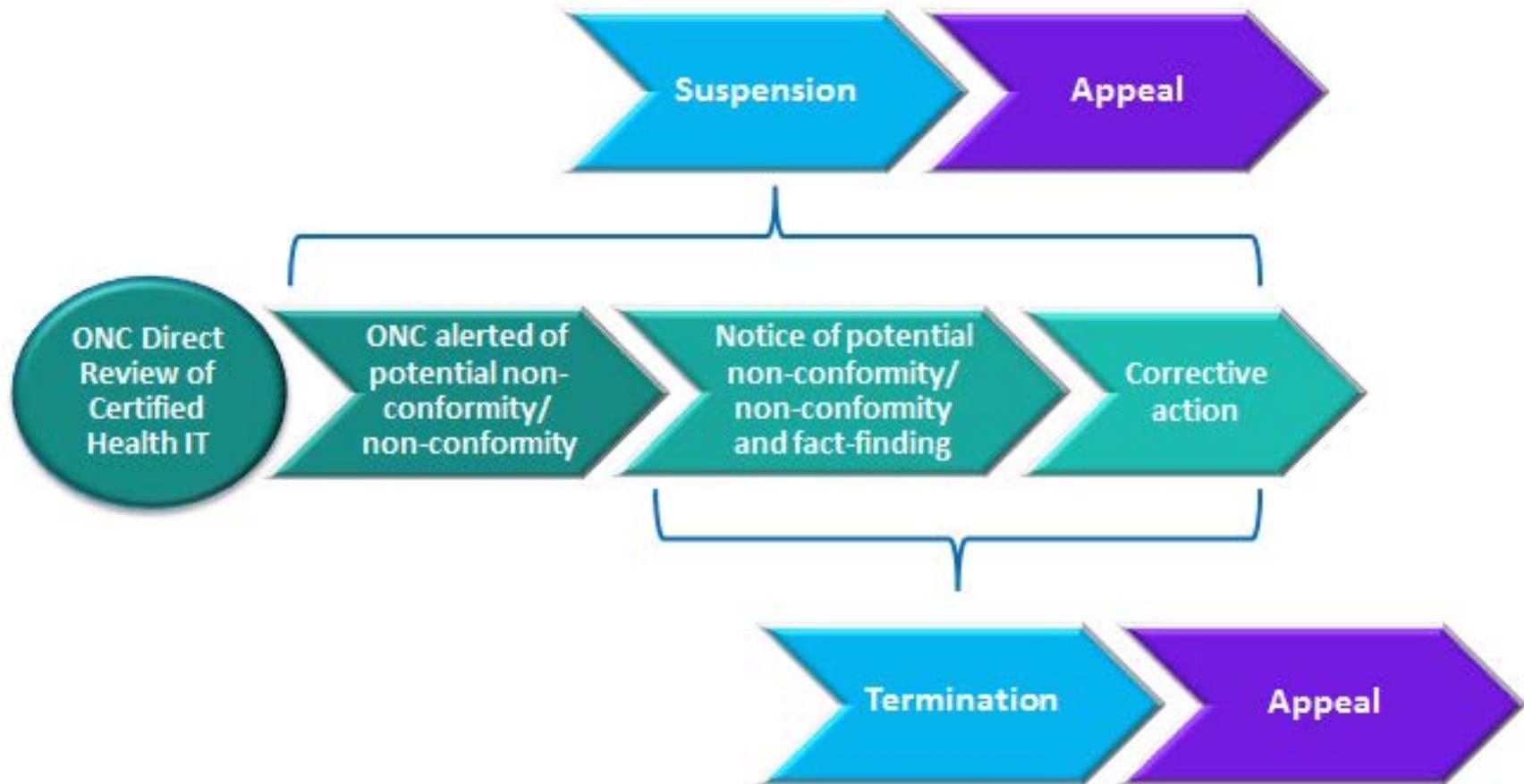
ONC Direct Review of Certified Health IT – Processes and Actions

- Initiation of Direct Review (§ 170.580): ONC could initiate direct review whenever it becomes aware of potential non-conformity or non-conformity in the <u>entire</u> certified health IT

- Notice and Fact-Finding (§ 170.580): ONC could issue a **notice of potential non-conformity or non-conformity** to the health IT developer with a 30-day response period and then conduct **fact-finding**

  » ONC could access and share w/in HHS, w/other federal agencies, and w/appropriate entities a developer's relevant records related to development, testing, certification, implementation, maintenance, and use of its product, as well as any complaint records related to the product

- Corrective Action, Suspension and Termination (§ 170.580): ONC could require **corrective action** for non-conformities, and, when necessary, **suspend** or **terminate** a certification. ONC may **<u>suspend at any time</u>** and may **<u>terminate prior to corrective action</u>**.

ONC Direct Review of Certified Health IT – Processes and Actions

Appeal:

- Developer can **appeal** ONC's determination w/in 10 days of notice

- Hearing officer would adjudicate appeal on behalf of NC and would issue a written determination to the developer within 30 days of receipt of the appeal, unless developer and ONC agree to finite extension approved by the hearing officer

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ONC Direct Review of Certified Health IT – Consequences of Termination

- General: The proposed rule does not address consequences of certification termination beyond requirements for recertification

- Testing and "Recertification" (§ 170.581):
  - ✓ All non-conformities adequately addressed
  - ✓ Recertified Complete EHR or Health IT Module (or replacement version) must maintain scope of certification that, at a minimum, includes all previous certified capabilities
  - ✓ Developer must explain in writing, as part of its request for permission to participate in the Program, the steps taken to address the non-conformities that led to termination
 - ✓ ONC must review and approve the request

- Program Ban (§ 170.581): Certification of <u>any</u> health IT of a health IT developer that has the certification of one of its health IT products terminated under the Program or withdrawn from the Program due to a potential non-conformity or non-conformity is prohibited, unless:

  1. The non-conformity is corrected and implemented to all affected users; or

  2. The certification and implementation of other health IT by the health IT developer would remedy the non-conformity for all affected users.

- Heightened Scrutiny (§ 170.581): Certified health IT that was previously subject of certification termination (or replacement version) shall be subject to heightened scrutiny for a minimum of one year

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ONC-ACB Response to a Non-Conformity – Proposals:

- Revise the Principles of Proper Conduct (PoPC) for ONC-ACBs (§ 170.523) to prohibit ONC-ACBs from reducing scope of a certification when health IT is under surveillance or a corrective action plan. This addresses two contexts:

  - » Health IT is suspected of a non-conformity (i.e., under surveillance)

  - » Health IT has a non-conformity (i.e., under a corrective action plan)

- Same proposed consequences for health IT and health IT developers related to certification termination under ONC direct review (i.e., § 170.581 proposals) should apply to certification terminations issued by ONC-ACBs

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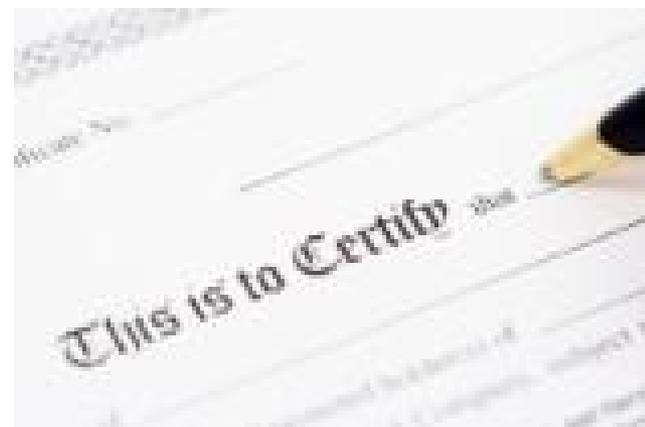
ONC-Authorized Testing Laboratories (ONC-ATLs)

- Proposal:

  » Means for ONC to have direct oversight of NVLAP-accrediting testing labs by having them apply to become ONC-ATLs

  » Means for **authorizing, retaining, suspending, and revoking ONC-ATL status** under the Program, which are similar to current ONC-ACB processes

  » To seek and acquire authorization an applicant must be NVLAP-accredited to ISO 17025, agree to the PoPC for ONC-ATLs, and comply with the proposed application documentation and procedural requirements

- Goal: 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

ONC-ATLs

Comparison of Current ONC-ACB and Proposed ONC-ATL Processes
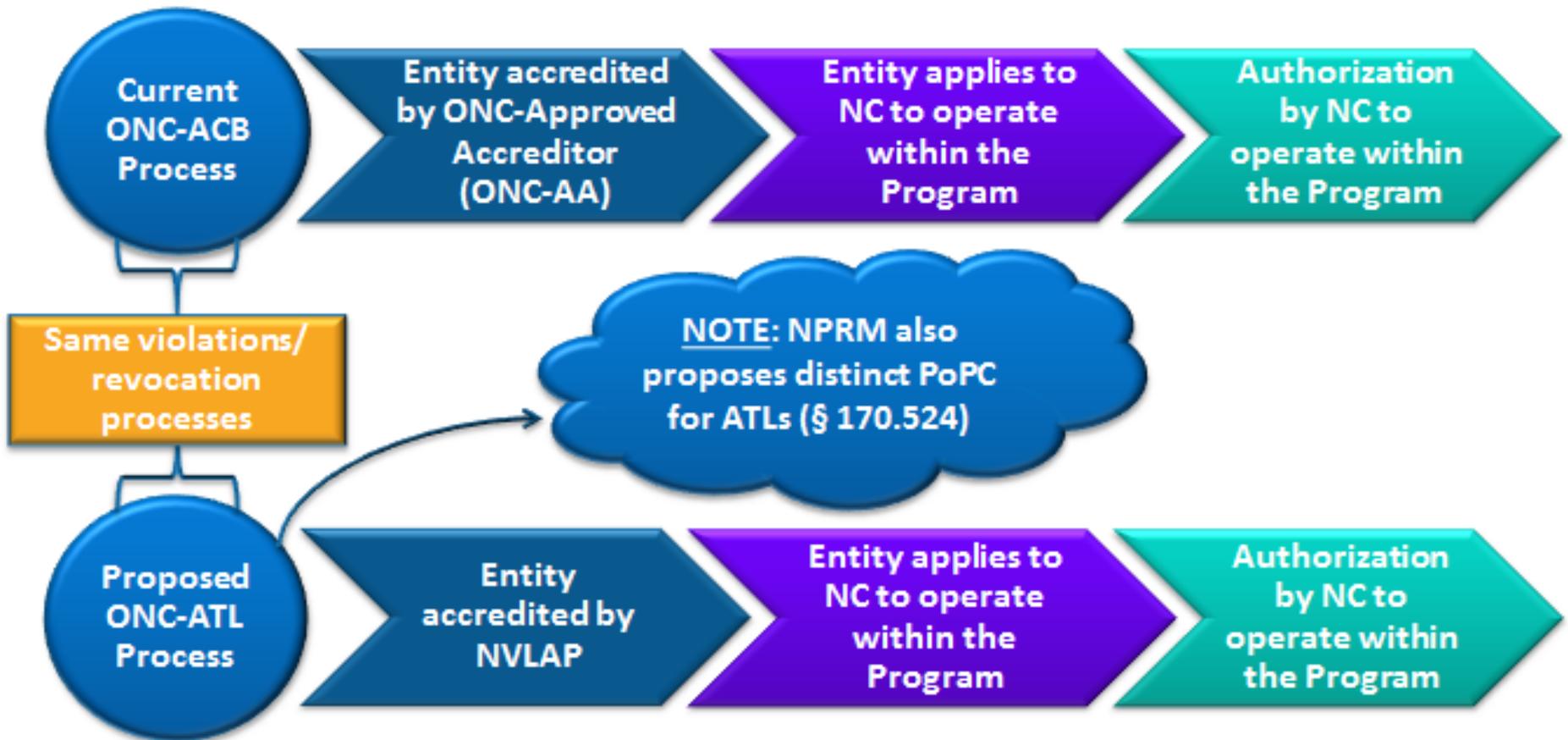
ONC-ATLs

- Authorization Period and Renewal: ONC-ATL would retain status for a 3-year period that could be continually renewed as long as the ONC-ATL follows proposed good standing and testing requirements, including PoPC for ONC-ATLs

- Proposed PoPC for ONC-ATLs (§ 170.524): **Relatively** corresponds with PoPC for ONC-ACBs (§ 170.523). One distinction, for example, is ONC-ATLs must maintain accreditation through NVLAP based on ISO 17025 standard.

Public Availability of Identifiable Surveillance Results

- Proposal: Require ONC-ACBs to make identifiable surveillance results publicly available on their websites on a quarterly basis

- Goals:
  - » Enhance transparency and provides valuable, balanced information about the **continued performance** of certified health IT and surveillance efforts
  - » We expect that the prospect of publicly identifiable surveillance results would motivate some health IT developers to improve their maintenance efforts, but also believe that most published surveillance results would reassure customers and users of certified health IT

Public Comment

- The "ONC Health IT Certification Program: Enhanced Oversight and Accountability" Proposed Rule was published in the Federal Register on **March 2, 2016**

- The comment period is open until **5 p.m. on May 2, 2016**

- You can review the proposed rule and comment here: https://federalregister.gov/a/2016-04531

- To assist in commenting on the proposed rule, ONC provides a **Microsoft Word version** of the proposed rule and a **Public Comment Template**. These documents are available at: https://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations

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Additional Information and Resources

- **Press Release and Fact Sheet:** https://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations

- **ONC Regulations:** http://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations

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