

USCDI Draft Version 2 Public Comment

CMS understands the purpose of the USCDI as defining a foundational set of electronic health information, detailed as data classes and elements, for interoperable health exchange to better patient care. CMS sees value in aligning this foundational set of data required for interoperability with data required for quality measurement across CMS quality programs, which has the same aim, of bettering patient care for all beneficiaries and addressing equity in care quality. By aligning data requirements for multiple purposes, and utilizing the USCDI as the single home for standardized, interoperability requirements, there is the opportunity to minimize confusion and deduplication and focus the entire stakeholder community efforts and resources at a common goal. This can create an interoperable ecosystem of high quality data while at the same time improving coordination of care and patient experience.

With these goals in mind, CMS believes there are still gaps in key data classes/elements in USCDI draft version 2, which we feel are critical for interoperability and sharing usable data. These include key data for addressing health equity and being able to react to emerging public health crises. The criteria used by ONC to make decisions on draft version 2 including addressing significant gaps and limiting to elements that only require modest standard development and implementation efforts due to the pandemic are useful guiding principles. However, we urge ONC to add several other data classes to USCDI version 2 that are critical for quality, equity and preparedness. All of the data classes and data elements we recommend were submitted by stakeholders for consideration, classified as Level 2 by ONC, and are readily available in most EHRs, but ONC did not add them to USCDI draft version 2.

Priority data classes and elements we urge ONC to add to USCDI version 2

We agree with the addition of the **Encounter Information Data Class** to USCDI version 2. However, we recommend ONC also add the following data elements, which ONC classified as Level 2: **encounter (discharge) disposition, encounter location**. These encounter-level data elements provide important information for interoperability and coordination of care, and provide context for recent encounters/transfers that impact patient care and care decisions. These two additional data elements are well defined in EHRs, well defined by standard terminology (specified in FHIR US Core IG Encounter profile), and we do not believe inclusion would add additional burden to providers/vendors.

In addition, we believe data elements needed for attribution are critical for inclusion in this set of core data for interoperability. These include: **Medicare patient ID (MBI), Provider/Facility ID (NPI, TIN, CCN), and Health insurance coverage type**. These data elements provide context to other data which are important for making them usable, and attributing the data back to patients, their providers, and their insurance providers. Making these attribution data elements interoperable also allows for connecting EHR data to a broader set of public health and equity data, including social determinants of health (SDOH) information gathered by other healthcare, state, local and tribal public health and social service organizations, and community-based organizations that can be merged and leveraged to evaluate and address disparities and address critical health issues as they arise, including COVID and emerging public health crises. Again, we feel these data elements are already well defined in EHRs and defined in standards (including FHIR), and regularly being shared already with CMS/payers and other healthcare providers. We recognize that provider ID was added to USCDI draft version 2, however we recommend adding applicable standards requirements to the data element to ensure the data is usable and expanding the data element to include facility ID as well (standards should include NPI, TIN, and CCN).

Another notable gap in USCDI draft version 2 is **patient reported information/outcomes data**, which represents a critical data source (the patient) that should not be overlooked when considering interoperable data. Data reported by the patient provides unique and important context about the patient and their health status, and has increasingly been identified as critical information to consider during care. If these data are not made interoperable, we miss an opportunity to share and use this data source to improve care and outcomes. Patient reported information can be defined as structured data captured that comes directly from the patient, related to the status of a patient's health condition, for example survey data captured from an instrument (PROMIS or HOOS, JR and KOOS, JR). This concept seems to be represented in both USCDI version 2 submissions related to observation codes/values and questionnaires (captured by way of an observation or a questionnaire/questionnaire responses). Although these data may be less standardized than other data requested for USCDI consideration, we believe this is an area where the requirements should push the digital capture and standardization of the data forward, as it is widely considered important across the healthcare stakeholder community. Additionally, there has been significant progress made in FHIR standards to represent this data, which can be used to guide applicable standard requirements.

Finally, **healthy equity information** is now more than ever centrally considered for use cases across the healthcare space to address social risk and disparities. **Social determinants of health (SDOH)** data class should be added to the USCDI to drive forward standard capture of this critical data. We specifically urge inclusion of the SDOH data class based on the work the HL7 Gravity Project has been completing.

Additional data classes and elements we strongly suggest ONC consider for USCDI version 2

In addition to the data classes and elements noted above, CMS also recognizes the importance of additional clinical data that would enhance the health information exchange ecosystem, and data that ultimately provides context to healthcare providers that can improve patient care. These data are already routinely captured in the EHR during the course of care, and there are standard terminologies and data models available. We urge ONC to also consider the addition of the following data elements:

- 1. Medication data elements:** addition of medication administered, discharge medications, medication dispensed, medication dosage/route, medication negation rationale (reason not given), to enhance the Medication data class already included in USCDI v1. These concepts are represented in the following FHIR resources: MedicationRequest, MedicationAdministration, and MedicationDispense.
- 2. Observations with results (values) (clinical assessments, diagnostic studies/exams):** specifically, observation codes, values, timing, and categories (i.e. FHIR `observation.category[exam]`) that represent discrete clinical observations. This may include screenings (i.e. depression screening), and diagnostic exams (bone density scan, eye exam).
- 3. ICD-10-CM terminology for problems:** this terminology was added to encounter diagnosis in USCDI draft version 2, and ICD-10-PCS is included as an optional terminology for procedures; we therefore recommend adding this terminology to 'Problems' data element as well, to align with the other related data element requirements and to represent a commonly used terminology.
- 4. Orders:** orders (service requests) for healthcare services. Specifically, we recommend including orders for comfort measures/hospice, medication orders, device orders, diagnostic study/exam orders, laboratory orders, and procedure orders. These can be represented by FHIR resources `ServiceRequest`, `DeviceRequest` and `MedicationRequest`. Requiring interoperability of these data elements would greatly enhance CMS', providers', and other payers' ability to leverage data

routinely collected in EHRs to better support and assess patient-centered high quality coordinated care, and equity and access to care, to the benefit of patients.

5. **Devices used (applied)**: specifically, discrete codes for devices used by a patient. This may include mobility devices, wearable devices, and implantable devices. This can be represented by the FHIR resource DeviceUseStatement.

Thank you for your consideration

CMS supports a broader vision for the USCDI, where the standard serves as the central mechanism for exposing usable, standardized interoperable data for multiple use cases, including quality measurement. We are committed to working collaboratively with ONC to ensure the USCDI meets stakeholder needs. We specifically urge ONC to add additional data elements to USCDI version 2 that are critical for data sharing and addressing emerging public health needs as well as health equity, highlighted in this comment response. We refer back to CMS's original USCDI submission for more details regarding applicable standards for the data elements and classes highlighted in this public comment. We believe these USCDI standards can add value to the system, and serve as the single home for standardized data requirements that can propel interoperability and better access to digital data across the system. We look forward to continued conversations with ONC to further this work.