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April 15, 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 National Committee for Quality Assurance (NCQA) thanks you for the opportunity to provide feedback on draft version 5 of the US Core Data for Interoperability (USCDI).

NCQA is a private, 501(c)(3) not-for-profit, independent organization dedicated to improving health care quality through our Accreditation and measurement programs. We are a national leader in quality oversight and a pioneer in quality measurement. Leveraging our strengths as a trusted third party, we are committed to helping organizations navigate their journey towards an equitable, digitally enabled health care system. Our mission to improve the quality of health for all Americans, with a focus on health equity and support for meaningful value-based payment models, propels our daily work.

NCQA is pleased to provide the following comments on the proposals and considerations outlined for USCDI v5:

1. Suggestions for improvement in the data classes or elements in Draft USCDI v5.

NCQA supports the new elements included in Draft USCDI v5. These additions will continue to drive interoperability across the health care system and create effective and equitable care delivery. NCQA finds alignment with several new and existing elements in Draft USCDI v5 and continues to push health IT innovation in the quality space. We recommend further refinement and modifications to the below USCDI data elements.

Sex Parameter for Clinical Use (SPCU): We encourage ONC to align this data element with the ongoing work of the Gender Harmony Project. To do so, we recommend including in USCDI V5 both the generic SPCU element in the Observation data class as well as context-specific SPCU elements in appropriate clinical data classes (including clinical tests, laboratory, diagnostic imaging, procedures). In addition, we recommend including specific usage notes with the data elements to clearly state that: a) SPCU value(s) should be based upon information such as an anatomical inventory, hormone lab tests, genetic testing, menstrual status, obstetric history, etc. and b) Implementation guidance should be assessed when using SPCU in a context-specific or generic way. SPCU may be used in specific clinical contexts, for example, when placing an order or when interpreting a result or used as a context-free categorization of a patient.

Including these SPCU elements in USCDI will begin to enable documentation and exchange of structured data based on clinical observations and reflects a step toward anatomy-based identification of clinical need. NCQA is focused on ensuring care is inclusive and gender-affirming, which advances health equity and aligns with clinical best practices. NCQA believes SPCU is a valuable data element to appropriately identify clinical needs of individual patients; we have included SPCU as denominator criteria in our update to the Breast Cancer Screening and Cervical Cancer Screening measures, both of which are widely used in federal and state programs. Additionally, in the CY 2025 Medicare Advantage Advance Notice, CMS highlighted our cross-cutting Gender-Affirming Quality Measurement in HEDIS.

Race and Ethnicity: NCQA recommends ONC update the Race and Ethnicity data elements included in the Patient Demographic/Information data class to align with the OMB revisions to the Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15), published on March 29, 2024; it replaces and supersedes OMB's 1997 Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity.

First, in alignment with the revised SPD 15, we recommend ONC combine the individual race and ethnicity elements to create one data element: Race and/or Ethnicity. Second, we recommend ONC update the terminology requirements for the Race and/or Ethnicity data element to reference the March 2024 revised SPD 15. We also encourage ONC to partner with CDC to ensure the CDC Race and Ethnicity Code Set is updated and appropriately included within the USCDI terminology requirements.

ONC plays a pivotal role in ensuring federal entities, NCQA and other organizations are positioned to align with these revised OMB standards to support collection and exchange of more accurate and useful race and/or ethnicity data. Our ability to maintain alignment with OMB's standards is directly facilitated by ONC's promulgation of the standards into the USCDI requirements, which subsequently will facilitate alignment across other standards, including FHIR.

Pronouns NCQA strongly supports the addition of pronouns in USCDI v5. NCQA's Health Equity Accreditation requires collection and sharing of pronouns with member/patient-facing staff. Health Equity Accreditation is now mandated in over 16 states, including Medicaid and Exchange markets. Inclusion of this element in USCDI can reduce burden to providers, reduce duplication of data collection efforts to meet state requirements, and ensure an affirming experience for individuals.

Diagnostic Imaging Test: NCQA recommends updating the terminology in the Diagnostic Imaging Test element to include CPT, SNOMED, ICD-PCS, in addition to LOINC. These represent terminology routinely used to capture diagnostic imaging tests, such as CT scans and mammography. This data element should reflect the alignment occurring in the health IT space.

Diagnostic Imaging Report: The current USCDI element 'Diagnostic Imaging Report' represents both the structured and unstructured components of the report. We recommend ONC add RadLex and SNOMED CT as appropriate terminology for representing structured components of an imaging report as clinical findings. This terminology aligns with HL7 FHIR US Core DiagnosticReport Profile for Report and Note Exchange guidance and the draft Breast Imaging Report profile. NCQA is developing measures that require the findings from imaging reports, specifically for mammography and CTs for breast and lung cancer screenings, which routinely represent the clinical findings using the ACR Reporting and Data Systems (RADS) which provides standardized imaging findings terminology, report organization, assessment structure and classification for patient imaging. Adding these terminologies to the USCDI element will support interoperable data exchange of these important clinical data.

Smoking Status: NCQA recommends adding clarification to the Smoking Status data element by providing usage examples. We recommend adding to the examples of items that fall under this element to include quit date and smoking duration, in addition to the examples of pack-years and current use that are already listed in this data element.

We also recommend updating the terminology to include LOINC in addition to SNOMED. Smoking status, tobacco-use status, and smoking behavior details (i.e., pack-years) are well defined by LOINC and/or SNOMED.

Comprehensive assessment of tobacco-use and smoking behaviors remain a public health priority and are essential to appropriately providing cessation intervention. These data elements are also crucial for understanding a patient's eligibility for lung cancer screenings, a screening that is recommended by the U.S. Preventive Services Task Force and that remains underutilized despite its proven effectiveness. NCQA is currently developing measures to incentivize routine tobacco use assessments and appropriate lung cancer screening for those eligible based on smoking history.

2. Should other data elements, already classified as Level 2 on the USCDI web pages, be added to USCDI v5 instead of, or in addition to, those in Draft USCDI v5? If so, why?

Carin Blue Button (BB) Common Payer Consumer Data Set (CPCDS): NCQA recommends adding Carin BB CPCDS elements to USCDI v5 to support exchange of adjudicated claims information (without financial information), as proposed by Carin Alliance. The CMS Interoperability and Prior Authorization Final Rule requires payers to share patient claims and encounter data with in-network providers with whom the patient has a treatment relationship. This new requirement provides a direct scenario where EHRs may begin to accept, store and use Carin BB CPCDS elements. Adding CPCDS elements to USCDI aligns requirements across payers and health IT, and will improve data sharing abilities across health plans and providers. Information sharing reduces redundancy in data collection and can improve the patient experience.

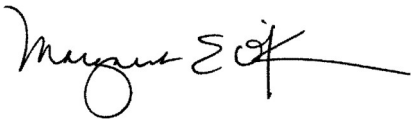
Orders Data Class: NCQA commends the addition of the new Orders data class with the inclusion of Referrals. We recommend adding an **Order/Referral Category data element** to the new data class (currently Level 2 element). An order/referral category element identifies the type of order, such as for a procedure, an intervention, or a service. We also recommend reclassifying the '**Reason for Referral' data element** from the Procedure data class to this new Orders class. With these updates, the new data class and information will allow for efficient exchange of information to support clinical care coordination.

NCQA also notes that this Orders Data Class is relevant for capturing social needs data and care coordination across the delivery system and among community services. We recommend ONC specifically add a distinct **social needs orders (and referrals) element** to the data class, separate from clinical orders/referrals. Social needs orders involve community linkages and resources with distinct terminology from clinical orders in that physicians may not always be tasked with their composition and follow-up and they often address non-clinical aspects of a patient's care. Adding a specific social needs orders data element supports exchange of these important pieces of information, and aligns with quality measures addressing social needs, NCQA priorities, and CMS stated quality priorities.

Last, we want to express our appreciation for ONC's USCDI+ initiative to define additional standardized interoperable data elements needed for quality measurement. NCQA is committed to transforming our quality measures to digital, and USCDI and USCDI+, will allow us to build on a foundational framework for this transition. We encourage ONC to leverage the expertise of measure stewards (like NCQA) to identify data elements that can enable a future, of near real-time, digital quality measurement.

Thank you for the opportunity to comment. We remain committed to working with ONC to build a more equitable, sustainable and responsible American health care system. If you have any questions, please contact Eric Musser, Vice President of Federal Affairs, at (202) 955-3590 or at musser@ncqa.org.

Sincerely,



Margaret E. O'Kane
President