



April 17, 2023

Micky Tripathi, PhD MPP
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 4 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 are strongly committed to collaborating with ONC in your effort to identify and implement a foundational set of electronic health information for interoperable health data exchange. We were pleased to see that Draft version 4 includes several priority data classes and elements that are essential to both improved public health and healthcare quality, including encounter identifier, facility information, laboratory data elements, treatment intervention preference, care experience preference, and average blood pressure.

While both of our respective agencies will be providing independent feedback on USCDI Draft version 4, this letter reflects a subset of shared, priority elements CMS and CDC are jointly recommending for inclusion in version 4. **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 continue to publicly commit to building a safer, more resilient health system¹, which will include both healthcare and public health.
 - **Public Health Emergencies:** The COVID-19 pandemic demonstrates the need to modernize and standardize how data are captured and exchanged across the health system.
 - **Health Equity:** Healthcare disparities measurement remains imperative to the mitigation of health and healthcare disparities across the health system—and must be grounded in standardized, interoperable data².
- **Interoperability:** Data elements critical to public health surveillance and quality measurement, with a relevance to a myriad of use cases will 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 data already included in the USCDI. Interoperable data prove useful when there is sufficient context to those data. Data elements that provide context can, therefore, promote utility and usability of data to improve patient care.

CMS and CDC strongly recommend the following data elements be added to USCDI version 4. Please refer to [Appendix A](#) for additional detail on CMS and CDC use case examples.

1. 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 does not differentiate among medications that are active, ordered, and actually administered/prescribed to the patient. Given these complexities, more clarity and structure are necessary in this data class to accurately evaluate and provide clinical care.
- We recommend the following elements be added regarding medications:
 - Medications Prescribed
 - Medications Administration/Medication Administered Code
 - Discharge Medications
 - Medication Administration Route
 - Medication Administration Dose
 - Medication Administration Date and Time
- We continue to urge adding more specificity to the USCDI Medications Data Class. These medication data elements are necessary for understanding adverse drug events, opioid use and misuse, and medication access.
- 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.

2. Surgical Operative Note

- Surgical notes are important to ensure patient access to data and capture interoperable information critical to patient safety, care coordination and hand-offs. Currently, the Procedure Notes data element is limited to non-operative procedures. CMS and CDC strongly recommend either expanding these notes to also include the surgical operation note or consider adding the distinct Operative Note data element to USCDI v4.

3. Vaccination Event Record Type

- 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.

4. Facility Address

- Together with the Facility Identifier, Name and Type, the Facility Address data element will supplement the core set of information necessary to identify facilities and link service and



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outcome data to a specific physical institution or facility. Currently, in the absence of a unique Organization/Hospital Identifier in the USCDI it can be difficult to differentiate specific service locations and link data or records for public health and healthcare purposes, such as monitoring hospital capacity and respiratory disease burden in acute care hospitals, identifying and responding to outbreaks in facilities, and tracking patient safety events. Accurate facility information, including name, address, and identifier, is essential to analyze facility level data and inform the allocation of resources such as therapeutics, supplies, staffing, and PPE to prepare for and respond to emergency events.

We also suggest that ONC take the following actions to clarify how several proposed or previously adopted data elements in USCDI are classified, defined, communicated, and standardized:

1. Sex

- CMS and CDC strongly support 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. 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.
- 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.

2. Encounter Location

- CDC and CMS recommend that this data element be updated to list the following applicable vocabulary standards on the primary page for the encounter data class and its constituent data elements (see: <https://www.healthit.gov/isa/uscdi-data-class/encounter-information>):
 - NHSN Healthcare Facility Patient Care Location (HSLOC): <https://www.cdc.gov/nhsn/cdaportal/terminology/codesystem/hsloc.html>
 - ServiceDeliveryLocationRoleType (HL7): <https://terminology.hl7.org/2.0.0/ValueSet-v3-ServiceDeliveryLocationRoleType.html>
 - SNOMED CT
 - Place of Service (CMS): https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set

3. Disability Status

- CDC and CMS recommend moving the current Disability Status data element from the Health Status Assessments data class to the Patient Demographics data class.
- Federal consideration of disability data as demographic has precedent. For example, the data collection standards established by the ACA include disability alongside many variables already included in the Patient Demographics data class, such as race, ethnicity, and sex, and by extension disability can be used when using demographic factors for stratification for equity.
- Collecting and transmitting data on disability in a standardized way alongside other demographic factors is vital to recognition of disability as a key component of identity and



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allows analysis of outcomes and conditions in an intersectional way, incorporating race/ethnicity, age, sex, and disability together for a more comprehensive understanding of patient demographics.

- CMS may additionally recommend a disability assessment data element in version 5 to qualify the disability type (e.g. functional, cognitive, physical, etc.).

4. Facility Type

- CDC and CMS agree that facility type should move forward as part of USCDI V4. The facility type element complements existing USCDI data elements, particularly “encounter location”, and provides contextual information for surveillance, compliance, and public health action. For example, information on facility type can help facilitate work to improve health equity by supporting efforts to identify, characterize, and take steps to respond to evidence of decreased or restricted access to care, inadequate care quality, and adverse outcomes.
- However, we also recognize that applicable standards for facility type vary in terms of granularity, maturity, breadth (examples include NUCC Healthcare Provider Taxonomy—Non-Individual; NHSN Facility Type; FHIR Location). To that end, we recommend that ONC also work with CDC, CMS, and other key healthcare and public health stakeholders to identify and evolve appropriate standards for Facility Type. Importantly, standards for facility type should be defined in ways that maintain clear differentiation from “encounter location” and associated standards

5. Average Blood Pressure

- CDC and CMS agree that Average Blood Pressure should move forward as part of USCDI V4. However, in the draft final USCDIv4 ABP data element description, ONC has defined ABP as “Mean value of two or more blood pressure readings in a specified time period.” CDC and CMS strongly recommend clarifying the language to say either “average” to eliminate any confusion end-users could have with using mean arterial pressure or “arithmetic mean” to differentiate between other types of means (e.g., geometric, harmonic).

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

1. Organization: Organization/Hospital Identifier

- Organization Identifiers complement and supplement Facility Identifiers, as the latter can sometimes be shared across facilities that are part of a single system (e.g., 9 hospitals sharing a single CCN). By Coupling the facility with an Organization ID that is unique to a specific location provides additional information that the providers, payers, and public health need to optimally track and respond to identifiable care quality, patient safety, and health outcomes issues in a specific location (e.g., outbreaks of infectious disease, medication errors)
- We are recommending reclassifying this data element to Level 2 for consideration for addition to future versions of USCDI. Organizational identifiers like NHSN OrgID are already widely used in critical national healthcare surveillance platforms, and these existing systems and associated standards provide a strong foundation for further application (e.g., quality measurement and public reporting).



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- CMS may also consider moving the CCN from the currently proposed Facility Information data class to the Organization data class if the Organization/Hospital Identifier data element is supported in version 5.

We thank you again for the opportunity to provide comment on USCDI draft version 4 and look forward to engaging with ONC on this effort. We strongly recommend the addition of these critical data elements to USCDI version 4 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 continuing to engage 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	Use Case Example	Related Standards
<p>Medications:</p> <ul style="list-style-type: none"> • Medications Prescribed • Medications Administration/Medication Administered Code • Discharge Medications • Medication Administration Route • Medication Administration Dose • Medication Administration Date and Time 	<p>The current concept of medications in USCDI draft version 4 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 route for optimizing patient safety. More clarity and structure are necessary in this data class to accurately evaluate and provide clinical care.</p>	<ul style="list-style-type: none"> ○ Public Health: Automated, electronic surveillance of antibiotic use in the United States requires standardized capture and transmission of multiple medication-related data elements not currently included in USCDI, including many of those listed here (e.g., administration route) ○ Quality: eQMs like Discharged with Antithrombotic Therapy or Discharged on Statin Medication require standardized capture and transmission of multiple medication-related data elements not currently included in USCDI, including many of those listed here (e.g., discharge medications) 	<ul style="list-style-type: none"> ○ These data elements are specified in the FHIR US Core and QI Core Implementation Guides: MedicationRequest, MedicationAdministration, MedicationDispense.
<p>Clinical Notes: Surgical Operation Note</p>	<p>Currently, the Procedure Notes data element is limited to non-operative procedures; expansion of procedure notes to also include the surgical operation note or addition of the distinct Operative Note data element should be considered.</p>	<ul style="list-style-type: none"> ○ Information captured in surgical notes provide critical data necessary for measurement of hospital quality and patient safety. Surgical notes information will also enhance care coordination and shared decision making. 	<ul style="list-style-type: none"> ○ Can be exchanged via LOINC 11504-8 or LG38755-1.
<p>Immunizations: Vaccination Event Record Type</p>	<p>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</p>	<ul style="list-style-type: none"> ○ Public Health: Immunization Information Systems (IIS) and other health IT systems rely on this information to automate processes for identifying, preventing, and resolving duplicate vaccinations, for example for COVID-19, thereby ensuring that a patient is vaccinated according to the ACIP schedule. 	<ul style="list-style-type: none"> ○ Can be exchanged via HL7 v2.5.1 and 2.8.2 Implementation Guides.



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Data Element	Description	Use Case Example	Related Standards
	<p>necessary to determine whether vaccinations are current, and whether any vaccinations need to be administered.</p>	<ul style="list-style-type: none"> ○ Quality: Providers rely on IIS for automated clinical decision support (CDS)—also known as evaluation and forecasting—to identify and indicate need for Hepatitis B or other, similar recommended immunizations for a given patient. As noted above, event record type is critical to ensure the accuracy of those recommendations. 	
<p>Facility Information: Facility Address</p>	<p>The Facility Address data element will complement the other Facility Information data elements such as Facility Name, Facility Identifier and Facility Type to provide the necessary information to identify specific physical institution or facility to link service and outcome data. In the absence of a unique Organization/Hospital Identifier in the USCDI, facility identifying information like name and address is critical to differentiate specific service locations and link data/records to for public health and healthcare purposes.</p>	<ul style="list-style-type: none"> ○ Public Health: Facility address information included as part of electronic case report enables swift, precisely targeted responses to C.auris outbreaks in hospitals and other facilities that may be geographically separate but operate under a single CCN. ○ Quality: CMS and other payers need facility address information to disaggregate reported performance on VTE prophylaxis (and other electronic measures of hospital quality and safety) by individual, geographically separate facilities that operate under a single CCN. 	<ul style="list-style-type: none"> ○ Specified in the FHIR US Core Location Profile.