



May 12, 2025

Mr. Steven Posnack
Acting Assistant Secretary for Technology Policy
Acting National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20201
Submitted electronically at healthit.gov

RE: Draft Version 6 of the United States Core Data for Interoperability

Dear Mr. Posnack:

On behalf of Allina Health, I am writing in response to the Draft Version 6 of the United States Core Data for Interoperability (USCDI) standards. Overall, we appreciate the office of the Assistant Secretary for Technology Policy's (ASTP) continued efforts with stakeholder outreach to help progress toward standardizing certain data elements in pursuit of an improved interoperable exchange of health information. Our brief comments seek clarity on proposed changes to existing data elements.

Allina Health, an integrated health system, is dedicated to the prevention and treatment of illness and enhancing the greater health of individuals, families, and communities throughout Minnesota and western Wisconsin. We serve our communities by providing exceptional care as we prevent illness, restore health, and provide comfort to all who entrust us with their care. As a nonprofit health care system with 28,000 employees, Allina Health cares for patients from beginning to end-of-life through our 90+ clinics, 12 hospital campuses, 13 retail pharmacies, specialty care centers and specialty medical services providing home care, senior transitions, hospice care, and emergency medical transportation services. We are focused on eliminating health disparities and unnecessary variations in quality of care and improving the health of our communities.

In its draft version 6 of the USCDI, ASTP is proposing to make significant changes to the *Unique Device Identifier-Implantable* element found within the Medical Devices class. The scope of this element would be broadened to include all other medical devices, including non-implantable devices. ASTP indicates the standard used to identify devices wouldn't change and believes this

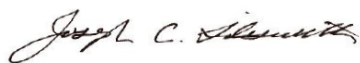
expanded element would enhance the data: “the need to exchange information extends to all devices, including non-implantable, effectively identify and report on device-related patient safety events, to respond to device safety recalls, and to conduct post-marketing surveillance on medical devices. The standard used to identify implantable and non-implantable devices is the same, and expanding the scope of the data element to include non-implantable devices highlights the importance of being able to exchange identifying information about the device in use.”¹

We appreciate the opportunity to provide feedback to ASTP during this process and commend the agency for its ongoing commitment to advance interoperability. In response to its proposed changes to the *Unique Device Identifier*, we encourage the agency to certify device manufacturers are fully capable of implementing any changes, including availability of data, to ensure seamless integration. We also seek additional clarity on the scope of the changes to the element. Depending on how ASTP defines *non-implantable devices*, tracking and capturing this data could introduce new workflows and add burden on providers. For example, there are countless instruments that aren’t traditionally considered ‘devices’ - would those be subject to these requirements? We believe the expansion of this element is well-intentioned and we kindly ask ASTP to further clarify what definition it is using to define *non-implantable devices* to enhance our understanding and aid in implementation.

Conclusion

On behalf of Allina Health, we appreciate the opportunity to provide comments on the ONC USCDI Draft v6. We ask that the agency continue with stakeholder outreach as this moves forward in conjunction with regulations that incorporate USCDI standards.

Sincerely,



Joe Silversmith
Manager, Federal Relations and Regulatory Affairs
Allina Health
Joseph.Silversmith@allina.com.

¹ https://www.healthit.gov/topic/standardsbulletin_25-1