



The Office of the National Coordinator for
Health Information Technology



Summary of Public Comments

ONC Metadata ANPRM

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October 21, 2011

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- On August 9, 2011, the ANPRM was published in the Federal Register.
- Public comments were due by September 23, 2011.
- ONC introduced metadata elements in 3 categories: Patient ID, Provenance, and Privacy.
- ONC also requested comment on 20 specific questions.
- In total, 51 comments were received.

Note: The following presentation outlines an initial analysis of the public comments made in response to ONC's Advance Notice of Proposed Rulemaking entitled "*Metadata Standards to Support Nationwide Electronic Health Information Exchange.*" This summary does not reflect the position of the Office of the National Coordinator for Health IT.

- ONC received comments from:
 - Associations, EHR vendors, HIT Software Companies (11/51).
 - Infrastructure experts and Standard Development Organizations (2/51).
 - Providers, Pharmacy or Pharmacy Organizations, Hospitals and Health Plans (21/51).
 - Others including Policy Organizations, Individual Citizens and Government Entities (17/51).

- **General - Use of Metadata:** 48 of the 50 commenters supported use of metadata.
 - Many were opposed to federal regulations and wanted industry (SDOs) to set metadata standards.
 - 9 commenters specifically said that metadata standards are not ready to be included for Stage 2.
- **General - Using CDA R2:** 16 out of 27 commenters supported use of HL7 CDA R2.
 - Of the 11 “no’s,” many were resistant to specifying CDA R2 as a standard and requested that regulations only specify the metadata elements and not architecture.

- The ANPRM posed 20 questions related to:
 - Patient Identity
 - Provenance
 - Privacy
 - Policy Pointers
 - Privacy Categorization Standards
 - Implementation Considerations / Use Cases
 - Additional Considerations
 - Additional Standards
 - Metadata Representation Structure

- **Commenters generally supported the patient identity data elements listed in the ANPRM but offered the following recommendations:**
 - **Name**: Require birth name, maiden name, and date ranges (*e.g., individuals can have several different last names from marriages/divorces, dates would be important for proper id*).
 - **Date of Birth**: Need to specify "month, day, year" format.
 - **Address** (current): 10/24 commenters who supported "address" as a metadata element stated that more detail must be provided before address is a useful metadata element (*without date ranges, address can be less reliable/useful*).
 - **Zip code** (current): 9/23 commenters supported "zip code" as a metadata element stated that more detail must be provided before it is a useful metadata element (*some stated that zip code should be changed to postal code to accommodate international addresses*).
 - **Additional Pt ID Elements**: 24/26 commenters stated that additional Pt ID elements are essential for accurate patient matching. A number of vendors stated that patient ID should NOT be part of data and that metadata should describe only the type of document in the package.

- **Additional metadata elements within the patient identity category suggested for inclusion:**
 - Gender (n=12)
 - Place of birth: (n=6) (city and state, or foreign country) is a data point that does not change over time.
 - Unique, voluntary patient identifier (n=3) /National patient ID (n=2)
 - Mother’s maiden name (n=4) or first name (n=2)
 - Birth order: (n=3) May be required to identify newborns, who may not yet have full demographic information available.
 - Race/ethnicity (n=3)
 - Previous address/zip with date ranges (n=2)
 - Phone /email address (n=2)
 - Insurance policy number (n=2)

- **Commenters suggested that the following elements should be considered for removal:**
 - Address: should be optional; of marginal additive value in making a positive patient identification and cannot be used with a high degree of certainty.
 - Zip code: not a good identity field as it is often inaccurately reported by patients or not known, and it may change over time as needed by the US Postal Service.
 - Name Prefix: changes routinely, and name prefix is not a contributor to unique identity, no added value.
 - Last 4 digits of SSN: consider as a secondary and not primary match criterion because it will not be unique. Consider using full SSN.
- A majority of commenters (26/30) believe that if an individual lacks address information, then it would NOT be appropriate to include the institution's address.

- **Additional Provenance Elements: 16/21 commenters stated that additional provenance elements are essential for accurate data linkage during queries.**
 - Specifically, commenters wanted additional data elements about:
 - Dates of service (n=6)
 - Actor and their credentials (n=5)
 - Author and their role (n=5)
 - Type of service performed (n=4)
 - Document type (i.e., consent, lab, summary doc) (n=2)
 - Document creation date/timestamp (n=3)
 - Source of the information (e.g., pt, family, provider, lab, etc) (n=2)
- Commenters (n=8) stated that the digital signature should not be included as part of the metadata.
- A majority of commenters recommended that time stamp, actor, and actor's affiliation be expressed in XML syntax rather than including in a digital certificate (n=17).

- Metadata should only describe the data set.
 - Privacy should be a separate layer from the metadata. Many commenters suggested looking into HITSP TP30.
- Many commenters had concerns that detailed privacy tags would inadvertently divulge sensitive information.

- **Policy Pointers:**
 - 19/28 commenters stated that the use of policy pointers would be problematic.
 - 11 commenters specifically stated that policy pointers should not be part of Stage 2 certification requirements.
- Reasons given to **exclude** policy pointers in metadata:
 - The use of policy pointers are immature due to lack of necessary standards, infrastructure, and industry experience.
 - Policy persistence is an issue. Current policy pointer technology does not scale as data sets age or policies are updated.
 - Currently, privacy policies cannot be expressed in a computable fashion.

- **Metadata Sensitivity Tags:**

- 21/27 commenters supported the use of sensitivity tags.
 - 11/21 yes's were conditional where commenters stated that more LOINC codes may not be accurate enough.
- Most commenters supported the use of LOINC, but also suggested SNOMED.
 - Many warned of value set being too granular and allowing inferences to be made.
- Most commenters agreed with the HIT Standards Committee's recommendation against adopting an approach that would tag privacy policies directly to the data elements.
- 8 commenters specifically stated that the ConfidentialityByInfoType value set should not be used. Instead they advocated for the use of ConfidentialityByAccessKind.

- As stated previously, most commenters supported the use of HL7 CDA R2.
- Some were concerned that changes proposed in the ANPRM to the CDA R2 header would be non-compatible.
- A few commenters specifically stated that no representation structure should be proposed without pilot testing.
- Several commenters asked that ONC specify only the metadata elements and not the representation structure.
- A number of vendors asked ONC to consider XDS instead of HL7 CDA R2.

Implementation Considerations/ Use Cases

- Commenters were divided regarding the level of difficulty in designing EHR technology to assign metadata for MU Stage 2.
 - Some believed that EHR technology is mature enough to include this capability.
 - Others felt strongly that not enough progress has been made to include this capability.
 - Additional analysis and real-world testing is needed before proposing metadata standards to support Stage 2.
- Other potential use cases identified for metadata included: Public health, research queries/clinical trials, disease registries, transitions of care, patient engagement, and billing purposes.

Additional Standards and other Considerations

- Most commenters believed that additional categories of metadata are not necessary other than patient ID, provenance and privacy.
 - Although as presented, most commenters felt that standards to support privacy metadata were either unavailable or immature.
- Several commenters pointed out that a metadata element could be used for patient ID, provenance, and privacy.
 - They are not mutually exclusive to one category.
 - Metadata categories are better described as uses of metadata.
- Some commenters recommended that ONC clearly define expectations and requirements for managing changes to metadata elements (such as name) over time.

Questions?