USCDI Version 5 CMS-CDC Joint Recommendations

January 29, 2024

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:

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 the final USCDI v4 included several priority data classes and elements essential for improved public health and healthcare quality, including Facility Identifier, Encounter Identifier, and Average Blood Pressure. While both of our respective agencies provided independent recommendations for USCDI v5, this letter emphasizes CMS and CDC's common interest in the importance of patient safety being reflected in the USCDI standards.

Many people continue to be impacted by medical errors that occur in healthcare. CDC and CMS continue to publicly commit to building a safer, more resilient health system, which will include both healthcare and public health. In 2022, CMS launched the CMS National Strategy, an initiative to promote the highest quality outcomes and safest care for all individuals. One of the goals of the CMS National Strategy initiative is safety and achieving zero preventable harm. This CMS quality effort is further supported by Meaningful Measures 2.0. CMS' Meaningful Measures initiative also prioritizes measures that promote patient safety, with goals of reducing preventable harm, safety culture within a healthcare organization, and safety for special populations. Likewise, CDC is committed to making healthcare safer for all. CDC efforts focus on collaborating with partners to protect patients from an array of harms related to healthcare associated infections, antimicrobial resistance, vaccine and medication safety and blood, organ and tissue transplantation. CDC maintains the nation's largest reporting system for patient harms in the National Healthcare Safety Network or NHSN.

As an integral aspect of patient safety, medication management is critical to patient care and coordination between providers, and related quality and public health enterprises. In the outpatient setting, CDC estimates more than 1 million Americans are seen in hospital emergency departments for adverse drug events (ADEs) each year, with over one-quarter of these patients requiring further hospitalization and most ADEs attributed to therapeutic use of blood thinners and diabetes medications.[1,2]

[1] Budnitz, D., Shehab, N., Lovegrove, M., et al. *US Emergency Department Visits Attributed to Medication Harms, 2017-2019*, JAMA, 2021. 326(13):1299-1309.

[2] Shehab, N., Lovegrove, M., Geller, A., et al. *US Emergency Department Visits for Outpatient Adverse Drug Events, 2013-2014*, JAMA, 2016. 316(20):2115-2125

In hospitals, medications remain the most common causes of patient harm. The HHS Office of Inspector General estimated one-quarter of Medicare patients experienced patient harm during their hospital stays in 2018—43% of those harms were due to medications, with blood thinners and diabetes also among the top 5 causes of medication harm.[3]

CMS and CDC are taking critical steps toward fulfilling the promise of automated quality measurement and public health surveillance. NHSN has already laid the groundwork for fully automated (FHIR-based) ADE surveillance for one of the most common causes of hospital harm—medication-related hypoglycemia as part of a suite of patient safety measures relevant to CMS quality and CDC public health programs.[4] For these important efforts to be fully realized, it is imperative that the required data elements for quality improvement and public health be included in nationally recognized minimum healthcare data standards defined by USCDI.

The medications data class in USCDI is inadequate to support patient safety, quality improvement, or public health. The medication data elements do not differentiate among medications that are active, ordered, and 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 and promote patient safety. Medication administration, specifically, is a critical concept for CMS and CDC programs that support quality improvement and public health surveillance.

We continue to emphasize the need for greater specificity in the USCDI Medications data class, which was also discussed in the ISWG Recommendations on Draft USCDI v4 (April 12, 2023). Finally, CMS and CDC urge ONC to reconsider a Medications Task Force, as recommended by the ISWG during Draft USCDI v4 discussions, to ensure the USCDI Medications data class supports data elements necessary for patient safety within interoperability standards.

CMS and CDC strongly recommend the following Medications data elements be added to USCDI:

- Medication Prescribed Code (Level 0)
- Medication Administration (Level 2)/Medication Administered Code (Level 0)
- Discharge Medications (Level 0)
- Medication Administration Route (Level 2)
- Medication Administration Dose (Level 0)
- Date Medication Administered (Level 0)

In addition to the Medications data class, patient safety impacts most data classes within the USCDI. In particular, CMS and CDC want to emphasize data element gaps within the data classes of Immunizations, Laboratory, and Facility Information. We have submitted these gaps in our individual

[3] U.S. Department of Health and Human Services (HHS), Office of Inspector General. *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018*. Retrieved from: https://oig.hhs.gov/oei/reports/OEI-06-18-00400.pdf

[4] Centers for Disease Control and Prevention (CDC), National Healthcare Safety Network. *NHSNCoLab*. Retrieved from: https://www.cdc.gov/nhsn/nhsncolab/index.html

organizational letters for USCDI v5 but want to emphasize in this joint letter that these additions would promote patient safety. Identification of whether vaccinations are current and whether any vaccinations need to be administered using the Vaccination Event Record Type and Immunization Status data elements are vital to patient safety outcomes. Identifying facility information, such as Facility Address, is critical to differentiate specific service locations and link data/records for public health and healthcare purposes. Data on when and how laboratory specimens are collected are critical to proper test interpretation, and laboratories are required to receive these kinds of details per CLIA requirement.

We thank you again for the opportunity to provide priority data element recommendations for USCDI v5 and look forward to engaging with ONC on this effort. We strongly recommend the addition of these critical data elements to future USCDI versions to improve patient safety.

Thank you,

Michelle B. Schreiber -S
Digitally signed by Michelle B. Schreiber -S
Date: 2024.01.26 13:09:55 -05'00'

Michelle Schreiber, MD
Deputy Director of the Center for Clinical Standards and Quality, Director for the Quality Measurement and Value-Based Incentives Group
Centers for Medicare & Medicaid Services

Jennifer Layden -S
Digitally signed by Jennifer Layden -S
Date: 2024.01.29 08:32:49 -05'00'

Jennifer Layden, MD, Ph.D
Acting Director, Office of Public Health Data, Surveillance, and Technology Centers for Disease Control and Prevention