President’s column: AMIA’s policy priorities for 2014

Policy and advocacy are significant components of the strategic objectives endorsed by the American Medical Informatics Association (AMIA) board of directors, which represents the interests of AMIA members. The elected leadership has a wide swath of interests to cover as the association is a multidisciplinary organization serving a broad range of concerns important to members active in translational bioinformatics, clinical research, consumer health, public health, and clinical informatics domains.

AMIA’s public policy priorities for 2014 have three primary areas of focus:

▸ **Research:** advocating for key federal agencies conducting and supporting informatics research (eg, working with Friends of AHRQ to support funding for the agency)

▸ **Practice/implementation:** providing guidance on the evolution of Meaningful Use and the regulation and certification of electronic health records (EHRs) and related software; promoting patient/consumer engagement during treatment

▸ **Workforce:** supporting education and training for biomedical and health informatics fellowships (eg, NLM Fellowships).

These priorities drive not only the actions of our Public Policy Committee, chaired by Dr. Margo Edmunds, VP of Evidence Generation and Knowledge Translation at AcademyHealth, but also our interactions with federal officials, legislators, and policy influencers, and also policy initiatives throughout the year, such as our 8th Annual Health Policy Invitational Meeting, September 4–5, 2014, which will be on personalized medicine. AMIA and its members will continue to play an integral role in shaping policy by being called upon to provide recommendations to assist in federal program implementation.

**AMIA AND FDASIA-RELATED ADVOCACY**

As an example of one of our practice and implementation priorities, the Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law on July 9, 2012, seeks to promote innovation, increase stakeholder involvement in FDA processes, and enhance the safety of the drug supply chain. It also expands the FDA’s authority by giving them the ability to collect user fees from industry to fund reviews of innovator drugs, medical devices, generic drugs, and biosimilar biological products.

The impact FDASIA has had on medical devices and related health information technology (HIT) is significant enough that the Office of the National Coordinator for HIT (ONC) requested the Health IT Policy Committee to establish an FDASIA Workgroup. The Workgroup was tasked with making recommendations on how to ‘thread the needle’ and apply the appropriate level of regulatory oversight to HIT through a risk-based regulatory framework to be completed through the collaborative efforts of three federal agencies: the FDA, ONC, and Federal Communications Commission (FCC). Official meetings were held from April 29, 2013 to August 13, 2013. The Workgroup consisted of 31 subject matter experts chaired by Dr. David Bates, Senior VP for Quality and Safety and Chief Quality Officer at Brigham and Women’s Hospital, a long time AMIA member and former board chair. Additionally, nine of the 31 members of the FDASIA Workgroup and five of the 24 members of the HIT Policy Committee were also AMIA members. Ultimately, their recommendations will be used by the Department of Health and Human Services to shape their proposed rules.

Key recommendations of the Workgroup, which AMIA supports, included the following:

▸ HIT should only be subject to FDA premarket requirements under specific conditions: for medical device accessories; for certain forms of high-risk clinical decision support, such as computer-aided diagnostics; and for higher risk software applications.

▸ The FDA should develop an enhanced program for post-market surveillance of HIT through a collaborative process with stakeholder participation.

▸ The FDA should establish a public process to account for customer ratings of HIT to enhance transparency.

The Workgroup also endorsed several recommendations from a previous Institute of Medicine (IOM) committee. These included having better post-market surveillance of HIT through standard formatting of reports and the suggestion that the FDA and other agencies should strongly discourage vendors from engaging in practices that obstruct the free flow of safety-related information.

Currently, the FDA regulates devices according to their level of risk. However, the level of risk for an EHR system varies depending on that system’s specific clinical software—a one-size-fits-all approach is not the best strategy. The new framework developed as a result of FDASIA should focus on outcomes assessment rather than product definitions. AMIA also supports the reevaluation of currently regulated products as well as new HIT. The definition of what is included in HIT should be broad, but should also have described exclusions such as those mentioned above.

As of this submission, no proposed rule has been published, though the Secretary is expected to act by the time this letter appears in the journal. We would be interested in your opinion on how AMIA’s perspective matches up with the proposed rule. Tweet your comments to @AMIAPolicy and to me @bfm. To learn more about AMIA’s public policy initiatives, please visit http://www.amia.org/public-policy.

Blackford Middleton

Correspondence to Dr Blackford Middleton, Department of Biomedical Informatics, Vanderbilt University Medical Center, Nashville, TN 37203-8363, USA; blackford.middleton@vanderbilt.edu

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The purpose of the Messages from AMIA section is to provide a forum for AMIA to inform and involve its current and potential members about the goals and the directions of the association. These messages, which reflect the directions and opinions of AMIA leaders only, are intended to inspire members and readers to connect with the association on strategic objectives and activities. See also http://www.amia.org/presidents-page.