August 25, 2017

Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

On behalf of over 18,000 board-certified orthopaedic surgeons represented by the American Academy of Orthopaedic Surgeons (AAOS), we appreciate the opportunity to provide input on the implementation of the 21st Century Cures Act (Cures Act) trusted exchange framework and common agreement provisions.

Comment Area 1: Standardization

We understand the importance of industry and federally recognized technical standards, policies, best practices, and procedure, however we do not support overlapping standards. This creates confusion in the market as to which standard should be used in different scenarios. We advise against legislation that set the use of a specific set of specifications. This could risk the use of antiquated technology for decades beyond its shelf life, as legislation can be difficult to overturn. Instead, we recommend leveraging an organization such as National Institute of Standards and Technology (NIST), to set the standards and policies for health information exchange. We recommend ensuring that all standards used are freely available and have extensive documentation to support adoption.

We recommend development of standards road map that telegraphs significant changes in the network well in advance and outlines the period of legacy support in the environment. Specifically outlining the current standard, when it becomes legacy, and what industry should be transitioning to. It is also important to ensure that the government also implements industry standards within its services and facilities, such as HIPAA compliance.

Comment Area 2: Transparency

The AAOS encourages conducting all exchange openly and transparently. We suggest establishing the need for an audit log that is maintained by the data owner, where the record of source is kept, that tracks where the data was sent, who requested the information, and what information was sent. This audit trail can then be made available to the patient upon request.

Comment Area 3: Cooperation and Non-Discrimination

Physicians need to be able to see and integrate certain key pieces of a patient’s demographics and health history into their electronic health records from other sources to provide more
comprehensive care. We recommend setting a standard that only allows stakeholders to participate in data exchange if they can meet minimum standards for data exchange and security.

**Comment Area 4: Security and Patient Safety**

AAOS suggests moving the focus from the legal definition of security and patient safety to the specifications and compliance of protecting patients. It would be helpful to develop objective specifications, similar to what the PCI Security Standards Council has developed for payment cards and cardholder data.

**Comment Area 5: Access**

We recognize that the New Medicare Cards initiative (formerly the Social Security Number Removal Initiative) is required by law under the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. However, we remain concerned about the burdens this initiative will have on patients, providers, and registries after the completion of the transition period in 2019. Although AAOS understands that CMS will be developing a “lookup tool” for providers, we are concerned about the burden that this places on providers to look up each patient and we would encourage developing an alternative electronic method that does not put the burden on providers. Conversion to a system which operates on MBI rather than HICN will require providers to devote resources and time to adjusting their workflow.

It is equally important to ensure uninterrupted access to this data for other stakeholders, as registries’ access to patients’ Social Security numbers plays an important role in their operations. Clinical data registries are a valuable tool to protect patient safety and promote quality improvement. Social Security numbers are important to a registry’s ability to track patients throughout the lifetime of both the patient and a medical device implant. The ability to track device implant and procedure outcomes is necessary to perform longitudinal studies for quality improvement. The New Medicare Cards initiative poses a challenge to a registry’s data validation processes by potentially disrupting the development of crucial longitudinal data. A unique patient identifier would be beneficial to ensure that patients and their caregivers have easy access to their electronic health information. A unique patient identifier would decrease costs and assure accuracy of patient tracking related to devices through time and across medical provider and systems.

Thank you for your time and consideration of the American Academy of Orthopaedic Surgeons’ suggestions on implementation of trusted exchange framework and common agreement provisions. We appreciate ONC’s continued efforts to engage stakeholders to achieve nationwide interoperability.