



Leslie Kux
Assistant Commissioner for Policy
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Submitted electronically via: www.regulations.gov

RE: FDASIA Health IT Report: Proposed Risk Based Regulatory Framework

Dear Ms. Kux:

The Heart Rhythm Society (HRS) appreciates the opportunity to provide comments in response to the *Food and Drug Administration Safety and Innovation Act (FDASIA) Health IT Report: Proposed Risk Based Regulatory Framework*. HRS is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients, and the primary information source for heart rhythm disorders. We represent more than 5,300 specialists in cardiac pacing and electrophysiology, including physician scientists and their support personnel, who performed electrophysiology study studies, pacemaker implants, ICD implants, and curative catheter ablation to diagnose, treat and prevent cardiac arrhythmias. This is an exciting time for electrophysiologists, in part due to advancements associated with health information technologies (HIT).

We commend the efforts of the US Food and Drug Administration (FDA), Office of the National Coordinator for Health Information Technology (ONC), and Federal Communication Commission (FCC), to establish an appropriate, risk-based regulatory framework for health IT that promotes innovation, protects patient safety, and avoids regulatory duplication. The proposed strategy is yet another step in getting us closer to realizing the tremendous benefits of using HIT to address longstanding challenges facing our healthcare system. We, too, are concerned that HIT can have a significant impact on patient safety, and we urge the FDA, ONC, and FTC to continue efforts that would address those challenges.

Interoperability

For electrophysiologists, the primary challenge with HIT continues to be a lack of interoperability standards. We believe interoperability is cornerstone to developing a robust health information technology network that could be used to improve quality and efficiency. In addition, we believe the lack of interoperability standards is a key barrier to improving patient safety in HIT, and should be a higher priority for FDA, ONC and FTC.

Since 2005, the Society has partnered with industry and *Integrating the Healthcare Enterprise* (IHE) to identify areas of clinical practice where gaps or "pain points" limits clinicians' abilities to provide optimal care. Working with industry engineers under the construct and guidance of IHE, HRS has sought to develop standards-based solutions to these clinical gaps in care in order to provide industry with the leadership and guidance to implement such solutions. We believe this standards-based approach benefits patients by enabling exchange of data among healthcare providers, provides a mechanism to improve patient safety, and provides the opportunity for industry to devote resources to developing higher level functionality and new products. It also provides the opportunity for data to be aggregated and utilized for registries and quality monitoring and will facilitate the development of new, more efficient workflow patterns.

Implantable Device Cardiac Observation (IDCO)

HRS is actively developing several IHE interoperability profiles under the Cardiology and Patient Care Devices Domains. The Implantable Device Cardiac Observation (IDCO) profile specifies the creation, transmission, and processing of discrete data elements and report attachments associated with implantable pacemaker (PM), implantable defibrillators (ICDs), and cardiac resynchronization therapy device (CRT) interrogations (observations) or messages. This profile has been developed by HRS in partnership with cardiac rhythm management (CRM) industry (all vendors represented), tested, validated and certified by the IHE's rigorous standards development process. It contains over 200 data elements identified by HRS clinicians as necessary and sufficient to evaluate and monitor the function of all pacemakers, ICDs and CRT devices regardless of vendor. Additional interoperability profiles in development include the Electrophysiology Report Content Profile, the National Cardiovascular Device Registry Interoperability Profile, the Retrieve ECGs for Display, and the Resting ECG Work Flow interoperability profiles.

Work on the IDCO profile was initiated in 2005. Prior to its development, clinicians voiced concern that data from ICDs was becoming difficult to manage. Data for an individual patient (which requires a proprietary programmer specific to each vendor) could now be acquired in an office setting, acute care setting, or remotely from the patient's home. The data could be printed on paper, or exported electronically. However, the electronic format also was proprietary, creating a high barrier to entry for any vendor who considered creating a product to manage and view the aggregate data. Compounding this challenge was the fact that new PM and ICD models, even from a single vendor, often would export data in new formats. This created a situation where meaningful aggregation of the data, even for a single patient, was extremely difficult and often virtually impossible.

The IDCO profile was developed in partnership with the CRM industry out of recognition that patient safety, quality, and efficiency of care required an interoperability standard to close this gap. The IDCO interoperability profile is now available for implementation and clinical use. Yet, we have been unsuccessful in convincing the CRM industry to implement the full IDCO profile in their market release products. This has limited our ability to seek adoption and implementation by the electronic health record industry and personal health record vendors. It also has limited our ability to encourage utilization of the interoperability profile for data registries, quality monitoring, and post-market approval FDA surveillance studies.

HRS believes that collaboration with federal agencies will be necessary in order to realize the full potential of meaningful interoperability of data acquired from PM's, ICDs and CRT devices.

Clinical Decision Support Systems

Clinical decision support (CDS) is an important and growing component of health information technology systems and EHRs. HRS notes that CDS is on the verge of being more directly incorporated into the systems used by EPs. In fact, several manufacturers in our industry have started to include advancements, such as clinical indicated-based templates for ICD programming and electroanatomic mapping systems that provide pattern-matching algorithms to determine the degree of match between QRS morphologies during pace mapping, in their products.

We agree there are varying levels of risk associated with multiple CDS technologies and products, and the presence of a "learned intermediary" presents an additional nuance in how the federal government might need to regulate CDS systems. HRS strongly supports regulatory oversight to ensure that CDS systems do what they are expected/supposed to do when they are employed, and regardless of whether or not a learned intermediary is present to intervene.

We also strongly support a feedback mechanism that allows clinicians, vendors and other stakeholders to learn from experience with these and other technologies.

We believe that healthcare is on the verge of transformation to a more patient-centric, value-based model in which remote physiologic monitors and other sensors will radically change delivery of care and improve patient safety. We urge the FDA, ONC and FTC to put more emphasis on the role of interoperability in patient safety, and prioritize the development and adoption of interoperability standards, in the final framework.

We appreciate the opportunity to submit comments for consideration by the FDA, ONC and FTC, and look forward to collaborating with you to address this, and other challenges to patient safety presented by HIT. If you have questions about these public comments or would like additional information about HRS activities, please contact Isabelle Le Blanc, Manager, Health Policy, at ileblanc@hrsonline.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'David J. Slotwiner', with a long horizontal line extending to the right.

David J. Slotwiner, MD
Chair, HIT Subcommittee
Heart Rhythm Society