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April 8, 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 (Temporary 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).

Our detailed comments and recommendations on the proposed rule follow our general comments below.

General Comments

AHIMA recognizes and supports the need for improvement of the overall infrastructure of the certification program, regardless of the number of certification bodies. An enhanced certification program must ensure all stakeholders are represented and engaged in the process, and that certification requirements accurately reflect market's needs. An independent accreditation body can define the open and transparent process, as well as the requirements that must be met, for an organization to become a certification body.

AHIMA understands the urgency in establishing an enhanced national certification program. However, given the startup time and resources needed to launch a certification organization, the very tight time constraints this rule establishes could pose a challenge for entities who wish to become ONC-Authorized Testing and Certification Bodies (ONC-ATCB). These challenges

notwithstanding, and whether or not other entities apply for ONC-ATCB status, we expect the Certification Commission for Health Information Technology (CCHIT) to apply for both ONC-ATCB and ONC-ACB status. Should CCHIT be so authorized, we are confident at least one strong certification body will exist during both the temporary and permanent certification programs. CCHIT demonstrates a strong record of success and AHIMA recommends that ONC consider accepting CCHIT certification as the bridge to temporary certification to ease the transition, reduce confusion, and expedite the establishment of the permanent certification process.

AHIMA would like to point out that the terms “temporary” and “permanent” could be misleading and confusing to vendors and providers selecting and implementing certified products. Some may infer that “permanent” indicates the certification of their products is permanent, rather than permanency of the program itself. AHIMA recommends replacing the term "temporary certification program" with "program for interim certification" and when the interim program becomes permanent, simply refer to it as the "certification program.”

I. Background

I. B. 2. c. HIT Certification Programs Proposed Rule (75FR11331)

AHIMA commends ONC for recognizing the need to certify “health information technology” (HIT), which should definitely 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.

However, AHIMA recommends that ONC prioritize the certification of other types of HIT systems to ensure alignment with priorities for meaningful use. For example, pharmacy and laboratory systems should be a high priority for HIT certification, due to their direct relationship to meaningful use, quality, and patient safety initiatives, while other clinical systems can be certified in later years.

I. B. 2. d. Physician Self-Referral Prohibition and Anti-Kickback EHR Exception and Safe Harbor Final Rules and ONC Interim Guidance Regarding the Recognition of Certification Bodies (75FR11332)

AHIMA supports alignment and consistency, and therefore supports ONC’s interpretation of the proposed new authorization process as the Secretary’s method for recognizing certification bodies in the context of the physician self-referral EHR exception and anti-kickback EHR safe harbor.

I. E. 3. ii. Urgency of Establishing the Temporary Certification Program (75FR11334)

As noted earlier in this response, AHIMA recommends that ONC consider leveraging the existing CCHIT certification process as the bridge to the permanent certification program to reduce complexity and uncertainty for vendors and eligible professionals and hospitals as the industry strives to address the requirements associated with Stage 1 meaningful use.

II. Provisions for the Temporary Certification Program

II. D. b. Types of ONC-ATCB Authorization (75FR11337)

ONC requests public comment on whether ONC-ATCBs should also be required to test and certify that any EHR Module presented by one EHR Module developer for testing and certification would properly work (that is, integrate) with another EHR Module presented by a different EHR Module developer. AHIMA believes the adoption and integration of HIT is critical to achieving widespread interoperability and demonstrating meaningful use of certified EHR technology. Although the proposed rule states that eligible providers and hospitals choosing to use a combination of certified EHR Modules have the responsibility to ensure the certified EHR Modules can properly work together, vendors of EHR Modules should be, as part of the certification process, required to demonstrate that certain core components can interoperate to support standardization, information exchange, and meaningful use.

AHIMA recommends allowing applicants the flexibility to specify the type of Complete EHR authorization they wish to seek, including inpatient, ambulatory, or both.

With respect to EHR Module certification, AHIMA agrees that ONC-ATCB applicants should only be authorized to test and certify the specified EHR modules. However, ONC should ensure a process exists allowing them to apply for authorization to test and certify additional modules and to allow for expansion over time.

II. E. 2. b. When Privacy and Security Certification Criteria Apply to EHR Modules (75FR11342-3)

AHIMA believes EHR Modules should be held to the same privacy and security standards as Complete EHRs and supports ONC's proposal to test and certify all EHR Modules according to privacy and security certification criteria adopted by the Secretary. We also agree that exceptions may apply in certain circumstances. AHIMA supports the proposed approaches to address these exceptions as described in the proposed rule.

II. E. 4. The Testing and Certification of "Minimum Standards" (75FR11343-4)

AHIMA supports ONC's proposal to regularly publish (on a quarterly basis) any secretarial determinations made with respect to "minimum standard" code sets. However, we recommend establishing one consistent mode for communicating the updates, preferably through posting notifications to the ONC Web site. AHIMA also suggests that if code set updates become available in the middle of a quarterly publication cycle, the update should be published during the subsequent release of the quarterly code set update.

With regard to the methods for identifying new versions of a "minimum standard" code set, AHIMA recommends that ONC establish relationships directly with the code set maintenance organizations to identify a standard mechanism for notifying ONC of changes and updates.

II. E. 6. Validity of Complete EHR and EHR Module Certification (75FR11346-7)

AHIMA supports the correlation of certification criteria with the schedule for updates to meaningful use objectives and measures. However, we agree that the relationship between meaningful use stage and currency of certification criteria may be confusing for the industry, especially eligible providers and hospitals attempting to address meaningful use requirements. AHIMA recommends that ONC develop a graphic to depict the relationship between the planned two-year schedule for updates to meaningful use objectives and measures, related certification cycles, and the corresponding calendar month and year.

II. F. Sunset (75FR11347)

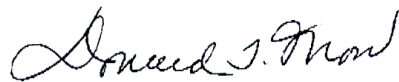
Regarding the date versus event issue, we recommend that ONC establish a set date for the temporary certification program to sunset in order to give the industry a target date for transition. However, if no qualified ONC-ACBs are authorized by the temporary program sunset date, the temporary certification program should be extended until an authorized ONC-ACB has been established.

AHIMA encourages ONC to clarify a key point in the transition between the temporary and permanent certification programs. ONC should explain how instances will be handled if an ONC-ATCB approved under the temporary certification program decides not to pursue permanent certification status. What happens to the products certified by that ONC-ATCB?

Conclusions

AHIMA appreciates the opportunity to comment on the Proposed Establishment of Certification Programs for Health Information Technology. If AHIMA 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
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