



Health Care Access for All

Synopsis of ONC Proposed Rule on HIT Certification Program

General Overview

- Notice of Proposed Rule Making (NPRM) under the authority of the Department of Health and Human Services, Office of the National Coordinator (ONC)
- Two comment deadlines: Temporary Certification Program (April 9, 2010) and Permanent Certification Program (May 10, 2010).
- Temporary Certification Program final rule expected late May, early June; Permanent Certification Program final rule expected three months following. Rules effective 30 days after publication.
- Both the Temporary and Permanent Certification Programs are for health information technology, not just EHRs.

Beginning of Proposed Meaningful Use Stage		Stage 1										Stage 2		
		Q2/10	Q3/10	Q4/10	Q1/11	Q2/11	Q3/11	Q4/11	Q1/12	Q2/12	Q3/12	Q4/12	Q1/13+	
Certification Program	Temporary ONC-ATCB	■	■	■	■	■	■	■	■	■				
	Permanent ONC-ACB								■	■	■	■	■	

Background

- In 2006 the ONC published a Certification Guidance Document (CGD) to explain the factors the ONC would use to determine whether to recommend to the Secretary a body for “recognized certification body” status.
- To date, the Certification Commission for Health Information Technology (CCHIT) has been the only organization that has both applied for and been granted “recognized certification body” status.
- Once final, this rule will supersede the CGD.

Temporary Certification Program

- Rule describes process by which an organization would become an ONC-Authorized Testing and Certification Body (ONC-ATCB).
- The temporary program has been established in order to ensure that certified EHR products are available prior to the beginning of meaningful use stage 1.
- Temporary program would sunset once the permanent certification program is established and at least one organization has been authorized by the ONC.

- Successful organizations must be able to test and certify Complete EHRs and/or EHR modules.
- ONC-ATCBs will need to conform to both International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 65:1996 and ISO/IEC 17025:2005.
- Required to test and certify complete EHRs or EHR modules only. If testing complete EHRs, would be expected to test and certify EHR modules as well.
- ONC-ATCBs are not required to test and certify how different EHR modules interact/integrate with each other. Providers will be responsible for making sure separate EHR modules can interact properly.
- ONC-ATCBs can only test and certify those complete EHRs or EHR modules that they have been granted authorization for.
- ONC-ATCBs only expected to test and certify Complete EHRs and/or EHR modules to the certification criteria adopted by the Secretary that are applicable to meaningful use Stage 1.

Permanent Certification Program

- Rule describes process by which an organization would become an ONC-Authorized Certification Body (ONC-ACB)
- Certification would need to be renewed every two years
- ONC-ACBs would need to be accredited by the ONC-Approved Accreditor (ONC-AAs). Rule describes process for becoming an ONC-AA. There will only be one ONC-AA at a time and status lasts 3 years.
- ONC-AAs would need to conform to ISO/IEC 17011:2004.
- Can only certify complete EHRs and/or EHR modules that have been tested by a National Laboratory Accreditation Program (NVLAP)-accredited testing laboratory.
- Must retain records related to certification for five years.
- Required to conduct annual surveillance on all products they have certified.
- ONC provides an option for differential certification, i.e. not re-certifying an entire EHR or EHR module, but rather the capabilities added in a meaningful use Stage 1, 2, or 3.

Areas for Comment

- The overall concept and details of the proposed program.
- Whether or not the ONC should permit applicants to seek authorization to test and certify only complete EHRs designed for an ambulatory setting or, alternatively, complete EHRs for an inpatient setting. Current rule requires both.
- ONC-AA status is three years, should it be extended to 5 years?
- If meaningful use criteria changes, but the functionality of the EHR module does not need to change to conform to the criteria should the module need to be re-certified?

To learn more about the HIT Certification Program NPRM visit:

<http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=1745>.

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