Federation of American Hospitals®

Charles N. Kahn III
President and CEO

April 15, 2024

Micky Tripathi, PhD
National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: United States Core Data for Interoperability, Draft Version 5 (Jan. 2024)

Dear Dr. Tripathi:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying public and privately held hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC, and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's and cancer services. These tax-paying hospitals account for nearly 20 percent of U.S. hospitals and serve their communities proudly while providing high-quality health care to their patients.

The FAH appreciates the opportunity to provide the Office of the National Coordinator (ONC) for Health Information Technology with feedback on its United States Core Data for Interoperability Version 5 (USCDI v5). The FAH continues to believe in the potential of health information technology (health IT) to improve the quality and efficiency of care provided to patients, reduce provider burden, and advance population health management and breakthroughs in health care research. The FAH appreciates ONC's commitment to improving interoperability and patient access to information through use of standards and believes that standardized data classes building on well specified data elements is a key building block of success.

United States Core Data for Interoperability

ONC adopted the USCDI v1 in the *21st Century Cures Act* Final Rule.[1] USCDI is considered the minimum data needed for interoperability and includes a range of data classes and elements that reference specific vocabulary standards and classifications. ONC has followed a structured approach to gather public input on updates to the USCDI, which has expanded significantly to allow a more comprehensive common understanding of an individual's health. Current regulations require developers of certified health IT to support USCDI v1 today and update their systems to support USCDI v3, which includes additional data elements and updated standards, by December 31, 2025.

The FAH supported the adoption of USCDI v3 as part of ONC's recent final rule, *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing* (HTI-1).[2] Among other things, USCDI v3 will allow standards-based collection of information related to social drivers of health (SDOH) – such as SDOH assessments, goals, and interventions – and health insurance information. However, certain data elements in USCDI v3 still lack standards, such as Care Team Member Role. Other data elements, such as Date of Diagnosis, leave room for multiple interpretations, which could lead to misunderstandings by clinicians creating and receiving the data.

Draft USCDI v5 includes 13 new data elements and two new data classes. As an overarching comment, the FAH recommends that ONC prioritize established and well-specified standards when updating to new versions of USCDI. Where standards are not already established, ONC should consider Fast Healthcare Interoperability Resources (FHIR) standards.

The FAH also offers the specific comments below regarding the data classes and elements proposed for inclusion in USCDI v5.

Clinical Notes: Emergency Department Notes

The FAH supports the addition of the Emergency Department Notes data element to the Clinical Notes data class. Its inclusion is crucial for improving the quality of patient care. This data element will provide health care professionals with a more robust and accurate picture of a patient's medical history, allowing for better-informed decision-making and improved patient outcomes.

Clinical Notes: Operative Notes

The FAH supports the addition of the Operative Notes data element to the Clinical Notes data class. We appreciate the significance of this proposal and the positive impact it could have on health care professionals and their patients.

[1] 85 Fed. Reg. 25,642 (May 1, 2020).
[2] 89 Fed. Reg. 1,192 (Jan. 9, 2024).

Immunizations: Lot Number

The FAH supports the addition of the Lot Number data element to the Immunizations data class to further identify immunizations that have been provided to patients. Immunization information is routinely exchanged between state, local, and federal entities. Adding this element to USCDI would align ONC's standards for interoperable exchange with existing standards for immunization data that is captured and exchanged through other federal entities, like the Centers for Disease Control and Prevention (CDC).

We recommend that ONC evaluate additional Immunizations data elements, such as vaccine manufacturer and material expiration date, for inclusion in USCDI. Though this information may be available when associated with other data elements that are already included in USCDI, such as the CVX (Vaccines Administered) or NDC (National Drug Code), many times these codes are missing or unavailable in HL7 (Health Level 7) and C-CDA (Consolidated Clinical Document Architecture) messages.

Laboratory: Test Kit Unique Device Identifier

FAH does **not** support the addition of "Test Kit Unique Device Identifier" under the Laboratory data class at this time as this would be premature and thus should be reconsidered. USCDI points generally to the Food and Drug Administration (FDA) Unique Device Identification (UDI) System as the relevant standard for this data element. However, there is not yet a unified nomenclature for lab test kits due to the uncertainty around tentative FDA and CMS coordinated guidelines for a test kit identification system. **Therefore, we urge ONC to partner with the FDA to develop standards for modified FDA and lab developed tests (LDTs) before including "Test Kit Unique Device Identifier" in USCDI.** Finalized guidance from FDA and CMS should be a prerequisite to incorporating this data element in USCDI. **Accordingly, the FAH recommends that ONC defer adding this data element until appropriate standards are available.**

Medications: Route

The FAH supports the inclusion of Route as a data element under the Medications data class. This information can be helpful when sharing data among healthcare providers, pharmacists, and clinicians.

Observations: Advance Directive Observation

The FAH requests further clarity on the proposed new data element Advance Directive Observation under the Observations data class, which lacks an associated standard. The FAH recommends that ONC provide clinical use cases to demonstrate how this data would be gathered and used before it is added to USCDI.

We also urge ONC to provide specific vocabulary standards that detail the level of granularity expected when capturing and exchanging this information. For example, this data element, if coupled with applicable standards, could enable caregivers to identify designated

surrogates of patients more effectively, should this information be necessary while receiving clinical care. Without this level of detail and comprehensiveness, however, we are concerned that shared data will not be easily understood, leading to increased, rather than decreased, burden on clinicians to accurately navigate and identify a patient's advance directive(s).

Orders: Orders

ONC proposes to add a new data class, Orders, to USCDI with a single data element, also called Orders. **The FAH is concerned that the new Orders data element, which lacks associated vocabulary standards, is too broad in scope and includes a vast range of information that is captured through various means throughout a patient's encounter or hospital stay.** The data element is defined as: "Provider-authored directive for the delivery of patient care services. Examples include but are not limited to diagnostic imaging, laboratory tests, interventions, referrals and consultations, and do-not-resuscitate."

The FAH suggests that ONC further clarify the intent and utilization of this data in the context of sharing health information. For acute care facilities, hundreds, or even thousands, of "orders" may be recorded for a single patient during their hospitalization. As a practical matter, orders may change multiple times during an encounter or hospital stay, and some may not be performed at all as clinical situations evolve. If every order is presented as a new data element when sharing records, this information could be voluminous and duplicative, resulting in confusion as well as undue burden on providers and health IT systems.

We also stress the importance of specificity when considering Orders as a core data element for interoperability. Without associated vocabulary standards, ONC risks creating a data class/element that includes large amounts of data that convey limited information, resulting in unnecessary confusion and burden while undermining the concept of "core" data that underlies USCDI.

Given the importance of orders to the care received by patients, the FAH strongly recommends that ONC reconsider the structure for how to capture orders within USCDI to maximize the usefulness and relevance of the data. Specifically, we believe individual order types paired with applicable vocabulary standards would be more useful in healthcare operations. For instance, orders for laboratory tests could instead reside under the Laboratory data class. The data element Tests under the Laboratory data class has an existing vocabulary standard for interoperable exchange. Two other data classes that are initiated through order – Imaging and Tests – also reference specific standards.

Patient Demographics/Information: Name to Use

The FAH supports the addition of Name to Use to the Patient Demographic/ Information data class. This information, to be provided by the patient, helps create a complete picture of an individual's preferences.

Patient Demographics/Information: Pronoun

The FAH supports the inclusion of Pronoun as a data element in the Patient Demographic/Information data class. Capturing this information, to be provided by the patient, creates a holistic record of an individual patient, resulting in improved patient care. We request that ONC add relevant vocabulary standards to support successful and accurate interoperable data exchange.

Patient Demographics/Information: Interpreter Needed

The FAH supports inclusion of Interpreter Needed, using the associated vocabulary standard, as a data element in the Patient Demographic/Information data class. This information is critical in delivering patients the best form of care. The inclusion and exchange of this information creates a holistic record of the individual patient, while supporting quality care and enhancing patient safety.

Provenance: Author and Author Role

ONC proposes to add two new data elements under the Provenance data class: Author and Author Role. Both of these data elements present challenges for successful interoperability and sharing of useful clinical data. Neither has an associated vocabulary standard. **Thus, the FAH requests more information for determining the value of adding the Author and Author Role data elements to USCDI in nationwide, interoperable health information exchange.**

We note that the proposed definition of Author as an "Actor that participated in the creation or revision of data" would encompass a wide range of individuals within a patient's care team as Authors. Depending on a caregiver's involvement and the structure of their role, this information may not be as useful for inclusion in USCDI for interoperable exchange. For example, a medical student may record an initial interaction with the patient and create a note. That note would then be reviewed and signed by the attending physician. When that record is shared with other providers, the inclusion of the medical student as an Author would likely not be as useful to others outside of the original care team members (although it could be requested by a patient, or legal personnel, if needed).

ONC proposes to define the new data element Author Role as follows: "Category of actor that participated in the creation or revision of data. Examples include but are not limited to provider, patient, family member, and device." This proposed definition is ambiguous, lacks an associated vocabulary standard, and does not adequately specify what could be considered an Author Role. For example, the Author of a lab result may not be a particular user, but may be the "system" itself, or possibly the legal certifier of the lab with CLIA. We do not believe it would be useful to record and transact this information within USCDI without a clear indication of who will be considered an Author and what the Author Role would be in this common scenario.

Further, we stress the need for clarity around the practical implementation of Author and Author Role and whether multiple authors of a single data element would be required. For

example, if a technician takes a patient's blood pressure, but a nurse signs off on it, would both be required to be included in this data element or just one? These ambiguities may make this difficult to implement.

The FAH recommends that ONC refrain from adding these data elements to USCDI until further clarification and specificity has been provided. If these data elements are included in USCDI standards, we urge that applicable vocabulary standards be provided by ONC to specify the level of granularity expected when capturing and exchanging this information.

Laboratory: Result Reference Range

The FAH does **not** support adding Result Reference Range to USCDI. The commonly utilized standard terminology is "reference interval." This has been more widely adopted by regulatory agencies, the College of American Pathologists, the Clinical & Laboratory Standards Institute, and others. **Accordingly, we recommend reconsidering the use of "Results Reference Range" and replace it with "Result Reference Interval" as it is the current adopted standard used across the laboratory industry.**

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The FAH appreciates the opportunity to comment on the draft USCDI v5. We look forward to continued partnership as we strive to advance the use of health IT to improve our nation's health care system. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1500.

Sincerely,