



## ONC POLICY UPDATE

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March 10, 2016



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## Overview of Proposed Rule on Enhanced Oversight and Accountability in the ONC Health IT Certification Program



# Agenda

- ONC Direct Review of Certified Health IT
- ONC-Authorized Testing Laboratories (ONC-ATLs)
- Public Availability of Identifiable Surveillance Results
- Public Comment
- Additional Information and Resources

# The Proposal 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

# ONC Direct Review of Certified Health IT

- Proposal: Expand ONC's role in the 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 w/the specific certification criteria, test procedures, and specific certification requirements
  - » Extend to the interaction of all capabilities within the certified health IT w/certified capabilities and the interaction of all capabilities w/ other products
  - » Focus on situations that pose a **risk to public health or safety** and other exigencies

# ONC Direct Review of Certified Health IT

Goals include:

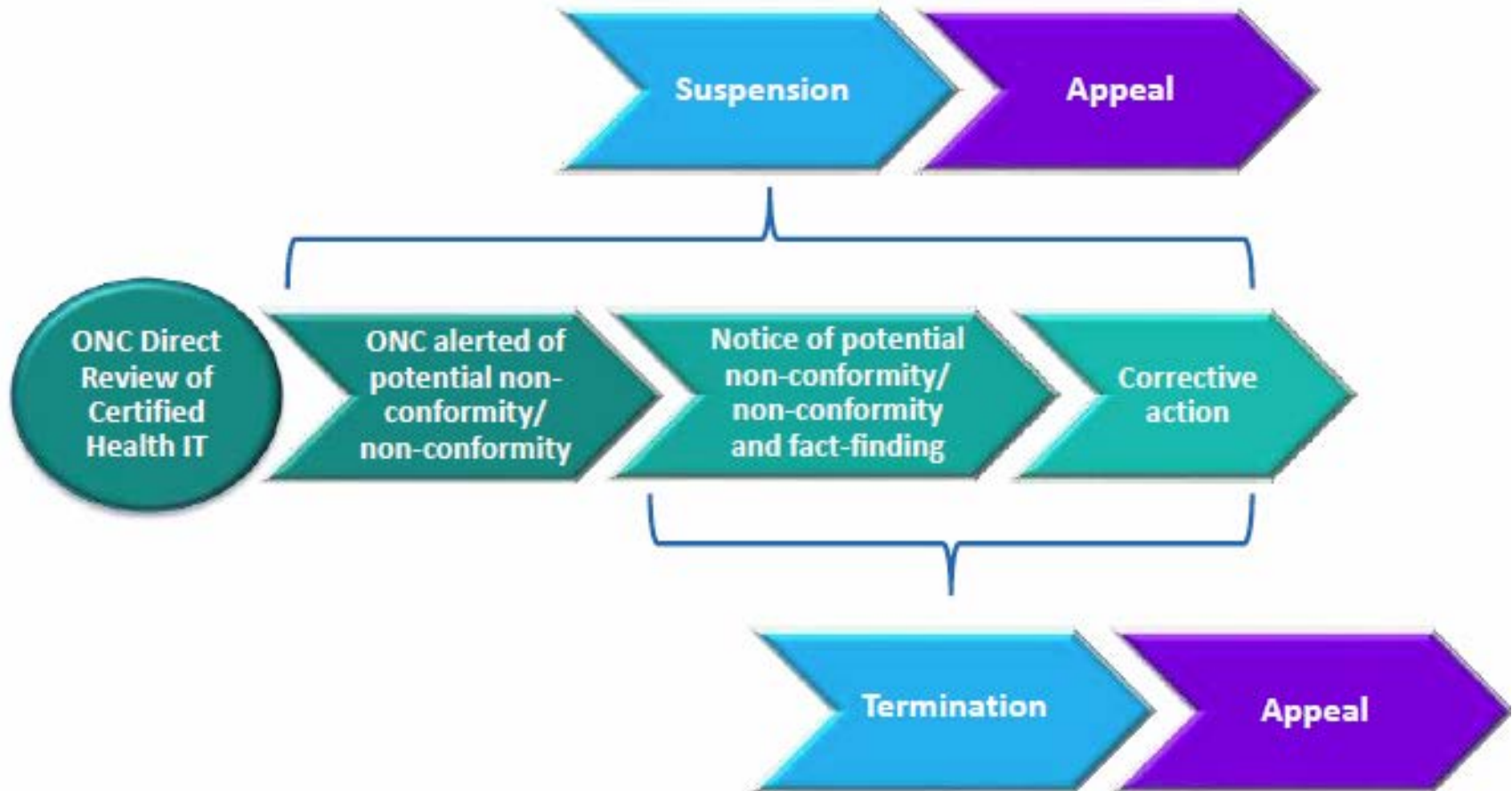
- Supporting greater accountability for health IT developers under the Program
- Providing greater confidence that health IT conforms to Program requirements
- Permitting ONC to work with health IT developers to remedy any identified non-conformities of certified health IT in a timely manner

# 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 ONC-ACB to investigate or address in 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

# ONC Direct Review of Certified Health IT

## ONC Direct Review Processes and Actions

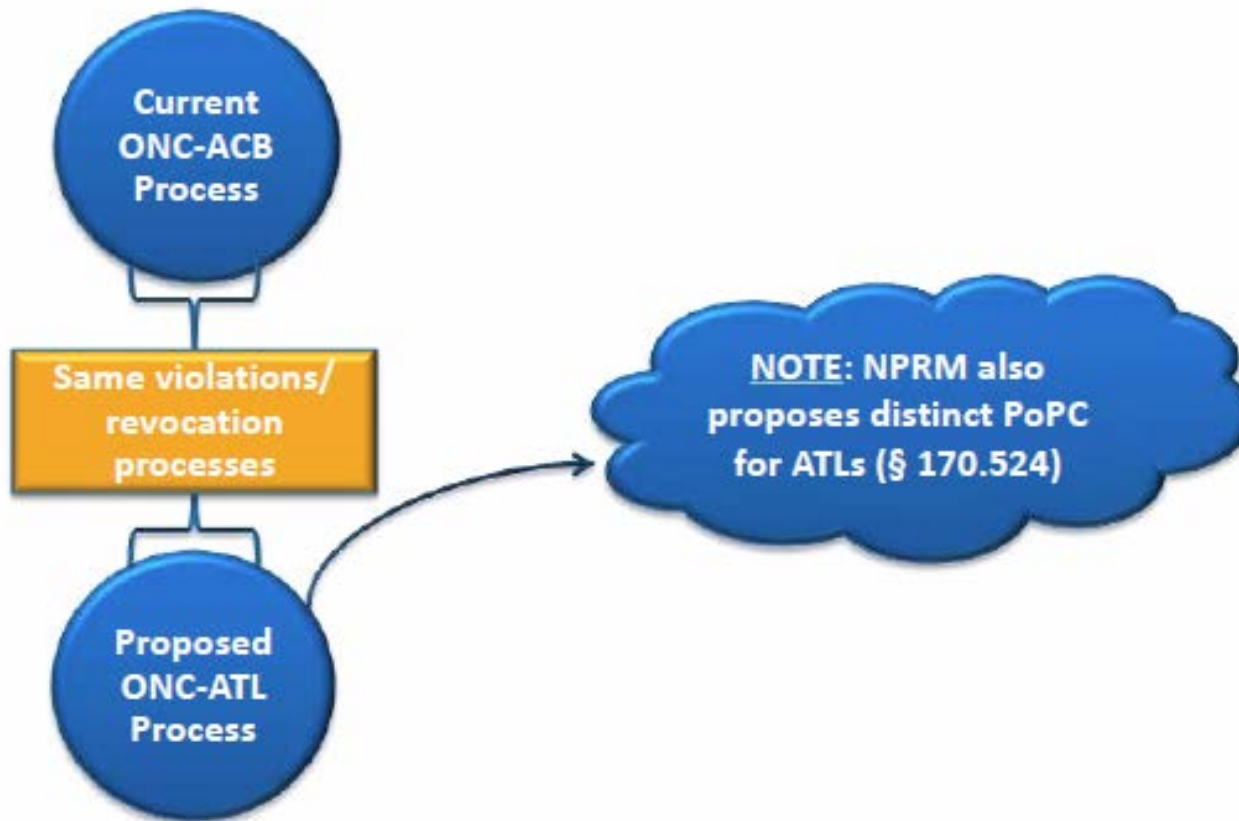




# ONC-Authorized Testing Laboratories (ONC-ATLs)

- Proposal:
  - » Means for ONC to have direct oversight of National Voluntary Laboratory Accreditation Program (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
- 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

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



# 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>

# 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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## Updating the Model Privacy Notice



# Model Privacy Notice: Improving Transparency for Consumers



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## Keeping Consumers in the Know: Help Us Update the Model Privacy Notice

February 26, 2016, 4:48 pm / Thomas A. Mason, M.D. / Chief Medical Officer, Elise Sweeney Anthony, J.D. / Acting Director, Office of Policy, Steven Posniak, M.S., M.H.S. / Director, Office of Standards and Technology, and Lucia Savage, J.D. / Chief Privacy Officer

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As ever more sophisticated retail health technology – like exercise trackers, wearable health technologies, or mobile applications that help individuals monitor various body measurements – comes into widespread use, it is increasingly important for consumers to be aware of companies' privacy and security policies, including data-sharing practices.

Given this diverse market and the array of innovative options from which consumers can choose, ONC is embarking on an effort to update the Model Privacy Notice (MPN) — a voluntary, openly available resource designed to help developers provide transparent notice to consumers about what happens to their data. The MPN's approach is to provide a standardized, easy-to-use framework to help developers clearly convey information about privacy and security to their users.

The 2011 version of the MPN was developed in collaboration with the Federal Trade Commission and focused on Personal Health Records (PHRs), which were the emerging technology at the time. We plan to update the MPN to make it applicable to a broad range of consumer health technologies beyond just PHRs – and we need your input to make it the best possible resource for the community.

We'll be at the [2016 HIMSS Annual Conference](#) to discuss the MPN, patient engagement, and other ONC efforts to support information transparency for consumers. In particular, join us on Wednesday, March 2 from 3-4pm in the Sands Expo Convention Center, Zeno Room 4602. For information on how to submit comments on how we can improve the MPN, follow [these instructions](#) [PDF – 440KB].



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# Overview of the Model Privacy Notice

- What is the Model Privacy Notice (MPN)?
  - » Provides a standardized, easy-to-use framework to help developers clearly convey information about privacy and security practices to their users
  - » ***Voluntary, openly available resource for developers and consumers***
- Why are we updating the MPN?
  - » The 2011 version focused on Personal Health Records (PHRs), which were the emerging technology at the time
  - » We plan to update the MPN to make it applicable to a broad range of consumer health technologies—beyond just PHRs



## Additional Resources

- » Federal Register Notice: <https://federalregister.gov/a/2016-04239>
- » ONC Website (background and for commenting):  
<https://www.healthit.gov/policy-researchers-implementers/personal-health-record-phr-model-privacy-notice>