



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

Submitted electronically via www.healthit.gov

RE: Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs

Dear Dr. Rucker:

The Heart Rhythm Society (HRS) appreciates the opportunity to provide feedback on the Agency's strategy on reducing regulatory and administrative burden relating to the use of health information technology (IT) and electronic health records (EHRs). 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 6,300 specialists in cardiac pacing and electrophysiology, including physician scientists and their support personnel, who performed electrophysiology study studies, pacemaker implants, implantable cardioverter defibrillators (ICDs) 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.

General Concerns

In its draft strategy, the Office of the National Coordinator (ONC) outlines three overarching goals designed to reduce clinician burden:

- Reduce the effort and time required to record health information in EHRs for clinicians;
- Reduce the effort and time required to meet regulatory reporting requirements for clinicians, hospitals, and healthcare organizations; and
- Improve the functionality and intuitiveness (ease of use) of EHRs.

We strongly support ONC's efforts described in the draft strategy, particularly those that center on improving the usability of EHRs, a source of significant clinician frustration and potential patient safety concerns. We also urge ONC to work closely with the Centers for Medicare and Medicaid Services (CMS) as it collaborates with the medical community to address (evaluation and management (E/M) documentation challenges, as outlined in the recent Medicare Physician Fee Schedule. However, the strategy does not adequately address challenges faced by specialists, such as electrophysiologists (EPs). EPs face significant challenges in the day-to-day use of health IT and EHRs due to a host of other challenges, which we discuss below.

Interoperability Standards for Electrophysiologists

Since 2005, HRS has partnered with industry and *Integrating the Healthcare Enterprise* (IHE) on developing the Implantable Device Cardiac Observation (IDCO) profile, which specifies the creation, transmission, and processing of discrete data elements and report attachments associated with cardiac implantable electronic device (CIED) technologies, including implantable pacemaker, 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.

As with many initial introductions of new standards, and although the IDCO profile¹ was developed in partnership with industry, we have been unsuccessful in convincing industry to implement the full IDCO profile in their market release products. As a result, only a limited set of data could be transmitted in the IDCO profile. In turn, this situation 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 episode serves as an example that development of the standard is a critical *first* step, but gaining momentum to achieve a critical level of adoption and implementation requires further partnerships, including with federal agencies. Therefore, we encourage ONC to prioritize the adoption of the IDCO profile, including the *ISO/IEEE 11073-10103:2014 (Health informatics -- Point-of-care medical device communication -- Part 10103: Nomenclature -- Implantable device, cardiac)*, as a recognized standard. This is essential to ensuring EPs can collect, record and capture all pertinent data involved in the management of patients with CIEDs within EHR technology.

Patient-Collected Data

Patients are increasingly collecting data on their health and wellness through a variety of digital health, mobile, and other medical devices. Some of these platforms provide patients with the ability to collect, record and store data on heart rhythm events, which can be shared with their healthcare professional or EP in an electronic format. Despite the important advantages to this level of patient engagement in the management of heart rhythm conditions, new challenges have emerged as EPs receive patient collected data.

EPs are increasingly faced with the task of processing and handling large amounts of clinical information their patients have collected on digital health, mobile, and other medical devices. The data is not always standardized and may not easily integrate with the EPs EHR system, if at all. EPs are also concerned about longevity of the data being collected, as data may not be readable as current software becomes obsolete. Perhaps most pressing is the large volume of data being shared, even by a single patient, which can be challenging. Patients sharing information from their device with their EP may be looking for an immediate response, particularly if they have a health concern. However, mechanisms to sort and prioritize clinician review of these submissions remains a challenge, which creates new medical liability concerns. Systems for standardized electronic collection, filing, and storage of this information in EHRs in a usable format is needed.

We urge ONC and its federal agency partners to work with HRS, patients, and the vendor community to establish guidance that may address some of these issues.

Adverse Events Resulting from Health IT

We remain concerned with the lack of structured mechanisms by which health IT-related patient safety events can be reported to, and subsequently addressed by, the facilities where EPs deliver patient care. We have previously urged ONC to work with CMS to update the Quality Assessment and Performance Improvement (QAPI) Condition of Participation (CoPs) to require hospitals and other facilities to include

¹ The IDCO profile relies on the ISO/IEEE 11073-10103 CIED nomenclature, which is also recognized by the US Food and Drug Administration (FDA)



their medical staffs, including EPs, in health IT purchasing decisions and implementation processes, as well as establish a process that would facilitate reporting of patient safety issues associated with EHR use and timely responses to medical staff concerns about patient safety and other health IT issues during and after implementation.

In *Health IT and Patient Safety: Building Safer Systems for Better Care*, the Institutes of Medicine (IOM) concluded that “all stakeholders must coordinate efforts to identify and understand patient safety risks associated with health IT by facilitating the free flow of information, creating a reporting and investigate system for health IT-related deaths, serious injuries, or unsafe conditions, and researching and developing standards and criteria for safe design, implementation, and use of health IT.” The American Medical Informatics Association (AMIA) also recommended that monitoring how health IT systems are used and reporting HIT-related adverse events are critical and should occur on a regular basis.

ONC’s *Health IT Patient Safety Action & Surveillance Plan* points to Medicare’s Conditions of Participation (CoPs) and the QAPI requirements to leverage existing CMS requirements with the safety of health IT. The following excerpt is from the ONC plan:

“The Medicare health and safety standards for many types of health care facilities already address areas of patient safety in which health IT is critical. For example, the Hospital Conditions of Participation (CoPs) include a requirement for each hospital to have a Quality Assessment and Performance Improvement program that includes internal adverse incident reporting and effective follow-up. By using health IT to promote effective reporting and follow-up, health IT can make patient care safer overall, as well as identify and improve patient safety issues related to health IT itself. For instance, hospitals are required under the CoPs to track adverse drug events. Inasmuch as health IT may be one cause of a medication error, the hospital’s incident reporting system should be able to identify the error and its potential causes. This is true of many of the other areas addressed in the Medicare health and safety standards.”

We urge ONC to work with CMS to update the Medicare CoPs and QAPI requirements to ensure hospitals collect and address health IT-related patient safety events reported by EPs.

Thank you for your leadership on these important issues. We look forward to working with ONC as the initiative progresses. If you have questions or would like additional information about HRS activities, please contact Isabelle LeBlanc, HRS’s Director of Health Policy, at ileblanc@hrsonline.org.

Sincerely,

A handwritten signature in black ink that reads "Joseph E. Marine".

Joseph E. Marine, MD, FHRS, FACC
Chair, Health Policy Committee
Heart Rhythm Society