

Don Rucker, MD National Coordinator for Health IT Department of Health and Human Services Washington, DC

Submitted electronically via www.healthit.gov

## **RE: Proposed Interoperability Standards Measurement Framework**

Dear Dr. Rucker:

The Heart Rhythm Society (HRS) appreciates the opportunity to provide feedback on the proposed industry-wide measurement framework for assessing the implementation and use of health care interoperability standards. 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).

## **Response to Questions**

Since 2005, the HRS 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 realized standards-based solutions to these clinical gaps in care in order to provide industry with the leadership and guidance to implement such solutions.

IHE covers multiple domains, including dental, eye care, pathology and laboratory medicine, patient care coordination, patient care devices, radiology, and pharmacy, among many others. Given the role IHE plays in convening disparate players in the development of voluntary, standards-based profiles, it stands to reason this may be an appropriate entity to help collect voluntary, industry-based measures. In fact, a survey co-branded with IHE would likely be well-received by those in industry given many health IT developers are engaged in profile development.

Regarding the objectives, goals and measurement areas, we appreciate that ONC uses IHE profiles as an example. 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. Although the IDCO profile was developed in partnership with industry, we have been unsuccessful in convincing industry to implement the full IDCO profile in their market release products. In turn, this has limited our ability to seek adoption and implementation by the electronic health record (EHR) 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 U.S. Food and Drug Administration (FDA) surveillance studies. This serves as an example that development of the standard is a critical *first* step, but the process doesn't end there. Gaining momentum to achieve sufficient adoption and implementation requires further partnerships, including with federal agencies.



We believe that updating the Interoperability Standards Advisory (ISA) on an annual basis would be very helpful for organizations like HRS that are working diligently to develop IHE profiles to improve patient care. We encourage ONC to prioritize this activity.

Finally, ONC should prioritize measurement for standards that have a high impact on the federal programs and the beneficiaries they serve, as well as those where the lack of standards pose a significant risk on patient outcomes.

Thank you for your leadership on this important issue. We look forward to working with ONC on these issues. If you have questions about these public comments or would like additional information about HRS activities, please contact Isabelle LeBlanc, HRS's Manager of Health Policy, at <u>ileblanc@hrsonline.org</u>.

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Sincerely,

David J. Slotwiner, MD, FHRS Chair, Health Policy Committee Heart Rhythm Society