April 11, 2024

Micky Tripathi, PhD, MPP
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St. SW; Floor 7 Washington, DC 20201

Dear Dr. Tripathi,

CMS-CCSQ Public Comment Letter on United States Core Data for Interoperability (USCDI) Draft Version 5

On behalf of The Centers for Medicare & Medicaid Services (CMS) and The Center for Clinical Standards and Quality (CCSQ), we submit the following comments on USCDI Draft version 5 (v5) for consideration. We recognize there are many needs and multiple perspectives that must be balanced by ONC and the USCDI Committee and thank ONC for the opportunity to contribute comments.

CMS continues to support the USCDI as the central mechanism in defining the foundational set of electronic health information for interoperable health exchange. This, in turn, defines what data patients have access to, and helps define what we are sharing across sites to support clinical care and best outcomes. CMS is committed to the digital transformation of its quality measurement programs. The USCDI, as well as the USCDI+, allows us to build on a foundational framework for this transition.

CMS is pleased to see some of our priority data elements added to Draft version 5, including Emergency Department Note, Operative Note, Medication Route, Interpreter Needed, Author, and Author Role. CMS is also supportive of the newly added Advance Directive Observation, Sex Parameter for Clinical Use (SPCU), Lot Number, and Orders data elements. CMS offers additional recommendations to some data elements in USCDI that could be enhanced by revising the definition and/or standards (Appendix A). In addition to this letter, we have also submitted comments under the elements in the ONDEC system.

There remain several critical elements we believe merit inclusion under USCDI v5 to support interoperability, patient care and access to data. CMS recommends the following data elements also be added to USCDI v5. Additional details relevant to adding these critical elements can be found in Appendix B. We have also submitted comments for each recommendation under the elements in the ONDEC system:

1. Data Class: Medications

   A. Data Element: Medication Administration (Level 2)
      a. **Recommendation:** Add to Final USCDI v5.
         i. **Rationale:** Although CMS appreciates the addition of prior CMS recommendations of Medication **Dose** and **Route** data elements to the USCDI,

the *Medications* data class continues to be inadequate to support patient safety, quality improvement, or public health. Current medication data elements do not differentiate among medications that are active, ordered, or administered to the patient. Given these complexities, more clarity and structure are necessary in this data class to accurately evaluate and provide clinical care and promote patient safety. Medication administration, specifically, is a priority concept for CMS and CDC programs that support quality improvement and public health surveillance. The completion or non-completion of a medication administration is critical clinical information from care and quality measurement perspectives. Addition of this data element to the *Medications* data class will facilitate a more comprehensive exchange of medication information, which will allow providers to make better-informed decisions and employ more coordinated care.

B. Data Element: Medication Prescribed Code (Level 0)

a. **Recommendation:** Advance this data element from Level 0 to Level 2.

i. **Rationale:** This is a joint CMS-CDC priority. This data element is used extensively in quality measurement and public health — for example, to monitor and respond to antibiotic prescribing patterns that facilitate the emergence of drug-resistant pathogens, but also exposes patients to needless risk for adverse effects. The **Medication Prescribed Code** data element was also previously supported and recommended by the ISWG Recommendations on Draft USCDI v4 (April 12, 2023). Finally, CMS continues to support the concept of a USCDI Medication Task Force to appropriately specify and advance this important data class.

2. Data Class: Immunizations

A. Data Element: Vaccination Event Record Type (Level 2)

a. **Recommendation**: Add to Final USCDI v5.

i. **Rationale**: The **Vaccination Event Record Type** data element provides critical information about whether a vaccination has ever been administered, planned, or reported. The current **Immunizations** data element is insufficient to identify whether the vaccination is based on the historical record or was administered at the facility submitting the vaccination record. By adding **Vaccination Event Record Type** for immunizations, ONC can also ensure data elements necessary to determine whether vaccinations are current, and whether any vaccinations need to be administered. This joint CMS-CDC priority data element should not add substantial burden on vendors or implementers, as this metadata should already be routinely captured. As this information helps improve accuracy of vaccine reporting, it can benefit many existing CMS vaccination quality measures.

3. Data Class: Recommend USCDI Add Advance Directives

a. **Recommendation 1:** Add an *Advance Directives* data class to Final USCDI v5.
    i. **Rationale**: Advance Directives are an important component in patient-centered care. They provide essential information on patients' preferences, especially when patients are unable to make the decisions for themselves. By creating a specific data class for Advance Directives, patient preferences are prioritized in their care and become more accessible for healthcare providers when providing patient care.

b. **Recommendation 2:** Add **Advance Directives** (Level 2) data element to Final USCDI v5, and recommend it be placed ideally in an *Advance Directives* data class. Currently this Level 2 data element is in ONDEC under the *Goals and Preferences* data class.
    i. **Rationale:** The **Advance Directives** data element (Level 2) is critical to enable the exchange of advance directives information that focuses on a narrative description and supporting documentation. Moving the **Advance Directives** data element from the *Goals and Preferences* data class to the *Advance Directives* data class enhances the utility and efficiency of patient records and allows providers to accurately access information on patient care preferences.

c. **Recommendation 3:** Add **Portable Medical Orders** (Level 2) data element to Final USCDI v5, and recommend it be placed (ideally) in an *Advance Directives* data class. Currently this Level 2 data element is in ONDEC under the *Orders* data class.
    i. **Rationale:** Portable medical orders are an important component of patient preferences. Currently, the **Portable Medical Orders** data element (Level 2) categorized under the *Orders* data class might be overlooked or undervalued in the broader context of various medical orders. By adding this data element under an *Advance Directives* data class in addition to the **Advance Directives** data element, it highlights the importance of prioritizing and representing patient preferences. More specifically, portable medical orders remain valid across various settings and do not expire upon patient discharge or require rewriting by a receiving clinician. This is fundamentally different from traditional Orders and should, therefore, be captured as a separate data element to facilitate easy retrieval and use.

d. **Recommendation 4:** Move the newly added Draft USCDI v5 **Advance Directive Observations** data element from the current *Observations* data class to an *Advance Directives* data class should this new data class become available.
    i. **Rationale**: The newly added **Advance Directive Observation** data element provides importance in that it notes that an Advance Directives exists. It serves as a "gateway" or first step in acknowledging an Advance Directives exists but does not always lead to the access and content of the Advance Directives. For this reason, we support congruent use of the **Advance Directive Observations**

data element along with an **Advance Directive** data element. This data element will be complementary to the above recommended Level 2 data elements. However, adding this data element under an *Advance Directives* data class will highlight the importance of prioritizing and representing patient preferences.

e. **Recommendation 5:** Add **Healthcare Agent** as a data element in USCDI under an *Advance Directives* data class.
    i. **Rationale:** A **Healthcare Agent** is a broad term that includes a healthcare proxy who is designated to speak for a patient if they are unable to speak for themselves. The current **Durable Medical Power of Attorney** data element is too narrow to capture the different types of proxies and representatives. Designating a Healthcare Agent is a valuable part of advance care planning that should be captured in an *Advance Directives* data class, if available.

4. Data Class: Recommend USCDI Add Care Plan

a. **Recommendation 1:** Add a *Care Plan* data class to Final USCDIv5.
    i. **Rationale:** We recommend a distinct *Care Plan* data class with a set of data elements (Care Plan Information, Assessment, Health Concerns, Goals, Interventions, and Outcomes/Evaluation). We define a care plan as a shared dynamic longitudinal plan representing all care team members (including patient/caregiver) prioritized concerns, goals, interventions, and evaluation/outcomes across all health and care settings. It can include a structured package of data elements that already exist in USCDI. By adding *Care Plan* as a distinct class in the Final USCDI v5, it would encompass all data elements relevant to patient care planning. We believe Patient Summary and Plan are distinct concepts with patient summary component closely aligning to *Clinical Notes* data class. We propose repurposing the *Patient Summary and Plan* data class to the new *Care Plan* data class. The existing **Assessment and Plan of Treatment** data element in USCDI does not include the core care plan data elements that align with the clinical workflow for shared, dynamic, and longitudinal care planning. Including a *Care Plan* data class with relevant data elements has the potential to improve communication and care coordination across the care teams, improve patient safety and patient experience, and provide access to patient and caregiver-centric data.

5. Data Class: Medical Devices

A. Data Element: Device Used (Level 2)

a. **Recommendation:** Add to Final USCDI v5.
    i. **Rationale:** The **Device Used** data element (Level 2) captures information about a wide range of mobility devices with significant impact on a patient's health

and includes discrete codes related to types of devices used by patients – specifically mobility (i.e., wheelchair), wearable (i.e., venous foot pump), and implantable devices. (i.e., pacemaker). These are critical components that must travel with a patient to ensure safe and effective care, as these devices can have significant impacts on a patient's functionality and health. Clinicians need to be aware of prior and recent healthcare interventions and the presence of implanted devices or use of external or mobility devices for optimal patient health-care provision. This data element can complement the **Disability Status** data element, by providing additional information about devices used/needed by the patient to support participation in their care. It also supports completion of required patient assessments at admission and discharge, during long-term care, rehabilitation, and home health care surrounding use of devices such as durable medical equipment and assistive devices. These data are extensively used by hospitals and providers in identifying frailty, advanced illness, and effectiveness of interventions in addition to informing providers clinical decision-making. Including this data element in Final USCDI v5 also facilitates efficient healthcare delivery by assisting providers in identifying critical healthcare interventions.

6. Data Class: Facility Information

A. Data Element: Facility Address (Level 2)

a. **Recommendation:** Add to Final USCDI v5.

i. **Rationale**: Together with the **Facility Identifier**, **Facility Name**, and **Facility Type**, 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. Currently, in the absence of a unique Organization/Hospital Identifier data element in the USCDI, it can be difficult to differentiate specific service locations and link data or records for public health and healthcare purposes, such as monitoring hospital capacity and respiratory disease burden in acute care hospitals, identifying and responding to outbreaks in facilities, and tracking patient safety events. Accurate facility information, including name, address, and identifier, is essential to analyze facility level data and inform the allocation of resources such as therapeutics, supplies, staffing, and PPE to prepare for and respond to emergency events. This is a joint CMS-CDC priority.

7. Data Class: Laboratory

A. Data Element: Specimen Collection Date/Time (Level 2)

a. **Recommendation:** Add to Final USCDI v5.

i. **Rationale**: The **Specimen Collection Date/Time** data element in the *Laboratory* data class can be critical for providing context in quality measurement. This

data element provides key information needed to confirm diagnoses, understand disease severity, and classify cases that require public health intervention, including outbreak identification and response. Knowing the date and time of specimen collection helps determine when a patient has a laboratory-verified illness. This data element helps healthcare providers interpret test findings correctly, especially in urgent care settings like Intensive Care Units (ICUs) and emergency rooms as well as during public health response to infectious disease outbreaks. The collection date/time of a specimen is particularly important in understanding when a disease process was present in a patient, which helps interpret laboratory findings for severity and transmissibility. Current CMS quality measures require date/time elements for different aspects of laboratory tests such as collection, recording, and reporting. Elevating this data element to Final USCDI v5 will be significant in helping to ensure accurate and effective patient care in addition to comprehensive and timely public health response. CMS would also highly recommend date/time data elements be incorporated to other areas to enhance collection and reporting of key healthcare activities such as radiology, immunizations, and clinical notes.

8. Data Class: Provenance

A. Data Element: Signature (Level 0)

a. **Recommendation:** Advance this data element from Level 0 to Level 1.

i. **Rationale:** Signatures are used for many applications and may encompass all manner of roles such as witness, notary, provider, or patient. The **Signature** data element is an important component of electronic health records and patient data exchange. The data element serves as a digital verification tool that ensures the authenticity and integrity of medical documents and electronic health information. By incorporating digital signatures, healthcare providers and organizations can reliably confirm that the content of the electronic health information (EHI) has not been altered from its original form, thereby maintaining the trust and accuracy of the data. This data element will also add to the security and efficiency of data interoperability, especially when medical records are shared or transferred between different health systems or provided electronically by the patient.

April 11, 2024

Thank you again for the opportunity to provide CMS-CCSQ comment on USCDI Draft version 5. CMS is actively engaging with federal partners and commented with CDC in February 2024 on shared priority data needs for USCDI, many of which are included in this letter. CMS also continues to have additional data element needs to support our quality measurement programs and look forward to working with ONC on the USCDI+ Quality domain to move forward additional priorities.

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

Appendix A: Recommended Updates to Existing Data Elements in Draft USCDI v5

Data Class	Data Element	Recommendation	Additional Details
Health Status Assessment	Functional Status	Change example from FASI to CMS assessments.	• Recommend replacing the FASI example to CMS assessments: e.g., Minimum Data Set (MDS) and Outcome Assessment Information Set (OASIS), etc.) which would include the broader range of patient assessments used in post-acute care.
	Disability Status	Move data element to the *Patient Demographics/Information* dat a class.	• Capturing and exchanging information about a person's disability is important information as part of the person's identity. Capturing this data in a standardized manner, along with other demographic information, supports a more comprehensive analysis of outcomes. • The ADA definition for "disability" indicates this is not a medical term but rather a legal term.
Observations	Sex Parameter for Clinical Use	Revise data element definition to align with Gender Harmony Project.	• CMS supports the Gender Harmony Project and ISWG recommendation to revise the definition to clarify that the SPCU data element is context-specific.
Orders	Orders	Update the data element description.	• Recommend updating the data element description to explain the **Orders** data element includes the details of each order, not simply a list of orders that provides no additional information. • In FHIR, Orders can be exchanged by service request, thereby creating opportunities for implementation guides to leverage this new data class. • ServiceRequest was new to FHIR in 4.1.0 STU 4 (http://hl7.org/fhir/us/core/2022Jan/StructureDefinition-us-core-servicerequest.html) and is still present in US Core 6.1.0 (http://hl7.org/fhir/us/core/StructureDefinition-us-core-servicerequest.html). • The serviceRequest Categories (http://hl7.org/fhir/us/core/ValueSet-us-core-

			servicerequest-category.htm) in US Core 6.1.0 include functions-status and cognitive-status and SDOH.
Patients Demographics/ Information	Sex	Change standards to align with the Gender Harmony Project.	• CMS continues to support previous ISWG recommendation of **Recorded Sex or Gender** data element as it allows the capture and exchange of more nuanced information, which is essential for proper care and can support patient care, care coordination, and quality measurement. This is a critical data element because, depending on context, the value may change and not be the static value on an original birth certificate.
	Gender Identity	Change standards to align with the Gender Harmony Project.	• CMS supports the previous ISWG and HITAC recommendation for expanding the Gender Identity data element definition to include the Gender Harmony Project's minimum value set in addition to the current USCDI standards. • GHP's minimum value set includes: 1. Female 2. Male 3. Nonbinary 4. Unknown
Patient Summary and Plan		Repurpose the data class to a new "Care Plan" data class.	• Patient Summary is already included in *Clinical Notes* data class, and US CORE Care plan IG includes 'Narrative Summary and Plan of Treatment'.

Provenance	Author & Author Role	Add more specificity of standards.	• Current HL7 FHIR standard supporting Author and Author Role: ○ HL7 FHIR R4 (v4.01: R4 – Mixed Normative (https://www.hl7.org/fhir/provenance-definitions.html)

Appendix B: Additional Details of Level 0 and Level 2 Data Elements to Advance in USCDI

Data Class	Data Element	Level	Recommendation	Additional Details
Goals and Preferences	Advance Directives	2	Add to Final USCDI v5 and recommend an *Advance Directives* data class.	• US Core for Patient Goal (http://hl7.org/fhir/us/core/2022Jan/SearchParameter-us-core-goal-patient.html) supports this data element and represents data from the following areas, noted in different areas across USCDI levels 1, 2, including Durable Medical Power of Attorney, Personal Advance Care Plan, and Living Will. • There are LOINC codes supporting this data element, including the Advance directive panel (75911-8) and an established value set PHVS_AdvanceDirectiveType_HL7_CCD. • Profiles leveraged in the published PACIO Advance Directive Interoperability Implementation Guide support capturing and exchanging advance directive information, including: ADI Personal Intervention Preference (https://build.fhir.org/ig/HL7/pacio-adi/StructureDefinition-PADI-PersonalInterventionPreference.html)
Medical Devices	Device Used	2	Add to Final USCDI v5	• LTPAC assessment tools leverage LOINC codes addressing use of devices including but not limited to: ○ 95131-9 (Mobility [wheelchair]) ○ 95025-3 (Manual Wheelchair.Most Dependent) ○ 95022-0 (Does the person use a motorized wheelchair and/or scooter) ○ 95027-9 (Motorized Wheelchair/Scooter.Usual) ○ 95042-8 (in the past month, has the person used, or expressed or demonstrated a need for an assistive device?) ○ 94887-7 (Limb prosthesis) ○ 94890-1 (Reacher/Grabber) ○ 94892-7 (Orthotics/Brace) ○ 94901-6 (Communication device)
Orders	Portable Medical Orders	2	Add to Final USCDI v5 under an *Advance Directives* data class, if available.	• Value sets under development with the draft Advance Directive Interoperability Implementation Guide support portable medical orders: https://build.fhir.org/ig/HL7/fhir-pacio-adi/branches/adi-stu2-merge-addmenu

Provenance	Signature	0	Advance to Level 1	• Signature is required as part of MDS, IRF-PAI, LCDS, and HIS assessments. LOINC codes supporting this data element include: ○ 85814-2 (IRF-PAI Signature of persons completing the assessment) ○ 85647-6 (Signature of person collecting or coordinating collection of assessment information Provider) ○ 85648-4 (Signature of persons completing the assessment) ○ 70127-6 (Signature verifying assessment completion)