



**American Hospital
Association**

Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802
(202) 638-1100 Phone
www.aha.org

September 21, 2011

Steven Posnack
Director, Federal Policy Division, Office of Policy and Planning
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington DC 20201

Submitted Electronically

Dear Mr. Posnack:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) greatly appreciates the opportunity to comment on the advance notice of proposed rulemaking (ANPRM) published in the *Federal Register* on August 9, 2011 regarding Metadata Standards to Support Nationwide Electronic Health Information Exchange (HIE). America's hospitals are working to implement health information technology (IT) solutions to support the safest, best possible care, improved efficiency, engaged patients and improved public health.

The AHA believes that inclusion of these standards in the Stage 2 meaningful use regulations would be premature in the absence of systematic evidence that they offer demonstrated benefits that outweigh the costs of implementation and are feasible for use in all care settings. The standards considered in the ANPRM are premature; they have not been adequately analyzed or tested in the real world to know if they are appropriate for widespread use at this time. In addition, the Office of the National Coordinator for Health Information Technology (ONC) has not thoroughly addressed the relevant policy and implementation issues associated with adoption of these standards. We urge ONC to refrain from any additional rulemaking until pilot tests have been conducted and evaluated, as recommended by the HIT Standards Committee.



BACKGROUND

The ANPRM builds on two pieces of work completed by advisory groups to the federal government.

In December 2010, the President's Council of Advisors on Science and Technology (PCAST) released a report titled *Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward*. The PCAST report recommended that the United States pursue HIE based on adoption of a "universal exchange language for healthcare information and an infrastructure for locating patient records, while rigorously protecting privacy and security." This approach would rely on tagged metadata that would identify component data elements held in individual health records that could then be pulled from the record and shared with others over a network. For example, records could be tagged to identify individual laboratory test results to be queried and shared upon request. According to PCAST, this approach would allow individuals (patients, providers, researchers, payers and others) to conduct secure, network-based searches for needed pieces of the records pertaining to an individual. PCAST also promotes the ability of individuals to outline individual patient preferences to be attached to different kinds of information, and use of data-level encryption.

In our January 19 letter to ONC on the report, we noted that while America's hospitals share the council's goal to move toward an HIE approach that supports the best possible care across the continuum of care settings and informs and engages patients, the "timeline implied by the report and repeated in ONC's request for information – that this could be part of stage 2 meaningful use – is unrealistic and would result in halting national progress toward implementation of [electronic health record (EHR)] technology." We further recommended that ONC "devote considerable resources and time to study in depth the approach recommended by the PCAST report and develop ... a detailed plan with reasonable timelines to transition to this approach ... The plan should fully identify and address the policy issues that must be resolved before this approach can be taken."

Subsequent to the PCAST report, and at the request of ONC, the HIT Standards Committee formed a workgroup to consider initial steps and standards that *might* be used to implement the approach envisioned in the PCAST report. The work of the HIT Standards Committee, summarized in the ANPRM, is laudable and provides a solid set of standards that *might* be used as an initial approach to applying metadata to a care summary. The ANPRM lays out standards associated with three types of metadata explored by the HIT Standards Committee that would support a query-based approach to sharing patient-level information:

- patient identity (name, date of birth, postal code, additional patient ID such as internal patient number or driver's license);
- provenance (data identifying the source of electronic information, such as tagged data element identifier, time stamp, actor and actor's affiliation); and

- privacy (data indicating whether the electronic document has any information in it that might require special handling due to privacy requirements, such as policy pointer, data type, sensitivity).

GENERAL COMMENTS

The AHA supports the incremental approach taken by the HIT Standards Committee and appreciates the limited focus on metadata needed to share structured documents based on the use of existing standards. We note, however, that the committee voiced significant concerns about the readiness of these standards in both its in-person discussions and its June 22 recommendation letter. The committee noted that these are untested standards, and much more information is needed to understand whether they work and how they would be used in practice. The committee letter concludes: “*We propose these standards with the understanding that ONC will conduct further testing and evaluation prior to proposing these through rulemaking*” (emphasis added). To the extent that the ANPRM is asking for input on what ONC should include in future ONC-funded data analyses and pilots, we welcome the opportunity to guide those efforts. Publishing an ANPRM does **not**, however, fulfill the need for rigorous study and pilot testing before moving forward with additional rulemaking.

It is premature to include metadata to support HIE through regulatory mechanisms. We strongly urge ONC to both conduct rigorous analysis on current implementation experience on use of metadata in health care and complete specific pilot tests of the standards recommended by the HIT Standards Committee, with external evaluations, before moving to a NPRM. The pilots should include working implementations in multiple sites that demonstrate the specific information flows envisioned and how the metadata standards support them. Such analysis would uncover the policy, resource and technical issues that arise from using metadata in HIE, as well as verifying that the standards themselves are appropriate. Furthermore, the development of metadata should be done to support multiple types of exchange to avoid significant revisions and re-work in the future. Therefore, the pilots should look beyond the single use case of a patient obtaining his/her summary care record from a health care provider, or having it transmitted to a personal health record.

Activities already underway could provide important guidance to ONC, and could be assessed as part of ONC’s future analyses before additional rulemaking. For example:

- The ONC-funded Indiana HIE Challenge Grant is developing tools and approaches to capture, index and search on key metadata. The project, being carried out by the Regenstrief Institute, is exploratory and will likely raise many policy, resource and technical issues that will need to be addressed before moving toward broader adoption of these approaches.

- ONC should investigate and learn from the state-designated HIE entities and other existing systems that manage patient identity to support HIE and have grappled with how to identify patients, gather and manage patients' preferences on participation in HIE, and manage privacy requirements. For example, ONC could look to the ongoing work to develop the Utah Statewide Secure Patient Directory Initiative, where patient identity information will be maintained centrally, but individual consent to have data shared will be gathered on a distributed basis by the providers and other entities in the initiative. Other existing HIEs should be surveyed for their activities in setting up electronic mechanisms for patients to opt-in or opt-out of HIEs, or to provide patients with limited privacy controls, such as naming physicians who can see their data.
- ONC should conduct additional testing and analyses of the specific metadata standards in the ANPRM, as recommended by the HIT Standards Committee. The ONC Standards and Interoperability (S&I) Framework recently launched the Query Health initiative, which focuses on the standards and services needed for query-based HIE to share population health information. It is unclear why ONC would choose to pilot other use cases and standards through the S&I framework, rather than the care summary use case presented in the ANPRM.

For all of these activities, external evaluations should be conducted. As these leading efforts and additional testing of specific metadata standards are evaluated, ONC should seek to understand:

- the applicability and feasibility of the standards used across all settings and types of providers, HIEs and technology vendors that would be affected by rulemaking;
- the extent to which the pilot results build on unique circumstances that may not be replicable elsewhere;
- the resources required for implementation;
- the policy issues that were raised, particularly in the area of building trust relationships and ensuring privacy and security of health information; and
- the scalability of the tested approaches, and particularly patient identification, beyond a local region or state to a system with millions of participants.

Without this kind of evidence and analysis to support policy development, ONC risks a premature rush to regulation that could be wasteful, or even result in harm to patients through exchange of incorrect health information or unintended exposure of protected health information.

Actual experience from Stage 1 of meaningful use highlights the hazards of premature regulatory action. The Centers for Medicare & Medicaid Services (CMS) announced in July 2011 that it will not be able to receive the meaningful use clinical quality measures electronically in 2012, as anticipated. Indeed, CMS declared that the standard adopted by ONC to support reporting of CQMs "was not feasible to use" in its recent proposed rule

on payments for hospital outpatient services (*Federal Register, Vol. 76, No.137, July 18, 2011*). Like the standards under discussion in the ANPRM, the current standard for reporting CQM data (the PQRI 2008 Registry XML Specification) was untested in the hospital context. For that reason, the AHA recommended against adopting that standard as premature in response to the proposed rules governing certification for meaningful use (see page 10 of our March 15, 2010 comment letter to ONC). Nevertheless, hospitals and physicians that want to meet the federal meaningful use requirements have purchased and installed products supporting the adopted CQM reporting standard. We believe that this experience should serve as a cautionary tale to ONC about the risks associated with including standards into the regulatory process prematurely.

Furthermore, the ANPRM in no way addresses the existing framework of law and regulation that governs the sharing of health information, most notably state medical records laws, national privacy and security requirements laid out in the *Health Insurance Portability and Accountability Act of 1996* (HIPAA), and state/local privacy laws. Consequently, the ANPRM does not answer the many technical and policy questions that the use of the proposed standards would raise. These issues include, for example, how records would be tagged with the required metadata and indexed, what happens if a query inaccurately matches individual data elements to individual patients, and how to ensure compliance with existing laws and regulations (including HIPAA) when sharing metadata.

While some might argue that the ANPRM only addresses the technical requirements to ensure that certified health IT products support this approach, the related policy issues must be addressed before moving forward with regulation. Including standards in regulatory requirements forces health IT vendors to prioritize these functionalities over others that may be more important to providers in their quest to use health IT to improve the safety and quality of care. The costs of retooling technologies to support the functions are then passed on to providers, who must upgrade products to be in regulatory compliancy. They also must install the technology and learn to use it. America's hospitals are currently investing billions of dollars in health IT solutions to meet Stage 1 meaningful use and other initiatives, such as the conversion to ICD-10 and information systems to support health reform initiatives such as accountable care organizations and value-based purchasing. They are not in a position to immediately replace that technology to pursue a new, untested metadata standard for HIE.

COMMENTS ON SPECIFIC STANDARDS AND QUESTIONS

The AHA responds to the specific standards and questions contained in the ANPRM below. We do not answer all of the questions, but note that our general comments pertain to all of the recommended data elements and standards.

Patient Identity

Question 1. Are there additional metadata elements within the patient identity category that we should include? If so, why? Should any of the elements be removed? If so, why?

In the area of patient identity, the ANPRM proposes five data elements that could be included to match patients with their health information: Name, date of birth, address, zip code and an alternate patient identifier such as the last four digits of the SSN or internal patient number. However, the ANPRM includes no independent analysis of the extent to which these data elements would return accurate matches in a nationwide exchange.

We recommend that ONC thoroughly study the accuracy of the proposed metadata elements in identifying patients and compare those results to other approaches before moving forward with rulemaking. The AHA has long supported the creation of a national approach to uniquely identify patients to connect records and to ensure that hospitals and physicians have the best information available when providing care for each patient. To the extent that the standards proposed in the ANPRM could result in a consistent and accurate national approach to matching patients to their records, it is very much welcome, as such a system would facilitate efforts to increase the safety and quality of care given to patients. However, previous discussions of HIE have noted that scaling up to national information exchange means that even with low error rates, many individual errors occur. If medical records are disaggregated into individual care summaries, the number of opportunities for error increases. These errors will also compound over time. Every mismatch of a patient to a piece of health information creates opportunity for clinical error, potentially harming patients and raising liability questions for physicians that act on data provided through a query-based search.

Question 2. In cases where the individual lacks address information, would it be appropriate to require that the current health care institution's address be used?

The AHA strongly opposes this approach. Including a health care institution's address in a patient record as the "patient's address" would violate policies of ensuring data accuracy by associating false data with an individual. It also could have the unintended consequence of creating false positive matches by attaching identical address information to multiple individuals, some of whom may have other similar characteristics, such as name. In addition, false negatives could arise if an individual's address is associated with multiple providers. Further, the contact information for the health care provider is already part of the proposed provenance metadata. Finally, treating the institution as the "home address" of a patient could have unintended legal consequences. It would misrepresent to anyone receiving this information in the future that this the appropriate address to make official contact with the patient when it is not.

Privacy

The privacy section of the ANPRM presents a set of metadata elements that could help the recipients of a patient care summary determine how best to ensure that they comply with various federal, state and local privacy requirements when accessing and using the enclosed protected health information (PHI). While it could prove promising, this is a brand new approach that has little to no implementation experience. Indeed, question 7 in the ANPRM states: *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)?*

Asking for individual responses to an ANPRM is not a sufficient mechanism to assess current experience regarding policy pointers. We recommend that ONC conduct a rigorous study of existing experience, as well as a comprehensive review of the existing, often conflicting state and local privacy laws to understand how they would impact a query-based approach to health information. In conducting this analysis, ONC also should consider what information a health care provider might need about the individual or entity requesting health information via an electronic query. Privacy laws and regulations put the burden of protection on the entity sharing the information, not the entity receiving the information. Therefore, in the area of privacy “flags,” it may be more important to have information about the entity asking to receive data, rather than the entity sending it, so that those holding PHI can make informed judgments about whether the requestor meets national, state and local requirements, as well as any patient preferences, to receive the PHI.

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 his/her 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?

As recommended by the HIT Standards Committee, considerable additional analysis and real-world testing is needed before any metadata standards are proposed to support Stage 2 of meaningful use. In considering the burden of implementing metadata standards, ONC should look beyond the work of EHR technology developers to understand the likely implementation steps and resources needed to use the capability in HIEs, as well as the policy infrastructure to support their use. These costs should be compared to and weighed against the benefits that might be derived from such implementation.

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

Steven Posnack
September 21, 2011
Page 8 of 8

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?

The standards under consideration are pre-mature for regulatory action. We recommend that ONC conduct additional study and pilot tests to better specify its goals in setting forth this approach, alternative approaches for achieving those goals, and the benefits and costs of both the proposed and alternative approaches.

In conclusion, the AHA appreciates the opportunity to provide comment on these issues. If you have questions or need additional information, please contact me or Chantal Worzala, director of policy at cworzala@aha.org.

Sincerely,

/s/

Linda E. Fishman
Senior Vice President, Public Policy Analysis & Development