



March 25, 2022

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Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW, 7th Floor Washington, DC 20201

Dear Dr. Tripathi:

Thank you for the opportunity to comment on the draft version 3 of the US Core Data for Interoperability (USCDI). The Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) rely on standardized data to assess quality of care, track health problems, and promote actions that safeguard the health of individuals across the nation. We appreciate the Office of the National Coordinator's (ONC) leadership in this space and strongly support USCDI's role as a central mechanism to identify and implement a foundational set of electronic health information for interoperable health data exchange. We were pleased to see that version 3 includes several priority data elements that are essential to both improved public health and healthcare quality data, including health insurance information, pregnancy status, disability status, laboratory specimen type, and occupation.

While both of our respective agencies will be providing independent feedback on USCDI version 3, this letter reflects a subset of shared, priority elements CMS and CDC jointly recommend should be included in version 3. **These recommended elements reflect joint priorities for our two agencies, including:**

- **Alignment:** Data that allow for alignment of standards requirements with CDC and CMS priorities, which is critical to support ongoing national promotion of an interoperable learning health system supported by a national data ecosystem. These priorities include:
 - **Patient Safety:** CDC and CMS [have publicly committed](#) to building a safer, more resilient health system¹, which we define as including both healthcare and public health.
 - **Public Health Emergencies:** The COVID-19 pandemic demonstrates our need to modernize and standardize how data are captured and exchanged across the health system.
 - **Health Equity:** Measuring healthcare disparities is a cornerstone of our shared approach to advancing health equity across the health system—and this cornerstone, in turn, must be grounded in standardized, interoperable data².
- **Interoperability:** Data elements that are critical to public health surveillance and quality measurement, but that also have broad relevance to a myriad of use cases, have the potential to enhance the USCDI goal of interoperable health information exchange to support patient care.

¹ A resilient health system uses data to protect patients and fosters greater assessment, transparency, inclusion, and learning within and across the health system.

² [Digital Inclusion as Health Care — Supporting Health Care Equity with Digital-Infrastructure Initiatives | NEJM](#)



- **Data Context:** Data elements that add context and utility to the other data already included in the USCDI. Interoperable data are not useful unless there is sufficient context to those data. Data elements that provide context promote utility and usability of data to improve patient care.

CMS and CDC strongly recommend the following data elements be added to USCDI version 3. Please refer to [Appendix A](#) for additional detail on CMS and CDC use case examples and [Appendix B](#) for a patient scenario example highlighting the importance for interoperability of these data:

1. [Facility Level Data: Facility Identifier](#)

- A facility, or organizational, identifier is critical for providing context for granular patient data and supports tracking data back to organizations. Facility identifiers are used for billing, support data aggregation across sources, as well as attribution. All of these activities are necessary for providing high quality care to patients, reducing disparities, and promoting interoperability and communication. Facility identifiers are also critical for public health surveillance and public health emergency activities.

2. [Medications:](#)

- We recommend the following elements be added regarding medications:
 - Medications Prescribed;
 - Medications Dispensed;
 - Medications Administration/Medication Administered Code;
 - Discharge Medications;
 - Dosage
- Management of medications is critical to patient care and coordination between providers, as well as related quality and public health enterprises. Understanding the context of medications is critical for patient safety and supports advancing health equity, as adverse drug events, opioid use and misuse, and medication access represent critical areas for improvement.
- We recognize concerns have been expressed about the readiness of these data elements for inclusion in version 3. We believe they meet the stated criteria for version 3, and we look forward to engaging with ONC to address the concerns expressed by the Interoperability Standards Work Group (ISWG). We support the use of subgroup committees within the ISWG to advance these more complex data elements.

3. [Medical Device or Equipment: Devices Used \(applied\)](#)

- Devices used, defined as discrete codes for types of devices used by patients (e.g., mobility devices, wearable devices, and implantable devices), provide information that must travel with a patient to ensure safe and high-quality care. Information about devices used or required by patients also advances health equity in complement to the Disability Status data element (added to USCDI draft version 3).

4. [Observations: Observation Code and Value](#)

- Clinical observations are an essential structure for recording different kinds of health information, with results informing clinical care and condition management decisions. Discrete clinical observations (codes and values) are used extensively for quality measurement and public health monitoring efforts.



5. Clinical Notes: Surgical Operation Note

- USCDI draft version 3 currently includes Procedure Notes that are limited to non-operative procedures. We urge ONC to expand these notes to also include the surgical operation note (LOINC 11504-8). Surgical notes are important to ensure patient access to data and capture interoperable information critical to patient safety, care coordination and hand-offs.

Finally, we urge ONC to consider reclassification of the following important data elements from Comment Level and Level 1, as they are critical data for consideration in future USCDI versions. We are committed to working to advance these data element alongside our ONC partners.

1. Encounter Information: Encounter Identifier

- Encounter identifiers are another critical data element that provides context to data and supports linking data, distinguishing between encounters, as well as tracking of data. All of these activities are important for supporting interoperability, public health reporting, and quality measurement. Furthermore, encounter identifiers can support public health emergency activities.

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

- Orders for end-of-life care (comfort care, palliative care, hospice) include information that is yet to be represented in USCDI that actionably communicates an individual's wishes at their end of life. 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.

We thank you again for the opportunity to provide comment on USCDI draft version 3 and look forward to engaging with ONC on this effort. We strongly recommend the addition of these critical data elements to USCDI version 3 and future USCDI versions to: advance interoperability and useability of data; enhance quality measurement and public health surveillance; improve patient safety and sufficient public health emergency preparedness; and increase health equity. We also look forward to engaging with ONC on the USCDI+ use cases for quality measurement and public health, and encourage efforts to maintain alignment across the USCDI and USCDI+ use cases.

Thank you,

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Appendix A. CMS and CDC Use Case Examples

Data Element	Description	CMS and CDC Use Examples	Related Standards
Facility Level Data: Facility Identifier	Facility/organization-level data is associated with laboratory tests (the testing facility), as well as health care provider locations including hospitals, ambulatory providers, long-term and post-acute care, and pharmacy providers. Facilities/organizations often have more than one identifier.	<ul style="list-style-type: none"> ○ CDC: Location data is used to support reporting of data for public health and emergency response (e.g., situation awareness reporting, electronic laboratory reporting, electronic case reporting). See https://build.fhir.org/ig/HL7/fhir-saner/ for details. ○ CMS: CMS prioritizes exchange of CMS Certification number (CCN), Provider Transaction number (PTAN), and National Provider Identifier (NPI)—unique identifiers for a healthcare organization. These identifiers are used for attribution in nationwide quality measurement. 	<ul style="list-style-type: none"> ○ Identifiers can be exchanged via the FHIR® US Core Organization profile.
Medications: <ul style="list-style-type: none"> ● Medications Prescribed; ● Medications Dispensed; ● Medications Administration/Medication Administered Code; ● Discharge Medications; ● Dosage 	The current concept of medications in USCDI draft version 3 does not differentiate those that are active, ordered, dispensed, or administered to the patient (in inpatient settings); nor does it provide the necessary details related to dose and route for optimizing patient safety. A list of medications only, as currently specified in USCDI, does not allow for the important contextual details to be understood.	<ul style="list-style-type: none"> ○ CDC: These data elements improve the ability to identify and evaluate national trends that pose potential threats to patient or public health, benchmark performance, and direct multi-level (e.g., community, facility, provider, patient) response efforts. ○ CMS: Medication data elements support quality measurement to identify appropriate administration, dispensing and management of medications, including opioids. 	<ul style="list-style-type: none"> ○ These data elements are specified in the FHIR US Core and QI Core Implementation Guides: MedicationRequest, MedicationAdministration, MedicationDispense.



USCDI Version 3 CMS-CDC Joint Recommendations



Data Element	Description	CMS and CDC Use Examples	Related Standards
Medical Device or Equipment: Devices Used (applied)	Information related to devices used by patients – specifically types of mobility, wearable and implantable devices – is critical information that must travel with a patient to ensure safe, effective care.	<ul style="list-style-type: none"> ○ CDC: Device information related to self-monitored blood pressure monitors, glucometers, and pulse oximetry meters are used throughout public health reporting. ○ CMS: Device data are used for quality measurement to support identifying frailty and advanced illness and also for prior authorization activities related to Durable Medical Equipment, Prosthetics/Orthotics & Supplies (DMEPOS). 	<ul style="list-style-type: none"> ○ Devices used are captured and can be exchanged in standardized terminology: SNOMED, LOINC, and HCPCS.
Observations: Observation Code and Value	Clinical observations, an essential structure for recording many kinds of health information, provide additional patient-centered information that needs to be interoperable to support appropriate clinical care and condition management decisions. Observations can capture important information to support advancing health equity, patient safety, and patient satisfaction.	<ul style="list-style-type: none"> ○ CDC: Observation elements are used for capture of information related to death (e.g., cause of death, location of death, autopsy performed) and pregnancy (e.g., pregnancy status, pregnancy outcome). ○ CMS: Discrete observations with associated codes and values are used extensively in CMS quality measurement for clinically administered assessments (for example, a pain scale rating), and screenings (for example, a tobacco use screening). 	<ul style="list-style-type: none"> ○ Observation data can be exchanged via the FHIR QI Core Observation profile. ○ Can be exchanged in standardized terminology: LOINC and SNOMED.
Clinical Notes: Surgical Operation Note	USCDI Draft version 3 includes Procedure Notes that are limited to non-operative procedures; surgical operation notes should also be included.	<ul style="list-style-type: none"> ○ CMS: Represents important data patients should have access to, and is critical for care coordination activities. 	<ul style="list-style-type: none"> ○ Exchanged via LOINC 11504-8.
Encounter Information: Encounter Identifier	Identifiers are unique numeric or alphanumeric string datatype associated with the episode of care (so it does not need a Value Set of answer options from a specified Code System).	CDC and 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	<ul style="list-style-type: none"> ○ CDC and CMS believe that the current state of “standardization” is sufficient to support the stated uses cases but are



USCDI Version 3 CMS-CDC Joint Recommendations



Data Element	Description	CMS and CDC Use Examples	Related Standards
		<p>data exchanged – e.g., did this data come from two distinct encounters or the same encounter—and enables linking those shared data with other relevant information.</p> <ul style="list-style-type: none"> ○ CDC: Encounter identifiers link data sets required to report events and episodes of care tracked by public health. ○ CMS: Encounter Identifiers are submitted for CMS electronic clinical quality measures (eQMs) to support distinguishing between episodes of care when multiple episodes of care are submitted for a quality measure. 	<p>committed to working with ONC on further standardization and/or guidance to decrease identifier variation and enhance usability, if deemed necessary.</p> <ul style="list-style-type: none"> ○ Unique encounter Identifiers are routinely captured and included in Clinical Document Architecture (CDA) and FHIR standards. ○ FHIR US Core Implementation Guide includes Encounter.Identifier, specifying a system and a value (although all the systems may define the identifiers differently). It is a “must support” element in the profile.
<p>Orders: Orders for End-of-Life Care</p>	<p>Orders for end-of-life care, specifically for hospice, palliative care, and comfort care, represents a priority data concept that is not yet represented in USCDI and must be prioritized to enhance patient care/wishes and interoperability.</p>	<ul style="list-style-type: none"> ○ CMS: End-of-life care information is used to support appropriate inclusion/exclusion of patients in CMS quality measures. 	<ul style="list-style-type: none"> ○ Orders for specific end-of-life care are typically structured and can be exchanged via ServiceRequest FHIR resource. ○ Can be exchanged in standardized terminology: LOINC and SNOMED.

Appendix B. Patient Scenario Example

To illustrate the importance of the CMS and CDC recommended data elements, and how they support the priorities specified, the following scenario shows how they apply in the real world:

A 72-year-old black woman was hospitalized due to complications from COVID-19 after her wife called 911 due to extreme difficulty breathing. The woman believes she contracted COVID-19 at a different hospital, where she recently had surgery to remove a large liver tumor (metastatic colorectal cancer) that had been shrunk to a resectable size using chemotherapy (a combination of cisplatin, 5-fluorouracil and doxorubicin) through hepatic artery infusion, which involves implanting a pump inside the patient that delivers chemotherapy directly to the tumor in the liver. She had multiple co-morbid conditions, including type 2 diabetes, hypertension, sickle cell disease, and metastatic colon cancer, and was prescribed multiple medications for those conditions, including metformin 500 mg p.o. b.i.d. for diabetes, amlodipine-valsartan 10 mg-160 mg p.o. q.d. for hypertension, and Oxbryta® (voxelotor) 1500mg p.o. q.d. for sickle cell disease. She was having trouble paying all the co-pays for her prescriptions, so she decided not to pick up her most recent bottle of Oxbryta® from the pharmacy since it was the most expensive co-pay. She also currently uses a wheelchair due to declined balance and mobility following chemotherapy.

As a result of the chemotherapy and subsequent surgery, her immune system was weakened. Her condition worsened four days into her hospitalization – respiratory rate averaged 38 breaths/min, SaO₂ was at 83%, and blood lactic acid came back at 2.5 mmol/L. She was transferred to the ICU and put on a ventilator³. She had been administered a prophylactic dose of heparin when she was first admitted to help prevent venous thromboembolism (VTE), but now that she needed supplemental oxygen and mechanical ventilation, her dose was increased to a therapeutic dose of heparin and 6 mg i.v. dexamethasone was added to inpatient medications.

In case her cancer situation worsened, the patient was involved with palliative care at the hospital where she had her tumor resection. Her wife mentioned this to her care team in hopes that the information was communicated to the current hospital. About 20 days after being transferred to the ICU, the patient's condition started improving, and she was transferred back to the floor. She was having pain in multiple areas of her body, likely due to her cancer treatment followed in short course by her hospitalization for COVID-19. A pain-intensity assessment was completed to assess the patient's pain. She was prescribed and administered i.v. p.r.n. codeine for the pain while in the hospital. After about five more days, she was discharged. Her discharge instructions included the use of p.o. (oral) p.r.n. codeine if she had continued pain. Within 1 day, however, she fainted and hit her head hard on the ceramic tile floor in her kitchen. Her wife once again called 911, where the patient ended up in the same hospital where she was previously treated for COVID-19. This time, unfortunately, she died soon after arrival in the emergency department.

³ <https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/hospitalized-adults--therapeutic-management/hospitalized-adults-figure/>



How this patient scenario related to the CMS and CDC joint priorities:

This patient's data needed to be accessible by and exchanged between multiple providers and healthcare organizations, and also reported in multiple ways by those entities, to support appropriate, high quality, and safe care. Interoperability of this data, in standardized formats, is essential.

For Public Health Reporting—The highlighted data elements are among those required for reporting from the healthcare organization to state and local health departments and/or CDC, and they must be reported, at minimum, for opioid use⁴, COVID-data (including NHSN⁵ and eCR⁶), central cancer registry reporting⁷, and mortality reporting⁸.

For Quality Measure Reporting—In order to measure appropriate and high-quality care is received by this patient, and all patients, CMS uses the highlighted data elements in its quality measures. For example, the following measures⁹ may relate to this patient:

- **CMS 157: Oncology: Medical and Radiation - Pain Intensity Quantified** (Observation codes and values)
- **CMS190: Intensive Care Unit Venous Thromboembolism Prophylaxis** (Medication administration, order for end-of-life care, devices used [applied])
- **CMS 506: Safe Use of Opioids - Concurrent Prescribing** (Discharge medications, medications prescribed/ordered)
- **CMS156: Use of High-Risk Medications in the Elderly** (medication dispense, dosage)

⁴ <https://www.cdc.gov/drugoverdose/od2a/surveillance.html>

⁵ <https://www.cdc.gov/nhsn/ltc/covid19/index.html>

⁶ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/electronic-case-reporting.html>

⁷ <https://www.cdc.gov/cancer/npcr/index.htm>

⁸ <https://www.cdc.gov/nchs/nvss/deaths.htm>

⁹ <https://ecqi.healthit.gov/>