April 17, 2023

CMS-CCSQ Public Comment Letter on United States Core Data for Interoperability (USCDI) Draft Version 4

On behalf of The Centers for Medicare and Medicaid Services (CMS) and The Center for Clinical Standards and Quality (CCSQ), we submit the following comment on USCDI Draft version 4 for consideration. We certainly recognize there are many needs and multiple perspectives to consider 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 has committed to transforming its quality measurement to digital, and the USCDI as well as the USCDI+ allows us to build on a foundational framework for this transition.

CMS was pleased to see some of our priority data elements added to Draft version 4, namely encounter identifier, facility identifier, care experience preference, treatment intervention preference, and average blood pressure, which support the goals of reducing disparities in care and promoting interoperability and communication. Despite these great additions, there are still several critical elements we feel must be added to USCDI version 4 to support interoperability, patient care and access to data. CMS recommends the following data elements also be added to USCDI version 4. We have also entered comments for each recommendation under the elements in the ONDEC system:

1. Data Class: Medications
   - **A. Data Element: Medication Administration/Medication Administered Code;** defined as a code (or set of codes) that specifies the medication administered to a patient.
   - **B. Data Element: Discharge Medications;** specifies the medication(s) active at discharge which should be taken by the patient upon release from a facility.
   - **C. Data Element: Medication Administration Route (new submission);** defined as the route of administration of a medication, or how the drug should enter the body, for example intravenous or oral.
   - **D. Data Element: Medication Prescribed Code;** defined as a code (or set of codes) that specify the medication prescribed.

   Rationale: CMS continues to urge ONC to consider 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. Specifically, these medication data elements are necessary for understanding adverse drug events, opioid use and misuse, and medication access.

   The current concept of medications in USCDI does not differentiate among medications that are active, ordered, and administered/dispensed to the patient. More clarity and structure are necessary in this data class to accurately evaluate and provide clinical care. These detailed medication data are used extensively in quality measurement and public health —for example, to monitor and respond to antibiotic prescribing patterns.

   Maturity: These elements are classified as Level 2 by ONC and continue to have strong standardization and be in wide use.

- *Current standards:*
  - In FHIR US Core, there is a distinction between "Medication" and "Medication Request"; base FHIR and FHIR Quality Improvement (QI) Core IG includes "Medication Administration" and "Medication Request" profiles.
  - Within Medication Request, the 'category' is used to define discharge medications.
  - Route information is also contextualized within the Medication Request, Medication Administration, and Medication Dispense profiles in US/QI Core Implementation Guides.
- *Current uses, exchange, and use cases*: Medication data are routinely captured in electronic health record (EHR) systems used by hospitals, providers, and other healthcare stakeholders, including pharmacies, and are routinely exchanged across providers and payers. As noted in the ISWG recommendations report for USCDI v3, many medication data elements are already required for Health Information Technology (IT) Certification via other standards (National Council for Prescription Drug Programs [NCPDP] SCRIPT, Consolidated Clinical Document Architecture [C-CDA]) and are therefore already routinely exchanged, posing little additional burden by adding them to the USCDI.

2. Data Class: Patient Demographics/Information

A. Data Element: Sex: CMS repeats and supports the ISWG and HITAC recommendation for USCDI v3 (on April 13, 2022) to include the HL7 Gender Harmony Project's data elements related to Sex – **Recorded Sex or Gender (RSoG) and Sex for Clinical Use (SFCU)** in addition to the existing standards for capturing sex.

Rationale: Further specification of data elements related to the concept of sex is necessary to improve health equity, represent diversity, and improve care, specifically for historically vulnerable and/or underserved populations – all ONC stated priorities for USCDI v4. For example, Sex for Clinical Use is critical because the appropriate sex value for an individual may differ for different procedures or tests. Likewise, Recorded Sex or Gender is critical because, depending on context, the value may change and not be the static value on an original birth certificate. These data elements allow the capture and exchange of more nuanced information, which is essential for proper care and will support patient care, care coordination, and quality measurement.

Maturity: These elements are classified as Level 2 by ONC.

- *Current Standards:*
  - CMS supports the ISWG USCDI v3 recommended minimum value sets (https://www.healthit.gov/sites/default/files/facas/2022-04-13_IS_WG_Phase_1_Recommendations_Report_revised.pdf), which are closely aligned with Gender Harmony recommendations, and represented by Logical Observation Identifiers Names and Codes (LOINC) terminology, for these critical data.
    - Recorded Sex or Gender: F[emale], M[ale], X [non-binary, intersex, unspecified, etc.], < [value not recorded or cannot be ascertained]
    - Sex for Clinical Use: Female, Male, Specified, Unknown
  - HL7 Cross Paradigm IG: Gender Harmony – Sex and Gender Representation (https://build.fhir.org/ig/HL7/fhir-gender-harmony/branches/main/index.html)
- *Current uses, exchange, and use cases:* Elements related to sex and gender are captured in nearly all clinical and administrative records and routinely exchanged as part of healthcare information exchange. As more appropriate and diverse terminology are standardized, the

capture and exchange of the data must also keep pace to ensure appropriate and high quality of care.

B. Data Element: Gender Identity: CMS supports the ISWG and HITAC recommendation for expanding the Gender Identity data element definition to include the Gender Harmony Project's minimum value set, with ISWG refinements.

Rationale: The additional values in the defined terminology work collectively with the sex data element to represent sex and gender diversity that supports improved care for vulnerable or underserved populations. The values for this data element are self-reported and not clinically determined, which allows for better representation of diversity.

Maturity: These elements are classified as Level 2 by ONC.

- *Current Standards:*
  - CMS supports the ISWG recommended minimum value sets (https://www.healthit.gov/sites/default/files/facas/2022-04-13_IS_WG_Phase_1_Recommendations_Report_revised.pdf) from the Gender Harmony Project, along with the two USCDI values:
    - Female; Male; Nonbinary; and Unknown; Additional gender category or other, please specify; Choose not to disclose
  - HL7 Cross Paradigm IG: Gender Harmony – Sex and Gender Representation (https://build.fhir.org/ig/HL7/fhir-gender-harmony/branches/main/index.html)
- *Current uses, exchange, and use cases:* Elements related to sex and gender are captured in nearly all clinical and administrative records and routinely exchanged as part of healthcare information exchange. As more appropriate and diverse terminology are standardized, the capture and exchange of the data must also keep pace to ensure appropriate and high quality of care.

3. Data Class: Orders

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

Rationale: 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 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 data element continues to be a joint CMS-CDC priority and supports advancing patient care quality, which aligns with the purpose of the USCDI (setting a foundation for broader sharing of electronic health information to support patient care).

Maturity: ONC recently advanced this data element to Level 2 based on maturity of standards.

- *Current standards:*
  - Newly added—HL7 FHIR US CORE Implementation Guide STU 5, Service Request Profile (http://hl7.org/fhir/us/core/StructureDefinition-us-core-servicerequest.html)
  - HL7 FHIR QI Core Implementation Guide STU4 based on FHIR R4, Service Request Profile (HL7.FHIR.US.QICORE\QICoreServiceRequest - FHIR v4.0.1)

  - Concepts captured in mature terminology: LOINC, Systematized Nomenclature of Medicine (SNOMED)
- *Current uses, exchange, and use cases*: Orders (service requests) for end of life care services are routinely captured in EHR systems used by hospitals and providers and are used in CMS quality reporting eCQMs across programs. The relevant information required to support a transfer of care request from one practitioner or organization to another that provides end of life care services is critical.

4. Data Class: Clinical Notes

A. Data Element: Surgical Operative Note; defined as the detailed note or report following a surgical procedure.

Rationale: Currently, the Procedure Notes data element is limited to non-operative procedures. CMS strongly recommends either expanding these notes to also include the surgical operation note (LOINC 11504-8) or consider adding the distinct Operative Note data element to USCDI v4. Surgical notes are important to ensure patient access to data and capture interoperable information critical to patient safety, care coordination and hand-offs. Existing disparities in surgical procedure rates and outcomes support that these data elements are critical additive tools to help mitigate health and health care inequities and address needs of underserved communities.

Maturity: ONC already includes non-operative clinical notes in the USCDI and has classified an Operative Note data element as Level 2.

- *Current standards:*
  - The Surgical Operative Note is standardized and captured by LOINC 11504-8; or the group LOINC code LG38755-1
- *Current uses, exchange, and use cases*: Surgical Operation Notes are routinely captured in EHR systems used by hospitals and providers for care coordination, and hand-offs. These notes include critical information for assessing patient safety and include important data patients should have access to.

B. 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.

Rationale: 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. This ensures capture of a critically unique encounter type that represents a key interface between and across acute and outpatient care settings. A separate Emergency Department Notes data element will also ensure patient access to this information. As historically vulnerable and underserved populations disproportionately use Emergency Departments for primary care, these clinical notes may be particularly useful in supporting the ONC USCDI v4 goals of addressing needs of underserved communities and public health interoperability needs related to emergency response.
Maturity:

- *Current standards:*

  - LOINC codes, Emergency department|ANYTypeofService|ANYKindofDocument|ANYRole|ANYSubjectMatterDomain, LOINC Group Code LG41825-7 or at a minimum, Emergency department Discharge summary note, LOINC 59258-4.
- *Current uses, exchange, and use cases*: Emergency department notes are exchanged and used routinely 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. They represent a unique and critical connection between inpatient and outpatient care settings and are therefore an important component of both acute and chronic disease management. The information is particularly important to reflect a patient's health status to support transitions of care.

5. Data Class: Facility Information

A. **Data Element: Facility Address**; defined as the location associated with the facility.

Rationale: Together with the Facility Identifier, Name and 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 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.

Maturity: This data element is classified as Level 2 by ONC.

- *Current standards:*
  - HL7 FHIR US Core Implementation Guide STU2-STU5 based on FHIR R4, Location Profile (https://bit.ly/FHIRLocation)
- *Current uses, exchange, and use cases*: 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.

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.

Rationale: CMS-CCSQ recommends the addition of the Author data element to USCDI. It is important to know who the author of the medical notes and information is for effective care coordination and care transitions. Provenance statements indicate clinical significance in terms of confidence in authenticity, reliability, and trustworthiness, integrity, and stage in lifecycle, all of which may impact security, privacy, and trust policies. The Author information is required for

billing and therefore, is accurate and can support audit trails. 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. For example, a medical student may initiate a note; it may then be reviewed and signed by the nurse, and ultimately signed off by the attending physician. This type of author trail is meaningful, and the attending physician is the clinician ultimately responsible for the care of the patient.

Maturity:

- *Current standards:*
  - HL7 FHIR R4 (v4.01: R4 – Mixed Normative and STU) (https://www.hl7.org/fhir/provenance-definitions.html)
- *Current uses, exchange, and use cases*: Author information is routinely captured in electronic health record (EHR) systems used by hospitals, providers, and other healthcare stakeholders, and should be readily available. Knowing the author of notes and records will allow for validation of the integrity of the data used in quality measures. This is meaningful information needed to ensure efficient care coordination along with the current Provenance data elements in USCDI.

7. Data Class: Immunizations

A. Data Element: Vaccination Event Record Type; defined as the associated data to indicate whether a vaccination event is based on historical record or was administered at the facility submitting the data.

Rationale: The immunization data element provides critical information about whether a vaccination has ever been administered, planned or reported. The current immunization data element is insufficient to identify whether the vaccination is based on the historical record or was administered at the facility submitting the vaccine. By adding vaccine 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 and CDC priority data element should not add any 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.

Maturity: This data element is classified as Level 2 by ONC and continues to have strong standardization and be in wide use.

- *Current standards:*
  - https://phinvads.cdc.gov/vads/ViewCodeSystem.action?id=2.16.840.1.114222.4.5.293HL7 v2.5.1 and 2.8.2 Implementation Guides: https://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html

- *Current uses, exchange, and use cases*: The vaccination event record type data element provides information that is currently lacking in the USCDI on timing of the immunizations that can improve accuracy of measurement. This data element also allows CDC to see where immunizations may be lacking and can support future CMS quality measure reporting.

8. Other priorities

A. **Organization: Organization/Hospital Identifier**: CMS encourages ONC to consider the advancement of the Organization Identifier, like the NHSN OrgID, 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 ID 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. We are recommending reclassifying this data element to Level 2 for addition to future versions of USCDI. CMS may also additionally recommend moving the CCN from the currently proposed Facility Information data class to the Organization data class if the Organization/Hospital Identifier data element is supported in version 5.

B. **Health Status Assessments**:

i. CMS recommends that "Health Status/Assessments" should be expanded to include not only the specified assessment question, but to also include the responses/results of such assessments and that these responses and results be incorporated into the USCDI in alignment with the PACIO Project IGs. Information garnered via patient health assessments is critical for planning patient-centered care and should be exchanged between providers during transitions of care to support care coordination. CMS is also encouraging ONC to adopt the value sets developed by the PACIO project for the "Personal Functioning and Engagement" FHIR IG that incorporates Functional Status and Cognitive Status data elements into PACIO's prior published IGs.

ii. In collaboration with CDC, CMS recommends moving the current Disability Status from the Health Status Assessments data class to the Patient Demographics data class. Collecting and transmitting data on disability in a standardized way alongside other demographic factors is vital to recognition of disability and allows analysis of outcomes and conditions in an intersectional way, incorporating race/ethnicity, age, sex, and disability together for a more comprehensive understanding of patient demographics. CMS may additionally recommend a disability assessment data element in version 5 to qualify the disability type (e.g., functional, cognitive, physical, etc.).

iii. Finally, CMS suggests removing pressure ulcer risk and falls risk as examples under the Functional Status data element definition as they are not representative of functional status. Examples that can be added to this data element include self-care including activities of daily living, mobility, or use of a device. We agree that pressure injuries and falls risk information are important to exchange so we will address the placement of this information under the Problems data class in a future version of USCDI.

C. **Goals:** Information about patient-document goals and preferences is important for clinical decision support and care coordination. While CMS supports the addition of Treatment Intervention Preference and Care Experience Preference data elements to the Goals data class, we recognize that "Goals" and "Preferences" are related but conceptually different. Hence, we recommend reframing the Goals data class to "Goals and Preferences" to capture

related data elements in one data class. This would allow for data elements such as Advance Directives and Portable Medical Orders to fit appropriately into this data class in future.

Thank you again for the opportunity to provide CMS-CCSQ comment on USCDI Draft version 4. CMS is actively engaging with federal partners, including CDC, to comment on shared priority data needs for USCDI, many of which are included in this letter, and look forward to continuing to engage with ONC. 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 including other orders for medical services, observations for clinical assessments and patient reported data, and non-implantable device information.

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