April 2, 2015

Dr. Karen DeSalvo  
Acting Assistant Secretary for Health  
National Coordinator for Health IT  
U.S. Department of Health & Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Dr. DeSalvo,

We write regarding the Office of the National Coordinator’s (ONC) efforts to define a shared Nationwide Interoperability Roadmap for achieving interoperable health IT that supports a broad scale learning health system. We appreciate the pathway proposed in the recently published draft Roadmap; however, we are concerned about a potential missed opportunity regarding medical device interoperability.

The need to securely, efficiently and effectively share and use electronic health information is absolute. The default frame of reference for electronic health information and data exchange is the electronic health record (EHR). This posture assumes that medical devices readily communicate with each other, and that their data is accurately reflected in health record systems. As you know, the reality is that neither occurs. ONC has the opportunity to use its authorities related to coordination and certification to ensure the advancement of medical device interoperability.

Representing the largest source of objective biometric and clinical data in the healthcare enterprise, medical devices warrant specific mention in the pathway to a learning health system. The prevalence of medical devices in acute, ambulatory and continuing care, and the criticality of the patient data generated render discussion of medical device data under the umbrella of electronic health information insufficient. To take full advantage of the value of medical devices, they must be able to share and act on information. In an increasingly complex clinical environment, we ought not divert busy clinicians from patient care to device management and tasks (e.g., integration, transcription, adjustment and reprogramming of devices) better achieved via automated, interoperable systems. Medical device interoperability constitutes far greater...
functionality than merely capturing device data in the EHR. Medical devices sit at the intersection of medicine and technology that presents great benefit to patient outcomes and experience, holds significant clinical and operational improvement potential for providers, and represents a powerful example of safety, quality and economic impact for the nation. As such, we must bring medical device interoperability to the forefront of the national dialogue for building a learning health system.

The current lack of medical device interoperability is without question the cause of many adverse drug events, medication ordering errors, transcription errors, redundant testing, inadequate monitoring and miscommunication, all of which contribute to preventable medical errors that adversely impact patients and caregivers. Missing symptom, test and relevant diagnostic data result in diagnostic errors and diminished patient outcomes. Medical device interoperability would mitigate much of the risk of preventable harm, thereby saving patients from preventable medical errors, which are reported to be the third leading cause of death in the U.S.\(^1\) Furthermore, healthcare professionals are too often forced to waste time manually entering data or trouble-shooting technology instead of taking care of patients. An analysis conducted by the Gary and Mary West Health Institute suggests medical device interoperability could result in more than $30 billion a year in savings to the healthcare system\(^2\).

ONC aptly recognizes contracting as a lever for change. In its capacity as coordinator, ONC can ensure that government-wide health IT contracts contemplate interoperability of medical devices. The pending contract for the Department of Defense (DOD) Healthcare Management Systems Modernization (DHMSM) program is a prime opportunity. We believe a comprehensive effort to modernize the military health system would be incomplete absent the seamless incorporation of medical device data.

ONC’s continuous efforts to improve its certification program, coupled with recent Congressional requests for reports on information sharing and interoperability, are opportunities to acknowledge and address medical device interoperability issues. As ONC prepares its reports on EHRs, it should consider all data inputs and outputs, which include data exchanged with and among medical devices. EHRs that do not seamlessly exchange data with medical devices are not conducive to a learning health system.

The nonprofit Center for Medical Interoperability is accelerating the seamless exchange of information to improve health care for all. Our mission is to achieve plug-and-play interoperability by unifying healthcare organizations to compel change, building a lab to solve shared technical challenges, and pioneering innovative research and development.

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Our solutions will empower patients, healthcare professionals and our nation to optimize the use of health information.

The undersigned Board of Directors of the Center for Medical Interoperability are committed to finding and disseminating solutions, and using our market presence to drive change. We seek your assistance in driving national awareness of the need for medical device interoperability, and ensuring that contracting and certification advance this foundational aspect of a learning health system.

Sincerely,

Michael M. E. Johns, M.D.
Founding Chairman, Center for Medical Interoperability

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