



NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS

September 23, 2011

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

**Re: RIN 0991-AB78
NCVHS Comments on Advanced Notice on Proposed Rule Making on “Metadata Standards to Support Nationwide Electronic Health Information Exchange” – 45 CFR Part 170**

Dear Mr. Posnack:

The National Committee on Vital and Health Statistics (NCVHS) is the statutory public advisory body on health data, statistics, and national health information policy to the Department of Health and Human Services (HHS).

The Advanced Notice of Proposed Rule Making (ANPRM) on “Metadata Standards to Support Nationwide Electronic Health Information Exchange” issued by the Office of the National Coordinator for Health Information Technology (August 9, 2011 Federal Register) calls for the adoption of a series of proposed ‘metadata’ standards to ‘tag’ certain information to a patient’s electronic summary of care record before a provider discloses the summary to the patient or, upon the patient’s request, transmits the summary to his or her personal health record.

The ANPRM builds on recommendations made by the HIT Policy and Standards Committees to ONC on some possible initial steps that could be taken to begin implementing the metadata tagging recommendations included in the report of the President’s Council of Advisers on Science and Technology (PCAST).

The proposed regulations focus on three categories of metadata:

1. Patient identity: the minimum necessary data required to uniquely select a patient from a population with a guaranteed degree of accuracy

2. Provenance: the minimum data elements required to document the history, origin and modifications of the data which the metadata is about
3. Privacy: the minimum data to document and transmit the data type, sensitivity and patient privacy preferences about the sharing of his/her health information

The ANPRM is also considering the adoption of standards for these metadata categories in support of Stage 2 of the Meaningful Use (MU) program, and establishing certification criteria for Electronic Health Record Systems (EHRs) to be capable of applying the metadata standards for Stage 2 MU (in the context of the purposes described above). The ANPRM argues that this metadata tagging capability may also be applied to other directed transfers of health information (i.e., as part of the requirements for transitions of care), and looking forward, the health care industry could gradually develop innovative ways to repurpose this capability to be applied to specialized extensions to meet future policy and organizational objectives.

Although metadata tagging has the potential to increase the reliability, dependability and trustworthiness of health information exchanges by including metadata descriptors about the data being exchanged, this approach is not in current use and there are no accepted standards for metadata tags. Consequently, we believe that it is premature to start the rulemaking process for metadata standards without having a better understanding of the current level of maturity of those standards, assessment of the degree to which they have been tested or even used in the industry, a careful analysis of possible unintended consequences, and, more importantly, a policy framework that defines their use. More specifically, we are concerned about several aspects of the proposed regulation. We have organized our comments into the following two areas: Overall regulatory approach and Scope, Priority areas and Recommended Standards.

1. Overall Regulatory Approach

We believe that the adoption of a series of standards for metadata tagging via formal regulations is premature and contrary to the practice of first testing and demonstrating how such standards (and the technical assumptions that go along with them) will actually work. We are concerned that the proposed standards, while they may be appropriate in content, are not mature enough to 1) be formally adopted as new national standards and 2) be required to be implemented as part of the Meaningful Use program. In this regard, we strongly agree with the conclusion reached by the HIT Standards Committee that the overall metadata tagging technology approach and, specifically, the standards to be used, should be thoroughly tested and evaluated prior to proposing these standards for adoption through regulation. The ANPRM mentions only once (and in a very brief, passing form) ONC's intent to "seek pilot testing of the metadata standard to gain insights into any implementation-level challenges that may exist." This



is contrary to the practice of first testing and vetting new standards before they are adopted by regulation.

We also agree with the concerns expressed by many commenters on the PCAST report regarding the timing of adoption of these recommendations. Industry and providers currently are focused on a number of time-sensitive initiatives, including Meaningful Use Stage 1, preparation for Meaningful Use Stage 2, the transition to updated administrative transactions and ICD-10 code sets, the implementation of new HIPAA standards and operating rules, and the move towards new forms of health care delivery and financing under the Affordable Care Act. Introducing yet to be tested standards in the midst of these initiatives would pose significant challenges and risks to the health care industry.

Recommendations

- Do not move to an NPRM until the proposed standards have been thoroughly tested in demonstration projects
- Specify the parameters, metrics, and expected outcomes for such pilots and demonstration projects
- Do not incorporate mandatory metadata tagging into MU Stage 2
- Do not create certification criteria for EHRs based on the proposed standards, until they have been thoroughly tested, demonstrated and evaluated

2. Scope, Priority Areas and Recommended Standards

■ Scope

The ANPRM specifically states that the immediate scope is the association of metadata with a summary of care record, and more precisely, the instance where a patient obtains a summary of care record from a health care provider's electronic health record system or requests that the summary of care record be transmitted to their personal health record.

However, there is some confusion about whether the proposed focus of the ANPRM is document-level metadata tagging or granular data element-level metadata tagging. In other words, it is unclear whether the proposed metadata tagging is to occur at the document level (such as the summary of care record) or at the level of specific data elements contained in a document, and whether such tags will 'stay' with the data elements once the document is opened and its data extracted.

Recommendations



- We strongly recommend clarification of the scope in any future proposed rule.
- We further recommend that any proposed regulations be clear and unambiguous about applying only to document-level tagging, as we do not believe data-element-level tagging is appropriate and mature enough at this point to be included in any formal regulations.

■ Overall Syntax and Format Standard

The ANPRM notes the intent to propose the adoption of the XML syntax and format requirements contained in the HL7 CDA R2 header (section 4.2 of the HL7 CDA R2) to express all the proposed metadata. In addition, there is an intent to propose additional metadata elements for certain information that is not currently required as part of the HL7 CDA R2 header.

While we generally agree with this approach, we are concerned that this standard will only be applicable to the specific use case, the summary of care record, and that it might not be extendable to other adopted message standards (such as those used in administrative transactions or other health information exchanges that do not use an HL7 structure). It will be important that the proposed rule clarify the scope and, more importantly, the limitations of the recommended syntax and format standard.

■ Priority Areas and Recommended Standards

- Patient Identity Metadata Standard: While we agree with the overall value that patient identify metadata will provide, this functionality needs to be guided by privacy and confidentiality policies for specified purposes.
- Provenance Metadata Standard: “Provenance”, in our view, represents the area that offers the most promising short-term applicability for the proposed new approach. We agree with the data elements identified for inclusion in the recommended metadata standard for Provenance (a tag data element identifier, a time stamp, the actor and actor’s affiliation and the actors digital certificate). We are concerned, however, that the purpose and applicability of the tag data element identifier is not clearly stated and explained in the ANPRM.
- Privacy Metadata Standard: Overall, we have several strong concerns regarding the adoption of metadata standards at the data element level for tagging summary of care documents with privacy information and, ultimately, the establishment of Meaningful Use Stage 2 requirements and certification



criteria associated with privacy metadata. Most of these concerns have already been discussed in detail in our August 26, 2011 Letter to the Secretary on “NCVHS Recommendations to Achieve the Goals of the PCAST Report on Health Information Technology”. We would like to emphasize a few points in this letter.

First, we believe that the lack of a policy framework for how privacy metadata will be expected to be used, received, acknowledged and enforced by organizations significantly constrains its value and limits its applicability. We are concerned that the ANRPM makes a number of technical and operational assumptions about how the system of privacy metadata tagging would work, many of which are yet untested and simply theoretical. For example, the Policy Pointer standard assumes the existence of a privacy policy repository or registry to which the metadata would point for access, retrieval and execution of privacy preferences.

The fact that patients may be able to set their privacy preferences and entities will use metadata tags to attach such preferences to specific documents does not establish a legal requirement on the receivers of such documents to honor, acknowledge, accept or enforce such preferences. Instead, the proposed approach, in the absence of enforceable policies, will create unrealistic and unenforceable expectations among consumers that their choices are to be acknowledged and enforced equally and consistently across health care organizations. We have noted in our PCAST Letter that technology should not dictate policy, and here we want to reinforce this point by noting that metadata tagging technology cannot and must not define privacy policy.

Second, we are concerned with the inclusion of patient identifiers in the metadata, without a much better understanding of how this information will be securely protected, transmitted and used. The risks of potential data breaches and misuse of information are not well defined and could be significant.

Third, we believe that the use of privacy metadata tagging could create significant liability risks and legal concerns among providers and others, potentially slowing down health information exchanges almost to a standstill.

Fourth, the Content Metadata standard is described in the ANPRM to “represent those elements needed to implement and reflect organizational policies as well as federal and state laws that would be applicable to the underlying data”. This description is confusing and creates an impression of



a 'tag' that will be so large and cumbersome (containing all applicable cited[?] organizational policies and federal and state laws) it will require very complex electronic mechanisms to execute appropriately on the data being tagged. It is not clear either to what extent the tag, in its two forms (or components, as referred to in the ANPRM, namely Data Type and Sensitivity) will apply to the entire document, sections of data inside the document, or specific data elements. Given that the immediate scope of the proposed regulations is the association of metadata with a summary of care record, the proposed rules should be clear as to the level which privacy metadata tags will apply.

Lastly, it seems clear that the proposed method relies heavily on theoretical concepts and assumptions, and little or no actual implementation or even testing of the entire approach is available.

In conclusion, we want to emphasize the need for ONC to first explore the feasibility of the proposed approach to metadata tagging through pilot and demonstration projects to inform development of a policy framework, including purpose, use cases, governance, privacy, and security, before adopting and requiring the use of metadata tagging standards.

NCVHS wishes to acknowledge the significant work done by ONC to advance the discussion on the use of a metadata tagging approach. At the same time, the Committee believes that the nation cannot afford to risk the important progress made thus far on the adoption and meaningful use of electronic health records and health information exchanges by diverting valuable resources towards the implementation of new, yet to be tested, standards under an overall metadata tagging approach that, we believe, is not mature for regulatory adoption.

Sincerely,

/s/

Justine M. Carr, MD
Chair
National Committee on Vital and Health Statistics

cc: The Honorable Kathleen Sibelius, Secretary, HHS
HHS Data Council

