September 28, 2021

CMS-CCSQ Submission for United States Core Data for Interoperability (USCDI) 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 recommendations for USCDI version 3 consideration. CMS encourages continued expansion of the USCDI to include high priority data elements necessary to support nationwide interoperability. This expansion will ease the burden of quality measurement and further support clinical care and quality improvement. We are committed to continuing our collaborative work with 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.

We specifically urge ONC to add additional data elements outlined below to USCDI version 3 which support high priority use cases identified by the USCDI Task Force, including: mitigating health and healthcare disparities; integrating patient generated health data (PGHD), including patient reported outcomes (PROs) and device data; and better enabling public health/pandemic responses. Our recommendations align with many of the USCDI Task Force recommendations presented to the Health Information Technology Advisory Committee (HITAC) on September 9, 2021.

Below we present the data elements we recommend for inclusion in USCDI version 3 summarized by data class. We have also entered comments for each recommendation under the elements in the ONDEC system.

1. Data Class: Health Insurance Information

CMS supports the USCDI Task Force recommendation to add the entire Health Insurance Data Class to USCDI Version 3. This data class is critical to support assessments of patient access to resources and care—a CMS priority. CMS calls for inclusion of two Health Insurance data elements:

A. Data Element: Coverage Type, defined as the type of all-payer healthcare entity, as defined by the US Public Health Data Consortium Source of Payment (SOP) code system, applicable to a patient. For example, Medicare, Medicare HMO, Medicare FFS, self-insured, dental care, state SCHIP, private health insurance, commercial managed care, and self-pay.

Rationale: This patient-level information provides context for how healthcare benefits are covered for a patient and supports analyses and measurement of patient access to resources and care. This information is vital for administrative purposes (billing) and for quality measurement to help define target populations and to assess quality differences among patients with differing insurance coverage.

Maturity:

- *Current standards:* This data element is standardly defined by the SOP code system. The Coverage Profile has also been added to QI Core Implementation Guide (STU 4) and coverage type information can be exchanged using '.type'. The FHIR Coverage resource is currently classified as Level 2 for maturity level by HL7, indicating "the artifact has been tested and successfully supports interoperability among at least three independently developed systems leveraging most of the scope (e.g., at least 80% of the core data elements) using semi-realistic data and scenarios based on at least one of the declared scopes of the artifact (e.g., at a Connectathon). These interoperability results must have been reported to and accepted by the FMG".
    - Code System SOP; value set: Payer (OID: 2.16.840.1.114222.4.11.3591)
    - FHIR Coverage resource, profile included in QI Core IG
- *Current uses, exchange, and use cases*: This information is currently electronically submitted by providers (hospitals, clinicians) using diverse EHR systems to CMS with every eCQM submitted for measurement. It is also necessary information for CMS and insurer reimbursement. Insurance type information is used by providers (e.g., hospitals, clinicians) for data used in billing.

B. Data Element: Subscriber ID, to enable exchange of the CMS Medicare Beneficiary ID (MBI), defined as the unique MBI used to identify Medicare patients.

Rationale: In the ONDEC system, there currently exists a data element for Subscriber ID under Health Insurance Data Class and a data element for Medicare Patient ID under patient demographics. MBI is a type of subscriber ID and may therefore be best represented under the Health Insurance Data Class as a specific Subscriber ID. We recommend the addition of Subscriber ID to USCDI version 3, which will allow for exchange of MBI as well as other subscriber IDs that may meet other use cases. MBI is a standardized identifier for all Medicare patients across the United States and is routinely exchanged with CMS. Providers and healthcare insurers need to support and exchange common identifiers for a shared patient/member. This ensures unique individuals' information can be identified and linked across care settings and data sources to support clinical care and other use cases, including quality measurement.

Maturity:

- *Current standards:*
    - MBI format specifications: https://www.cms.gov/Medicare/New-Medicare-Card/Understanding-the-MBI.pdf where MBI is assigned to all Medicare beneficiaries.
    - FHIR Coverage profile included in QI Core IG: This information can be exchanged via '.subscriberID'.
- *Current uses, exchange, and use cases*: MBI is exchanged across the nation for all Medicare beneficiaries to facilitate provider-payer data exchange and member-mediated information exchange.

2. Data Class: Organization

A. **Data Element: Organization/Hospital Identifier**, to enable exchange of CMS Certification number (CCN) and Provider Transaction number (PTAN)—unique identifiers for a healthcare organization.

Rationale: Identifiers are critical for tracking and linking where patients receive care and for managing public health reporting and emergency response. Many nationally used organization/hospital identifiers support this, including CCN and PTAN. We recommend the addition of organization/hospital identifier to USCDI version 3, which will allow for exchange of CCN, PTAN, and other organization identifiers that may meet other use cases. All hospitals in the US are assigned a CCN and exchange this information regularly, and all Medicare providers are assigned a PTAN. The CCN verifies Medicare/Medicaid certification for survey and certification, assessment-related activities, and communications. The CCN represents physically distinct care settings even when these settings share a common tax ID number. Exchange of these identifiers supports facility-specific quality, prior authorization activities, and other assessments that are limited without this information.

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 and PTAN are exchanged across the nation for CMS reporting. Exchange of these identifiers supports facility-specific quality, prior authorization activities, and other assessments that are limited without this information.

3. Data Class: Medications

A. **Data Element: Medication Administration;** 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: Medications Dispensed;** defined as a code (or set of codes) that specifies the medication dispensed

D. **Data Element: Medication Dosage (and Route);** defined as the dose and route instructions for medications
E. **Data Element: Medication Negation Rationale**; defined as the reason a medication was not ordered/administered

Rationale: CMS recommends adding more specificity to the USCDI Medications Data Class because interoperability of medication information and management of medications is critical to ensure patients receive appropriate and safe care. The current concept of medications in USCDI does not differentiate among medications that are active, ordered, and actually administered/dispensed to the patient. Given these complexities, more clarity and structure are necessary in this data class to accurately evaluate and provide clinical care. Additionally, the currently required data lack important clinical specificity (dosage and route instructions). Finally, the reason a medication was not given (negation rationale) provides important context for clinical care and patient engagement and improves patient-provider communication when this information travels with the patient across care settings. These additional medication details are critical to contextualize a medication and ensure patients and clinicians understand the mediations necessary for a patient, and how those should be taken, throughout the continuum of care. These detailed medication data are used extensively in quality measurement and are routinely exchanged when prior authorization is required.

Maturity:

- *Current standards:*
    - In FHIR US Core, there is a distinction between "Medication" and "Medication Request"; base FHIR and FHIR QI Core IG includes "Medication Administration" and "Medication Dispensed" profiles.
    - Within Medication Request, the 'category' is used to define discharge medications.
    - Dose and route instructions are also contextualized within the Medication Request, Medication Administration, and Medication Dispense profiles in US/QI Core IGs.
    - Negation details are expressed within the status reason (for not done) in Medication Request profile and Not Done profiles within QI Core.
- *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.

4. Data Class: Observations

CMS recommends adding to the USCDI an observation data class with associated codes, values, and the performer, as a data capture structure that allows for exchange of standard clinical assessments and observations that routinely occur and are captured in discrete, structured fields.

A. Data Element: Observation codes; CMS recommends adding observation codes related to clinician-administered assessments/observations to the USCDI. These include observations for screenings (i.e., depression screenings), clinical assessments, and risk assessments (i.e., pain intensity assessment, fall risk assessment) via standard assessment instruments.

B. Data Element: Observation values; defined as the discrete values (results) of the observations

Rationale**:** In addition to lab and vital signs, many clinical observations assessed for patients shape quality patient care. Clinical observations are an essential structure for recording many kinds of health information, with results that inform clinical care and condition management decisions and are used extensively throughout CMS quality measurement. USCDI v2 added a data class for Clinical Tests, which includes some, but not all, of these observations/results. CMS specifically uses the following types of clinical assessments/observations in measurement and requests the observation code and value structure be added to the USCDI to support exchange: clinically-administered assessments, clinical screenings. These types of observations are administered and captured in discrete fields with specific associated codes and values, are exchanged via the FHIR Observation profile, and are specified by category codes in FHIR to distinguish between different types of observations.

Maturity:

- *Current standards:*
    - Mature and standardized terminology exists via LOINC and SNOMED to represent clinical observations and assessments.
    - The Observation FHIR resource, included in the QI Core IG, is used to exchange this information.
        - Category is used, within the profile, to specify the type of observation.
- *Current uses, exchange, and use cases*: These data are already extensively captured in EHRs by providers in discrete fields, and routinely exchanged for quality measurement and care coordination. For example, LOINC codes are used to define depression screening assessment tools used, and the results (or values) can take the form of quantitative results, ordinal scale values, or categorial values.

C. Data Element: Performer; CMS recommends inclusion of patient-reported data, or structured data that comes directly from the patient related to the status of a patient's

health condition, in the USCDI. This data is typically captured via questionnaires and transformed into observations for storage and exchange. The observation performer data element (observation.performer in FHIR) is crucial for understanding context for observations derived directly from the patient.

Rationale: CMS is committed to an expanded use of patient generated data and recommends the inclusion of data in the USCDI that comes directly from the patient – in this specific case, patient reported outcome survey data with data captured in a structured way and can be exchanged as observations, with the performer specified as the patient. This is important not only to quality measurement but to advancing patient-centered clinical care, increasing patient access to data, and improving patient engagement. This data element has been identified by the USCDI Task Force as a priority area, and the standards around this concept have continued to mature and have continued to be tested in FHIR Connectathons (most recently in September 2021).

Maturity:

- *Current standards:*
  - *Argonaut Questionnaire Implementation Guide*
  - *FHIR Structured Data Capture (SDC) Implementation Guide*
  - *LOINC*
- *Current uses, exchange, and use cases*: Testing of FHIR resources continues in Connectathons, and CMS continues to capture patient reported data in quality measurement programs, as this is a priority area of focus across the healthcare ecosystem. This includes survey data captured from an instrument, such as PROMIS or HOOS and KOOS about mental or physical status. Use of PRO data is expanding nationally. Rapid technology advancements are simplifying mobile data collection and increasing integration of PRO data collection into clinical workflows and electronic medical records.

5. Data Class: Medical Device or Equipment

A. Data Element: Devices Used (applied); defined as discrete codes for types or categories of devices used by patients (non-implantable devices: mobility devices and wearable devices; and implantable devices).

Rationale: Information related to devices used by patients – specifically mobility, wearable and implantable devices – is critical information that must travel with a patient to ensure safe, effective care. Additionally, this information is widely used for quality measurement use cases; for example, it supports identification of disability (i.e., walking or hearing assistive devices) and/or frailty to ensure patients receive necessary support during the continuum of care. Device use information is also critical information for prior authorization activities, as many DMEPOS require prior authorization. Types of devices used by patients are a type of observation, with a discrete code for the device used, that is documented and

can be exchanged to support patient care in the same model structure as other clinical observations. Therefore, ONC may consider operationalizing this data in the USCDI like other observation data as discussed above.

Maturity:

- *Current standards:*
    - Extensive guidance exists in FHIR US Core and QI Core IGs for how to exchange device information (as observations, procedures)
    - SNOMED, LOINC, HCPCS terminologies are standardly used to code devices
        - i.e., Frailty Device, value set OID: 2.16.840.1.113883.3.464.1003.118.12.1300
        - i.e., https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/DMEPOS/Downloads/FINAL-RULE-MASTER-LIST-of-DMEPOS-Subject-to-Frequent-Unnecessary-Utilization-2018-03-30.pdf
- *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 to ensure patients receive the support they need during the continuum of care. Device use information is used for prior authorization activities, as many DMEPOS require prior authorization.

6. Data Class: Orders

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

Rationale: End of life care orders are especially critical for care coordination and care decision making. This concept may be used to share relevant information required to support a transfer of care request from one practitioner or organization to another that provides end of life care services, which often happen at different organizations. Interoperability of these orders would also allow orders to move more easily between organizations, facilitating patient choice.

CMS also continues to support inclusion of the broader Orders data class to capture and exchange all orders for medical services (service requests). This information confirms appropriate and high-quality care is provided in quality measurement, is relevant information required to support a referral or a transfer of care request from one practitioner or organization to another, and is used for prior authorization activities.

Maturity:

- *Current standards:*

    - Orders can be exchanged in mature FHIR standards, including Service Request profile included in QI Core.
    - 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).

7. Other priority areas

A. **Disability Status Information:** Capturing data related to disability status is critical for care. Exchange of this information nationwide fosters management of patients with disability to ensure all receive appropriate care. We recommend ONC support the exchange of disability status data via the USCDI. Disability status can be captured in standardized fields related to existing data elements in USCDI: Problems, Devices Used, and via the proposed USCDI data class, Functioning.

   FHIR allows for concepts related to disability data to be exchanged in many standardized formats, including the patient profile disability status extension in QI Core IG, and via LOINC and SNOMED terminology (i.e., Disability Status value set (OID: 2.16.840.1.113762.1.4.1099.49)). This allows for flexibility in the definition of disability used across use cases (e.g., defining disability using frailty and/or functional status vs. defining disability based on qualifying status for disability programs, such as social security), while still allowing for data capture and exchange to occur in a standardized fashion. We recommend ONC add the Functioning data class to the USCDI to support exchange of this critical information and discussion around exchanging disability status information via USCDI data classes and elements.

B. Advanced Directives orders: CMS also supports the advancement of the Advanced Directives data class, identified as a priority area by the USCDI Task Force. This complements the above submission regarding end-of-life care orders to ensure all receive appropriate and respectful patient care.

Thank you for the opportunity to provide comment and priority data element recommendations. 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.