21ST CENTURY CURES ACT: INTEROPERABILITY, INFORMATION BLOCKING, AND THE ONC HEALTH IT CERTIFICATION PROGRAM PROPOSED RULE

Updates to Principles of Proper Conduct for ONC-Authorized Certification Body (ONC-ACB)

WHAT ARE THE UPDATES TO THE PRINCIPLES OF PROPER CONDUCT?

**ONC-ACBs NOW MUST:**

1. Accept test results from any ONC-ATL in good standing.
2. Review and confirm health IT developer submission of real world testing plans and results. Make plans and results publicly available per the real world testing Condition of Certification.
3. Collect health IT developers’ quarterly attestations and note on the Certified Health IT Product List (CHPL) when Health IT Modules are updated under the Standards Version Advancement Process flexibility.
4. Ensure that health IT developers seeking to take advantage of the Standards Version Advancement Process flexibility comply with the applicable requirements, retain records of the timing and content of developers’ § 170.405(b)(5) notices, and timely post each notice’s content publicly on the CHPL.
5. Review and submit health IT developer Conditions and Maintenance of Certification attestations to ONC to make them publicly available.
6. Report to ONC any information that could lead ONC to perform direct review, including potential noncompliance with a Condition of Certification.

**NEW FLEXIBILITIES FOR ONC-ACBs:**

1. The role of the ONC-Approved Accreditor (ONC-AA) would be eliminated, permitting ONC-ACBs to obtain and maintain accreditation to ISO/IEC 17065, with an appropriate scope, from any accreditation body that is a signatory to the Multilateral Recognition Arrangement (MLA) with the International Accreditation Forum (IAF).
2. Certain randomized surveillance requirements would be eliminated.
3. ONC-ACBs would be able to certify Health IT Modules that they have been evaluated for conformance with certification criteria without first passing through an ONC-ATL as long as the conformity method was approved by the National Coordinator.

**NO LONGER REQUIRED:**

1. Disclosure requirements regarding certified health IT limitations.
2. Transparency attestations by health IT developers regarding the sharing of information in their mandatory disclosures.

**CLARIFICATION:**

ONC-ACBs must retain records through the “life of the edition” plus three years after an edition sunsets.

We define the “life of the edition” as beginning with the codification of an edition of certification criteria in regulation and ending when the edition is removed from regulation.

This informational resource describes select proposals in the proposed rule but is not an official statement of any policy. Please refer to the official version of the proposed rule as published in the Federal Register.