March 22, 2022

CMS-CCSQ Public Comment Letter on United States Core Data for Interoperability (USCDI) Draft Version 3

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 3 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 also 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 several of our priority data elements added to draft version 3, including health insurance and disability status information, which support the goal of reducing disparities in care. Despite these great additions, there are still several critical elements we feel must be added to USCDI version 3 to support interoperability, patient care and access to data. CMS recommends the following data elements also be added to USCDI version 3. We have also entered comments for each recommendation under the elements in the ONDEC system:

1. Facility Level Data: Facility Identifier (or Organization Identifier)
   Identifiers are critical for billing, linking billing/clinical EHRs, supporting data aggregation across data sources and reducing burden, as well as attribution and tracking of data. All of these activities are necessary for providing high quality care to patients, reducing disparities, promoting interoperability and communicating across silos. Facility identifiers are also critical for public health reporting and tracking, an ONC stated priority for USCDI version 3.
   CMS specifically prioritizes exchange of CMS Certification number (CCN), Provider Transaction number (PTAN), and National Provider Identifier (NPI)—unique identifiers for a healthcare organization.

Maturity:
- *Current standards:*
    - HL7 FHIR US Core Implementation Guide STU3 and STU4 based on FHIR R4, Organization Profile must support an identifier (https://www.hl7.org/fhir/us/core/StructureDefinition-us-core-organization.html)
    - Organization Profile is included in the HL7 FHIR US Core Capability Statement: https://www.hl7.org/fhir/us/core/CapabilityStatement-us-core-server.html; data included in this profile must be able to be exchanged, including the Organization Identifier
- *Current uses, exchange, and use cases*: CCN, PTAN, and NPI are exchanged across the nation for CMS reporting to appropriately attribute outcomes and measure results. Exchange of these identifiers supports facility-specific quality, prior authorization activities, and other assessments that are limited without this information.

2. Medications:
   a. **Medications Administration/Medication Administered Code;** defined as a code (or set of codes) that specifies the medication administered to a patient
   b. **Medications Dispensed;** defined as a code (or set of codes) that specifies the medication dispensed
   c. **Discharge Medications;** specifies the medication(s) active at discharge which should be taken by the patient upon release from a facility
   d. **Dosage (and route);** defined as the dose and route instructions for medications

Management of medications is critical to patient care and coordination between providers, as well as related quality and public health enterprises. The current concept of medications in USCDI Draft version 3 does not differentiate those that are active, ordered, or actually administered to the patient, and do not provide necessary details for patient safety (i.e., dose and route). Medication details support an ONC criteria for public health reporting and investigation including using data to support safer use of opioids.

Maturity:
- *Current standards:*
  - In FHIR US Core, there is a distinction between Medication and MedicationRequest; base FHIR and FHIR QI Core IG includes MedicationAdministration and MedicationDispense profiles.
  - Within MedicationRequest, the 'category' is used to define discharge medications.
  - Dose and route instructions are also contextualized within the MedicationRequest, MedicationAdministration, and MedicationDispense profiles in US/QI Core IGs.
- *Current uses, exchange, and use cases*: Medication data is routinely captured in EHR systems used by hospitals, providers, and other healthcare stakeholders including pharmacies. Medication details are routinely exchanged across providers and payers. Medication data is used extensively in CMS quality measurement. Additionally, when prior authorization is necessary for a medication, details related to the medication (e.g., why the medication is given, the quantity needed) are exchanged to support the approval process.

3. Clinical Notes: Surgical Operation Note
   USCDI Draft version 3 currently includes Procedure Notes that are limited to non-operative procedures. We strongly recommend ONC expand these notes to also include the surgical operation note (LOINC 11504-8). Surgical notes are important to ensure patient access to data, as well as interoperability of data for care coordination and hand-offs.

Maturity:
- *Current standards:*
  - The Surgical Operation Note is standardized and captured by LOINC 11504-8
- *Current uses, exchange, and use cases*: Surgical Operation Notes are routinely captured in EHR systems used by hospitals and providers.

4. Medical Device or Equipment: Devices Used (applied)
   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)– are

critical information that must travel with a patient to ensure safe, effective care, as these devices can have significant impact on a patient's functionality and health. This data element can complement Disability Status data element (added to Draft v3), by providing additional information about devices used/needed by the patient to support participation in their care.

Maturity:

- *Current standards:*
    - Extensive guidance exists in FHIR US Core and QI Core IGs for how to exchange device information (as observations, procedures)
    - Devices used concepts are captured in mature terminology: SNOMED, LOINC, HCPCS
- *Current uses, exchange, and use cases*: This information continues to be widely captured and exchanged for nationwide CMS quality measurement. For example, it supports identification of disability (i.e., walking or hearing assistive devices) and/or frailty. Device use information is also critical information for prior authorization activities, as many DMEPOS require prior authorization.

Additionally, we urge ONC to consider reclassification of two important data elements from Level 1 and Comment Level:

5. Orders: Orders for End-of-Life Care

   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. This data needs to be interoperable and shareable to reduce discordance between care provided and patient wishes and enhance value of care at end of life. This element represents a priority data concept that is not yet represented in USCDI and must be prioritized.

Maturity:

- *Current standards:*
    - Orders can be exchanged in mature FHIR standards, including Service Request profile in the QI Core IG
    - End-of-Life Care concepts are captured in mature terminology: LOINC, 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 including IQR, QPP, and Promoting Interoperability programs. CMS requires the submission of order (service request) related data for quality measurement for eligible hospitals/CAHs and clinicians using ONC Certified Health Electronic Record Technology (CEHRT)—this includes orders (service requests) for an intervention (i.e., palliative care, hospice, comfort care).

6. Encounter Information: Encounter Identifier

   Encounter identifiers are critical for linking data, distinguishing between encounters, as well as tracking of data. Encounter identifiers provide important contextual information to support interoperability, quality measure reporting, and public health reporting.

Maturity:

- *Current standards:*

- o HL7 FHIR US Core Implementation Guide STU4 based on FHIR R4, Encounter Profile must support an encounter identifier (https://www.hl7.org/fhir/us/core/StructureDefinition-us-core-encounter.html)
- *Current uses, exchange, and use cases*: CMS recognize that there may be variation in how encounter identifiers are formatted across facilities (i.e., there is not yet one, universal formatting standard), but the information provides context to the granular data exchanged – for example did this data come from two distinct encounters or the same encounter—and enables linking those shared data with other relevant information. Encounter Identifiers are submitted for CMS eCQMs to support distinguishing between episodes of care when multiple episodes of care are submitted for a quality measure.

Thank you again for the opportunity to provide CMS-CCSQ comment on USCDI Draft version 3. CMS is actively engaging with federal partners, include 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 USCDI+ QM use case to move forward additional priorities including other orders for medical services, observations for clinical assessments and patient reported data, and non-implantable device information.