May 16, 2013

The Honorable John Thune
Dirksen Senate Office Building, Room: 511 Dirksen
Washington DC, 20510

The Honorable Lamar Alexander
Senate Office Building, Room: 455
Washington DC, 20510

The Honorable Pat Roberts
Hart Senate Office Building, Room: 109
Washington DC, 20510

The Honorable Richard Burr
Russell Senate Office Building, Room: 217
Washington DC, 20510

The Honorable Tom Coburn
Russell Senate Office Building, Room: 172
Washington DC, 20510

The Honorable Michael Enzi
Russell Senate Office Building, Room: 379A
Washington DC, 20510

Dear Senators:

The Heart Rhythm Society (HRS) appreciates the opportunity to provide comments in response to your recent white paper, *REBOOT: Re-examining the Strategies Needed to Successfully Adopt Health IT.* 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 perform electrophysiology study studies, pacemaker (PM) implants, implantable cardioverter defibrillator (ICD) implants, and curative catheter ablation to diagnose, treat and prevent cardiac arrhythmias.

HRS is committed to improving the quality and efficiency of healthcare and wholly supports provisions in the American Recovery and Reinvestment Act of 2009 (ARRA) that work toward that goal by encouraging the adoption and meaningful use (MU) of electronic health records (EHRs). We appreciate and support efforts led by the Office of the National Coordinator (ONC) and the Centers for Medicare and Medicaid Services (CMS) to increase physician adoption of certified EHR technology through financial incentives for "MU." This is an exciting time for electrophysiologists, in part due to advancements associated with health information technology (HIT).

Nonetheless, we share the Senators' concerns that the current HIT programs fail to support a framework for the development of data standards and interoperability standards. Both of these elements– data standards and interoperability standards–are required for development of a HIT infrastructure that can support the ultimate goal of the HITECH Act: "…to use health IT to create measurable improvements in population health through a transformed health care delivery system."

Lack of Standards to Support Interoperability

HRS is equally concerned about the lack of standards to support interoperability or a long-term plan by ONC to address this issue, as noted in your white paper. Many, including members of the federal HIT Policy Committee (HITPC), share this concern. In his testimony before the House Committee on Science, Space and Technology, Subcommittee on Technology and Innovation, Marc Probst, Chief Information Officer (CIO) and Vice President of Information Systems, Intermountain Healthcare, made the following statement:

"We need national standards to ensure, as the IOM recommends, 'that the digital infrastructure captures and delivers the core data elements and interoperability needed.' The federal government has made a major investment in electronic medical records, having committed $20 billion from the stimulus bill to it. We must now ensure that, as the capacities of many individual providers grow, they evolve into an efficient and effective national network.
…I serve as a member of the Health Information Technology Policy Committee (HITPC)...[t]he first task of the HITPC was to define "Meaningful Use" and the requirements for certification of electronic health records (EHRs)…[t]he majority of these requirements deal with functions that an EHR should be able to perform and requirements for what functions or data should be shared between EHRs. ***It is time now, however, for the HITPC to focus more on the longer-term plan and activities outside of Meaningful Use that are needed to fulfill our mandate provided in ARRA to 'make recommendations to the National Coordinator relating to the implementation of a nationwide health information technology infrastructure.*** *[Emphasis added]'"*

Again, HRS has long appreciated the need for standards development; the cornerstone for building meaningfully interoperable HIT systems. Since 2005, HRS has partnered with industry and *Integrating the Healthcare Enterprise* (IHE) to identify areas of clinical practice where gaps or "pain points" limit 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.

HRS Standards Development Activities

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 PM implants, 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, which can be utilized to evaluate and monitor the function of all PMs, 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 electrocardiograms (ECGs) for Display, and the Resting ECG Work Flow interoperability profiles.

The IDCO profile was developed in partnership with the CRM industry out of recognition that patient safety, research, 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 EHR industry and personal health record (PHR) 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. As clinician, we depend upon EHR vendors and health care vendors to store and exchange data seamlessly in a manner that supports the patient/physician interaction and promotes the highest quality and most efficient care possible. Data management and interoperability should occur in the background.

Developing the standard is the first step, but gaining momentum to achieve sufficient adoption and implementation requires further partnerships. While the primary focus of our submission is interoperability of data acquired from PMs and ICDs, 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. As such, the challenges that we face with implementation and adoption of the IDCO Profile will be relevant to others.

Recommendation

To realize the full potential of meaningful interoperability of data acquired from PMs, ICDs and CRT devices, federal agencies should require that suppliers (CRM vendors) implement and demonstrate the ability of their products to export data by implementing the full IDCO profile. Specifically, the FDA should require CRM vendors to implement the full IDCO profile in market release products to ensure quality and safety of care for PM and ICD recipients and for post-market surveillance activities. The ONC should include support for the full IDCO profile as part of the EHR Certification Requirement for MU. Given that CMS already requires Medicare patients to be enrolled in the National Cardiovascular Data Registry (NCDR) ICD Registry, it should further require the NCDR ICD Registry to support the IDCO interoperability standard to allow tracking of device and patient post-implant. We also recommend that CMS create a mandate which requires its suppliers (i.e., CRM vendors) to adopt the IDCO Profile and implement features that it deems important for quality of care and patient safety.

Not only will the aforementioned recommendations support efforts to improve interoperability, they will also address other issues related to quality improvement, patient engagement, and patient safety and adverse events.

Lack of Robust Data on the Impact of the EHR Incentive Program and Meaningful Use (MU) Criteria

Making the decision to invest in an EHR system continues to require a considerable amount of time and personnel and financial resources for many electrophysiologists, particularly those in smaller, private practices. We are greatly concerned about the rapid pace with which criteria for future stages of MU are being proposed given that many of the objectives have not been sufficiently evaluated for efficacy, feasibility, and value. Furthermore, these criteria may pose challenges for electrophysiologists moving forward without interval assessment of these challenges after early stage criteria adoption. Currently there remains a paucity of evidence regarding the feasibility of Stage 1 and Stage 2 criteria and the effects of those criteria on physician practice and overall patient care and safety.

In addition, there are still widespread gaps in certified EHR technology functionality. ONC's recently released data brief, *Data Brief No. 7, Physician Adoption of Electronic Health Record Technology to Meet Meaningful Use Objectives: 2009-2012,* notes that half or more of physicians had the capability to meet only 12 of the required 15 MU Core objectives. Data from the aforementioned CDC data brief also revealed that 27 percent of office-based physicians who planned to apply or already had applied for MU incentives had computerized systems with capabilities to support only 13 of the 15 Stage 1 Core Set objectives for MU.

Recommendation

HRS encourages federal agencies, in collaboration with medical specialty societies, to develop and conduct a systematic, independent evaluation of physician experience regarding HIT implementation under the EHR Incentive Program. This should be conducted before increasing the requirements for future stages of MU. The Society also recommends that ONC, in collaboration with CMS, query physicians who did not participate in earlier stages or failed to meet MU requirements to determine which objectives and measures, including associated thresholds, posed the greatest challenge from an administrative, financial, and clinical perspective. We would appreciate the opportunity to assist in developing questions for such a survey to ensure that the broad scope clinical challenges are adequately captured.

In addition, and given the aforementioned challenges, we recommend that future stages of MU rely more heavily on menu set options rather than core criteria. Flexibility to choose among criteria that are most relevant to a physician's patient population and practice setting will ensure increased buy-in and trust among participants, increased adoption across a range of specialists, more MU of EHRs, and ultimately higher quality care.

Unique Patient Identification

The Heart Rhythm Society has concern that the present engineering/software work-around to correctly match medical data to individual patient records are insufficiently robust. There remains a possibility that critical medical data could be routed to an incorrect patient record. This may have devastating consequences. A unique patient identifier or equivalent robust engineering solution is required.

Recommendation

We urge the Senators, Department of Health and Human Services, and the ONC to work with healthcare industry engineers to ensure that each patient is uniquely and correctly identified. This will ensure that all medical data is associated with the correct patient.

Conclusion

Implementation of the EHR incentive program has failed to take into account the significant grass roots collaboration that existed before 2009 between health care providers and vendors of medical equipment, both for delivery of patient care and for electronic medical records. Healthcare providers and manufacturers of medical equipment have long recognized the need for ***data standards***, and ***interoperability standards***. A leading example is the effort by the Radiological Society of North American (RSNA) and the collaboration with clinicians and industry to develop the data standard of DICOM (Digital Imaging and Communication in Medicine). Collaboration between physicians, engineers, and vendors resulted in the development of the DICOM standard that has made radiographic images portable and transferrable to healthcare providers across the globe, regardless of EHR vendor, radiographic equipment, or even PC operating system.

Clinicians (working with medical societies), medical equipment manufacturers, and HIT vendors must work together to define base data elements. This work must be done by medical societies in collaboration with standards development and other organizations, including the American National Standards Institute, IEEE, HL-7, SNOMED-CT and LOINC. Interoperability standards organizations, such as IHE, then will bring these standard data elements into an interoperability profile that is vendor-neutral. HIT vendors will then be able to take these base standards and create usable HIT products that offer value-added features and make the data interpretable, as well as accessible. The EHR incentive program should be redirected to build upon the earlier efforts of clinicians, medical societies and the health care industry to develop data and interoperability standards critical to meaningful use of health information technology.

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HRS looks forward to engaging in a broad dialogue on advancing HIT, which we believe is a fundamental component of a patient-centered, value-based healthcare system. We look forward to working with you and other federal agencies to identify the most effective strategies to encourage adoption and implementation of interoperability data standards both for the specific challenges we have encountered related to remote monitoring of CRM devices, and for the structured data standards that are relevant to all fields of medicine. We believe interoperability data standards are essential to achieving meaningful integration of health information and that they will be critical building blocks in the construction of a HIT

data architecture that will foster meaningful use of patient data.

HRS would be happy to meet with you and your staff to discuss additional opportunities for improving federal programs aimed at encouraging the adoption of EHRs. If you have questions about these public comments or would like additional information about HRS activities, please contact HRS's Director of Quality Improvement, Del M. Conyers, MPH at dconyers@hrsonline.org.

Sincerely,

David Slotwiner, MD
HRS Health Information Technology Subcommittee Chair