



September 23, 2011

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, Metadata Standards to Support Nationwide Electronic Health Information Exchange, Advance Notice of Proposed Rulemaking**

Dear Mr. Posnack:

The Elsevier Clinical Practice Model (CPM) Resource Center is pleased to submit written comments on the advanced notice of proposed rulemaking (ANPRM) entitled, *"Metadata Standards to Support Nationwide Electronic Health Information Exchange"* posted in the Federal Register on August 9, 2011.

Building off of our comments on the President's Council of Advisors on Science and Technology (PCAST) Report submitted on January 19, 2011, we believe there is a need to "think differently" about a universal exchange language in order to expedite the exchange of meaningful patient information both between professionals and between healthcare settings.

Our interest in the PCAST Report and the Office of the National Coordinator for Health Information Technology's (ONC's) subsequent work to develop metadata standards stems from our work as the only provider of evidence-based clinical content solutions and services that are built on a proven professional practice framework. Elsevier CPM Resource Center works with a growing healthcare consortium to develop standardized tools and resources to minimize duplication and repetition and to prevent potential medical problems for patients. The CPM Framework™ consists of six clinical practice models that can be applied across the continuum of care. These practice models are: (1) Health and Healing Model; (2) Applied Evidence-Based Practice Model (with evidence-based guidelines for chronic care); (3) Health Informatics Model (with integrated care processes and documentation); (4) Partnership Culture Model; (5) Interdisciplinary Integration Model; and (6) International Consortium Model.

One of the resources we offer is an updated and unified relational database that stores tagged data elements for comprehensive care planning/coordination and documentation of clinical services by a diverse interdisciplinary team. This database can be used in virtually any health information technology system. The result is standardized clinical documentation support that is evidence-based and designed to capture individual details at the patient level. The content of the database is available in XML, and each data element is tagged to allow integration into a facility's EHR. In addition, each tagged data element supports practice and content interoperability by supporting common terminology and language for comprehensive patient information exchange. Today, nearly three hundred healthcare settings use the CPM Framework™ embedded within their health information technology systems with proven results of increased care coordination, reduced medical complications and decreased costs. Healthcare settings using the CPM Framework™ include Kaiser Permanente and Sutter Health, both of which were mentioned in the PCAST Report. Given this experience, we believe that Elsevier CPM Resource Center along with members of the CPM Consortium are well positioned to pilot test the metadata standards for health information exchange related to tagged patient care summaries to improve transitions of care, quality improvement and measurement and transfer of patient information from an electronic health record (EHR) to a personal health record (PHR).

*Elsevier CPM Resource Center offers the following comments on the ANPRM on metadata standards to support nationwide electronic health information exchange:*

#### Patient Identity Metadata

We support the HIT Standards Committee's conclusion that there needs to be a standard set of patient identity metadata including name, date of birth, address, zip code and specific patient identifiers. We further support the expression of the patient's identity according to the HL7 CDA R2 header syntax as a methodology to leverage how the data is represented for health information exchange. The HL7 CDA provides a document markup standard that specifies the structure and semantics of a clinical document (such as a discharge summary, progress note and procedure report) for the purpose of exchange. The CPM unified relational database stores tagged data elements and could provide a strong blueprint for clinical documents that should be exchanged, including patient profiles, interdisciplinary plans of care, assessments and interventions, patient education outcomes, interdisciplinary goal outcome summaries, discipline-specific evaluations. Each of these clinical documents support data that can be formatted for patient care summaries leveraging the standard documentation and embedded tagged metadata standards. Each of the clinical documents are available for various patient populations as well (e.g., adult, pediatrics, obstetrics and newborn).

## Provenance Metadata Standards

We agree with the HIT Standards Committee's recommendations regarding provenance metadata standards, including recommendations that having a tagged data element (TDE) identifier; a time stamp; and the actor, the actor's affiliation, and the actor's digital certificate are important standard sets. These standards are important as they make the specific contributions that each clinical discipline provides to a patient clear through the metadata.

## Privacy Metadata Standards

We agree with ONC that there needs to be defined privacy metadata standards to assure privacy for the patient, however these metadata standards should only apply to health information exchange that is not already contemplated under current law. Based on our experience, the clinical content can be tagged as privacy metadata standards and "double wrapped" as envisioned in the ANPRM. The policy pointer and content metadata could aid in the protection of patient privacy. Elsevier CPM Resource Center thinks Logical Observation Identifiers and Codes (LOINC) codes alone would be limiting and urges ONC to consider using Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) to support the sharing of more significant information across specialties and sites of care.

In addition to the comments above, we have provided our comments on the specific questions raised by ONC in the ANPRM below.

- **Question 1:** Elsevier CPM Resource Center recommends that the following additional metadata elements within the patient identity category should be considered: patient gender; immediate next of kin's name and address; and any secondary name or patient name preference if different from the patient's given name.
- **Question 2:** Elsevier CPM Resource Center recommends that in cases where an individual lacks an address and there is no next of kin address available, it would be appropriate to require that the current health care institution's address be used – provided that the use of the institution's address is clearly indicated.
- **Question 3:** Elsevier CPM Resource Center does not believe it would be difficult to include a "display name" metadata element and to assure a structured consistency to naming conventions.
- **Question 4:** Elsevier CPM Resource Center recommends that the actual discipline of the clinical provider be a part of the tagged data set (e.g., MD, DO, RN, PT, OT, SLP, RT, and other licensed and non-licensed clinicians). It is important to make the various actors transparent and to identify each discipline's unique contribution to the care of a patient.

As health care shifts to new models, including accountable care organizations and medical homes, transparency will be even more important as these new models will require contributions by a diverse team of health care professionals and the quality of their coordination will be a significant factor determining patient outcomes.

- **Question 5:** Due to the diverse nature of the clinicians that contributors to care, we recommend that consideration be given to XML syntax rather than relying on the inclusion of provenance metadata elements in a digital certificate. This approach may allow for the identification of more clinicians who are part of an interdisciplinary team and allow for the data to better track the true reality of those who contribute to a patient's care and the care provided to that patient.
- **Question 6:** Elsevier CPM Resource Center does not recommend including any additional privacy metadata elements at this time.
- **Question 7:** Elsevier CPM Resource Center believes that stakeholders have little, if any, experience with policy pointers. Policy pointers are a new standard that accompany the national health information exchange. As such, we believe it will be important to clearly identify what clinical content is deemed "private."
- **Question 8:** Elsevier CPM Resource Center believes that policy pointers are new, yet we believe that the concept is mature enough to be included as part of the metadata standards ONC is considering. Regarding the persistence of URLs, appropriate infrastructure and policies would need to be put in place to assure the URLs are kept current with relevant information.
- **Question 10:** Elsevier CPM Resource Center recommends SNOMED-CT for additional granularity to cover a more extensive domain of the patient's condition, treatment and status. This is also in alignment with recommendation of the HIT Standards Committee's endorsement of SNOMED-CT in addition to LOINC. SNOMED-CT can be used to describe a patient's condition or diagnosis, transactions in the care and clinician encounter, communications and the adverse effect caused by medications and/or other treatments. SNOMED-CT will provide more granularity regarding the care that has been provided to a patient.
- **Question 11:** Elsevier CPM Resource Center agrees that coded values for sensitivity should be developed to indicate that tagged data may require special handling according to an established policy. We are not aware of a common value set in existence today regarding how those values should be referenced, but we would be interested in further exploring a common approach based on a common content interoperable framework as a pilot-approach. We also advocate for allowing mutual

decision making between the provider and patient regarding the specific tagging of potential sensitive data so we are engaging patients in the decision-making process.

- **Question 12:** Elsevier CPM Resource Center believes that consideration should be given to privacy preferences related to identified sensitive data elements.
- **Question 13/14:** Elsevier CPM Resource Center's experience demonstrates that having a common evidence-based, professional practice and content tagged database that enables standardized documentation makes it easier for EHR technology developers to include metadata standards for the purpose of patient summary records as well as specific patient documents (patient profiles, interdisciplinary plans of care, discharge summaries, progress evaluation notes, etc.). The CPM common database has been intentionally designed to be delivered with the tagging upfront, updated every six months to reduce the expenses that would be incurred by each technology developer or health care setting if they each had to replicate this costly process. We believe that any metadata standards adopted by ONC should be flexible enough to include updates on a continuous basis.
- **Question 15:** Elsevier CPM Resource Center foresees other potential use cases for the extension of metadata standards, including population health reporting based on disease and/or condition. With the identification and coding of the disease and/or condition along with tagged clinical content within the CDA document, we believe the set of metadata currently under consideration would support this use.
- **Question 17:** Elsevier CPM Resource Center believes that aligning the clinical documentation tools/data entry on the front end will be important in order to support standardizing practice to be aligned with the metadata standards. We believe this will require domain expertise of the intentional design of the tagged-data and how it is expressed within an EHR along with a knowledge-base of how the clinical documentation and patient care summaries are tagged to the metadata categories so implementation can be expedited and remain intact to meet future certification criteria. This will require not only EHR development expertise but also practice and content interoperability expertise. It also will call for advanced uploading or scripting tools to assure the clinical content and metadata standards are intact and standardized across all venues of care.
- **Question 20:** Elsevier CPM Resource Center urges ONC to consider also using metadata to tag evidence-based clinical content and the National Quality Forum (NQF) e-quality measures related to specified diagnostic conditions to achieve performance-related standards. We also advocate for the inclusion of NQF's ten care coordination

performance measures (2010) and the nurse sensitive outcomes as delineated by the American Nurses Association (ANA) on pressure ulcers as key performance indicators.

Elsevier CPM Resource Center appreciates the opportunity to comment on the metadata concepts included in this ANPRM. We appreciate ONC's effort to engage healthcare stakeholders in reviewing the recommendations of the HIT Policy and Standards Committees' recommendations in response to the PCAST Report and look forward to further discussion with ONC on this important issue to assure a standardized approach to sharing patient information in the most comprehensive, meaningful and protective manner. Lastly, as ONC considers metadata pilots to realize the PCAST vision, we welcome further exploration and engagement of the CPM Consortium to help with pilot programs for sharing data across multiple systems across the nation.

If you have any questions, please feel free to contact me at (616) 530-9206 or at [m.troseth@elsevier.com](mailto:m.troseth@elsevier.com).

Sincerely,

Michelle R. Troseth, MSN, RN, DPNAP  
Executive Vice President and Chief Professional Practice Officer