



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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December 7, 2016



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

ONC Direct Review of Certified Health IT

- 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.

ONC Direct Review of Certified Health IT

- **Example A: Slow-down under load (81 FR 72420)***

- » Clinicians at several hospitals in multiple states report that a cloud-based EHR is taking up to 5 minutes to display medication and allergy lists
- » No indication that hospitals have substandard hardware or network infrastructure
- » The health IT did not perform this way when installed but has become slower over time as number and size of records has increased

ONC may choose to initiate direct review:

- » Certified capabilities may be implicated, including problem list (§170.315(a)(6)) and medication list (§170.315(a)(7))
- » Reasonable belief that certified health IT may be contributing to serious risks to public health or safety, including —
 - Clinicians abandoning use of certified health IT and resorting to memory to order/manage meds. and allergies.
 - Multiple hospitals/facilities affected, suggesting large number of patients may be affected.
 - Serious injury or death is likely to materialize if immediate action is not taken to mitigate unsafe conditions.

*** Refer to the Final Rule at 81 FR 72420–25 for a more detailed discussion of this and other examples. For purposes of this overview, some facts and analysis have been abbreviated or omitted. Examples are hypothetical and illustrative; any actions or determinations by ONC would depend on the particular facts and circumstances presented, as described in detail in the EOA Final Rule.**

ONC Direct Review of Certified Health IT

Assuming ONC were to initiate review:

- » It would examine the certified capabilities to determine why they are not performing in an accurate and reliable manner and whether the cause of the problem was within the ability of the health IT developer to reasonably influence or control.
- » The facts suggest that the problem is common across multiple customers and is not the result of any actions of the developer's customers or users. Because the problem developed over time, the developer would have been aware of the problem and could have prevented it by employing best software practices to prevent a system related slow-down under load.
- » **If this were established, ONC would issue a notice of non-conformity.**

- **Compare Example B (81 FR 72421)***

- » ONC initiates review of a locally-hosted EHR system that is reported to be dropping medication orders.
- » ONC determines that the orders were dropped as a result of the hospital's decision not to comply with developer's recommended minimum hardware and network requirements.
- » ONC does **not find a non-conformity**.
- » ONC ceases review but may refer information to other agencies, if appropriate.

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ONC Direct Review of Certified Health IT

• Example F: Missing problems/diagnoses (81 FR 72424–25)*

- » During a span of two weeks, over a dozen users at multiple health care facilities report to ONC and to the ONC–ACB that the EHR is displaying inaccurate or missing diagnoses (problems) and that, as a result, patients are not receiving appropriate care.
- » In one reported instance, a patient was diagnosed with renal impairment, and this diagnosis was entered into the patient’s active problem list in the EHR by her primary care physician (PCP).
- » The PCP then referred the patient to an orthopedist for an unrelated musculoskeletal issue. The orthopedist is affiliated with the same health system as the PCP and has access to the same instance of the EHR. But when the orthopedist accessed the patient’s problem list, the diagnosis for renal impairment was missing from any relevant sections as displayed in the EHR.
- » Unaware of this diagnosis, the orthopedist prescribed a medication for musculoskeletal pain that should either be avoided or minimized in patients with renal impairment.
- » As a result, the patient suffered acute renal failure.
- » Similar instances involving other missed or inaccurate diagnoses and resulting harm to patients have also been reported to ONC and the ONC–ACB.

ONC-ACB initiates in-the-field surveillance to assess conformity with problem list criterion at § 170.315(a)(6)

ONC concurrently initiates direct review because the certified health IT may be performing in a manner that is causing or contributing to a serious risk to public or health or safety.

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ONC Direct Review of Certified Health IT

Scenario 1

(non-conformity identified and resolved by ONC-ACB through traditional surveillance):

- » The ONC-ACB' surveillance finds that the PCP modified the problem list from a “quick summary screen,” which due to a software error did not write the updated diagnosis (problem) back to the database.
- » The “quick summary screen” is an alternative workflow to the “standard office visit” screen that was tested during certification.
- » The ONC-ACB concludes that the failure of the problem list capability to function in accordance with § 170.315(a)(6) was reasonably within the control of the developer, who should have anticipated the risk during the course of normal software development. Any additional read/ write/display functionality may initially contain code errors, and all functions of certified health IT should be subjected to adequate testing. The developer could have reasonably taken actions to avoid the risk by employing an adequate software regression testing methodology.
- » Based on the surveillance and analysis above, the **ONC-ACB finds a non-conformity to § 170.315(a)(6) and requires the developer to take corrective action.**
- » ONC concurs with the ONC-ACB's finding of non-conformity and, at this time, forbears from taking any action against the developer because the nonconformity involves a straightforward violation of a certification criterion, which is well within the scope of the ONC-ACB's responsibilities and does not appear to exceed the ONC-ACB's resources.
- » ONC continues to **closely monitor the situation and coordinate with the ONC-ACB.**
- » If at any time ONC were to believe that the ONC-ACB could not effectively administer the necessary corrective action or that ONC's direct intervention were necessary to more quickly and effectively mitigate the risk to public health or safety, **ONC could immediately issue a notice of nonconformity and notice of suspension.**

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ONC Direct Review of Certified Health IT

Scenario 2

(no non-conformity; resolved by ONC-ACB through traditional surveillance):

- » The ONC–ACB’s surveillance reveals that the missing diagnosis was due to a system workflow implementation that the healthcare organization had customized.
- » Contrary to the developer’s recommendations, the healthcare organization had removed the problem list from the “quick visit” EHR workflow that is presented to ambulatory PCPs.
- » This resulted in the PCP not being able to quickly and easily update the problem list properly, resulting in incomplete problem lists.
- » **In contrast to scenario 1, the ONC– ACB finds that there is no nonconformity because these factors are beyond the developer’s ability to reasonably influence or control.**
- » **ONC concurs with the ONC–ACB’s determination and ceases its direct review of the certified Health IT Module(s).**

* Refer to the Final Rule at 81 FR 72420–25 for a more detailed discussion of this and other examples. For purposes of this overview, some facts and analysis have been abbreviated or omitted. Examples are hypothetical and illustrative; any actions or determinations by ONC would depend on the particular facts and circumstances presented, as described in detail in the EOA Final Rule.

ONC Direct Review of Certified Health IT

Scenario 3

(non-conformity identified and resolved by ONC via direct review):

- » Based on its surveillance, the ONC–ACB concludes that the issue is not the result of any technical or functional deficiencies with the problem list capability but rather a **poorly-designed user interface** that has contributed to problems being recorded incorrectly or not at all.
- » **ONC agrees that these usability issues are beyond the scope of the ONC–ACB’s expertise and responsibilities under the Program. However, the issues are not beyond the scope of the Program, and as such ONC continues its direct review.**
- » **ONC finds a non-conformity.** ONC concludes that the problem list capability was designed in a way that does not adhere to commonly accepted usability guidelines. In this case, ONC finds that in order to add a diagnosis to the problem list, a user is forced to navigate through an excessive series of windows, confirmation dialogues, and an inordinate amount of clicks to properly select the correct diagnosis. This in turn results in incomplete problem lists due to clinicians’ difficulty navigating the overly complex workflow, inability to complete the laborious series of steps due to time constraints, or a combination of both factors.
- » The developer could have reasonably anticipated the risk through an understanding of software usability and human factors best practices, and the developer could have reasonably taken actions to avoid the risk, such as by ensuring adequate usability testing prior to software release.
- » ONC would notify the developer of the non-conformity and to work with the developer to expeditiously and comprehensively correct the nonconformity and prevent similar safety risks from recurring. This might include, for example, instituting corrective actions to assist the developer in improving its user-centered design and other quality assurance processes.

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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

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

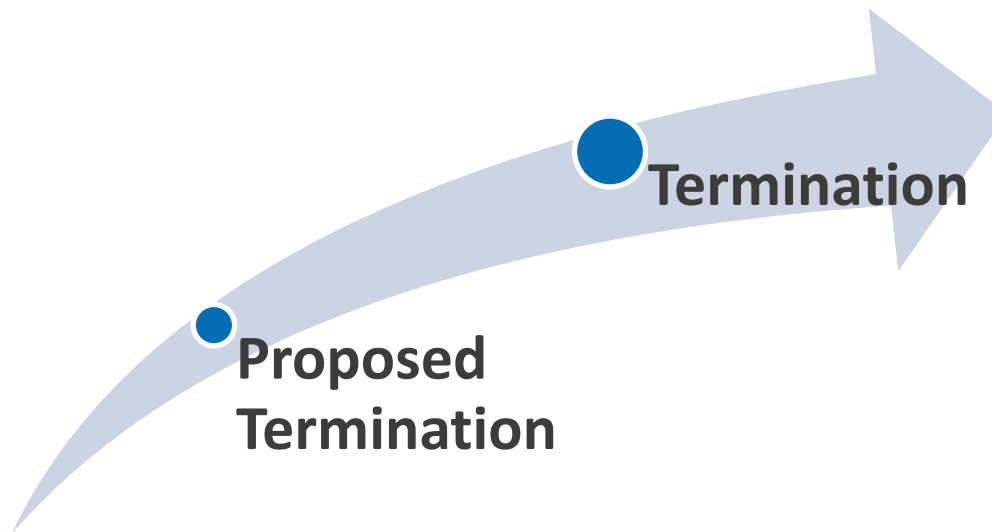
Suspension

- 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)

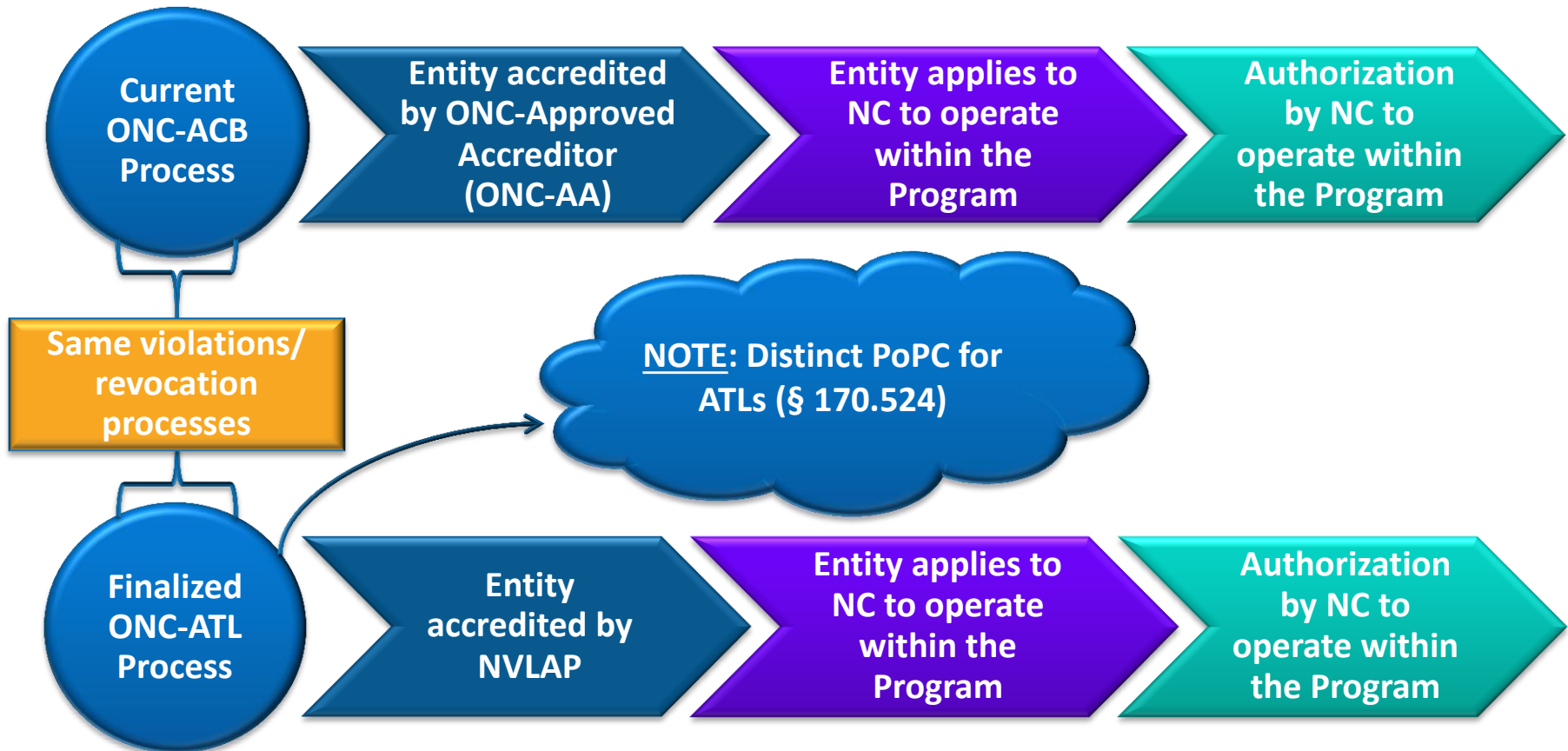
Note: Provisions of the Certification Ban are not effective until the final rule is effective on December 19, 2016.

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



ONC-ATL – Authorization Scope (§ 170.511)

- Perform the testing of Complete EHRs or Health IT Modules to a ***portion*** of a certification criteria, ***one*** certification criterion, or ***many*** or all certification criteria
- This provides opportunities for entities that may perform industry testing of health IT for limited and/or distinct capabilities (e.g., electronic prescribing) that align with certification criteria to participate in the Program

Transparency and Availability of Identifiable Surveillance Results

Transparency and Availability of Identifiable Surveillance Results

- 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.

**Balanced
View of
Surveillance
Results**

