September 23, 2011

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

Re: RIN 0991-AB78

Dear Mr. Posnack:

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) advance notice of proposed rulemaking to establish metadata standards to support nationwide electronic health information exchange as published in the August 9, 2011 *Federal Register* [76FR48769]. Our comments focus on those areas of particular interest to our members.

AHIMA is a not-for-profit professional association representing more than 63,000 health information management (HIM) professionals who work throughout the healthcare industry. AHIMA's HIM professionals are educated, trained, and certified to serve the healthcare industry and the public by managing, analyzing, reporting data vital for patient care, while making it accessible to healthcare providers and researchers when it is needed most. AHIMA and its members also participate in a variety of projects with other industry groups and agencies Department of Health and Human Services related to the use of secondary data for a variety of purposes including quality monitoring, reimbursement, public health, patient safety, biosurveillance, and research.

As you may be aware, AHIMA has been closely engaged in promoting the need for standards related to metadata for a variety of purposes necessary to ensure the accurate provision and understanding of health information and data. We have consistently called for a governance process for US standards for terminology and classifications and this would include a standard vocabulary associated with metadata in order to achieve true interoperability

General Feedback
AHIMA supports ONC's efforts to solicit public comments on the development of standards for metadata in response to the recommendations listed in the Executive Office of the President President's Council of Advisors on Science and Technology (PCAST) report, "Report to the President realizing the full potential of health information technology to improve healthcare for

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Americans: The Path Forward.[1]" We believe, however, that the current health information technology environment is too premature to move forward in developing standards for metadata. We encourage ONC to explore this technology further by conducting additional demonstration programs that would enable thorough testing and evaluation prior to proposing standards for adoption through the regulatory process. This would also enable exploration of the challenges and successes of implementation.

Metadata is not only important at the level of electronic exchange of summary records, but it is also critical for the source system creating and maintaining the data. AHIMA recognizes that applying this technology has the power to potentially increase reliability, dependability, and trustworthiness of electronically exchanged health information.

- Metadata is a critically important in establishing the integrity of the electronic health record (EHR) for business and legal purposes as described by the American Bar Association's publication *The Foundations of Digital Evidence*[2]. Healthcare policy and standards for EHR systems must address a comprehensive approach to metadata and its management to ensure a foundation of authenticity and integrity attributes for records created in these systems.

- Detail the minimum metadata elements for record provenance at the following key record lifecycle events:
    1. Originate (User ID, Patient ID, Date/Time, System ID)
    2. Amend (User ID, Patient ID, Date/Time, System ID)
    3. Attest (User ID, Patient ID, Date/Time, System ID)
    4. Access (User ID, Patient ID, Date/Time, System ID)
    5. Transmit/Disclose (User ID, Patient ID, Date/Time, System ID)
    6. Receive from External System (User ID, Patient ID, Date/Time, System ID)
    7. Deidentify (Alias) and Reidentify (User ID, Patient ID, Date/Time, System ID)
    8. Converge (User ID, Patient ID, Date/Time, System ID)
    9. Translate (User ID, Patient ID, Date/Time, System ID)
    10. Archive (User ID, Patient ID, Date/Time, System ID)
    11. Destroy or Identify as M (User ID, Patient ID, Date/Time, System ID)
    12. Deprecate (User ID, Patient ID, Date/Time, System ID)

- Retention and storage of minimum metadata elements must be addressed by the healthcare industry. Concerns with retention and storage of audit records, transaction logs and metadata has been identified as a challenge by vendors and providers. Healthcare policy and standards must identify the minimum set that requires retention for the life of the record.

Patient Identity Metadata Standards
Question 1: *Are there additional metadata elements within the patient identity category that we should consider including?   If so, why and what purpose would the additional element(s) serve? Should any of the elements listed above be removed? If so,why?*

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[1] Executive Office of the President President's Council of Advisors on Science and Technology. *Report to the President realizing the full potential of health information technology to improve healthcare for Americans: The Path Forward*. Washington: December 2010.

[2] Paul, George L. "Foundations of Digital Evidence" American Bar Association, ABA Publishing, 1st Edition KF9650.P385 2008.

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AHIMA encourages ONC to refer to the e-prescribing community for positive patient identity matching in the use of drug coverage. Information such as patient last name, first name, date of birth, gender, and ID plus ID indicator is currently used within e-prescribing. Adding the data element for gender would meet the current level of identity used. So with the addition of gender, the patient ID portion of the rule would at least meet the level currently in use for e-prescribing. We also recommend including a data element for "alias" in the patient identity category. This data element(s) will enable the use of an alternative or signal to the provider that the patient may also have another name.

Question 2: *In cases where individuals lack address information, would it be appropriate to require that the current health care institution's address be used?*

At a minimum AHIMA supports capturing this data set in lieu of a personal address provided by the patient. However, we strongly caution the use of this data set for long term purposes as the name of a facility may give away sensitive information such as in pediatrics or abuse victims' situations. We encourage ONC to consider developing a flag and a method to help protect the privacy, identity, and the location where the patient is receiving care.

Question 3: *How difficult would it be **today** to include a ''display name'' metadata element? Should a different approach be considered to accommodate the differences among cultural naming conventions?*

In the current EHR environment AHIMA members do not experience the ability to accommodate names from different cultures. By requiring this capability it could push the industry forward in enabling this in the EHR systems.

Also, according to HL7, the structure of an HL7 CDA R2 name provides the "display name" capability, because the name components are provided in display order. There is also the capability in CDA Release 2 to provide a search string for the display name, as shown in this example: <name use='SRCH'>Henry Levin the 7th</name>[3]

Provenance Metadata Standards
Question 4: *Are there additional metadata elements within the provenance category that we should consider including? If so, why and what purpose would the additional element(s) serve? Should any of the elements listed above be removed? If so, why?*

AHIMA has identified several elements of this section that requires additional clarification.
Actor – This term should be clarified further to describe the author, specialty and organizational affiliation, the service(s) performed and the date upon which the services were performed.
X.509 digital certificate – Further clarification is needed to identify the authorized "actors" to sign the certificate. AHIMA encourages ONC to develop the structure and process for certificate signature.

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[3] Keith W. Boone (GE Healthcare), e-mail message to HL7 Structured Documents list group, September 14, 2011.

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The CDA document has the ability to be associated with multiple digital signatures for many different purposes. We believe that these should be separated from the document because the use cases for access to content and verification of the signature are often different. This will also allow for more secure protection of sensitive data.

AHIMA recommends incorporating the ability to allow for multiple "actors" and their role within the provenance data. There may be situations where it is critical to provide an alternative to the initial actor identified. We encourage ONC to allow provenance metadata to work in reverse whereby the patient submits data to a provider. In this situation, the data is tagged with information about the patient serving as the "actor" of this information to inform providers that this information attributed to the patient.

The summary care record most likely will pull information from a variety of sources. The metadata should not reflect just the summary record; it should represent each of the data submitted to create the summary care record from the source system. This will increase the confidence of the providers receiving the information from other sources and enable the source credibility and the ability to audit the data.

Question 5: *With respect to the provenance metadata elements for time stamp, actor, and actor's affiliation, would it be more appropriate to require that those elements be expressed in XML syntax instead of relying on their inclusion in a digital certificate? For example, time stamp could express when the document to which the metadata pertain was created as opposed to when the content was digitally signed. Because this approach would decouple the provenance metadata from specific security architecture, would its advantages outweigh those of digital certificates?*

AHIMA supports the use of X.509 certificates, however as stated above in question #4 we recommend signing the data elements themselves as well as separating this from the signature of the document.

Privacy Metadata Standards
Question 6: *Are there additional metadata elements within the privacy category that we should consider including? If so, why and what purpose would the additional element(s) serve? Should any of the elements listed above be removed? If so, why?*

Inclusion of the policy pointer should provide additional details regarding the handling of patient information such as not re-disclosing certain information, information may be used for certain purposes. No matter what information is being transmitted, there should not be any hints on what information is being held within the envelope to ensure privacy of sensitive information.

Question 7: *What experience, if any, do stakeholders have regarding policy pointers? If implemented, in what form and for what purpose have policy pointers been used (for instance, to point to state, regional, or organizational policies, or to capture in a central location a patient's preferences regarding the sharing of their health information)?*

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AHIMA encourages ONC to also review HITSP Technical note 900 in draw concepts for the input into the policy pointer development process.

Question 8: *Is a policy pointer metadata element a concept that is mature enough to include as part of the metadata standards we are considering? More specifically, we request comment on issues related to the persistence of URLs that would point to privacy policies (i.e., what if the URL changes over time) and the implication of changes in privacy policies over time?*

AHIMA views this as an ability to identify issues that may develop regarding the exchange of information across state lines. Privacy policies will (and do) vary across states and within jurisdictions. There needs to be a mechanism in place within the exchange environment in which users can identify and refer to such policies. With regard to the metadata element concept being "mature enough" to handle these types of points, at this point in time we do not believe it is.

Question 9: *Assuming that a policy pointer metadata element pointed to one or more privacy policies, what standards would need to be in place for these policies to be computable?*

Privacy laws differ from state to state and as the need for exchange of data increases, it is critical to address the variations in state laws before standards are identified and selected.

Question 10: *With respect to the privacy category and content metadata related to ''data type,'' the HIT Standards Committee recommended the use of LOINC codes to provide additional granularity. Would another code or value set be more appropriate? If so, why?*

AHIMA generally supports the use of this standard however we caution ONC in the use of LOINC codes as they are generally not linked in current systems to their data element. For example, in order to interface labs with HIEs, facilities must manually enter the proper LOINC code for each lab test. If LOINC codes are currently integrated by vendors with systems, it will take facility manpower to manually match these up.

Additional Questions
Question 13: *With respect to the first use case identified by the HIT Policy Committee for when metadata should be assigned, how difficult would it be for EHR technology developers to include this capability in EHR technology according to the standards discussed above in order to support meaningful use Stage 2?*

AHIMA's membership believes the EHR technology is mature enough to include this capability in Stage 2 as there is wide variation in capabilities within the vendor industry. An alternative might be to signal the industry on what should be included moving forward into Stage 3 of meaningful use.

Question 14: *Assuming we were to require that EHR technology be capable of meeting the first use case identified by the HIT Policy Committee, how much more difficult would it be to design EHR technology to assign metadata in other electronic exchange scenarios in order to support*

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meaningful use Stage 2?   Please identify any difficulties and the specific electronic exchange scenario(s).

Should ONC choose to identify additional data elements to the metadata requirements, AHIMA believes this will create challenges for developers and current users of the EHR systems that have already been implemented. If the metadata were prepared, wrapped, and submitted in a similar fashion to the scenarios initially created by ONC we don't believe this would create too much of a challenge however this may not be a realistic expectation.

Question 15: *Building on Question 14, and looking more long term, how would the extension of metadata standards to other forms of electronic health information exchange affect ongoing messaging and transactions? Are there other potential uses cases for metadata that we should be considering? Would the set of metadata currently under consideration support these different use cases or would we need to consider other metadata elements?*

Other use cases that would be beneficial in further analysis and consideration are addressing public health. By incorporating public health it will help further and enhance the development of electronic health information exchange within communities. By including a few more demographic data elements it could extend the value of using metadata.

Exchange of health information for payment purposes is an emerging and critically important use case for ONC to consider. Payers rely on identification and provenance metadata both from the source EHR application and for the exchange/summary record. Payers are beginning to require the ability to machine-process records from EHR systems to support the claims payment and medical review processes. Metadata is required to convey the authenticity and integrity of the record used for payment determination purposes.

As noted above, AHIMA has been addressing issues related to metadata for several years and we would like to extend our knowledge and expertise to ONC, if needed during the pre-NPRM period. In the meantime, 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,
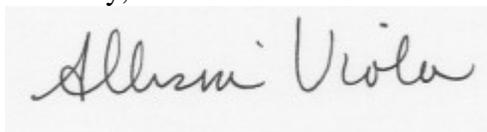
Allison Viola, MBA, RHIA
Director, Federal Relations

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