

March 7, 2011

Patrick Gallagher
Director
National Institute of Standards and Technology
Co-Chair, National Science and Technology Council's Sub-Committee on Technology
Attention: Ajit Jillavenkatesa
100 Bureau Drive
Gaithersburg, MD 20899

Mr. Gallagher:

Epic appreciates the opportunity to comment on the December 8, 2010 Request for Information on the effectiveness of Federal agencies' participation in the development and implementation of standards and conformity assessment activities and programs. Epic is an electronic health record (EHR) developer based in Verona, Wisconsin. Our suggestions in this letter are based on two decades of experience programming electronic health records and participating in the EHR industry in standards and interoperability initiatives.

Standards-Setting Processes and Benefits

Standard-setting activities are the most successful when they gather the participation of the groups that will eventually be held to those standards. These groups have the domain knowledge to balance practical need with technical feasibility. In the healthcare interoperability sector, there is a rich history of clinicians, healthcare professionals, and experts from every level of the technical infrastructure convening to define both needs and solutions to create a base of standards from which interoperability can be made practical.

For example, Integrating the Healthcare Enterprise (IHE), a multi-stakeholder group made up of both users and industry experts, continually and consistently works together through voluntary workgroups to define the use of base standards. In addition to these definitions, IHE also coordinates their yearly testing and demonstration, is responsible for certifying systems as compliant, and advertises and advocates for the use of these profiles across the industry throughout the United States and the world. Through this functional approach, systems that are certified in a role defined by IHE can continue to distinguish themselves competitively while still working from a base set of functionality that allows them to communicate with other systems.

The benefit of having data exchanging standards is a faster and less costly implementation of the exchange for its participants. As long as standards set a base requirement and allow for

extendibility, innovation and competitiveness are not harmed. Organizations that want to contribute more can do so; with time, if such contributions are really beneficial to all, they should become standards.

The organizations that introduced them benefit again as they already have done what is now required, thus allowing them to use their resources to innovate again. Standardization has spurred innovation by allowing more time to spend on new ideas and development that otherwise would have been taken to implement and code one off exchanges.

Perspectives on Government's Approach to Standards Activities

Where possible, the role of the Federal government should be that of convener, organizing stakeholders, providing support, and setting and meeting reasonable deadlines with the help of domain experts. The role of the Federal government should be to encourage and coordinate standard-setting activities. The history of the industry's voluntary participation in standards-setting activities, however, speaks to vendor commitment with little to no Federal intervention and to our recognition of the need for meaningful standards, and so we urge the government to examine progress to date when considering how their participation can advance the process.

Beyond their potential role as convener where no effective convener exists, Federal/Government agencies should participate in the standard setting activities like other stakeholders with the understanding that they can bring valuable input to the table. Sometimes the needs of these agencies are different from current trends. We should approach such needs as additional use cases and strive to meet them as priorities permit. Rare needs should be treated as extensions to the standards that others can implement if they wish to do business with the respective federal agency. See, for example, the Social Security Administration; the SSA CDA implements extensions of the C32 document, which is appropriate as SSA data needs can be different. However, the transactions used for the exchange are typical IHE implementations. This is a great example of use of existing standards with additions of needed extensions.

Additional Comments

Where possible, industry-led standard-setting activities already involve stakeholders from foreign interests. Such an approach best accommodates any overlap of standards because the standards are written a priori from an international perspective and for an international user base.

Finally, like many voluntary organizations, standard-setting groups are most limited by the time of their volunteers. Most volunteers can address small tasks about which they are passionate, but may not have the time to coordinate large-scale efforts that require joint participation by many people. Federal agencies can play a valuable role in recognizing the

contribution capacity of the many players and organizing these contributions into a comprehensive whole.

Thank you for your consideration. We hope our perspective is useful as you consider your role in this process.

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