CMS-CCSQ Submission for United States Core Data for Interoperability (USCDI) Version 5

September 20, 2023

Micky Tripathi, PhD 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, DC 20201

Dear Dr. Tripathi:

On behalf of The Centers for Medicare & Medicaid Services (CMS) and The Center for Clinical Standards and Quality (CCSQ), we submit the following recommendations for the United States Core Data for Interoperability (USCDI) version (v) 5 consideration. CMS encourages continued expansion of the USCDI to include high priority data elements necessary to support nationwide interoperability. This expansion will support clinical care, care coordination and quality improvement, while easing the burden of quality measurement. We are committed to continuing our collaborative work with the Office of the National Coordinator for Health Information Technology (ONC) and other federal partners to ensure the USCDI meets stakeholder needs and to ensure the USCDI is the central mechanism in defining the foundational set of electronic health information for interoperable health information exchange (HIE).

We specifically continue to urge ONC to add additional data elements outlined below to the USCDI v5 which support high priority areas identified by ONC. We have also entered comments for each recommendation in the ONC New Data Element and Class (ONDEC) system.

Our recommendations are as follows:

- The inclusion of 8 data elements and 1 data class (Advance Directives) previously submitted to USCDI be added to USCDI v5.
- The advancement of 3 data elements in the previously recommended Provenance data class to Level 1 for future inclusion in USCDI.
- The enhancement of the definition and inclusion criteria of 4 existing data elements currently in USCDI v4.
- Support of one new data element addition (proposed by the Office of Minority Health [OMH]) to the USCDI v5.

All data elements target ONC high priority areas. Refer to **Table 1** for a summary of the recommended data classes and data elements.

Table 1: Summary of USCDI v5 Recommendations

Data Class	Data Element	Submission Status (New, Previous, Currently in USCDI v4)	Level Category
Organization	Organization/Hospital Identifier *	Previous	Level 0
Facility Information	Facility Identifier +	Currently in USCDI v4	USCDI v4
Facility Information	Facility Address *	Previous	Level 2
Clinical Notes	Emergency Department Notes *	Previous	Level 2
	Surgical Notes *	Previous	Level 2
Orders	Orders for End of Life Care *	Previous	Level 2
Medications	Medication Administration Route *	Previous	Level 2
	Medication Prescribed Code *	Previous	Level 2
Provenance	Author *	Previous	Level 2
	Signature ^	Previous	Level 0
	Author Role(s) ^	Previous	Level 0
	Purpose of Capture ^	Previous	Level 0
Patient Demographics/ Information	Sex +	Currently in USCDI v4	USCDI v4
	Gender Identity +	Currently in USCDI v4	USCDI v4
	Interpreter Needed #	New	
Advance Directives *	Advance Directives *	Previous	Level 2
	Durable Medical Power of Attorney *	Previous	Level 1
	Living Will *	Previous	Level 1
	Personal Advance Care Plan *	Previous	Level 1
Health Status Assessments	Disability Status +	Currently in USCDI v4	USCDI v4

Table 1 Key

* Add to USCDI v5 ^ Advance Level Category to Level 1 + Enhancement of data element in USCDI v4 # New data element submission

Recommendations for Addition of Previously Submitted Data Elements to USCDI v5

1. Data Class: Organization

A. Data Element: Organization/Hospital Identifier; defined as unique identifiers for a healthcare organization.

Recommendation: We recommend this data element be moved up to Level 2 from Level 0. We also recommend ONC move CCN from Facility Identifier into the Organization/Hospital Identifier data element, as the CCN identifies organizations and hospital systems, rather than individual facilities. The recommendation is also supported by the Interoperability Standards Work Group (ISWG) and Health Information Technology Advisory Committee (HITAC) recommendations on both the Draft USCDI v3

(April 13, 2022) and Draft USCDI v4 (April 12, 2023). An organizational/hospital identifier is critical for providing context for granular patient data and supports tracking data back to organizations—this type of contextual data element ensures usability of interoperable clinical data. They can also support exchange of data between hospitals and post-acute care providers. CMS encourages ONC to consider the advancement of the Organization/Hospital Identifier data element as a complementary data element to Facility Identifier as both are ultimately necessary to support efficient direction of quality improvement efforts and public health. Coupling the facility with an Organization Identifier that is unique to a specific location provides additional information that the providers, payers, and public health need to optimally track and respond to identifiable care quality, patient safety, and health outcomes issues. This remains a joint CMS and Centers for Disease Control and Prevention (CDC) recommendation, with some recent discussions and slight updates from our previous recommendations to USCDI on how to provide a necessary distinction between larger organizations and individual facilities that is currently not being captured in the USCDI. We no longer recommend the NHSN OrgID be added to the Organization/Hospital Identifier data element, but rather the NHSN OrgID be utilized in the Facility Identifier data element, which we discuss in further detail under the Facility Identifier data element. CMS specifically prioritizes exchange of CMS Certification Number (CCN), Provider Transaction Number (PTAN), National Provider Identifier (NPI), and Clinical Laboratory Improvement Amendments (CLIA) number as organization identifiers. These identifiers are exchanged across the nation for CMS reporting to appropriately attribute outcomes and measure results. They are used extensively for electronic clinical quality measure (eCQM) reporting, linking data sources for quality measurement, and for post-acute care reporting and payment purposes. Among other purposes, organization identifiers are also used to support public health use cases, including electronic case reporting and emergency response activities.

2. Data Class: Facility Information

A. Data Element: Facility Identifier; defined as sequence of characters representing a physical place of available services or resources.

Recommendation: We are pleased to see that Facility Identifier data element was added to USCDI v4. However, we recommend that the Facility Identifier data element be limited to capturing an individual facility instead of an organization or health system (with multiple facilities). We also recommend the NHSN OrgID be added to the Facility Identifier data element in addition to existing standards to capture individual facilities. This recommendation is a slight change from the CMS-CDC recommendation for draft USCDI v4 where NHSN OrgID was recommended under the Organization/Hospital Identifier. Additional discussion amongst CMS and CDC concluded that NHSN OrgID can more adequately capture an individual hospital or individual facility and that the CCN, which is currently in the Facility Identifier data element, is more appropriate as an organizational identifier.

B. Data Element: Facility Address; defined as the physical location associated with the facility.

Recommendation: We recommend this Level 2 data element be added to USCDI v5. Together with the Facility Identifier, Facility Type, and Facility Name, the Facility Address data element will supplement the core set of information necessary to identify facilities and link service and outcome data to a specific physical institution or facility. This was previously identified as a joint CMS-CDC priority. Currently, in the absence of a unique Organization/Hospital Identifier in the USCDI, it can be difficult to differentiate specific service locations and link data or records for public health and healthcare purposes. Location information is routinely captured in EHR systems. Since Facility Names and Facility Identifiers (e.g., CCNs) can be shared by separately located facilities, Facility Address can provide critical identifying information to differentiate specific locations and accurately link data to optimally track care quality and health outcomes.

3. Data Class: Clinical Notes

A. Data Element: Emergency Department Notes; defined as the summary of a patient's interval status during an emergency department encounter, including narrative and free text data.

Recommendation: We recommend this Level 2 data element be added to USCDI v5. Emergency Department Notes should be a distinct clinical note data element to distinguish data from other Progress Notes, for the purposes of coordination of care and care continuity for routine exchange throughout the course of care. Emergency Departments can be fully integrated within a healthcare system, fully independent and administratively distinct from a nearby healthcare or hospital system, or some intermediate state between these extremes. This ensures capture of a critically unique encounter type that represents a key interface between and across acute and outpatient care settings and therefore an important component of both acute and chronic disease management. A separate Emergency Department Notes data element will also ensure patient access to this information and will support transitions of care. This data element is currently classified with LOINC Group Code LG41825-7 or at the Emergency Department Discharge Summary Note LOINC 59258-4, at a minimum. This aligns with the ISWG Recommendations on Draft USCDI v4 (April 12, 2023) to include LOINC 59258-4 Emergency Department Discharge Summary as the generic or minimum Emergency Department Note codes.

B. Data Element: Surgical Notes; defined as the detailed note or report following a surgical procedure.

Recommendation: CMS strongly recommends either expanding the current Procedure Notes data element that is in USCDI to include the Surgical Operation Note (LOINC 11504-8) in addition to Non-Operative Procedure Notes or consider adding the distinct Operative Note data element that is at Level 2 to USCDI v5. Surgical notes are routinely captured in EHR systems and important to ensure patient access to data and capture

interoperable information critical to patient safety, care coordination, and hand-offs. This element was previously identified as a joint CMS-CDC priority, and the recommendation aligns with ISWG Recommendations on Draft USCDI v4 (April 12, 2023) to include all note types coded in the LOINC Document Ontology, or at least the Surgical Operation Note (LOINC 11504-8) and Tumor Board Notes.

4. Data Class: Orders

A. Data Element: Orders for End of Life Care; defined as orders for hospice, palliative care, and comfort care.

Recommendation: We recommend this Level 2 data element be added to USCDI v5. Orders for End of Life Care (comfort care, palliative care, hospice) include information that has the power to actionably communicate an individual's wishes at their end of life and is yet to be represented in USCDI. These data are routinely captured in EHR systems and need to be interoperable and exchangeable to reduce discordance between care provided and patient wishes, and to enhance value of care at end of life. This critical information is required to support a transfer of care request from one practitioner or organization to another that provides end-of-life care services. This data element was previously identified as a joint CMS-CDC priority and supports advancing patient care quality.

5. Data Class: Medications

A. Data Element: Medication Administration Route; defined as the route of administration of a medication, or how the drug should enter the body, for example intravenous or oral.

B. Data Element: Medication Prescribed Code; defined as a code (or set of codes) that specify the medication prescribed.

Recommendation: We recommend these two data elements that are currently at Level 2 be added to USCDI v5. CMS has previously advocated for adding more specificity to the USCDI Medications Data Class as interoperability of medication information and management of medications is critical to patient care and coordination between providers, as well as related quality and public health enterprises. We continue to support the concept of a USCDI Task Force to appropriately specify and advance this important data class and urge ONC to consider adding the highlighted CMS-CDC prioritized data elements to ONC USCDI v5. These data elements were supported by the ISWG Recommendations on Draft USCDI v4 (April 12, 2023) to change the Medication Prescribed Code data element definition to, "A code (or set of codes) that specify medication prescribed or ordered, and to include textual description if no code is available." For the Medication Administration Route, the recommendation was to define elements for documenting data elements for medication administration statuses.

6. Data Class: Provenance

A. Data Element: Author; defined as an agent that bears some form of responsibility for an activity taking place, which serves as metadata of other USCDI data**.**

Recommendation: We recommend this Level 2 data element be added to USCDI v5. It is important to know who the author of the medical notes and information is for effective care coordination and care transitions. With the move toward patient-centered care, there could be multiple contributors of data including patients and other caregivers. The Author data element will provide a complete picture of information from an outside entity. The current data elements in the Provenance data class, Author Time Stamp and Author Organization, will be more meaningful if they can be attributed to the source of the information i.e., the Author. Specifically, CMS recommends including all authors who contribute to the care and documentation of care of a patient, or at least the final legal author.

B. Data Element: Signature; defined as the digital signature on the target Reference(s)**.**

C. Data Element: Author Role(s); defined as the meta data that can identify participation of the author in the action taken or authorship of other data classes/data elements**.**

D. Data Element: Purpose of Capture; defined as the reason for the origination of data classes and data elements**.**

Recommendation: We support the PACIO Project's recommendation of the advancement of the Signature, Author Role(s), and Purpose of Capture data elements from Level 0 to Level 1. These data elements represent necessary metadata around documents to validate and accurately understand the information that is gathered from numerous sources.

7. Data Class: Advance Directives

A. Data Element: Advance Directives (Level 2); defined as a legal document that states a person's wishes about receiving medical care if that person is no longer able to make medical decisions because of a serious illness or injury. The Advance Directives data element is critical to enable the exchange of advance directives information that focuses on a narrative description and supporting documentation, in particular PDFs or scanned images.

B. Data Element: Personal Advance Care Plan (Level 1); defined as a means for an individual to express their goals and preferences under certain circumstances that may be pertinent when planning his or her care.

C. Data Element: Living Will (Level 1); defined as a document where a person specifies whether he or she wants (or does not want) "life-sustaining treatments", external cardiac compression (CPR), the application of an electric current to the heart

(defibrillation), or the use of a tube placed into the windpipe through the mouth or nose to help the person breathe, should that person suffer a medical emergency and be unable to communicate with the care team. Since USCDI v4 includes data elements for Treatment Intervention Preferences and Care Experience Preferences, this data element is the only information still needed to capture and share this important patient generated information.

D. **Data Element: Durable Medical Power of Attorney (Level 1)**; defined as a document to appoint one or more people to serve as advocates or "healthcare agents" empowered to make medical treatment decisions on behalf of that person if the person is incapacitated and cannot communicate with medical personnel.

Recommendation: CMS, along with the PACIO Project, continue to support the addition of the Advance Directives data class that was previously identified as a priority area by the USCDI Task Force and CMS. The PACIO Community believes these four data elements and Orders for End of Life Care, along with Care Experience Preferences and Treatment Preferences data elements that are currently in USCDI v4, provide the most essential information to give a holistic view of the individual's wishes, necessary to inform care. Advance directives guide transitions and delivery of care that closely align with patient values that improve patient satisfaction. When incorporated into systems that assist healthcare professionals in decision-making, advance directives can activate customized notifications and best practice recommendations, which in turn can guide medical staff toward choices that are both well-informed and ethical. For individuals undergoing treatment from various healthcare providers or experts, the Advance Directives data class streamlines the delivery of uniform and personalized medical attention across multiple healthcare disciplines. This data class supports CMS's objective to foster a healthcare system that is both effective and attentive to the unique healthcare preferences of each patient, thereby elevating patient well-being and satisfaction.

This information is routinely captured in patient or encounter summary documents. For the Level 1 data elements under this data class, there have been advancements in both the CDA and FHIR standards with the CDA guidance having been balloted twice within HL7 and the FHIR IGs being in later stages of ballot reconciliation with anticipated publication in the next few months. Specifically, for the Durable Medical Powers of Attorney data element, the FHIR IG currently is resolving dispositions to comments from the January 2022 ballot. There are LOINC Codes that represent this data element and it is part of both CDA and FHIR IGs (81335-2 Patient Healthcare Agent). Also, there is a well-established value set for representing a primary, secondary, or tertiary healthcare agent when multiple agents are established. (Healthcare Agent or Proxy Choices, urn: oid: 2.16.840.1.113762.1.4.1046.35).

Recommendations to Enhance/Edit Existing USCDI v4 Data Elements/Data Classes

As part of the ongoing effort to improve the comprehensiveness of USCDI, we recommend the enhancement of existing data classes and elements in USCDI v4. These recommendations focus on definition and criteria updates to existing USCDI data elements to improve quality and care coordination.

1. Data Class: Patient Demographics/Information

A. Data Element: Sex; defined as a documentation of a specific instance of sex and/or gender information.

Recommendation: CMS, along with CDC, repeats and supports the ISWG and HITAC Recommendations on Draft USCDI v3 (April 13, 2022) and Draft USCDI v4 (April 12, 2023) to include the HL7 Gender Harmony Project's data elements, definitions, and value sets related to Sex, **Recorded Sex or Gender (RSoG)** and **Sex for Clinical Use (SFCU)**, in addition to the existing standards for capturing sex.

B. Data Element: Gender Identity; defined as a person's internal sense of being a man, woman, both, or neither.

Recommendation: CMS supports the ISWG and HITAC recommendation included in the ISWG and HITAC Recommendations on Draft USCDI v3 (April 13, 2022) and Draft USCDI v4 (April 12, 2023) for expanding the Gender Identity data element definition to include the Gender Harmony Project's minimum value set, with ISWG refinements.

2. Data Class: Health Status Assessments

A. Data Element: Disability Status; defined as assessments of a patient's physical, cognitive, intellectual, or psychiatric disabilities. (e.g., vision, hearing, memory, activities of daily living).

Recommendation: CMS, along with the PACIO Project and CDC, also repeats the recommendation to move the Disability Status data element from the Health Status Assessments data class to the Patient Demographics/Information data class. The rationale being that identifying a person with a disability does not necessarily have any bearing on how healthy a person is or the status of one's health.

Support of New Data Element Submission by OMH to USCDI v5

3. Data Class: Patient Demographics/Information

A. Data Element: Interpreter Needed; defined as documentation of whether a person needs or requests language interpretation services.

Rationale: CMS supports Interpreter Needed as a new data element submission by OMH to USCDI v5. The addition of the Interpreter Needed data element aligns with ONC's priorities to enhance health equity and support diverse populations, ultimately improving healthcare quality. The inclusion of this data element addresses the language service needs of historically underserved populations and for those with limited English proficiency. In addition, the element allows the patient to provide essential information for proper care and quality measurement. This data element is currently being collected as part of standardized PAC assessments in the Quality Reporting Program (https://del.cms.gov/DELWeb/pubDataEleDetail?asmtId=4&asmtItmId=A1100A) to inform the need for language access services.

By including the Interpreter Needed data element, healthcare providers can better tailor their services to meet the unique linguistic needs of each patient. The integration of this data element into USCDI v5 supports the broader objective of capturing and exchanging nuanced information related to language access services. It primarily elevates individualized care by enhancing patient understanding and the quality of care in the hospital, outpatient care, and post-acute care settings. This data feature also streamlines the referral process and care transitions by offering a standardized format for sharing interpretation requirements, optimizing operational workflows, and enriching the patient experience. In public health epidemiology, it can contribute to disease tracking and facilitate contact tracing efforts. This data element also could be instrumental in health equity studies by providing more precise data on language disparities. Finally, its integration could simplify federal data collection mandates, thereby lessening the administrative load on healthcare facilities.

We thank you for the opportunity to provide comments and priority data element recommendations for USCDI v5. We look forward to continued engagement with ONC and strongly recommend the addition of these critical data elements to USCDI to support advancement of interoperability and useability of the data; improved patient care; and enhanced quality measurement. We recognize there are many elements under consideration and aimed to focus recommendations on data elements with widespread use cases across providers, payers, and patients that are critical for exchange to improve patient care and outcomes.

Thank you,

Michelle Schreiber

Michelle Schreiber, MD
Deputy Director of the Center for Clinical Standards and Quality, Director for the Quality Measurement and Value-Based Incentives Group
Centers for Medicare & Medicaid Services