

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0991-AB78

Metadata Standards to Support Nationwide Electronic Health Information Exchange

AGENCY: Office of the National Coordinator for Health Information Technology, Department of Health and Human Services.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: Through this advance notice of proposed rulemaking (ANPRM), the Office of the National Coordination for Health Information Technology (ONC) is soliciting public comments on metadata standards to support nationwide electronic health information exchange. We are specifically interested in public comments on the following categories of metadata recommended by both the HIT Policy Committee and HIT Standards Committee: patient identity; provenance; and privacy. We also request public comments on any additional metadata categories, metadata elements, or metadata syntax that should be considered. The immediate scope of this ANPRM is the association of metadata with summary care records. More specifically, in the scenario where a patient obtains a summary care record from a health care provider's electronic health record technology or requests for it to be transmitted to their personal health record. Public comment, however, is also welcome on the use of metadata relative to other electronic health information contexts.

DATES: To be assured consideration, written comments must be received at one of the addresses provided below, no later than 5 p.m. on [INSERT DATE 45 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Similarly, electronic comments must be

received by Midnight Eastern Time on [INSERT DATE 45 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER] as the Federal Docket Management System will not accept comments after this time.

ADDRESSES: Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments, identified by RIN 0991– AB78, by any of the following methods (please do not submit duplicate comments).

- Federal eRulemaking Portal: Follow the instructions for submitting comments. Attachments should be in Microsoft Word or Excel, Adobe PDF; however, we prefer Microsoft Word. <http://www.regulations.gov>.
- Regular, Express, or Overnight Mail: 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. Please submit one original and two copies.
- Hand Delivery or Courier: 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. Please submit one original and two copies. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your

comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: a person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered to be proprietary. We will post all comments received before the close of the comment period at [http:// www.regulations.gov](http://www.regulations.gov).

Docket: For access to the docket to read background documents or comments received, go to [http:// www.regulations.gov](http://www.regulations.gov) or U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection).

FOR FURTHER INFORMATION CONTACT: Steven Posnack, Director, Federal Policy Division, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology, 202– 690–7151.

SUPPLEMENTARY INFORMATION:

Acronyms

ANPRM	Advance Notice of Proposed Rulemaking
ASTM	American Society for Testing and Materials
ARRA	American Recovery and Reinvestment Act of 2009
BPPC	Basic Patient Privacy Consents
CCR	Continuity of Care Record
CDA R2 PCD	Clinical Document Architecture Release 2: Patient Consent Directives
CDC	Centers for Disease Control and Prevention

CDISC	Clinical Data Interchange Standards Consortium
CFR	Code of Federal Regulations
CMS	Centers for Medicare & Medicaid Services
EHR	Electronic Health Record
EPAL	Enterprise Privacy Authorization Language
EO	Executive Order
HIEs	Health Information Exchanges
HHS	Department of Health and Human Services
HL7 CDA R2	Health Level 7 Clinical Document Architecture Release 2
HL7 V2	Health Level 7 Version 2
HIT	Health Information Technology
HITECH Act	Health Information Technology for Economic and Clinical Health Act
ICD-9	International Classification of Diseases, 9 th Revision
ICD-10	International Classification of Diseases, 10 th Revision
IHE	Integrating the Healthcare Enterprise
IHE XDS	Integrating the Healthcare Enterprise Cross Enterprise Document Sharing
LOINC	Logical Observation Identifiers Names and Codes
NIEM	National Information Exchange Model
OID	Object Identifier
OMB	Office of Management and Budget
OSTP	Office of Science and Technology Policy
ONC	Office of the National Coordinator for Health Information Technology
P3P	Platform for Privacy Preferences

PCAST	President's Council of Advisors on Science and Technology
PHSA	Public Health Service Act
RFI	Request for Information
TDE	Tagged Data Element
UEL	Universal Exchange Language
URI	Uniform Resource Identifier
URL	Uniform Resource Locator
UUIDs	Universally Unique Identifiers
XML	eXtensible Markup Language

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I. Background

A. Legislative History

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and established “Title XXX—Health Information Technology and Quality” to improve health care quality, safety, and efficiency through the promotion of health information technology (HIT) and the electronic exchange of health information. Section 3003(b)(1)(A) of the PHSA states that “[t]he HIT Standards Committee shall recommend to the National Coordinator standards, implementation specifications, and certification criteria described in subsection (a) that have been developed, harmonized, or recognized by the HIT Standards Committee. . . .” Section 3003(b)(2) of the PHSA states that “[t]he HIT Standards Committee shall serve as a forum for the participation of a broad range of stakeholders to provide input on the development, harmonization, and recognition of standards, implementation specifications, and certification criteria necessary for the development and adoption of a nationwide health information technology infrastructure that allows for the electronic use and exchange of health information.”

Section 3001(c)(1)(A) of the PHSA, under “Duties of the National Coordinator,” states that the National Coordinator shall “review and determine whether to endorse each standard, implementation specification, and certification criterion for the electronic exchange and use of health information that is recommended by the HIT Standards Committee under section 3003 for purposes of adoption [by the Secretary] under section 3004.”

Section 3004 of the PHSA identifies a process for the adoption of health IT standards, implementation specifications, and certification criteria and authorizes the Secretary of Health and Human Services (the Secretary) to adopt such standards, implementation specifications, and

certification criteria. As specified in section 3004(a)(1), the Secretary is required, in consultation with representatives of other relevant Federal agencies, to jointly review standards, implementation specifications, and certification criteria endorsed by the National Coordinator for Health Information Technology (the National Coordinator) under section 3001(c) and subsequently determine whether to propose the adoption of any grouping of such standards, implementation specifications, or certification criteria. Section 3004(b)(1) of the PHSA requires the Secretary to adopt an initial set of standards, implementation specifications, and certification criteria for the areas required for consideration under section 3002(b)(2)(B) by December 31, 2009 and permits the Secretary to adopt the initial set through an interim final rule. Section 3004(b)(3) of the PHSA directs the Secretary to “adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule” developed by the HIT Standards Committee under section 3003(b)(3) of the PHSA¹ for the assessment of policy recommendations developed by the HIT Policy Committee.

B. Regulatory History

1. Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Interim Final Rule and Final Rule

On January 13, 2010, the Department of Health and Human Services (HHS) published in the Federal Register an interim final rule with a request for comment, which adopted an initial set of standards, implementation specifications, and certification criteria (75 FR 2014). The certification criteria adopted in that interim final rule established the required capabilities and specified the related standards and implementation specifications that certified electronic health record (EHR) technology would need to include to, at a minimum, support the achievement of

¹ PHSA section 3004(b)(3) incorrectly references section 3003(b)(2) when referring to the schedule developed by the HIT Standards Committee. We have used the correct citation: 3003(b)(3),

meaningful use Stage 1 as proposed by the Centers for Medicare & Medicaid Services (CMS) for eligible professionals and eligible hospitals under the Medicare and Medicaid EHR Incentive Programs. For consistency with other regulations, hereafter, references to “eligible hospitals” shall mean eligible hospitals, critical access hospitals, or both, as defined in 42 CFR 495.4.

On July 28, 2010, HHS published in the Federal Register a final rule (75 FR 44590) to complete the Secretary’s adoption of the initial set of standards, implementation specifications, and certification criteria, and to more closely align such standards, implementation specifications, and certification criteria with final meaningful use Stage 1 objectives and measures (the “Standards and Certification Criteria Final Rule”). Complete EHRs and EHR Modules are tested and certified according to adopted certification criteria to ensure that they have properly implemented adopted standards and implementation specifications and otherwise comply with the adopted certification criteria.

2. Revisions to Initial Set of Standards, Implementation Specifications, and Certification Criteria for EHR Technology; Interim Final Rule.

On October 13, 2010, HHS published in the Federal Register an interim final rule (75 FR 62686) with a request for comment to remove the implementation specifications related to public health surveillance from the adopted standard and certification criterion. In response to public comment on the interim final rule published on January 13, 2010, we adopted in the Standards and Certification Criteria Final Rule the following implementation specifications for HL7 2.5.1: Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0 and the Errata and Clarifications National Notification Message Structural Specification (45 CFR 170.205(d)(2)). After publication of the Standards and Certification Criteria Final Rule, various stakeholders and state public health

agencies made numerous inquiries and expressed concerns about the appropriateness of these implementation specifications. Upon further review of the implementation specifications and consultation with the Centers for Disease Control and Prevention (CDC), we determined that these implementation specifications were adopted in error. Therefore, we revised 45 CFR 170.205(d)(2) to remove these particular adopted implementation specifications and removed from 45 CFR 170.302(l) the text “(and applicable implementation specifications)” to provide additional clarity.

C. The President's Council of Advisors on Science and Technology (PCAST) Report

On December 8, 2010, the President's Council of Advisors on Science and Technology (PCAST) released a report entitled “Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward” (the PCAST Report).² PCAST is an advisory group of the nation's leading scientists and engineers who directly advise the President and the Executive Office of the President. PCAST makes policy recommendations in many areas where the understanding of science, technology, and innovation is key to strengthening our economy and forming policy that works for the American people. PCAST is administered by the Office of Science and Technology Policy (OSTP) within the Executive Office of the President. Generally speaking, the PCAST Report included both a broad vision and specific recommendations to accelerate the nation’s progress toward electronic health information exchange. Many of the PCAST Report’s recommendations are related to electronic health information exchange activities that ONC could directly affect.

1. Request for Information on PCAST Report Recommendations Affecting ONC Activities

² <http://www.whitehouse.gov/administration/eop/ostp/pcast>

On December 10, 2010, the Office of the National Coordinator for Health Information Technology (ONC) issued a Request for Information (RFI) to seek public comment on the PCAST Report's vision and recommendations and how they may be best addressed (75 FR 76986). The RFI sought specific feedback on nine questions which are best organized according to the following categories:

- The standards, implementation specifications, certification criteria, and certification processes for EHR technology and other types of HIT that would be required to implement some of the PCAST Report's recommendations;
- The current state of information technology solutions needed to support the PCAST Report's vision as well as lessons that could be learned from other industry implementations;
- The steps that could be taken to best integrate the changes envisioned by the PCAST Report into future stages of meaningful use; and
- The impact of the PCAST recommendations on ONC programs and ongoing activities.

In total, ONC received 105 timely comments on the RFI from stakeholders throughout the health care industry. These comments were consolidated into a summary report to inform the deliberations of the PCAST Workgroup formed under the HIT Policy Committee (discussed below). The following major themes emerged from public comments: timelines; the effects on ONC programs; implementation of the PCAST recommendations; privacy and security; and standards.

- Timelines. Several commenters supported the PCAST recommendations to increase information exchange capacity before meaningful use Stage 2. A significant majority

of commenters, however, were concerned that attempting to fully implement the PCAST recommendations in the midst of meaningful use Stages 2 and 3 along with other changing standards such as the International Classification of Diseases, 9th Revision (ICD-9) transition to International Classification of Diseases, 10th Revision (ICD-10) could have potential negative effects. Many commenters suggested that the recommendations serve to inform a long term strategy rather than direct an immediate deviation from already laid groundwork created by meaningful use Stage 1 and other ONC electronic health information exchange activities.

- Effects on ONC Programs. A majority of commenters encouraged ONC to leverage the success of ongoing programs and avoid reinventing the wheel in the midst of the Medicare and Medicaid EHR Incentive Programs. Many commenters stated that fully implementing the PCAST Report's recommendations would require redesigning many of the ongoing federal HIT grants and contracts which could impose substantial costs to current participants. Some suggested that ONC begin with pilots to develop and test PCAST technology solutions before moving into broader implementation efforts.
- Implementation of PCAST Recommendations. Commenters generally agreed that health information exchanges (HIEs) and the electronic exchange of health information should be the focus of future stages of meaningful use. Regarding the exchange of individual data elements outside of a document structure, many agreed with the value of exchanging individual data elements but recommended that such a program begin with pilot testing that takes into account patient-linking and public trust issues.

- Privacy and Security. Several commenters supported the concept of giving patients granular consent as envisioned in the PCAST Report. However, many expressed concern that tagging patient privacy preferences to the data would lead to a static, rather than a dynamic, data control environment which could prevent patients from updating their privacy preferences once the data was released. The research community largely supported PCAST's concept of creating a subset of de-identified data for the purpose of research.
- Standards. Most commenters believed that ONC should learn from and leverage existing standards that incorporate metadata concepts. Some commenters asserted that ONC should pursue the metadata approach outlined in the PCAST Report because current standards do not allow for innovation, flexibility, or scalability and that today's predominantly document-centric environment would not support PCAST's vision. Others contended that the PCAST Report's interoperability and electronic exchange goals could be met with existing and emerging standards.

2. The PCAST Workgroup

In January 2011, ONC asked the HIT Policy Committee to provide a more detailed assessment of the PCAST Report's ONC-related recommendations, how implementing the recommendations could affect ONC's programs, and potential approaches ONC could pursue to realize the vision described in the PCAST Report. To respond to this request, the HIT Policy Committee, in conjunction with the HIT Standards Committee, formed an interdisciplinary PCAST Workgroup to analyze the RFI comments as well as solicit expert testimony through a public hearing held in February 2011.

In April 2011, the HIT Policy Committee transmitted to ONC an analysis report that suggested incremental steps for ONC to pursue to achieve the vision described in the PCAST Report. As a feasible first step, the HIT Policy Committee suggested that ONC focus on facilitating the development and adoption of a minimal set of standards for metadata that could be “wrapped around” or attached to a summary care record when a patient seeks to download their health information from, for example, a health care provider’s patient portal or when a patient directs his or her health care provider to transmit his or her health information to a personal health record (PHR). Generally speaking, the term “metadata” is often used to mean “data about data” or, in other words, “data that provides more information or detail about a piece of data.”

The HIT Policy Committee suggested that it would be practical to include this capability as part of the EHR certification requirements to support meaningful use Stage 2 under the Medicare and Medicaid EHR Incentive Programs. Moreover, in the context of this first “use case,” the HIT Policy Committee noted that a minimum set of metadata (and accompanying standards) should focus on these three categories: patient identity (data elements about a patient), provenance (data elements about the source of the clinical data), and privacy (data elements about the type(s) and sensitivity of clinical data included). Additionally, the HIT Policy Committee noted that if these metadata are available, they could potentially increase the level of trust that receiving providers would place in clinical information that they receive through patient-mediated exchange, such as from a PHR, and could enable patients to more easily sort and re-share their own health information.

D. Analysis of Metadata Standards

1. ONC-Commissioned Analysis

In parallel with the work being done by the PCAST Workgroup, ONC commissioned an in-depth analysis of several widely implemented standards that include metadata. This analysis examined the various data elements each standard includes and identified certain categories of metadata that could be readily adopted as metadata standards. On April 20, 2011, this analysis was presented to the HIT Standards Committee, which included metadata options for patient identity, provenance, and privacy.

- Patient Identity Metadata: The analysis generally described patient identity metadata as the necessary data required to uniquely select a patient from a population with a guaranteed degree of accuracy. The research also indicated that patient identity metadata should include a patient's current full name, previous names with associated date ranges (as an optional element), date of birth, postal code, and one type of patient identification data (ID) along with the origin of that ID. The following standards were reviewed and compared relative to how patient identity metadata is represented: Health Level 7 Version 2 (HL7 V2) messages; Integrating the Healthcare Enterprise Cross Enterprise Document Sharing (IHE XDS) Metadata; Health Level 7 Clinical Document Architecture Release 2 (HL7 CDA R2); American Society for Testing and Materials (ASTM) Continuity of Care Record (CCR); Google CCR; and National Information Exchange Model (NIEM).
- Provenance Metadata: The analysis generally described provenance metadata as data that provides information on a dataset's history, origin, and modifications. Research suggested that provenance metadata should include information that describes the event that led to the creation of the tagged data as well as other associated events that provide causal links to the data. The research also indicated that provenance

metadata include information about when and how the tagged data had been exchanged in the past. It emphasized that digital signatures could be used as metadata as a way to ensure that the data had not been altered since its creation. The report gave comparisons on the NIEM, IHE XDS Metadata, HL7 CDA R2, and Clinical Data Interchange Standards Consortium (CDISC) standards related to providing the above information on provenance.

- Privacy Metadata: For privacy metadata, the commissioned analysis of metadata standards examined what data could be used to convey and communicate patient preferences (permissions or limits) associated with the sharing of his or her health information. The analysis first concluded that it was not feasible to include the privacy policy with each tagged data element because policy can change over time, and that a pointer to an external registry would be most appropriate. Noting that there was not sufficient information to determine how such privacy policy registries would be implemented, the research indicated that privacy metadata related to the underlying contents (i.e., what kind of information is within a document or message) and its sensitivity (i.e., by whom, and what the recipient(s) of the data is/may be obligated or prevented from doing after accessing the data) would be the most useful to include in an initial set of metadata. The research compared the ability of Platform for Privacy Preferences (P3P), Enterprise Privacy Authorization Language (EPAL), Basic Patient Privacy Consents (BPPC), IHE XDS, and Clinical Document Architecture Release 2: Patient Consent Directives (CDA R2 PCD) metadata standards to convey the above information.

2. HIT Standards Committee Analysis and Recommendations

In April 2011, after the receipt of the ONC-commissioned analysis on metadata standards, the HIT Standards Committee formed a “metadata power team” to further consider this analysis in order to identify metadata standards that would be appropriate for electronic health information exchange. On May 18, 2011, after a series of public meetings, the metadata power team presented to the HIT Standards Committee their review of the metadata elements that would be best to consider for patient identity and provenance. On May 25, 2011, the metadata power team held another meeting which focused on the analysis of privacy metadata elements.

On June 22, 2011, the metadata power team submitted its complete analysis and a set of recommendations to the HIT Standards Committee on the data elements that should be included as part of metadata standards for patient identity, provenance, and privacy. The HIT Standards Committee discussed and subsequently approved the metadata power team’s findings. The HIT Standards Committee submitted its recommendations on metadata elements and standards to the National Coordinator and expressed its expectation that ONC would conduct further testing and evaluation prior to proposing these standards for adoption through rulemaking.

Upon receipt of the HIT Standards Committee’s metadata standards recommendations, the National Coordinator followed the process outlined in the sections 3001(c)(1)(A) and (B) of the PHSA. These provisions require the National Coordinator to “(A) review and determine whether to endorse each standard, implementation specification, and certification criterion for the electronic exchange and use of health information that is recommended by the HIT Standards Committee under section 3003 for purposes of adoption under section 3004; [and] (B) make such determinations under subparagraph (A), and report to the Secretary such determinations, not later than 45 days after the date the recommendation is received by the Coordinator....”

The National Coordinator endorsed the HIT Standards Committee recommendations on metadata standards and reported this determination to the Secretary for consideration under section 3004(a) of the PHS Act. Per section 3004(a)(2), if the Secretary determines “to propose adoption of any grouping of such standards, implementation specifications, or certification criteria, the Secretary shall, by regulation under section 553 of title 5, United States Code, determine whether or not to adopt such grouping of standards, implementation specifications, or certification criteria.” In accordance with section 3004(a)(3), the Secretary must also provide for publication in the Federal Register all determinations made by the Secretary under this provision. This ANPRM constitutes publication of the Secretary’s determination.

II. Metadata Standards under Consideration

Section 3001 of the HITECH Act establishes ONC by statute and requires, under section 3001(b), the National Coordinator to “perform the duties under [section 3001](c) in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information” Since the HITECH Act’s enactment in February 2009, ONC has developed a portfolio of initiatives to foster a nationwide health information technology infrastructure. The PCAST Report, published in December 2010, built on our progress to date and complemented our existing initiatives. It expressed a vision, with associated policy goals, that focused on key challenges ONC could undertake to accelerate its efforts in several electronic health information exchange areas. One such area, a cornerstone of the PCAST Report’s vision, was to increase the health care industry’s ability to understand and parse the health care data under its stewardship at a more granular level. The PCAST Report noted that the development of metadata standards was a critical first step to facilitating more granular understanding of data and to establishing a “universal exchange language (UEL).” The

PCAST Report described the UEL as, “some kind of extensible markup language (an XML variant, for example) capable of exchanging data from an unspecified number of (not necessarily harmonized) semantic realms. Such languages are structured as individual data elements, together with metadata that provide an annotation for each data element.”

We believe that the use of metadata holds great promise and the adoption of metadata standards can help rapidly advance electronic health information exchange across a variety of different exchange architectures. The purpose of this ANPRM is to seek broad public comment on the metadata standards we are considering proposing for adoption in the next notice of proposed rulemaking with regard to the standards, implementation specifications, and certification criteria intended to support meaningful use Stage 2. We are considering whether to propose, as a requirement for certification, that EHR technology be capable of applying the metadata standards in the context of the use case selected by the HIT Policy Committee (i.e., when a patient downloads a summary care record from a health care provider’s EHR technology or requests for it to be transmitted to their PHR). For example, if a patient seeks to obtain an electronic copy of her health information, her doctor’s EHR technology would have to be capable of creating a summary care record and subsequently assigning metadata to the summary care record before the patient receives it. From an EHR technology developer’s perspective, we believe this approach would be the least difficult to implement in support of meaningful use Stage 2. However, generally speaking, we believe this capability may also be able to be applied to other directed transfers of summary care records (e.g., as part of requirements concerning transitions of care). Additionally, looking prospectively, once EHR technology is capable of applying metadata, we believe that the health care industry could gradually develop innovative ways to repurpose this general capability to create more specialized extensions to meet future

specific policy and organizational objectives. For instance, the EHR technology's capability to assign metadata to documents or more granular data elements could be used within an organization to appropriately filter data prior to making a disclosure or to process information more efficiently for quality improvement and measurement. In addition to the specific metadata standards discussed below, we also request public comments on any other metadata categories, metadata elements, or metadata syntax that we should consider.

Consistent with the recommendations of the HIT Standards Committee, ONC is interested in learning about and requests public comment on any real-life testing or use of these or other metadata standards relating to patient identity, provenance, or privacy. ONC also intends to seek pilot testing of these metadata standards to gain insights into any implementation-level challenges that may exist.

A. Metadata Standards Discussed and Specific Questions for Public Comment

This section discusses the metadata standards we are considering for each of the three categories (patient identity, provenance, and privacy) as recommended by the HIT Standards Committee and includes specific questions for the public's consideration. Consistent with the recommendations of the HIT Standards Committee, we are considering proposing that the metadata would need to be expressed according to the requirements in the HL7 CDA R2 header (section 4.2 of HL7 CDA R2). We are also considering whether to propose the adoption of additional metadata elements for certain information that is not currently required as part of the HL7 CDA R2 header. The HIT Standards Committee recommended the use of the HL7 CDA R2 header based on its belief that the HL7 CDA R2's XML format for describing generic clinical documents would best support the implementation of its recommendations. It specifically noted that among its many benefits the HL7 CDA R2 could best accommodate the international

representation of names and could potentially support additional information if desired. The HIT Standards Committee first recommended the use of the HL7 CDA R2 header for patient identity metadata. Subsequently, it acknowledged and determined that even though other standards could support the metadata elements under consideration in the provenance and privacy categories that the use of the HL7 CDA R2 header for these two categories would complement its already recommended use for patient identity metadata. Its overall rationale for the selection and recommendation of the HL7 CDA R2 header was that it provides wide coverage across metadata elements and working from a single standard would make implementation easier.

At the end of this section, we provide a complete example of how the metadata could be expressed. We request public comment on the metadata standards discussed below and in response to the specific questions listed below.

1. Patient Identity Metadata Standards

We are considering the following standard set of patient identity metadata recommended by HIT Standards Committee. This standard set would include the following data elements expressed according to the requirements explained below.

- Name: would include the patient's name prefix (e.g., Mr. Ms. Dr.), given names (e.g., first and middle names/middle initial), family names, and name suffix. Inclusion of "other name" components, such as patient's maiden name, previous names, or mother's name for newborns would be optional.
- Date of birth: would include the patient's date of birth.
- Address: would include the patient's current primary address.

- Zip code: would represent the zip code of the patient's current primary address. Zip codes for other addresses would be optional but, if included, would need to include date ranges for when the zip codes were applicable.
- Patient identifier(s): would include one or more of the identifiers used by a health care provider to uniquely identify the patient to which the underlying metadata pertain. For example, the last four digits of the social security number; the patient's driver's license number; the patient identification number assigned to the patient by a health care provider; or any combination of the above.

For each of the above elements, consistent with the HIT Standards Committee's recommendation, we would consider requiring that they be expressed according to HL7 CDA R2 header syntax. We would not expect, however, to require the implementation of the surrounding structure that a complete, valid HL7 CDA R2 header would include. Rather, our intent would be to leverage the way in which the HL7 CDA R2 header expresses how each data element would be represented and not to require that the HL7 CDA R2 header's structure also be implemented.

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?

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?

In addition to the patient identity metadata that we would expect to be expressed using the HL7 CDA R2 header, we are considering requiring an additional metadata element to be included for "display name." In this case, and as discussed by the HIT Standards Committee, we

currently believe that extending name metadata beyond the HL7 CDA R2 header requirements³ to include a display name is important to accommodate names that do not always follow a “first name, middle name, last name” format or to identify newborns whose names have not yet been assigned. We would expect to require that the display name metadata element be an XML element whose value is a string that captures the patient’s name as it should be displayed or written. Without this addition, we believe that many systems may accidentally parse parts of a patient’s name incorrectly due to the fact that in some cultures names are not structured according to first, middle, and last name segments. For example, the naming conventions in some cultures do not follow this structure and can result in the last name being incorrectly parsed or transposed. Therefore, for this metadata element, we are considering whether to propose that a full name string element be included to facilitate matching in cases where name components are incorrectly categorized.

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?

We are also considering whether to propose as a second extension, beyond the HL7 CDA R2, the use of a uniform resource identifier (URI) to act as a namespace for the patient identifier metadata as opposed to the use of an object identifier (OID) as specified in HL7 CDA R2. Currently, the definition of the “id root” attribute in the HL7 CDA R2 header is defined to only accept OIDs, universally unique identifiers (UUIDs), or specific HL7 reserved identifiers, none of which can hold a URI. A URI could be used as a means to identify the associated ID type that would be used. For instance, <id extension="1234567"

³ The HL7 CDA R2 schema’s definition of name only supports the following components: delimiter, family, given, prefix and suffix.

root="<http://www.nh.gov/safety/divisions/dmv>"/> indicates that the ID type is a New Hampshire driver's license. This extension would allow for an extensible, flexible mechanism to uniquely identify an individual, without having to explicitly specify what type of identifier is used. In the event multiple types of identifiers are used, a means to properly attribute the right information to each identifier would be necessary. We believe a URI can effectively serve this purpose.

2. Provenance Metadata Standards

We are considering the following standard set of provenance metadata recommended by the HIT Standards Committee. The standard set would include the following data elements expressed according to the requirements explained below – a tagged data element (TDE) identifier; a time stamp; and the actor, the actor's affiliation, and the actor's digital certificate. These provenance metadata function as part of a “wrapper” that would convey the “who, what, where, and when” of the data being electronically exchanged. As with patient identity metadata, we would expect these provenance metadata elements to be expressed according to HL7 CDA R2 header syntax requirements, where applicable.

- TDE identifier: would allow for other TDEs to link to this particular instance, thus preserving clinical context, and allow users to keep a log of the set of TDEs used for a particular task. For example, a TDE containing diagnostic study information could contain the identifier of another TDE that describes the encounter that led to that study.
- Time stamp: would express when the content to which the metadata pertains was digitally signed.
- Actor and actor's affiliation: would, in the form of a digital certificate, include the name of the actor who digitally signed the content to which the metadata pertains and

the organizational affiliation of the actor. The HIT Standards Committee noted that this scheme allows for exchanges to occur involving either organizational actors or individual actors.

The HIT Standards Committee also recommended that the X.509 standard for certificates be used to digitally sign the content to which the metadata pertains. It noted that that digital certificates and digital signatures could be used to provide non-repudiation and tamper-resistance. The HIT Standards Committee further acknowledged that while its expectation was that an actor and its affiliation would be expressed in an X.509 certificate that there should be optional metadata fields for actor and actor affiliation for reasons including situations where EHR technology can understand the XML format of the HL7 CDA R2 header syntax, but cannot process more complex cryptographic signatures. As a final recommendation on provenance, the HIT Standards Committee recommended an optional portion of the actor/affiliation metadata should point to the entity record in the Enterprise-Level Provider Directory, which may be a URL (this concept is included in the metadata example illustrated below).

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?

Generally, as recommended by the HIT Standards Committee, the metadata elements for time stamp, the actor, the actor's affiliation, and the actor's digital certificate all rely on one security architecture, the use of digital certificates. We are considering whether for the purposes of adopting metadata standards it would be beneficial to decouple the metadata elements from a particular security architecture. In short, we are contemplating whether it would be more

effective and appropriate to adopt provenance metadata elements that do not rely on a single security architecture, but rather can be used in various security architectures.

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 a specific security architecture, would its advantages outweigh those of digital certificates?

3. Privacy Metadata Standards

At the outset, we note that the HIT Standards Committee made its recommendations on privacy metadata standards with the underlying assumption that any personally identifiable information would be exchanged in an appropriately secure manner (i.e., encrypted). In its assumed model, the HIT Standards Committee basically envisioned clinical content which is “double wrapped” – first according to the metadata standards we are considering and then encrypted prior to the entire package of data being transported – meaning only the recipient of the entire package would be able to view the metadata once it has been decrypted. In other words, and from ONC's perspective, if circumstances would require the content to which the metadata pertain to be encrypted, the metadata would also be encrypted.

As recommended by the HIT Standards Committee, we are considering the following standard set of privacy metadata which would include the following data elements expressed according to the requirements explained below – a “policy pointer” and content metadata elements.

- Policy pointer: would be a Uniform Resource Locator (URL) that points to the privacy policy in effect at the time the tagged data element is released. This metadata element would support the potential for external privacy policy registries to be used.
- Content metadata: would be used to represent those elements needed to implement and reflect organizational policies as well as those federal and state laws that would be applicable to the underlying data to which this metadata would pertain. Content metadata would be comprised of two components:
 - Data type: would describe the underlying data to which this metadata pertains from a clinical perspective. For this metadata element, we are considering whether to propose that Logical Observation Identifiers Names and Codes (LOINC) codes be used to provide additional granularity.
 - Sensitivity: HL7 vocabulary for sensitivity would be used to indicate at a more granular level the type of underlying data to which this metadata pertains in order for the potential for automated privacy filters to apply more stringent protections to the data in the event it is selected for a future disclosure.

Again, we would expect that these privacy metadata would be expressed according to the HL7 CDA R2 header syntax requirements.

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?

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)? Could helpful concepts be drawn from the Health Information Technology Standards Panel (HITSP) Transaction Package 30 (TP30) “Manage Consent Directives?”

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 (i.e., how would new policy available at the URL apply to data that was transmitted at an earlier date under an older policy that was available at the same URL)?

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?

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?

Question 11: The HIT Standards Committee recommended developing and using coded values for sensitivity to indicate that the tagged data may require special handling per established policy. It suggested that a possible starter set could be based on expanded version of the HL7 ConfidentialityByInfoType value set and include: “substance abuse; mental health; reproductive health; sexually transmitted disease; HIV/AIDS; genetic information; violence; and other.”

During this discussion, several members of the HIT Standards Committee raised concerns that a recipient of a summary care record tagged according to these sensitivity values could make direct inferences about the data to which the metadata pertain. Consistent with this concern, HL7 indicates in its documentation that for health information in transit, implementers should avoid

using the ConfidentialityByInfoType value set. HL7 also indicates that utilizing another value set, the ConfidentialityByAccessKind value set which describes privacy policies at a higher level, requires careful consideration prior to use due to the fact that some items in the code set were not appropriate to use with actual patient data. In addition, the HIT Standards Committee recommended against adopting an approach that would tag privacy policies directly to the data elements. What kind of starter value set would be most useful for a sensitivity metadata element to indicate? How should those values be referenced? Should the value set be small and general, or larger and specific, or some other combination? Does a widely used/commonly agreed to value set already exist for sensitivity that we should considering using?

Question 12: In its recommendations on privacy metadata, the HIT Standards Committee concluded that it was not viable to include the policy applicable to each TDE because policy changes over time. Is this the appropriate approach? Are there circumstances in which it would be appropriate to include privacy preferences or policy with each data tagged element? If so, under what circumstances? What is the appropriate way to indicate that exchanged information may not be re-disclosed without obtaining additional patient permission? Are there existing standards to communicate this limitation?

B. Metadata Example

The following is a complete example of how the standard sets of metadata elements for the three categories discussed above could be expressed.

Metadata Element	Expressed according to HL7 CDA R2 Requirements (where applicable)	Notes
Provenance - TDE ID	<id extension="http://stelsewhere.com/id/12345" assigningAuthority="St. Elsewhere Hospital"/>	
Privacy - Content Data Type	<code code="11488-4" displayName="Consultation note" codeSystemName="LOINC"/>	
Provenance - Timestamp	<effectiveTime value="20101217093047"/>	

Metadata Element	Expressed according to HL7 CDA R2 Requirements (where applicable)	Notes
Privacy - Content Sensitivity	<confidentialityCode code="Other"/>	
Patient ID - ID	<id extension="1234567" root="http://www.nh.gov/safety/divisions/dmv"/>	Note that in a CDA R2 Header, the root attribute would typically be an OID
Patient ID - Address	<addr use="HP"> <streetAddressLine>1234 Main St. Apt 3</streetAddressLine> <city>Bedford</city> <state>MA</state> <postalCode>01730</postalCode> </addr>	
Patient ID - Name	<name> <prefix qualifier="AC">Dr.</prefix> <given> John</given> <given>William</given> <family>Smith</family> <displayName>Dr. John William Smith</displayName> </name>	Note that displayName is not part of the HL7 CDA R2 header
Patient ID - DOB	<birthTime value="19600427"/>	
Provenance - Actor	<assignedPerson> <providerDirectoryEntry href="http://providerdirectory.org/1234"/> <name> <family>Smith</family> <given>John</given> <prefix>Dr.</prefix> </name> </assignedPerson>	Note that providerDirectoryEntry is not part of the HL7 CDA R2 header
Privacy – Policy Pointer	<id extension="http://policy.example.org/9876543" root="policy_pointer_oid"/>	
Provenance - Affiliation	<representedOrganization> <id extension="http://stelsewhere.com/" assigningAuthority="St. Elsewhere Hospital"/> <name>St. Elsewhere Hospital</name> <telecom use="1-800-555-1234"/> </representedOrganization>	

III. Additional Questions

To better inform future proposals, we seek public comment on the following specific questions. Commenters are also welcome to provide feedback on any of the considerations and expectations we expressed above even where a specific question is not asked.

Question 13: With respect to the first use case identified by the HIT Policy Committee for when metadata should be assigned (i.e., a patient obtaining their summary care record from a health care provider), 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?

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

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 (e.g., exchanging information for treatment by a health care provider, for research, or public health) 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?

Question 16: Are there other metadata categories besides the three (patient identity, provenance, and privacy) we considered above that should be included? If so, please identify the metadata elements that would be within the category or categories, your rationale for including them, and the syntax that should be used to represent the metadata element(s).

Question 17: In addition to the metadata standards and data elements we are considering, what other implementation factors or contexts should be considered as we think about implementation specifications for these metadata standards?

Question 18: Besides the HL7 CDA R2 header, are there other standards that we should consider that can provide an equivalent level of syntax and specificity? If so, do these alternative standards offer any benefits with regard to intellectual property and licensing issues?

Question 19: The HL7 CDA R2 header contains additional “structural” XML elements that help organize the header and enable it to be processed by a computer. Presently, we are considering leveraging the HL7 CDA R2 header insofar as the syntax requirement it expresses relate to a metadata element we are considering. Should we consider including as a proposed requirement the additional structures to create a valid HL7 CDA R2 header?

Question 20: Executive Order (EO) 13563 entitled “Improving Regulation and Regulatory Review” directs agencies “to the extent feasible, [to] specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt;” (EO 13563, Section 1(b)(4)). Besides the current standards we are considering, are there performance-oriented standards related to metadata that we should consider?

Dated: _____ August 4, 2011 _____

Kathleen Sebelius,

Secretary.

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