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May 5, 2010

US Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Hubert H. Humphrey Building
200 Independence Ave., SW, Suite 729D
Washington, DC 20201

RE: RIN 0991 – AB59 (Permanent Certification Program)

Dear Dr. Blumenthal:

The American Health Information Management Association (AHIMA) is pleased to comment on the Office of the National Coordinator for Health Information Technology's (ONC) Proposed Establishment of Certification Programs for Health Information Technology, as published in the March 10, 2010 *Federal Register* (45 CFR Part 170).

AHIMA is a professional association representing more than 56,000 health information management (HIM) professionals who work throughout the healthcare industry. HIM professionals are educated, trained, and certified to serve the healthcare industry and the public by managing, analyzing, protecting, reporting, releasing, and utilizing data vital for patient care, while making it accessible to patients, healthcare providers, and appropriate researchers when it is needed most. AHIMA members are also deeply involved with the development and analysis of healthcare secondary data reporting and the development, planning, implementation, and management of electronic health records (EHRs).

On April 8, 2010, we submitted comments in response to the temporary certification program. This letter contains our detailed comments and recommendations in response to ONC's proposed permanent certification program.

III. Provisions of Permanent Certification Program

III. D. 1. c. Application for ONC-ACB Status (75FR11348-50)

AHIMA supports ONC's proposal to require ONC Authorized Certification Bodies (ONC-ACBs) to submit annual surveillance plans to the National Coordinator and annually report their surveillance results. We also agree that making the ONC-ACB surveillance results publicly available would be very useful for prospective purchasers.

In the event that ONC identifies patterns of unsatisfactory surveillance results where the ONC-ACB has not taken the appropriate measures to evaluate and address the poor performing products, ONC should first investigate the ONC-ACB to determine why it did not

take the appropriate action. If, as a result of this or other investigations, the ONC-ACB's certification status is revoked, AHIMA recommends that ONC initiate steps to assess poor performing products to determine if they should be placed on "conditional" status with six months to resolve surveillance concerns. If the vendor fails to resolve the surveillance concerns within six months, decertification may be warranted. Providers who implemented decertified products and are able to demonstrate meaningful use should continue to receive incentive payments and should not be required to replace the product.

III. D. 4. b. Expiration of Status under the Permanent Certification Program (75FR11350)

AHIMA supports ONC's proposal to require ONC-ACBs to submit an updated application for review 60 days prior to expiration of its status under the permanent certification program. However, we also recommend that ONC-ACBs report the results of the certification reviews conducted during the prior certification period, including the number of products passing and failing certification; number of products failing the initial certification test and subsequently achieving certification after remediation; and surveillance results from the previous certification period, to evaluate the ONC-ACB's past performance and provide ONC with an overall assessment of the certification program.

III. E. 3. Authorization to Certify Other HIT (75FR11350)

As stated in our response to the temporary certification program, we commend ONC for recognizing the need to certify "health information technology" (HIT), which should include health information exchange (HIE) and personal health record (PHR) systems, rather than just EHR systems. Clinical systems (for example, PAC systems, medication/pharmacy systems, and laboratory systems) should be included under "HIT" to ensure they are interoperable with EHR systems. Certification of these other types of HIT will support key objectives for meaningful use.

AHIMA recommends that ONC prioritize the certification of other types of HIT systems to ensure alignment with priorities for meaningful use. We also encourage ONC to maintain consistency of these priorities during the transition from the temporary and permanent certification program. Examples of systems that should be of high priority for HIT certification include pharmacy and laboratory systems, due to their direct relationship to meaningful use, quality, and patient safety initiatives, while other clinical systems can be certified in later years.

III. E. 6. Maintaining Good Standing as an ONC-ACB; Violations That Could Lead to Revocation of ONC-ACB Status; Revocation of ONC-ACB Status (75FR11350)

AHIMA supports ONC's proposal to prohibit an ONC-ACB from reapplying for ONC-ACB status for one year if its status is revoked due to a Type-1 violation.

III. E. 7. Validity of Complete EHR and EHR Module Certification (75FR11351)

AHIMA agrees that Complete EHRs and EHR Modules tested and certified under the temporary certification program should be tested and recertified under the permanent certification program, especially if certification criteria are added, replaced, or amended. In

addition, AHIMA strongly urges ONC to implement a controlled change management process that provides adequate notification and lead time of new and updated certification criteria. Vendors must have sufficient time to incorporate and test new and updated certification criteria prior to each corresponding meaningful use stage.

AHIMA supports the notion that if new meaningful use measures do not impact required capabilities of an EHR Module and corresponding certification criteria, then recertification of EHR Modules may not be necessary. However, if any other certification criteria are added or updated as part of the same certification cycle, recertification of all criteria should be required to ensure other system functionality are not negatively impacted.

III. E. 8. Differential Certification (75FR11351)

Although AHIMA understands the challenges associated with an increasing number of certification criteria over time, we recommend that Complete EHRs and EHR Modules undergo **comprehensive** certification at each stage. Purchasers of Complete EHRs and EHR Modules need assurance that the certification process and certified products are credible and reliable. As vendors strive to enhance their products to comply with new and revised certification requirements, previously certified functions could inadvertently be negatively impacted. Differential certification may not identify these issues.

III. F. 2. ONC-AA Ongoing Responsibilities (75FR11352)

ONC requests public comment on the proposed responsibilities for an ONC-Approved Accreditor (ONC-AA). We believe the responsibilities outlined seem reasonable and do not have any additional recommendations to provide at this time.

III. F. 3. Number of ONC-AAs and Length of Approval (75FR11352)

AHIMA agrees with ONC's proposal to approve only one ONC-AA at a time. However, we strongly recommend extending the length of an ONC-AA's status from three to five years. A five year period will provide consistency, stability and efficiency to the certification program.

III. G. Promoting Participation in the Permanent Certification Program (75FR11352)

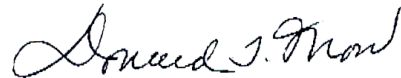
Based on the industry's practical experience with EHR certification during the past five years, we believe the certification program requirements described in this proposed rule do not create entry barriers for organizations seeking ONC-ACB status. In addition, we believe the requirements are rigorous enough to create meaningful certification bodies.

ONC has established a reasonable and objective process for establishing ONC-ACBs. AHIMA does not endorse the establishment of a temporary ONC-managed certification process and believe this would not be a good use of ONC's resources. If only one ONC-ACB comes forward, it is not necessarily the result of the certification program requirements. The proposed program permits multiple entry points for organizations to pursue ONC-ACB status, allowing the market to decide how many ONC-ACBs are acceptable.

Conclusions

AHIMA appreciates the opportunity to comment on the Proposed Establishment of Certification Programs for Health Information Technology. If we can provide further information, or if there are questions or concerns in regard to this letter and its recommendations, please contact me at (312) 233-1135, or at donald.mon@ahima.org. In my absence, please feel free to contact AHIMA's vice president for policy and government relations, Dan Rode, at (202) 659-9440, or at dan.rode@ahima.org.

Sincerely,



Donald T. Mon, PhD

AHIMA Vice President of Practice Leadership

cc: Dan Rode, MBA, CHPS, FHFMA
Allison Viola, MBA, RHIA