



# HEALTH IT LAW & INDUSTRY



## REPORT

Reproduced with permission from Health IT Law & Industry Report, 2 HITR 31, 03/22/2010. Copyright © 2010 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

### Certification

## HHS Issues Proposed Rule Establishing Certification Programs for Health Information Technology

SARAH S. NELSON,  
DANIEL F. GOTTLIEB AND  
BERNADETTE M. BROCCOLO

**O**n March 10, 2010, the Office of the National Coordinator for Health Information Technology (ONC) published a proposed rule (Proposed Rule)<sup>1</sup> for establishing temporary and permanent programs for testing and certifying that electronic health record

<sup>1</sup> 75 Fed. Reg. 11327 (March 10, 2010) (to be codified at 42 C.F.R. pt. 170), available at <http://edocket.access.gpo.gov/2010/pdf/2010-4991.pdf>.

*The authors are attorneys in the health care practice at McDermott Will & Emery LLP. Sarah Nelson is resident in the firm's Los Angeles office and may be contacted at (310) 551-9324 or [snelson@mwe.com](mailto:snelson@mwe.com). Daniel Gottlieb is resident in the firm's Chicago office and may be contacted at (312) 984-6471 or [dgottlieb@mwe.com](mailto:dgottlieb@mwe.com). Bernadette Broccolo is a member of the Advisory Board for BNA's Health IT Law & Industry Report, is resident in the firm's Chicago office, and may be contacted at (312) 984-6911 or [bbroccolo@mwe.com](mailto:bbroccolo@mwe.com).*

(EHR) technology is Certified EHR Technology. Certified EHR Technology is EHR technology that meets the ONC's technological capability, functionality and security requirements (EHR Certification Requirements)<sup>2</sup> for supporting the achievement of meaningful use<sup>3</sup> by eligible hospitals and professionals under the Medicare and Medicaid EHR incentive programs established by the Health Information Technology for Economic and

<sup>2</sup> The EHR Certification Requirements, which were issued in a related, interim final rule (the Interim Final Rule) containing the standards, implementation specifications and certification criteria that EHR technology must meet to be Certified EHR Technology for purposes of the meaningful use incentives. Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Interim Final Rule, 75 Fed. Reg. 2013 (Jan. 13, 2010) (to be codified at 45 C.F.R. pt. 170), available at <http://edocket.access.gpo.gov/2010/pdf/E9-31216.pdf>

<sup>3</sup> At the same time the Interim Final Rule was issued, CMS issued a proposed rule (the Proposed Rule) containing criteria for demonstrating meaningful use of certified EHR technology, which also included proposed Medicare and Medicaid regulations for the calculation and payment of the HITECH Act's incentives to qualified providers under Medicare Parts A and B, Medicare Advantage organizations under Medicare Part C, and state Medicaid programs. 75 Fed. Reg. 1843 (proposed January 13, 2010) (to be codified at 42 C.F.R. pts. 412, et al.), available at <http://edocket.access.gpo.gov/2010/pdf/E9-31217.pdf>

Clinical Health Act (HITECH Act).<sup>4</sup> The Proposed Rule is the third in a series of interim final or proposed regulations that have been issued under the HITECH Act to implement the EHR incentive programs. It follows closely on the heels of the January 13, 2010, rulemaking in which the ONC established the EHR Certification Requirements by interim final rule and CMS proposed criteria for meaningful use Stage 1 and reimbursement rules for earning the Medicare and Medicaid EHR incentives.<sup>5</sup>

The proposed Certification programs are of keen interest both to EHR technology vendors, which must obtain certification of their technology under the temporary or permanent program to serve the eligible provider market, and to eligible providers (both individuals and institutions) who must make sure that the EHR technology they are purchasing will support their qualification for the Medicare and Medicaid incentives.

All stakeholders should consider submitting comments on the proposed temporary program by the April 9, 2010 deadline and the proposed permanent program by the May 10, 2010 deadline. While the rulemaking process progresses, vendors should also begin planning for the testing and certification process, and organizations interested in serving as an ONC-Authorized Testing and Certification Body under the temporary testing and certification program should both request an application from the ONC and move quickly to position themselves to participate in the program.

## Two Certification Programs

CMS has established three “stages” of objectives and measures for demonstrating “meaningful use.” This phased approach is designed to enable eligible professionals, eligible hospitals and critical access hospitals (CAHs) to incrementally improve and expand their adoption and implementation of EHR technology<sup>6</sup> and reflects CMS’ recognition that existing technology and interoperability made certain of the more ambitious (and critical) goals of EHR adoption difficult to achieve immediately.<sup>7</sup> While the Stage 1 meaningful use criteria concentrate on electronically recording patient data to facilitate coordination of care, implementation of clinical decision support, and the reporting of clinical quality measures,<sup>8</sup> Stage 2 and Stage 3 will focus more on the interoperability of EHR technology, an increase in

efficiency and an improvement in population health. Depending on when a provider elects to begin implementing meaningful use of EHRs, the provider will establish as its base Stage 1, 2 or 3 meaningful use criteria.<sup>9</sup>

The ONC Proposed Rule establishes both a streamlined temporary testing and certification program and a more robust permanent certification program. At the HIMSS 2010 Town Hall earlier this month, the ONC stated that two programs also allow “for the transition time necessary to develop a rigorous permanent certification program, which would follow mature industry best practices related to testing and certification[.]”<sup>10</sup>

The temporary program is intended to provide eligible professionals and hospitals with confirmation that their EHR technology is certified in time to earn incentive payments for their 2011 payment years. Specifically, eligible professionals must demonstrate meaningful use Stage 1 of Certified EHR Technology during a 90-day period of the 2011 calendar year (CY) and eligible hospitals must demonstrate meaningful use Stage 1 during a 90-day period of the 2011 Medicare fiscal year (FY), which is October 1, 2010 to September 30, 2011, to earn incentive payments for CY 2011 and FY 2011, respectively.

The proposed regulations for the temporary certification program have a 30-day public comment period ending April 9, 2010, while the proposed regulations for the permanent certification program have a 60-day public comment period ending May 10, 2010. The ONC will issue separate final rules for each certification program. The shorter comment period for the temporary certification program is intended to ensure that Certified EHR Technology is available prior to the dates on which eligible professionals and hospitals would need to demonstrate meaningful use of Certified EHR Technology for 2011.

## Temporary Certification Program

Under the temporary certification program, the ONC will select an organization(s) to become an ONC-Authorized Testing and Certification Body (ONC-ATCB) with authority to test and certify Complete EHRs (as defined below) and/or EHR Modules (as defined below) as meeting the Certification Requirements. To become an ONC-ATCB, an organization must request and submit an application to demonstrate its competency and ability to both test and certify Complete EHRs and/or EHR Modules. Applicants must indicate whether they are seeking to test and certify Complete EHRs or only specific EHR Modules, and in the latter case indicate which EHR Modules. The ONC will accept applications prior to the issuance of a final rule for the temporary certification program in order to expedite the decision process.

A Complete EHR is EHR technology that has been developed to meet all of the applicable EHR Certification Requirements. The use of the word “applicable” reflects the fact that some requirements apply to EHR technology used in the ambulatory setting by eligible

<sup>4</sup> HITECH Act, Pub. L. No. 111-5, § 4001-4302 (2009) (to be codified in various sections of title 42 of the United States Code).

<sup>5</sup> For additional information regarding the HITECH Act and the earlier regulations, see McDermott’s White Papers: “Economic Stimulus Package: Policy Implications of the Financial Incentives to Promote Health IT and New Privacy” at [http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object\\_id/ea996ed0-ba3b-480a-988a-135230c441d6.cfm](http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/ea996ed0-ba3b-480a-988a-135230c441d6.cfm); and “HHS Establishes the Initial Pathway for Qualifying for HITECH Act Incentives Dollars for Meaningful Use of Certified Electronic Health Record Technology” at [http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object\\_id/0c356337-b1ab-47fc-bf1b-a452db2ae132.cfm](http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/0c356337-b1ab-47fc-bf1b-a452db2ae132.cfm).

<sup>6</sup> CMS has specifically solicited comments on the phased approach and possible alternatives. See *id.* at 1572.

<sup>7</sup> See, e.g., *id.* at 1853 (“...the primary reasoning for developing different stages of meaningful use is the current lack of HIT infrastructure and penetration of qualified EHRs necessary to support the ambitious goals of the Stage 3 criteria of meaningful use.”).

<sup>8</sup> *Id.* at 1852.

<sup>9</sup> *Id.* at 1852-53.

<sup>10</sup> “Proposed Establishment of Certification Programs for Health Information Technology Notice of Proposed Rulemaking,” (March 2, 2010), available at [http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS\\_0\\_11673\\_911041\\_0\\_0\\_18/HIMSS\\_ONC\\_Certification\\_NPRM\\_townhall.pdf](http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_911041_0_0_18/HIMSS_ONC_Certification_NPRM_townhall.pdf)

professionals and other criteria apply to EHR technology used by eligible hospitals in the inpatient setting. An EHR Module is any service, component or combination thereof that can meet at least one of the certification “criteria” included in the EHR Certification Requirements. A vendor may present an EHR Module for testing and certification as part of a pre-coordinated bundle of EHR Modules, which could otherwise constitute a Complete EHR.

The Certification Commission for Health Information Technology (CCHIT), which has certified health information technology (HIT) as interoperable for purposes of the HIT donation exception and safe harbor under the Stark Law and the federal health care program anti-kickback statute for four years, has announced that it will apply to be an ONC-ATCB. The ONC expects only a few organizations to be designated ONC-ATCBs.

Part 1 of the application requires documentation to demonstrate testing and certification processes in accordance with International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) ISO/IEC Guide 65, which specifies standards for operating a certification program. Part 2 requires the applicant to complete a proficiency examination and demonstrate that it can competently test and certify Complete EHRs and/or EHR Modules.

Once certified by the ONC, an ONC-ATCB would perform testing and certification of complete EHRs and/or EHR modules. “Testing” describes the process used to determine the degree to which a Complete EHR or EHR Module can meet specific, predefined, measurable, quantitative requirements. The results would be able to be compared to and evaluated in accordance with predefined measures. “Certification” describes the assessment (and subsequent assertion) made by an authorized certifying organization (e.g., an ONC-ATCB in the temporary program), once it has analyzed the quantitative results rendered from testing along with other qualitative factors, that a complete EHR or EHR module has met all the applicable certification criteria adopted by the Secretary of HHS.

The temporary certification program is set to automatically sunset after the permanent certification program is established by final rule and at least one certification body is authorized by the ONC.

### Permanent Certification Program

The permanent certification program divides the tasks of testing and certification as recommended by the Health Information Technology Policy Committee and the National Institute of Standards and Technology (NIST), provides for an organization to accredit certifying bodies and establishes requirements for surveillance of Certified EHR Technology. The ONC serves as the only accrediting organization in the temporary certification program, assessing and approving each ONC-ATCB’s ability to perform both testing and certification.

**Appointment of an ONC-AA to Accredit ONC-ACBs.** The ONC will appoint an ONC-approved accreditor (ONC-AA) to accredit other organizations to certify EHR technology. The ONC approves only one ONC-AA at a time and its status expires every three years. Organizations that seek authority to certify EHR technology must apply to the ONC-approved accreditor to be accredited to become an ONC-Authorized Certification Body (ONC-ACB). Following accreditation, an organi-

zation must submit an application to the ONC demonstrating that it is accredited, obtain approval from the ONC and execute an agreement with the ONC to adhere to the Principles of Proper Conduct for ONC-ACBs. An ONC-ACB must renew its status every two years.

If an organization wishes to test (rather than certify) EHR technology, it must apply for accreditation from NIST through the National Voluntary Laboratory Accreditation Program (NVLAP). The ONC-ACBs will only be permitted to accept test results from NVLAP-accredited testing laboratories when evaluating EHR technology for certification.

A single organization (which may have subsidiaries or components) may be approved to perform both testing and certification functions, as long as the organization is accredited by both the ONC-AA and NIST.

**Maintaining ONC-ATCB Good Standing.** To maintain good standing, an ONC-ATCB must adhere to the Principles of Proper Conduct for ONC-ATCBs. ONC-ACBs must adhere to the Principles of Proper Conduct for ONC-ACBs. Additionally, both must refrain from engaging in other types of inappropriate behavior such as misrepresenting the scope of their authorization, testing/certifying EHRs without authorization, or not following other applicable federal and state laws.

The ONC-ATCB Principles of Proper Conduct and the ONC-ACB Principles of Proper Conduct both require operating within various standards for testing and certification, maintaining a quality management system, attending mandatory ONC trainings, maintaining a training program for personnel, promptly reporting changes in management, policies or facilities to the ONC, allowing ONC inspections, providing lists of certified products to the ONC, retaining records and refunding any fees for tests and certifications that are not completed. The ONC-ACB Principles of Proper Conduct also require ONC-ACBs to maintain accreditation by the ONC-AA, submit an annual surveillance plan and to only certify HIT that has been tested by a NVLAP-accredited testing laboratory.

The ONC may propose to revoke an organization’s status for either a Type-1 or Type-2 violation. Type-1 violations include false, fraudulent or abusive activities that affect the temporary or permanent certification programs, or another program administered by HHS or the Federal government. Type-2 violations include violations of the Principles of Proper Conduct, or other inappropriate behavior such as misrepresenting the scope of an organization’s authorization, testing/certifying EHRs without authorization or not following other applicable federal and state laws.

If the status of an ONC-ATCB or ONC-ACB is revoked due to a Type-1 violation, the organization is prohibited from reapplying to either program for at least 1 year. When the status of an ONC-ATCB or ONC-ACB is revoked for a Type-2 violation, they may reapply at any time for either certification program.

An ONC-ATCB’s or ONC-ACB’s revocation of status for a Type-2 violation will not call into question the legitimacy of certifications previously issued by that organization. For Type-1 violations that lead to an organization’s status being revoked, however, when the violation calls into question the legitimacy of previous certifications, developers of the EHR technology products that were previously certified would have 120 days

to get their HIT recertified by another ONC-ATCB or ONC-ACB, as applicable, after the ONC publishes a notice listing the products affected.

**Surveillance of EHR.** To satisfy surveillance requirements under the permanent certification program, an ONC-ACB must periodically evaluate EHR technology it has previously certified, to confirm that such technology continues to conform to the Certification Requirements. The products that were certified in a controlled environment must perform in an acceptable, if not the same, manner in the field as the certification process. An ONC-ACB must submit an annual surveillance plan to the ONC and annually report surveillance results.

There is no similar requirement to submit an annual surveillance plan specified in the temporary certification program. Due to the short duration of the temporary certification program the requirements for surveillance are less stringent.

### Differences Between the Programs

The following chart summarizes the major differences between the two programs:

	Temporary Program	Permanent Program
<b>Anticipated Operational Period</b>	Second quarter of 2010 through the first quarter of 2012	First quarter of 2012 and on
<b>Accrediting Bodies</b>	ONC	ONC-AA
<b>Certification Bodies</b>	ONC-ATCBs	ONC-ACBs
<b>Testing Bodies</b>	ONC-ATCBs	NIST (NVLAP)
<b>Public Comment Period</b>	30 days	60 days

### Conclusions and Observations

The ONC's adoption of the two certification programs, particularly the streamlined temporary program, reflects its recognition of the need to enable EHR technology vendors to quickly obtain certification of their EHR technology so that eligible providers can have Certified EHR Technology in place to earn incentive payments for CY 2011 or FY 2011.

While the certification programs are currently in proposed form, the short amount of time before the 2011 payment years behooves vendors to begin planning for the testing and certification process. Organizations that are interested in serving as an ONC-ATCB should also move quickly to position themselves to participate in the streamlined temporary testing and certification program.