

Notice of Proposed Rule Making  
Office of the National Coordinator for Health Information Technology  
Proposed Establishment of Certification Programs for Health Information Technology

The Department of Health and Human Services released March 2 a proposed rule (<http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=1746>) creating a temporary program and a permanent program to certify health information technology.

This rule is a companion to two rules released previously and still open for public comment:

- The proposed rule from the Centers for Medicare and Medicaid Services (CMS) to guide implementation of the EHR incentive programs. The rule, entitled Electronic Health Record (EHR) Incentive Program (CMS-0033-P) is available at: <http://www.gpo.gov/fdsys/pkg/FR-2010-01-13/pdf/E9-31217.pdf>. (Comments due March 15, 2010)
- The interim final rule from the Office of the National Coordinator for Health Information Technology (ONC) on certification criteria and standards for EHR systems. The rule, entitled Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Health Information, is available at: <http://www.gpo.gov/fdsys/pkg/FR-2010-01-13/pdf/E9-31216.pdf>. (Comments due March 15, 2010)

In the newly released rule, entitled Proposed Establishment of Certification Programs for Health Information Technology, ONC proposes a temporary program would test and certify initial electronic health record products for health care providers seeking incentive payments for “meaningful use” of certified EHR technology under the Medicare and Medicaid EHR Incentives Program.

ONC has adopted a shortened comment period and plans an expedited process to establish the temporary program in time for certified products to be available as the Medicare and Medicaid EHR Incentive Programs begin. ONC proposes to sunset the temporary program when ONC has authorized at least one certification body under the permanent certification program, which ONC hopes will happen by the end of 2011.

ONC proposes to replace the temporary program by a permanent program that separates testing and certification responsibilities, introduces accreditation requirements, establishes requirements for certification bodies and allows them to certify technologies besides EHRs. In the permanent program, ONC would recognize a single ONC-Approved Accreditor, which would be approved to accredit multiple certification bodies. These ONC-Authorized Certification Bodies (ONC-ACBs) would certify, but not test, EHR technologies. Testing would be done separately by testing laboratories to be accredited by the National Institute for Standards and Technology (NIST).

The proposed rule provides direction to entities that want to apply to become certification bodies, such as application information and processes, required expertise, and expected codes of conduct.

The rule discusses at length the urgency of establishing the temporary certification program and short-cuts the regulatory process to make this happen.

The proposed rule also raises important questions for the long-term that will greatly impact hospitals. These include:

- Discussion of how a hospital that combines multiple products to create an EHR system could demonstrate certification for meaningful use. ONC's approach could require hospitals to pursue separate certification as a "self-developed EHR" at considerable effort and cost (estimated to be as much as \$50,000).
- Discussion of how EHR Modules that address only one part of meaningful use work together or with a base EHR system. ONC does **not** propose to include testing of whether Modules work together as part of the certification process.
- Discussion of the need for "surveillance" of certified EHR products that have already been installed in the field to judge ongoing performance. How will this be done? What will the implications be for a provider whose system is chosen for surveillance purposes? If the installation is found to be flawed?
- Discussion of how the certification requirements will be changed over time if CMS changes its meaningful use requirements. How often will upgrades be needed (ONC suggests every 2 years)? Will whole EHRs need to be upgraded or just certain parts?
- Discussion of how privacy and security requirements would apply to EHR modules. Does each module need to meet all the privacy and security certification criteria?

CHIME is reviewing the proposed rule in depth and consulting with members about their concerns. HHS will accept comments on the temporary certification program for 30 days after the rule is published in the Federal Register, and comments on the permanent program for 60 days after publication. While both programs are described in the proposed rule, HHS anticipates issuing separate final rules for the two programs.