April 3, 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 welcome the opportunity to provide comments on ONC's "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version" ("Roadmap"). The Gary and Mary West Health Institute is an independent, nonprofit medical research organization that works with healthcare providers and research institutions to create new, more effective ways of delivering care. Established in 2009, with offices in San Diego, CA and Washington, D.C., it is solely funded by philanthropists Gary and Mary West as part of West Health, two organizations with a shared mission of transforming the American healthcare experience. We believe that interoperability is an indispensable step toward that goal.

As such, we share your recognition of the need for seamless sharing of health and healthcare related information, and applaud the recent steps taken to drive overdue progress in this regard. As our healthcare system struggles with the appreciation that otherwise preventable medical harms are the third leading cause of death in our country, the imperative to accumulate, share and swiftly respond to healthcare information has become paramount. We believe interoperability is the *sine qua non* of the healthcare delivery system of the 21st century – without it, information is neither readily available, swiftly integrated, nor effectively used, resulting in otherwise avoidable delay, duplication and harm. Interoperability is essential for efficiency, effectiveness and safety.

Our single largest concern with the Roadmap in its current form is the absence of specific mention of medical device interoperability. For clarity, we believe the specific inclusion of medical devices in the drive toward an interoperable healthcare delivery system must take place along two different but related avenues.

The first is the capture and integration of medical device data into the enterprise EHR systems. As medical devices represent the largest source of objective data in healthcare, it is critical that such devices have their data seamlessly imported and integrated into the medical record for both real-time decision-making as well as retrospective review and learning. While many hospital systems already connect some subset of bedside medical devices to their enterprise systems, this practice is non-uniform, poorly coordinated and non-standardized. It often requires special purpose 'bridging' hardware and software that adds costs, creates additional opportunities for malfunction, complicates implementation and frustrates system-wide integration and learning.

The second and more critical avenue for including medical devices into the interoperability roadmap relates to the absence of, and need for, functional medical device interoperability. Medical devices are individually safe and effective, providing enormous benefits in the care of patients across a range of clinical settings. However, in actual use, as many as a dozen such devices (and sometimes more) are aggregated around a patient's bed, each performing its unique function as if in isolation. The lack of

connection and coordination between these disparate devices creates a complex challenge for the bedside clinicians and a resultant set of hazards for the patients. Because these separate devices are neither connected nor interoperable, the bedside clinician must become the 'sneakernet' that orchestrates the integrated functionality – a circumstance that distracts and burdens busy clinicians with tasks better managed by communication technologies and feedback/control methodologies that are commonplace in other industries.

We have recently conducted a national survey of more than 500 nurses in which half of the nurses surveyed described witnessing a medical error because of lack of medical device coordination.[1] Our previous work estimates that in addition to avoiding these medical errors, the seamless sharing of medical device data and functional medical device interoperability could save hospitals and healthcare systems more than $30 billion annually.[2]

This is why we insist that medical device interoperability be specifically included in the national dialogue for building a learning health system. In the absence of such specific and careful inclusion into the broader plan, our concern is that the end result will not achieve the stated goals.

Regarding the topic of Supportive Business, Cultural and Regulatory issues, the roadmap is correct in stating that the Medicare and Medicaid EHR Incentive Program is a primary driver for the current state of health information exchange, primarily in the EHR space. One increasingly obvious limitation of the program is that the companion set of certification criteria does little in the way of providing a business case for vendors, whether EHR or medical device, to adopt or implement interoperability standards. Vendors have understandably focused on meeting the requirements set out in regulation, creating proprietary systems with little or no adherence to open standards that would facilitate seamless semantic or functional interoperability. From a market-based perspective, owing to the lack of truly interoperable systems, purchasers have not been able to require interoperability as a purchasing requirement.

In order to bring about the seamless, functional interoperability that lies at the very heart of our long-awaited, high-value, learning healthcare system, it will be essential to first recognize sufficient open, interoperability standards for both EHRs and medical devices and then either institute strong regulatory requirements and/or create market-based incentives.

The West Health Institute helped create the Center for Medical Interoperability in an attempt to bring the market power of the purchasers together to demand seamlessly interoperable solutions. The Center brings together leading hospital systems to drive demand for interoperability among the devices they purchase. We believe that this will help create the market incentive for interoperability that is missing today.

Cognizant of the difficulties inherent in creating, maintaining and enforcing detailed technical process requirements at a federal level, and with awareness of the general limitations of using process metrics to achieve specific outcomes, it appears most appropriate for federal efforts to use healthcare payment reform to focus on incentivizing the widespread interoperability so essential to improving our

[1] "Missed Connections: A Nurses Survey on Interoperability and Improved Patient Care." *Harris Poll*. 2015. West Health < http://www.westhealth.org/sites/default/files/Nurses-Survey-Issue-Brief.pdf>
[2] "The Value of Medical Device Interoperability." *West Health. 2013. <http://www.westhealth.org/sites/default/files/The-Value-of-Medical-Device-Interoperability.pdf>*

national healthcare information structure. Examples of positive incentives would include incremental payment for timely sharing of healthcare and medical device information. Examples of negative incentives could include withholding payment for duplicate tests or complications in care that could reasonably be expected to have been avoided by having full, complete and seamlessly integrated information available.

Additionally, regarding Core Technical Standards and Functions, ample standards already exist for the transfer and recognition of medical device information. However, to achieve widespread, functional medical device interoperability, it is essential that open (non-proprietary) standards be recognized by the appropriate regulatory agencies, including ONC and FDA.

FDA's draft guidance on medical device interoperability is long overdue and is required to help guide vendors in the production of interoperable medical devices. A consistent implementation of open standards with recognized communications architecture will facilitate eco-system wide interoperability and will make device development and regulatory approval more predictable. The referenced standards should be open and maintained by their authoring organizations.

In order to fully realize full implementation, adoption and adherence of standards, Certification and Testing is imperative. It is envisioned that adherence to the aforementioned open standards will be determined via comprehensive testing, the details of which should be determined by relevant HHS agencies.

Modification of existing medical devices to specifically include interoperability is in the interest of the patient population and yet requires additional effort by the device manufacturers; therefore, it is essential that incentives for innovation be put in place to assure timely development and deployment. A predictable and expeditious regulatory environment would certainly be encouraging and spur new development. We are concerned that if medical device interoperability is not included in the Roadmap, the lag to create widespread, functional interoperability in pursuit of the triple-aim will be delayed significantly.

Thank you for the opportunity to provide comments. We applaud ONC's efforts to deliver on the promise of a truly interoperable healthcare delivery system. We look forward to ensuring that the large and growing array of life-saving medical devices are specifically included into the scope of the Roadmap to ensure that the goal of a smart, integrated and learning healthcare delivery system is achieved.

*****

We appreciate the opportunity to provide comments on the aforementioned issues. Should you have any questions, please contact my colleague, West Health Institute's Chief Medical and Science Officer, Joseph M. Smith, MD, PhD at jmsmith@westhealth.org.

Sincerely,

Nicholas J. Valeriani
Chief Executive Officer