

September 23, 2011

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

Re: RIN 0991-AB78, Metadata Standards to Support Nationwide Electronic Health Information Exchange

Submitted via http://www.regulations.gov

Dear Mr. Posnack,

eHealth Initiative appreciates the opportunity to comment on the Advance Notice of Proposed Rulemaking (ANPRM) on metadata standards to support nationwide electronic health information exchange.

eHealth Initiative (eHI) is an independent, non-profit, multi-stakeholder organization. Its mission is to drive improvements in the quality, safety and efficiency of healthcare through information and information technology (IT). eHI advocates for the use of health information technology (HIT) that is practical, sustainable and addresses stakeholder needs, particularly those of patients. The comments below were developed through our multi-stakeholder consensus process.

eHI supports the goal of a health information exchange system in which patients and providers are able to privately and securely exchange health information. Following the release of the PCAST report in December 2010, ONC undertook parallel data gathering and analytic activities that we support: an RFI seeking comment on the PCAST Report vision and recommendations, a charge to the HIT Policy Committee to provide a detailed assessment of the PCAST report, and a commissioned analysis of implemented standards that include metadata, with

findings shared with the HIT Standards Committee to support further consideration of metadata standards appropriate for electronic health information exchange.

Pilot testing of the HIT Policy and HIT Standards Committee recommendations is a necessity. The evaluation of pilot tests and the dissemination of the results will add real world insight that may highlight areas for modification prior to implementation on a larger scale in the future. eHI is concerned that the recommendation by the HIT Standards Committees - to study, test and evaluate metadata standards prior to implementation - is not consistent with stated intent of the ANPRM to inform the metadata standards that may be included in proposed rulemaking on standards, implementation specifications and certification criteria intended to support Meaningful Use Stage 2.

In our letter of April 29, 2011 concerning the proposed Federal Health IT Strategic Plan 2011 - 2015, we expressed concern about near-term implementation of the PCAST report recommendations:

"With respect to steps to implement the recommendations of the PCAST report as discussed in the Strategic Plan, although we support the overall goals of that report, including meta-data tagging of healthcare data, we urge caution in pursuing the specific PCAST implementation recommendations. Like others who have reviewed this report, including the HIT Policy Committee, we have substantial concerns about the practicality and desirability of many of these recommendations and urge an approach that builds on current standards and technology, such as the ability of HL7 CDA documents, like the CCD, to provide a robust approach to meta-tagged data and the availability of standards based health information exchange, using Integrating the Healthcare Enterprise profiles, to provide for effective queries of distributed healthcare information."

eHI is pleased that ONC issued this ANPRM to solicit input, and we also appreciate that HIT Standards Committee and ONC have taken very seriously the comments that eHI and others made regarding the PCAST report's proposed approach to healthcare metadata. We believe that the appropriate use of metadata can play a major role in enhanced data usefulness and liquidity. We also recognize and are pleased that this approach focuses on the "document" level of healthcare data, rather than granular, individual data elements within healthcare documents, and seeks to leverage existing standards and approaches to metadata applied at that level.

In response to the Request for Comment on proposed recommendations for Meaningful Use Stage 2, eHI submitted a letter on February 25, 2011 that included

a recommendation on the use of standards to support electronic transmittal of the summary of care record:

"eHI recommends that the Workgroup propose that a material, but achievable, percentage of the provision of the summary of care record must be transmitted electronically, consistent with standards-based capabilities. This approach will move the HIE objective beyond a test to support care coordination via health information exchange."

eHI agrees with the intent to consider the application of metadata to facilitate queries of documents within the context of a use case. Data about a summary of care record could assist those searching for data about a particular patient. However, this approach should be advanced within the context of a pilot test that will identify successes and challenges to be addressed prior to widespread use in support of the future requirements of meaningful use.

eHI requests that ONC utilize the findings from the pilot tests underway to inform subsequent rulemaking on standards, certification and implementation specifications that would incorporate metadata. We recommend that ONC utilize external evaluators of the pilots and broadly disseminate the evaluation results. eHI also urges ONC to continue to work with other federal agencies to ensure that the timing of, and requirements for, standards-based electronic exchange of health information are implementable. The goal of moving toward a healthcare system in which information is exchanged among affiliated and unaffiliated providers and their patients, through the use of interoperability standards, is one that we support. However, this must be accomplished within a process that engenders confidence on the part of all stakeholders.

With respect to the overall approach to metadata proposed, eHI offers these additional remarks:

eHI recommends that ONC reconsider the specific approach in the ANPRM, that metadata be expressed according to the requirements of HL7 CDA R2 header. We are concerned that there are limits to the specific approach incorporated in the ANPRM, and there are industry-recognized alternatives that should be considered. For the future, ONC is urged to consider the development of a metadata vocabulary, and foster the establishment of a governance process for that vocabulary to ensure consistency across the industry.

eHI also recognizes that a patient's privacy preferences may change over time. Therefore ONC should consider pointers to applicable privacy policies within the metadata rather than tightly binding actual privacy policy in the metadata. We believe metadata has the potential to increase privacy protections, and can

accomplish this without adding a duty for patients to continually update their preferences.

Finally, eHI does not agree with the ANPRM expectation that the patient identity description should be included in the metadata.

eHealth Initiative appreciates the opportunity to comment on the ANPRM on metadata standards. If you have any questions, please contact me at Jennifer.Covich@ehealthinitiative.org.

Sincerely,

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Jennifer Covich Bordenick Chief Executive Officer eHealth Initiative