March 15, 2010

David Blumenthal, MD
U.S. Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: HITECH Initial Set Interim Final Rule
Hubert H. Humphrey Building
200 Independence Ave., S.W., Suite 729D
Washington, D.C. 20201

RE: RIN 0991 – AB58

Dear Dr. Blumenthal:

The American Health Information Management Association (AHIMA) welcomes the opportunity to comment on the Office of the National Coordinator for Health Information Technology's (ONC) Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Interim Final Rule (IFR), as published in the January 13, 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 deeply involved in the development, planning, implementation and management of electronic health records, in addition to the analysis and reporting of healthcare data for secondary use.

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

General Comments
AHIMA appreciates the establishment of the HIT Policy and Standards Committees and believes the committees' efforts are important to achieving national interoperability. However, we would appreciate clarification on the relationship between these FACA committees and other industry initiatives addressing issues related to standards, implementation and certification, such as the National eHealth Collaborative (NeHC), the Health Information Technology Standards Panel (HITSP), and the National Health Information Network (NHIN).

Office of the National Coordinator for Health Information Technology
AHIMA Comments on *Standards and Certification IFR*
P a g e | **2**

I. Background

I.B.4.a. HIPAA Transactions and Code Sets Standards (75FR2017)

HIM professionals work continuously to ensure the integrity, uniformity, and consistency of health information and data and view the adoption and final use of the ICD-10-CM/PCS as a giant step in the direction of increasing the utility of electronic health records and improving the individual and population health in the United States. AHIMA commends HHS for moving the industry toward implementation and use of the HIPAA transactions and code set standards and supports alignment with the initial set of standards and implementation specifications for meaningful use. However, AHIMA recognizes this transition to HIPAA 5010 and ICD-10-CM/PCS is no small undertaking and may compete for resources and attention as healthcare organizations strive to achieve meaningful use incentives. As a result, it is critical that ONC work closely with CMS to provide clear and aligned messages to the healthcare industry of the impending HIPAA 5010 and ICD-10-CM/PCS implementation and ensure these requirements are not lost in the shuffle as standards, implementation specifications and certification criteria are implemented for meaningful use.

I. D. Future Updates to Standards, Implementation Specifications, and Certification Criteria (75FR2020)

AHIMA appreciates ONC's efforts to promote the adoption of interoperability standards; however, we believe there should be a more consistent approach to nationwide interoperability. The current environment encourages individual experiments in lieu of a statewide or national approach. Funding should be leveraged to support a more defined national approach and promote a consistent interoperability format –such as those used for international banking (allowing bank cards to be used worldwide) or the Canada Health Infoway initiative which supports nationwide EHR access.

III. Section-By-Section Description of the Interim Final Rule

III. B. 4. Definition of Qualified EHR (75FR2022)

The definition of a Qualified EHR should also include the ability to produce a health record for legal, business, and disclosure purposes. An EHR system must be able to create, maintain, and manage records within a framework of ever-changing jurisdictional rules, regulations, and laws that are intended to assure electronic records are valid, accurate, and trustworthy. To that end, AHIMA recommends that ONC update the definition of Qualified EHR to state ''an electronic record of health-related information on an individual that: (A) Includes patient demographic and clinical health information, such as medical history and problem lists; and (B) has the capacity: (i) To provide clinical decision support; (ii) to support physician order entry; (iii) to capture and query information relevant to health care quality; *(iv) to produce a record of care for legal, business, and disclosure purposes*, and *(v)* to exchange electronic health information with, and integrate such information from other sources.''

Office of the National Coordinator for Health Information Technology
AHIMA Comments on *Standards and Certification IFR*
P a g e | **3**

To support the inclusion of new criterion (iv) above, the HL7 Records Management and Evidentiary Support Functional Profile should be included as the accompanying standard for this criterion.

III. B. 5. Definition of EHR Module (75FR2022)

AHIMA commends ONC for recognizing the need to certify EHR modules. We believe certification should allow providers the flexibility to select certified modules that are most useful to them. In addition, given the manner in which the definition is written, the modular approach will enable certification of other HIT technology across the enterprise that can be used in conjunction with the EHR, as well as other EHR components that support HIM within the enterprise. However, to enable EHR modules to work together, there should be a requirement that such modules are certified to work with each other (i.e., are interoperable across modules, not just certified to function successfully as an individual module).

III. B. 6. Definition of a Complete EHR

According to the IFR, a complete EHR is "…EHR technology that has been developed to meet all applicable certification criteria adopted by the Secretary… encompass EHR technology that can perform all of the applicable capabilities required by certification criteria adopted by the Secretary and distinguish it from EHR technology that cannot perform those capabilities…[and]…have capabilities beyond those addressed by certification criteria adopted by the Secretary." This definition is understandable and reasonable. Certification requirements, such as those from CCHIT, are a subset of functions of an EHR. As such, there needs to be a description of what the other "capabilities beyond those addressed by certification criteria" are. The HL7 Electronic Health Record System Functional Model (EHR-S FM) provides a set of functional requirements for EHR systems across various care settings, and can thus fill this need. AHIMA recommends that the IFR include, or at least refer to, the HL7 EHR-S FM as the standard to support the definition of a Complete EHR.

III. B. 8. Definition of Disclosure (75FR2023)

Accounting of disclosures is a very critical issue. Since the issue is so complex, AHIMA has submitted a separate letter specifically addressing the definitions, certification criteria and standards regarding Privacy, Security, and Accounting of Disclosures.

III. C. Initial Set of Standards, Implementation Specifications, and Certification Criteria (75FR2023-2024)

In response to ONC's goals and approach to adopting standards, implementation specifications and certification criteria, AHIMA supports the premise for keeping implementation costs low. However, one way to contain costs is through support of non-proprietary standards that are generally available in the public domain and easily implemented. Currently, though the term "standard interfaces" is used in system implementation, such interfaces are proprietary, point to point, and vendors often charge significant fees for any modifications to such interfaces. The standards and implementation

Office of the National Coordinator for Health Information Technology
AHIMA Comments on *Standards and Certification IFR*
P a g e | **4**

specifications defined in this IFR should include the promotion of true standard interfaces that all vendors and healthcare organizations can implement one way, which can reduce the costs of interoperability.

III. C. 1. Adopted Certification Criteria (75FR2024-2029)

Table 1 – Certification Criteria
Incorporate clinical lab-test results into EHR as structured data: AHIMA supports recommendations presented by the Health Information Exchange Workgroup during the HIT Policy Committee meeting held on February 17, 2010[1] to include the HL7 2.5.1 content exchange standard in the certification criteria for eligible provider and hospital EHR technology. The IFR's certification criteria specify that systems must be able to accept LOINC if LOINC is delivered to the system, but the IFR is silent on the content exchange requirements. We recommend that ONC also specify the content exchange standard as certification criteria.

Report quality measures to CMS or the states: AHIMA supports recommendations presented by the Adoption/Certification Workgroup during the HIT Policy Committee meeting held on February 17, 2010.[2] The workgroup highlighted the need for greater detail on how to calculate reporting metrics for items involving the percentage of *electronic* usage versus *manual* usage and called out the need for the IFR to include certification criteria for "Reporting Metrics," which would ensure automatic calculation of all metrics that are required to be reported.

Provide patients with timely electronic access to their health information within 96 hours of the information being available to the eligible professional: AHIMA requests further clarification on the term "electronic access" as described in the objective and corresponding measure. This could represent a variety of electronic methods and expectations should be clarified for eligible providers.

AHIMA also recommends that the objective be revised to state "Provide patients with *secure* and timely electronic access" and certification criteria should be added to address the necessary security and encryption requirements to support the objective.

---

[1] Micky Tripathi, Co-Chair, "Comments on Notice of Proposed Rule Making (NPRM) and Interim Final Rule (IFR)" (presented to the Health Information Technology Policy Committee, Washington, DC, February 17, 2010).
[2] Paul Egerman, Co-Chair, "Comments on NPRM, IFR" (presented to the Health Information Technology Policy Committee, Washington, DC, February 17, 2010).

Office of the National Coordinator for Health Information Technology
AHIMA Comments on *Standards and Certification IFR*
P a g e | **5**

III. C. 2. b. Content Exchange and Vocabulary Standards (75FR2031)

III. C. 2. b. i. Patient Summary Record (75FR2031)
Continuity of Care Document (CCD): The CCD is one of the most productive outcomes of the Healthcare Information Technology Standards Panel's (HITSP) work to harmonize competing standards. HL7, ASTM, and others developed the CCD for the purpose of having a single standard for exchanging core information among physicians. Following the adoption of the CCD by HITSP, the Certification Commission for Health Information Technology (CCHIT) began incorporating CCD into EHR certification criteria.

Both HITSP and CCHIT have vetted the issues surrounding the CCD and ASTM Continuity of Care Record (CCR) standards through an open consensus process and determined that the CCD should be the standard implemented by the industry. AHIMA supports industry movement toward one standard for the exchange of the patient summary record and recommends adoption of the CCD to avoid confusion and rework in the future.

Problem Lists: While we support the use of problem lists and understand the need to rely on ICD-9-CM for Stage 1, the quality of problem lists can be expected to be highly variable due to non-standard system dependent solutions and how clinicians define problems. This can result in a tendency to rely heavily on ICD-9-CM or other coded data, which may not adequately express the patient's current and past diagnoses and other data required for a useful problem list. We recognize that problem lists can be critical drivers of other functionality in the EHR such as clinical decision support, patient reminders, quality measures, and the support of clinical information exchange between providers.

We propose that problem lists not be generated from coded data entered by others as is sometimes the case in current practice, but rather that clinicians directly enter the appropriate information and as part of their workflow that can be converted to coded data for the above stated uses.

ICD-9-CM and/or ICD-10-CM code sets are acceptable as a short-term solution when healthcare providers are not yet ready to implement SNOMED CT® in EHR systems. Use of a classification system offers some value in reuse of data for administrative purposes, including claims submission for reimbursement.

Ultimately, AHIMA recommends use of SNOMED CT® for optimal clinical data capture and reuse of information captured in problem lists. We appreciate the evolution process and understand the limitations and variability the current options provide. The use of a classification system limits data mining for clinical research, quality of care measurement and communication between care providers and patients.

Office of the National Coordinator for Health Information Technology
AHIMA Comments on *Standards and Certification IFR*
P a g e | **6**

*Please also refer to Appendix A of AHIMA's EHR Incentive Program response letter for a more detailed discussion of Problem Lists.

III. C. 2. b. v. Quality Reporting (75FR2032)

ONC requests public comment on whether the Health Level Seven (HL7) Quality Reporting Document Architecture (QRDA) Implementation Guide is mature enough to be used in Complete EHRs and EHR Modules during meaningful use Stage 1. QRDA, a standard for communicating health care quality measure information, was developed and balloted through HL7's ANSI-accredited standards development process and was published as a draft standard for trial use in early 2009. This standard conforms to the requirements of the HL7 Clinical Document Architecture Release 2.0 (CDA) and reuses templates developed for the ASTM/HL7 Continuity of Care Document (CCD) and other CDA implementation guides. QRDA uses the same approach, model and code base that has been adopted by HITSP and widely implemented.

The CMS PQRI 2008 Registry XML Specification was designed for aggregate reporting from stand-alone registry products and not specifically structured for use with EHR systems. The CMS PQRI XML specification was not developed through a public, consensus-driven process, which we believe strengthens technical specifications and supports implementation and interoperability. Furthermore, CMS developed a QRDA-based PQRI specification in 2009 that is being reviewed and tested by the vendor community.

AHIMA strongly urges ONC to include QRDA as an adopted quality reporting standard during meaningful use Stage 1. Even though QRDA has not yet been widely implemented, it was recently successfully tested as part of the HITSP Interoperability Demonstration during the IHE Connectathon and HIMSS Interoperability Showcase. QRDA uses the same "templated CDA" strategy adopted by HITSP and aligns with new eMeasure specifications. Adopting QRDA now will prevent switching of standards and rework for vendors in the future.

III. C. 2. b. vi. Submission of Lab Results to Public Health Agencies (75FR2032)

AHIMA supports recommendations presented by the Health Information Exchange Workgroup during the HIT Policy Committee meeting held on February 17, 2010[3] to extend the same HL7 2.5.1 certification criteria for hospital lab reporting to all lab result reporting (not just to public health reporting as currently specified). Clarifying this expectation will support hospital laboratory results delivery to eligible professionals attempting to comply with meaningful use incentive requirements.

---

[3] Ibid. 1

Office of the National Coordinator for Health Information Technology
AHIMA Comments on *Standards and Certification IFR*
P a g e | **7**

III. C. 2. c. Privacy and Security Standards (75FR2034)
See AHIMA's specific letter addressing Accounting of Disclosures.

III. C. 4. Additional Considerations, Clarifications, and Requests for Public Comments (75FR2036)

III. C. 4. b. Human Readable Format (75FR2036)
Although it may be reasonable for certification criteria to incorporate use of additional vocabularies and code sets in parallel with Stage 2 meaningful use, we strongly urge ONC to specify the proposed requirements as early as possible to allow vendors adequate time to assess, implement and test standards in preparation for future certification requirements.

III. C. 4. c. Certification Criterion and Standard Regarding Accounting of Disclosures (75FR2036-2037)
See AHIMA's specific letter addressing Accounting of Disclosures.

III. C. 3. d. Additional Requests for Public Comment (75FR2037)
As previously mentioned, AHIMA recommends that ONC incorporate additional certification requirements that address ability to produce a health record for legal, business, and disclosure purposes, including the ability to create, maintain, and manage records within a framework of ever-changing jurisdictional rules, regulations, and laws that are intended to assure electronic records are valid, accurate, and trustworthy. The HL7 Records Management and Evidentiary Support Functional Profile should serve as the foundation for defining this type of criteria to ensure the legal validity of electronic records and support health care operations and interoperability.

Subpart C – Certification Criteria for Health Information Technology

§ 170.302(r) Audit Log
Systems offer the capability for system administrators to routinely "turn off" audit logging processes to increase system performance and address storage capacity issues. As audit data are used to support record integrity, compliance activities related to breaches, and inappropriate access, it is critical that audit logs be required during routine operations of the system, data be maintained in a secure manner and accessible in a human readable format. Many systems have logs but are often difficult to access (or can only be accessed by the vendor through special processes and with expense). Not addressing accessibility and security as part of the requirement will result in a mandate that is critical but may not be fully realized by the healthcare provider depending on the vendor that they select.

Office of the National Coordinator for Health Information Technology
AHIMA Comments on *Standards and Certification IFR*
P a g e | **8**

Additional requirements are needed to support the intent and purpose of the audit log for record integrity purposes and ensure that a minimum set of audit logging procedures are completed. AHIMA recommends the following requirements be added:

- Always be on during normal production for the minimum elements specified in 170.210(b)
- Maintained in a secure manner and alterations to the log tracked.
- Produced in a human readable format.
- Retained in conjunction with the retention period of the record.

Conclusions
AHIMA appreciates the opportunity to comment on the Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology IFR. This is a critical step toward achieving widespread interoperability and AHIMA stands ready to work with ONC and the healthcare industry to advance health IT standards and certification criteria.

If AHIMA can provide any further information, or if there are any questions or concerns in regard to this letter and its recommendations, please contact me at (312) 233-1135 or 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 dan.rode@ahima.org.

Sincerely,
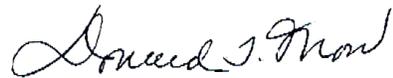
Donald T. Mon, PhD
AHIMA Vice President of Practice Leadership

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