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Submitted Electronically via www.regulations.gov

The Honorable Micky Tripathi, Ph.D., MPP
Office of the National Coordinator for Health
Information Technology
U.S. Department of Health and Human Services
330 C Street, SW, 7th Floor
Washington, D.C. 20201

RE: U.S. Core Data for Interoperability (USCDI) version 5

Dear National Coordinator Tripathi:

On behalf of the Allegheny Health Network (AHN), we are grateful for the opportunity to comment on the proposed additions to the United States Core Data for Interoperability ("USCDI") standards, specifically, the draft additions to the USCDI version 5 that include medical device identifiers and additions to provenance which includes author and author role.

As a nonprofit health network, we aim to extend our reach to as many people as possible to offer them a broad spectrum of care and services. We have 14 hospitals and more than 200 primary-and specialty-care practices in more than 300 clinical locations and offices. In addition, AHN has approximately 2,600 physicians in every clinical specialty, 22,000 employees, and thousands of volunteers. AHN's service area spans western Pennsylvania and portions of New York, Ohio and West Virginia where we provide world-class medicine to patients in our communities.

The USCDI standards are essential for ensuring that health information can be shared between different healthcare providers and systems. They provide a common set of data elements that can be used to represent patient information, such as demographics, diagnoses, medications, and test results. This allows for more efficient and effective care coordination, as well as improved patient safety.

However, the proposed additions to the USCDI standards are not necessary, are contrary to the approach historically taken to audit-type information, may present security concerns, and will only serve to increase the complexity and cost of implementing and maintaining electronic health records ("EHRs").

The addition of Unique Device Identifier ("UCI") for Implantable Devices requires healthcare providers to track data that should be tracked by either the device manufacturer or the Food and Drug Administration ("FDA"). This also raises some patient safety concerns, as the risk of cyberattack against medical devices is a growing concern—while presently, there has not been attacks on individuals to harm them by hacking implantable medical devices, this is a doomsday scenario that receives much attention from cybersecurity experts. Accordingly, keeping UDI confidential is preferable, and while it is important information that should be available to the patient, we should be

mindful that such information is available via appropriate means, like a secure database populated by the device manufacturer or in conjunction with the FDA.

Further, the addition of author and author role presents confusion and undue burden on healthcare systems that utilize EHR technology to streamline patient care and access to records. Historically, audit information has not been considered to be part of the individual's medical record. Medical records contain information about the individual's health and medical care, while audit information relates to the use of the EHR system. As such, audit information has not been subject to the same privacy and security regulations as medical records. The inclusion of audit type information will likely lead to confusion among healthcare providers, and also presents a change from the historic approach without a clear need for inclusion of this information in this manner.

The addition of this information is unnecessary, as it does not provide useful information to the patient, but also is likely to cause confusion. An order from the doctor is going to be signed by the doctor, the note that the doctor wrote will include the author of the note but including "author" on every piece of data that might make it into a medical record is unlikely to lead to useful information to the patient, while being overburdensome. Healthcare providers may need to consider changes to their workflows to ensure that author metadata doesn't lead to patient confusion (for example, if someone enters information but was not technically the "author"). Moreover, healthcare staff, not including nurses and clinicians, may not be comfortable with their information appearing in a medical record simply because they scanned in a document at the direction of a clinician.

Finally, the ongoing inclusion of new data points has been difficult and expensive for healthcare providers. Healthcare organizations are already overburdened with regulatory and administrative requirements, and it requires significant effort by our IT teams when these changes are made and require policy re-evaluation, build updates, build testing, staff education, regulatory review, and interpretation. The continuous addition of new USCDI data elements has created more work, confusion, and expense for the healthcare industry, while in some instances, like here, provide little to no value to patients or providers.

For these reasons, we urge you to reconsider the proposed additions to the USCDI standards.

Sincerely,

Jacqueline M. Bauer
General Counsel and Chief Administrative Officer

cc: Jim Benedict, President, Allegheny Health Network
Daniel A. Onorato, EVP, Corporate Affairs, Highmark Health