



May 1, 2015

Karen DeSalvo, MD, MPH, MSc
National Coordinator
Office of the National Coordinator for Health IT/Office of the Secretary
Department of Health and Human Services

RE: Draft 2015 Interoperability Standards Advisory

Dr. DeSalvo,

The Heart Rhythm Society (HRS) appreciates the opportunity to provide comments on the open draft of the 2015 Interoperability Standards Advisory. HRS represents more than 5,600 heart rhythm specialists, including physicians, scientists, and allied professionals, who perform electrophysiology study studies, pacemaker implants, ICD implants, and curative catheter ablation to diagnose, treat and prevent cardiac arrhythmias.

We applaud ONC for its efforts toward providing the industry with a single, public list of the standards and implementation specifications that can best be used to achieve a specific clinical health information interoperability purpose and also to prompt dialogue, debate, and consensus among industry stakeholders when more than one standard or implementation specification could be listed as the best available. HRS continues to be a leader in the development of interoperability standards and use-case profiles for the specialty. Working in partnership with medical device manufacturers, electronic health record (EHR) vendors, and other cardiology organizations, has led to significant successes in this space, and is a model that could be emulated in other domains.

Section V. Questions Regarding the Interoperability Standards Advisory

ONC solicits comment on several questions related to the draft list of standards, including whether any standards or implementation specifications are missing from the list.

Since 2005, the HRS has partnered with industry and *Integrating the Healthcare Enterprise* (IHE) to identify areas of clinical practice where gaps limit clinicians' abilities to provide optimal care. Working with industry engineers under the construct of IHE, HRS has developed standards-based solutions to these clinical gaps in care in order to provide industry with the leadership and guidance to implement such solutions. For example, the Implantable Device Cardiac Observation (IDCO) profile under the Patient Care Devices Domain specifies the creation, transmission, and processing of discrete data elements and report attachments associated with implantable pacemakers (PMs), implantable defibrillators (ICDs), and cardiac resynchronization therapy device (CRT) interrogations (observations) or messages. This profile was developed by HRS in partnership with cardiac rhythm management 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 continue to face challenges in convincing all of 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 EHR vendors (minus a few that have started the adoption process) 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.

To help improve adoption of the IDCO, HRS convened a group of clinicians, federal agency staff, private sector experts, CRM device manufacturers, EHR vendors and accrediting organizations, to draft a health policy statement and white paper which will give guidance to stakeholders regarding implementation of structured reporting and interoperability data standards specific to electrophysiology clinical workflow.

The health policy statement will serve as the formal means to promote the concept of structured reporting for electrophysiology, data dictionaries, interoperability standards and will outline sample structured reports for all electrophysiology procedures, beginning with AF ablation and longitudinal management of patients with ICDs. Additional structured reports will be added over the upcoming years. The white paper will give technical guidance to industry, regulatory and accreditation agencies for implementation of the structured reports presented in the health policy statement. Both documents are expected to be released in Summer 2015.

Again, despite recognition by many engineers working in the CRM and EHR space that the IDCO profile is an important step toward interoperability, electrophysiologist's demand for such functionality is not always enough to prompt adoption. EHR vendors tell us they face financial pressures and can only expend finite resources based on a strong business case. For finance executives within EHR vendor companies to authorize funding to incorporate the profile, we believe the profile needs to be recognized by the ONC in the certification criteria, as it is our understanding that the "business case" comes down to federal requirements and recognition, such as those set forth in the certification criteria and in this proposed interoperability standards advisory. Therefore, we urge ONC to recognize the full IHE IDCO profile in its final 2015 Interoperability Standards Advisory. This activity would go a long way toward helping EHR vendors strengthen the business case for incorporating the profile into their respective systems.

In addition, and beyond the aforementioned benefits of the IDCO profile, HRS maintains that such functionality will help electrophysiologists better engage patients in their heart rhythm care, which is also key to improving outcomes. Improved patient engagement through use of the IDCO profile is evidenced by results from a 2011 ONC Challenge Grant on Consumer-Mediated Information Exchange, whereby a group of key stakeholders in Indiana delivered data to patients' personal health records (PHRs) through remote monitoring of their ICDs. Major outcomes of the Challenge Grant project were reduced time between cardiac events and clinician review of the data, which improved patient outcomes, and reduced emergency room and office visits by patients with ICDs.

We also believe the collection of these data would be useful toward helping electrophysiologists develop clinical decision support metrics based on data received from implanted devices, prompting earlier intervention if or when problems arise. Incorporating the IHE IDCO profile into the certification criteria supports the federal governments broader effort to ensuring patients receive the right care, at the right time.

ONC has already incorporated IHE profiles in the draft advisory, therefore, we surmise that the agency recognizes the value these consensus driven profiles to increasing interoperability.

Thank you for your leadership on this important issue. We look forward to working with CMS staff 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 ileblanc@hrsonline.org.

Sincerely,

A handwritten signature in black ink that reads "Richard Fogel MD". The signature is written in a cursive style with a large, stylized 'R' and 'F'.

Richard Fogel, MD, FHRS
President, Heart Rhythm Society