

CMS-CCSQ Submission for United States Core Data for Interoperability (USCDI) Version 4

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U.S. Department of Health and Human Services
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Dear Dr. Tripathi:

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 the United States Core Data for Interoperability (USCDI) version (v) 4 consideration. CMS encourages continued expansion of the USCDI to include high priority data elements necessary to support nationwide interoperability. This expansion will support clinical care, care coordination and quality improvement, while easing the burden of quality measurement. We are committed to continuing our collaborative work with the Office of the National Coordinator for Health Information Technology (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 continue to urge ONC to add additional data elements outlined below to the USCDI v4 which support high priority areas identified by ONC, including: mitigating health and healthcare disparities; addressing the needs of underserved communities; and addressing public health interoperability needs. We have also entered comments for each recommendation in the ONC New Data Element and Class (ONDEC) system. The elements highlighted have continued to be CMS priority, previously raised for consideration for prior USCDI versions.

1. Data Class: Facility Level Data/Organization

- A. Data Element: Organization/Facility Identifier;** defined as unique identifiers for a healthcare organization. CMS specifically prioritizes exchange of CMS Certification number (CCN), Provider Transaction number (PTAN), National Provider Identifier (NPI), and Clinical Laboratory Improvement Amendments (CLIA) number, and supports the Interoperability Standards Work Group (ISWG) and Health Information Technology Advisory Committee (HITAC) recommendations on the draft USCDI v3 (from April 13, 2022).

Rationale:

A facility, or organizational, identifier is critical for providing context for granular patient data and supports tracking data back to organizations—this type of contextual data element ensures usability of interoperable clinical data. Facility identifiers are used for billing, support data aggregation across sources, as well as attribution. They can also support exchange of data between hospitals and post-acute care providers. All of these activities are necessary for providing high quality care to patients, reducing healthcare

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inequities and disparities, and promoting interoperability and communication – all ONC stated priorities for the USCDI. Facility identifiers were also previously identified as a joint CMS-Centers for Disease Control and Prevention (CDC) priority as a critical element for public health reporting, surveillance and emergency response – an ONC stated priority for USCDI v4. For example, CDC and CMS rely on facility identifiers to measure the incidence of healthcare associated infections and other patient safety events in facilities, and to direct technical assistance and quality improvement support to underperforming facilities. Furthermore, the ISWG recommended this element for final USCDI v3, and received HITAC support, noting the need for an identifier combined with an assigning authority.

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

- *Current standards:*
 - Health Level Seven International (HL7) Fast Healthcare Interoperability Resources (FHIR) US Core Implementation Guide (IG) STU3-STU5 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, NPI, and CLIA numbers are exchanged across the nation for CMS reporting to appropriately attribute outcomes and measure results. They are used extensively for electronic clinical quality measure (eCQM) reporting, linking data sources for quality measurement, and for post-acute care reporting and payment purposes. Facility identifiers are also used extensively for electronic case reporting (eCR) and electronic lab reporting (ELR) and are critical for public health agencies ability to monitor the spread of reportable conditions. Exchange of organization identifiers supports facility-specific quality, prior authorization activities, and other assessments that are limited without this information. Additionally, there is active work underway to create an IG for healthcare directories ([HL7.FHIR.US.DIRECTORY-EXCHANGE\Home - FHIR v4.0.1](#)) as part of the FAST Da Vinci accelerator initiative, which includes the critical organization and provider identifiers necessary to appropriately use and attribute exchanged data. Among other purposes, organization identifiers are also used to support public health use cases, including electronic case reporting and emergency response activities. For instance, during the early COVID-19 pandemic phase, there was insufficient data tracking across organizations, further complicated by the need to track emergency response resources across individual facilities. Exchange of facility/organization identifiers can mitigate such delays in emergency response activities.

2. 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 urges 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—we continue to support the concept of a USCDI Task Force to appropriately specify and advance this important data class. The highlighted additional data elements serve the ONC USCDI v4 stated priorities related to mitigating health inequities and disparities, addressing needs of underserved populations, and addressing public health reporting needs. 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 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. These detailed medication data were also previously identified as a joint CMS-CDC priority area as they are used extensively in quality measurement and public health—for example, to monitor and respond to antibiotic prescribing patterns that facilitate the emergence of drug-resistant pathogens, but also exposes patients to needless risk for adverse effects. They are also routinely exchanged when prior authorization is required.

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

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- *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. Medication data are used extensively in CMS quality measurement and public health for surveilling national trends. 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. 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.

3. 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. These data elements were widely supported during USCDI v3 consideration and recommended by the ISWG and supported by HITAC.

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

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- 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. The information is 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. CMS also uses sex and gender information for quality measurement and continues to support Gender Harmony project efforts, reflected in this recommendation.

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 and/or underserved populations. The values for this data element are self-reported and not clinically determined, which allows for better representation of diversity. The ISWG supported the expansion of the Gender Identity data element with the Gender Harmony Project’s minimum value set in addition to the two fields from USCDI that add critical data, for which CMS supports.

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) 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. The information is 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. CMS also uses sex and gender information for quality measurement and continues to support Gender Harmony project efforts, reflected in this recommendation.

4. Data Class: Vital Signs

A. Data Element: Vital signs results: Date and timestamps; defined as associated, or clinically relevant, date and timestamps for required vital signs.

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Rationale: The date and timestamp metadata associated with vital signs already included in USCDI provide the critical context to making the vital sign information usable for patient care, care coordination, public health tracking, and quality measurement. Specifically, the clinically relevant date/time (i.e., FHIR US Core Vital Sign Profile effective[x]) is essential clinical information. We request ONC add date and timestamp data elements to USCDI, or further clarify which types of date/timestamps (i.e., administered, occurred, resulted, issued/entered) for which elements are required under the existing Provenance Author Time Stamp element.

Vital sign information must be usable (i.e., includes the appropriate metadata) to support critical use cases identified as ONC USCDI v4 priorities including addressing needs of historically vulnerable and/or underserved populations, mitigating health inequities, and addressing public health interoperability needs. By adding date and timestamp elements for vital signs, ONC can also ensure data elements necessary to calculate a clinical average (i.e., average blood pressure) are available for specific use cases, without adding any substantial burden on vendors or implementers, as this metadata should already be routinely captured. Additionally, CMS uses this information extensively in quality measurement to define appropriate measurement populations and numerator events to support improving patient care.

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

- *Current standards:*
 - HL7 FHIR US Core Implementation Guide STU3-STU5 based on FHIR R4, Vital Signs profiles; must have a clinically relevant time (dateTime) structured in a standardized format (<http://hl7.org/fhir/R4/vitalspanel.html>); [HL7.FHIR.US.CORE\US Core Vital Signs Profile - FHIR v4.0.1](#))
- *Current uses, exchange, and use cases:* This data element has been used at scale between multiple different production environments to support the majority of anticipated stakeholders. Date and timestamps for vital signs are critical pieces of information exchanged with test results for clinical care and care decision support. A result itself is not useful unless the context of the timing of that result is also available. Vital sign date/time metadata is electronically exchanged for quality measurement used across CMS programs.

5. 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 was previously identified as a joint CMS-CDC priority and supports advancing patient care

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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 eQMs across programs. The information is important for quality improvement, clinical decision support, and care coordination to ensure patients are provided the proper end-of-life care as needed. 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.

6. 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. This element was previously identified as a joint CMS-CDC priority, and the recommendation aligns with the ISWG recommendation for USCDI v3 to include all note types coded in the LOINC Document Ontology, or at least the Surgical Operation Note (LOINC 11504-8) and Tumor Board Notes. 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

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- *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 (new data element); defined as the summary of a patient’s interval status during an emergency department encounter, including narrative and free text data.

Rationale: Clinical notes provide important clinical information necessary for care coordination and patient care. Specifically, 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. Additionally, this recommendation aligns with the ISWG recommendation for USCDI v3 to include all note types coded in the LOINC Document Ontology.

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.

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.

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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. Vaccine efficacy analyses use this information to determine immunization population coverage. Statistical analyses help to identify underserved populations so that resources are redirected appropriately and used efficiently. This 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=2.16.840.1.114222.4.5.293> HL7 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. Immunization information may not directly provide disparity information, but it is needed together with other disparity-related data (e.g., race, ethnicity, location) to identify vaccine breakthroughs or problems with vaccination access/coverage which may also speak to broader health disparities related to general access to medical care and services. This data is particularly important for COVID-19 reporting. 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. Data Class: Encounter Information; Data Element: Encounter Identifier; defined as unique numeric or alphanumeric string datatype associated with the episode of care.

Rationale: CMS-CCSQ recommends reclassification of this data element to Level 2 and continues to find value in the addition of the data element to USCDI. This data element was previously identified as a CMS-CDC joint priority. Encounter identifiers are critical for providing context to other clinical data and supporting linking of data across care settings, distinguishing between encounters, as well as tracking of data, including between acute, post-acute and other care settings. All of these activities are important for supporting interoperability, quality measurement, and public health reporting. Furthermore, encounter identifiers (IDs) can support public health emergency activities, which is a stated ONC USCDI v4 priority.

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Maturity:

- *Current standards:*
 - HL7 FHIR US Core Implementation Guide STU4, STU5 based on FHIR R4, Encounter Profile must support an encounter identifier (<https://www.hl7.org/fhir/us/core/StructureDefinition-us-core-encounter.html>)
 - Although there is no universal formatting standard for encounter IDs, the current state of “standardization” is sufficient to support the stated uses of linking and contextualizing data.
- *Current uses, exchange, and use cases:* CMS recognizes 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 eQMs to support distinguishing between episodes of care when multiple episodes of care are submitted for a quality measure. This data element is also used for public health reporting.

B. Advanced Directives: CMS continues to support the advancement of the Advanced Directives data class, previously identified as a priority area by the USCDI Task Force and CMS. This complements the above submission regarding end-of-life care orders to ensure all patients receive appropriate and respectful care. Advanced directives guide transitions and delivery of care that closely align with patient values that improves patient satisfaction. This information is routinely captured in patient or encounter summary documents. Information about patient-document goals and preferences is important for clinical decision support and care coordination.

We thank you for the opportunity to provide comments and priority data element recommendations for USCDI v4. We look forward to continued engagement with ONC and strongly recommend the addition of these critical data elements to USCDI to support advancement of interoperability and useability of the data; improved patient care; and enhanced quality measurement. 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.

Thank you,

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