

February 7, 2011

National Institute for Standards and Technology
Re: "Standardization feedback for Sub-Committee on Standards."

The Newborn Coalition is pleased to provide the National Institute of Standards and Technology our comments on involvement of federal agency participation in standardization activities led by private sector, on health information technology, data exchange, and interoperability.

The Newborn Coalition (<http://www.newborncoalition.org>), came together to promote adoption and use of HIT to lower costs and improve quality in newborn health, is pleased to offer our comments on the role of NIST in the standardization of our growing national HIT infrastructure. Our membership is diverse; it includes health care providers, large employers, patient advocates and consumers, insurers, and others that share our views.

These comments reflect those of the Coalition and not necessarily those of any individual member.

The Newborn Coalition believes that the National Institute of Standards and Technology has a critically important and prominent role to play in the setting of HIT standards. We believe that NIST should play a leading role in setting high standards in Interoperability, Privacy & Security, as well as appropriate application of Taxonomies & Vocabularies. We believe that NIST, with the advice of relevant committees and agencies, should be setting thematic definitions of HIT standards and then evaluating the methods of transparent and open sourced projects, such as the Direct Project, in reaching those goals.

We believe that the Sub-Committee on Standards under the National Science and Technology Council's Committee of Technology should use the relative rates of progress in standards development and market activation between the ONC Committee policy and standards development and The Direct Project as evidence in deciding the role NIST should play in the standards setting process.

The Office of the National Coordinator has undertaken a tremendous effort to define policies and standards for HIT under the auspices of its Committees; we support this work and believe that it is a critical step in the path to HIT ubiquity in the United States. The ONC committees play two critical roles in the development of national HIT infrastructure: defining the clinical quality measures necessary for meaningful use of HIT and defining the outcomes sought in provider adoption. While the ONC Committees have done a great deal of work to define these policies, implementation of these measures has been slowed by the HIT standards committees combined workload on developing guidelines for reaching quality measures as well as those for interoperability and Exchange. While The Newborn Coalition believes that interoperability and exchange are the most critical elements in a robust health information system, we believe that such standards should be developed organically within the active health technology market. We believe that a collaborative and transparent effort by an ever-growing number of eager professionals will foster innovation in the health technology market in a way that the reactionary development of technology aimed at reaching the minimum requirements of meaningful use cannot; this is evident in the success of the Direct Project.

The Direct Project develops specifications for a secure, scalable, standards-based way to establish universal health addressing and transport for participants (including providers, laboratories, hospitals, pharmacies and patients) to send encrypted health information directly to known, trusted recipients over the Internet. The Newborn Coalition supports efforts such as the Direct Project due to its rapid pace as well as its collaborative spirit; this was evident in the February 2, 2011 announcement by HHS and OSTP that two members of the Direct Project had already exchanged clinical data using the NHIN framework. This exchange is critical in reaching the outcomes desired in the Meaningful Use program but it still not occurring at a sufficient rate in among Stage 1 adopters.

We believe that the efforts of the Direct Project are also evidence in a divergence in beliefs between the HIT development community, the Presidents Council of Advisors on Standards and Technology (PCAST), and the work of the ONC Committees. Early efforts of the Direct Project, as well as the PCAST report, ran contrary to the findings of the ONC committees because they were focused on interoperability and exchange. This is evident in the Direct Project's recommendation to use secure email as the basis for exchange and the PCAST report's focus on data element exchange and not the exchange of a CCR/CCD outlined by ONC.

In general, we believe that the resources dedicated to CMS to encourage provider adoption of EHRs are appropriate and necessary for the development of a robust HIT infrastructure. However, we believe that resources dedicated to decentralized standards development as well as EHR certification and accreditation should be refocused on developing high benchmarks for HIT standards that foster cooperation and innovation in the technology development market. By creating national standards for interoperability and exchange that promote the innovative application of technologies developed in the free market, standards development will constantly be improved through the application of lessons learned and shared in the cooperative development

of infrastructure for health information exchange. We believe that NIST should play a leading role in developing national benchmarks for interoperability and exchange.

We are please that the Sub-Committee on Standards under the National Science and Technology Council's Committee of Technology is investigating the role that NIST can play in setting standards for HIT. The Newborn Coalition has long been a champion of health technologies, the collaborative power of the health technology development market, as we as the critical importance of a common focus on interoperability and standardized information exchange. We look forward to continuing to participate in this process and helping to foster the dialogue on the importance of health information technology.

Sincerely,

Jim Bialick
Executive Director
Newborn Coalition