April 17, 2023

Micky Tripathi, Ph.D.
National Coordinator for Health Information Technology
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 4 of the United States Core Data for Interoperability

Dear Dr. Tripathi:

On behalf of Allina Health, I am writing in response to the Draft Version 4 of the United States Core Data for Interoperability (USCDI) standards. Overall, we appreciate The Office of the National Coordinator for Health Information Technology's (ONC) continued efforts with stakeholder outreach to help progress toward standardizing certain data elements in pursuit of an improved interoperable exchange of health information. We raise some questions and concerns on the proposed data elements and classes, mainly on potential overlap and redundancy of data collection.

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 not-for-profit health care system with 28,000 employees, Allina Health cares for patients from beginning to end-of-life through our 90+ clinics, 11 hospital campuses, 15 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.

Background

The USCDI is a standardized set of data for interoperable exchanges across the health care industry. The data set was to be built over time to allow for staged implementation for improved interoperability. The USCDI version 1 (USCDI v1) was adopted as a standard in the ONC Cures

Act Final Rule, published May 1, 2020. The standard was included as a required part of certain certification criteria in the 2015 Edition Cures Update and is referenced in the context of information blocking.

The USCDI v4 provides additional updates that builds off changes from USCDI v3. According to ONC, this version includes data elements that focus on patient care and facilitating patient access while promoting equity, reducing disparities, supporting underserved communities, integrating behavioral health data with primary care, and supporting public health data interoperability.[1] This includes proposing to add 20 data elements across one new (Facility Information) and eight existing data classes, which if finalized, would result in a USCDI v4 with 112 data elements organized in 19 data classes.

New Data Classes, Data Elements, and Reclassification of Existing Elements

Facility Information – Facility Identifier

Facility Information data provide details to patients and providers regarding the physical location where care was received, or services were provided (or might be provided in the future). We agree that this data class would be useful to include in USCDI v4. The *Facility Identifier,* which is comprised of a sequence of characters representing a physical place of available services or resources, as an encoded alternative to the name and type of facility being referenced. Without further directive or an expanded definition, this element adds confusion and would be challenging to articulate for purposes of implementation. It is unclear what value this element would provide as the sequence of characters may not be easily understood by all who access this data. ONC is better suited to only add elements that could be reasonably understood by those with access.

Goals – Treatment Intervention Preference and *Care Experience Preference*

Expression of goals, preferences, and priorities are key to determining how treatment is delivered in a person-centered way. The advance care planning process may include expressions of interventions, religious beliefs, and overall care experience preferences (e.g., a birth plan developed by the patient to express their preferences for treatment and care experience during labor and delivery). To make these types of preferences available for exchange, ONC added two data elements *Treatment Intervention Preference* and *Care Experience Preference*

Allina Health supports the importance of advancing the needs of underserved communities, including patients whose treatment goals and preferences are not well represented in health IT. However, we do offer the following recommendations on how ONC is proposing to adopt such elements.

First, the definition offered for *Treatment Intervention Preference* seems very similar to what is traditionally considered a health care directive. This is important information for health IT products

[1] https://www.healthit.gov/sites/default/files/page/2023-01/Standards_Bulletin_2023-1.pdf

to be capable of capturing but would be redundant considering what is already collected. If this is not meant to be a health care directive, we request the agency further define what is meant to be captured by this element as the current definitions offered in the draft do not provide enough information to understand what is to be collected and when. Lastly, *Treatment Intervention Preference* does not seem to neatly fit into the *Goals* data class. If ONC finalizes this element as part of USCDI v4, we recommend reconsidering whether *Goals* is the most appropriate data class for it to housed.

Allina Health agrees that the proposed data element, *Care Experience Preference,* is important to add to a standardized set of data. However, many health IT developers and users have separate applications to store information related to maternity care and birth plans. ONC should consider this nuance as it evaluates whether to adopt this in the final version. Specifically, merging these data fields from separate applications into one comprehensive space will not be a light undertaking and significant time should be allotted to build and test these potential changes.

Medications – Medication Adherence

In USCDI v3, ONC added *Medications* data elements to expand the information about medication type and dosage, however ONC does not believe these data elements addressed the extent to which a patient adheres to clinical instructions. Exchanging medication adherence information can aid medication reconciliation and inform a provider about prescription and over-the-counter medications, supplements, herbals, and other substances a patient is taking at the time of care.

ONC emphasizes that patient-reported data enhances the patient's participation in their care, however we do not agree that this type of data is suitable as part of the USCDI. Specifically, we are concerned that this information hinges on whether patients are being forthright and honest with this information, which is not always the case. We contend that this information is already being captured within the EHR in alternative locations. Extracting this information and instituting a separate, structured data field to be shared would be redundant.

Laboratory – Specimen Identifier

ONC added several data elements to this class to address ongoing public health reporting needs and to provide patients and providers with more detailed information about laboratory data. Additionally, ONC added data elements that provide more information about the laboratory specimen, including *Specimen Source Site, Specimen Identifier, and Specimen Condition and Disposition*. This data is usually contained within laboratory information systems and can be shared with and by electronic health records.

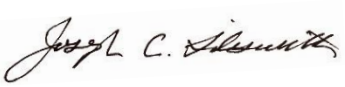
Allina Health questions the relative value in adding the data element *Specimen Identifier* to the *Laboratory* class*.* According to the ONC definition, the element would be a sequence of characters assigned by a laboratory for an individual specimen. Without further directive or an expanded

definition, this element adds confusion and would be challenging to articulate for purposes of implementation. Furthermore, we don't understand the value that this element would provide. Seemingly, the only group that may benefit from *Specimen Identifier* would be the person tasked with assigning a character sequence to each specimen. This element would not be particularly useful to other providers, staff, or patients.

Conclusion

On behalf of Allina Health, we appreciate the opportunity to provide comments on the ONC USCDI Draft v4. We ask that the agency continue with stakeholder outreach as this moves forward in conjunction with regulations that incorporate USCDI standards.

Sincerely,



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