1730 M Street, NW, Suite 502
Washington, DC 20036

phone » (202) 659-9440
fax » (202) 659-9422
web » www.ahima.org

May 7, 2012

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: 2014 Edition EHR Standards and Certification Proposed Rule
Hubert H. Humphrey Building Suite 729D
200 Independence Avenue, SW
Washington, DC 20201

Re: RIN 0991-AB82

Dear Secretary Sebelius:

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) Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition Proposed Rule (NPRM), as published in the March 7, 2012 *Federal Register* (45 CFR Part 170).

AHIMA is a professional association representing more than 64,000 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, validating the integrity of, reporting, releasing, and utilizing data vital for patient care, while making it accessible to patients, healthcare providers, authorized requestors, 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 NPRM follow our general comments below.

General

Future Updates to Standards, Implementation Specifications, and Certification Criteria
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 interoperability and access through an established blueprint.

Definition of Base EHR

The definition of a Base 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 Base EHR to state ''1. Includes patient demographic and clinical health information, such as medical history and problem lists; 2. 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 exchange electronic health information with, and integrate such information from other sources; v. to protect the confidentiality, integrity, and availability of health information stored and exchanged; and vi. ***to produce a record of care for legal, business, and disclosure purposes***.''

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities. Amendments. 2014 Edition EHR Certification Criterion §170.314(d)(4) (Amendments)

We suggest that ONC review the text supporting the proposed criterion for protecting electronic health information. The documentation describes "*amending*" a patient's record as allowing clinicians to correct errors or update the information within their record. Further down the description refers to the act of "*appending*" patient supplied information by using free text and/or scanned material.

We believe "*amend*" and "*append*" are distinct concepts and should not be combined into one certification criterion. If the intent is to allow these functions of correcting and/or attaching information to the patient's record then they should remain separate. Amending should not permit any overwriting of the existing documentation and should be dated, timed and authenticated. Appending data should accurately capture the date, time, and authentication of the appended information. Amending the patient record should be allowed via the two methods proposed – entering free text or scanning external documents. Scanned documents, however, should have to adhere to a standard such as .pdf or .jpg as specified in the final rule.

EPs **provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.** ***EHs and CAHs*** **provide patients the ability to view online, download, and transmit information about a hospital admission.** 2014 Edition EHR Certification Criterion - §170.314(e)(1) (View, download, and transmit to 3rd party)

AHIMA supports ONC stating that it would not be necessary or prudent to propose separate metadata standards at this time. We also support refraining from proposing a metadata standard for "privacy" and working with Standards Development Organizations (SDOs) and other stakeholders toward understanding and identifying what could be the ultimate privacy standard.

We encourage ONC to maintain awareness of the Office for Civil Rights (OCR) NPRM *HIPAA Privacy Rule Accounting of Disclosures under the Health Information Technology for Economic and Clinical Health Act* that was published in May 2011. Healthcare industry stakeholders are awaiting the final rule and trust that ONC will align requirements under this objective with those of OCR to preclude the confusion of conflicting regulations. Associated with this is the disclosure timetable as well. The CMS meaningful use proposed rule stage 2 states that EPs provide information to patients within four business days of its availability. OCR/HIPAA permits a 30 day timeframe. We encourage ONC to establish consistency in the regulatory timeframe under meaningful use.

2014 Edition EHR Certification Criterion. §170.314(g)(4) (Safety-enhanced design)

AHIMA supports ONC's effort to integrate safety-enhanced design requirements for certification of EHRs and EHR modules. Moreover, we assert that EHR technology usability and user centered design impacts provider and hospital ability to treat patients and capture data to support their care. It is imperative that health data be captured accurately and timely to maintain integrity of that information and to support the care and safety of patients.

We also believe these steps need to integrate safety enhanced designs aligned with the priorities and goals outlined in the report developed by the National Quality Forum (NQF) to provide input to HHS Secretary's National Quality Strategy.

Patient Safety Events – AHIMA supports ONC's consideration for leveraging the Agency for Healthcare Research and Quality's (AHRQ) current Patient Safety Organization (PSO) Common Format program to capture information about patient safety events. However we believe that requiring this as a mandatory certification criterion for Stage 2 would create significant challenges for EHR vendors particularly with implementing the new patient safety design components. This requirement should remain optional to allow the vendor community to focus on the human factors, safety culture, and usability of their EHR systems. We encourage ONC to consider this as a requirement for Stage 3 thus allowing time for developers and users of the systems to assess the new features.

Maintain an up-to-date problem list of current and active diagnoses. 2014 Edition EHR Certification Criterion §170.314(a)(5) (Problem list) Standards §170.207(a)(3) (SNOMED CT® International Release January 2012)

AHIMA supports the use of SNOMED CT® for optimal clinical data capture and reuse of information captured in problem lists. The use of a classification system such as ICD-10-CM limits data mining for clinical research, quality of care measurement and communication between care providers and patients. ICD-10-CM is a classification, and it is still designed to capture diagnoses and reasons for encounters, not every "problem." ICD-10 CM and PCS, where appropriate, should continue to be required for billing purposes. System vendors should not utilize the problem list for billing since billing practices and national coding guidelines require that claims only reflect those conditions attended to during the encounter being billed.

The problem list includes all conditions that may or may not be active and may or may not have been attended to during the encounter.

According to a paper recently published by AHIMA, "*Problem Lists in Health Records: Ownership, Standardization, and Accountability*" a controlled vocabulary is useful to support consistency across care settings. However, use of a classification may result in loss of information and difficulty of expressing conditions that fall outside the scope of the code set. The granularity of problem list data frequently changes during the care and treatment process, making encoding useful for information query and retrieval, but not as useful for repurposing for other things, including patient billing, quality measure reporting, or reimbursement from third-party payers.

Although compliance with "meaningful use" criteria for funding purposes may eventually require SNOMED CT codes for encoding problem lists, the healthcare community may question the need to encode problem list data at all. Some clinicians may ask, "If the primary purpose of the problem list is for effective patient care, why is a code needed?" SNOMED CT embedded in the EHR system enables encoding without code "assignment" by clinicians to support information retrieval from problem lists. Health information principles assert that the purpose of encoding is to facilitate search and retrieval of problems.

Another issue to avoid is the use of the problem list for billing – it should inform coding for reimbursement, but should not be considered as the final diagnosis set. Some providers want to use problem lists in this manner and it just doesn't work well using ICD. Problem list data can be mined for identification of problems identified, but they are not the same as confirmed final diagnoses.

For more information regarding the use of SNOMED CT®, AHIMA recommends referring to the following articles:

- AHIMA Workgroup. "Problem List Guidance in the EHR." *Journal of AHIMA* 82, no.9 (September 2011): 52-58.
- AHIMA Best Practices for Problem Lists in an EHR Work Group. "Best Practices for Problem Lists in an EHR." *Journal of AHIMA* 79, no.1 (January 2008): 73-77.

The EP, EH, or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral. 014 Edition EHR Certification Criteria §170.314(b)(1) (Incorporate summary of care record) §170.314(b)(2) (Create and transmit summary care record).

AHIMA supports the ONC's consideration of requiring specific data elements to be captured during the transition of care. We believe this will ensure a consistent list of data that must be captured and submitted to the receiving setting of care or provider. We do not believe this should be a separate certification criteria.

AHIMA does not support the proposal made that certified EHR technology include a requirement for performing demographic matching. We refer to a statement submitted to the ONC HIT Standards Privacy and Security Tiger Team by Dr. Scott Schumacher and Lorraine Fernandes, RHIA IBM Software Group, Information Management. We support their rationale expressed below:

- The patient matching function should be external to the EHR, as specialized technologies are used for this. One danger with having "some type" of demographic matching as part of the EHR is that organization may come to rely on this as their "only type" of matching and thus ignoring the other functions and processes critical to identity management.
- Key among these functions is data stewardship and early patient identification. Correct identification of the patient occurs in advance of the clinical data capture or creation, typically at the point of registration. Best practices require that ambiguities be resolved before clinical treatment thus many institutions develop patient identity solutions prior to implementing an EHR.
- Many business processes are used in managing the data stewardship function, and as we understand, business processes are not included within certification.
- Lastly, exchange of a CCD (or other discrete data) is generally conducted through a gateway and other specialized approaches such as Direct, not in the EHR itself. Matching these records, whether through technology or business processes, therefore happens outside the EHR in the same manner as patient-presented information.[1]

The EP, EH, or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation. 2014 Edition EHR Certification Criterion - §170.314(b)(4) (Clinical information reconciliation)

AHIMA supports ONC's proposal to require that EHR technology includes:
1. Ability to display data elements from two or more sources.
2. Ability to merge or remove individual data elements.
3. Ability to review and validate the accuracy of a final set of data elements.

We encourage ONC to include the certification requirement that the EHR technology perform demographic matching or verification between the data sources. This process would further ensure the integrity of patients' health information and improve patient safety by avoiding the inadvertent combination of health information belonging to two different patients.

2014 Edition EHR Certification Criteria §170.314(c)(1) (Clinical quality measures—capture and export) §170.314(c)(2) (Clinical quality measures—incorporate and calculate) §170.314(c)(3) (Clinical quality measures—reporting) Standard §170.204(c) (NQF Quality Data Model)

[1] Lorraine Fernandes, e-mail message to Deven McGraw, April 12, 2012.

ONC requests comments on whether any standards would be adequate for CQM data export. Quality Reporting Document Architecture (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 Phase III effort was recently launched in January 2012. It continues to be co-sponsored by the HL7 Structured Documents and Child Health Work Groups, and is supported by the Centers for Medicare & Medicaid Services (CMS). The work effort will update and ballot the QRDA Category I DSTU, and include a U.S. Realm Quality Data Model (QDM)-based QRDA Category I Implementation Guide to direct implementers on how to construct QRDA Category I instances in conformance with HITECH eMeasures.[2]

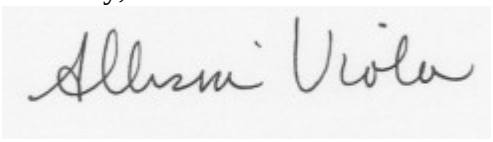
AHIMA strongly urges ONC to include QRDA as an adopted quality reporting standard during meaningful use Stage 2. Adopting QRDA now will prevent switching of standards and rework for vendors in the future.

Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.
2014 Edition EHR Certification Criterion §170.314(d)(7) (Encryption of data at rest)

AHIMA strongly supports ONC's proposal to include the requirement of encrypting data at rest. However, we encourage ONC to evaluate the necessary steps to incorporate the ability to access a patient's health information during urgent or emergency situations.

We thank you for the opportunity to provide comments on the proposed regulation and if AHIMA can provide any further information or if there are any questions regarding this letter and its recommendations, please contact me at (202) 659-9440 or allison.viola@ahima.org, or AHIMA's vice president, advocacy and policy, Dan Rode, at (202) 659-9440 or dan.rode@ahima.org. If we can be of further assistance to you in your efforts, we would welcome the opportunity to provide support.

Sincerely,



Allison Viola, MBA, RHIA
Senior Director, Federal Relations

cc: Dan Rode, MBA, CHPS, FHFMA, Vice President, Advocacy and Policy

[2] "Quality Reporting Document Architecture Project – Project overview," HL7 International, accessed April 25, 2012, http://wiki.hl7.org/index.php?title=Quality_Reporting_Document_Architecture