



September 30, 2022

The Honorable Micky Tripathi, PhD, MPP
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW; Floor 7
Washington, DC 20201

Re: United States Core Data for Interoperability (USCDI)v3; comments for consideration for USCDIv4.

Comments submitted electronically

Dear National Coordinator Tripathi:

The American Medical Informatics Association (AMIA) appreciates the opportunity to comment on the draft USCDI v3 data elements and classes. AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, and public health experts who bring meaning to data, manage information, and generate new knowledge across the health and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

AMIA commends ONC's efforts to ensure a transparent process as it evaluates data collection for future iterations of USCDI. AMIA supports a deliberate yet incremental approach to the expansion of data classes and elements. A balance must be achieved between the addition of data fields, especially in areas that are not yet well defined through standardized terminology, and a recognition of the need to minimize burden on front line clinicians. To minimize provider burden, AMIA urges a sustained ONC commitment to automation. Further, there is a need to tie data collection to clinical relevance.

AMIA offers the following comments on specific data classes and elements:

- Assessment and Plan of Treatment – There is a need to recognize that the burden of data collection falls on the end-user clinician. Data should be derivative of the clinical work flow. When conducting a Social Determinants of Health (SDOH) assessment, AMIA encourages ONC to ensure that vocabulary standards avoid stigmatizing language and ensure respect for all people. Further, as standards change and evolve, AMIA encourages routine updates and alignment with HL7 FHIR Accelerator, The Gravity Project.
- Care Team Members – There is a need to identify who is considered a care team member. Additionally, the credential of each care team member, as applicable, should be specified.
- Clinical Notes - Data quality is fundamental to meaningful interpretation of care notes. Included provenance should disclose when "notes" are generated from pick lists or which have been cut and pasted from elsewhere.
- Clinical Tests – AMIA suggests that ONC include an element to specify the underlying procedure/test with inclusion of the manufacturer's specific reference range for each applicable procedure/test.
- Diagnostic Imaging – AMIA suggests that ONC specify which provider types are referred to as "credentialed professional." Additionally, ONC may wish to include an element to signify the artificial intelligence component of imaging reports, along with a requirement for generation of a report with prioritized results.
- Disability Status – AMIA suggests that Disability Status, under Health Status/Assessments, be moved to Patient Demographics/Information. The disability community on the whole has argued that questions to assess disability should be addressed to everyone; they should not single out some people for a report as part of health status.
- Encounter Information – With reference to the Primary Encounter diagnosis field, AMIA encourages ONC to replace "diagnosis" with "diagnoses."
- Goals – This data class is defined as "desired state to be achieved by a patient." AMIA believes that elements need to be defined (ie: patient-defined or generated, clinician-captured, obtained through interdisciplinary team members such as care coordinators or social workers, or those goals from clinician orders or advanced care planning documents. Identifying the source of the information in this data class is central to interpreting the outputs. For example, the desired goal or outcome stated by the patient captured from a direct patient responses or clinical care, may or may not have

the same value as goals captured from submitted advanced care planning documents or prior clinician orders.

- Health Status Assessments – Health status assessments will vary by care team member. ONC should consider adding an element to identify the care team member conducting the health status assessment, with inclusion of the credential of the care team member. Additionally, it is imperative to consider the sensitivity of the data being collected including the potential misuse of health information and health information technology to investigate and prosecute individuals who can get pregnant, and healthcare professionals trusted with their care.
- Immunizations - Immunization history is often not reiterated in the electronic health record but rather is most complete in state immunization registries or vaccination records such as the recent development of Smart Cards for COVID-19. Retrieval of immunization records should be automated and not require exceptional effort on the part of providers.
- Laboratory - ONC should require the inclusion of the manufacturer's specific reference range for each applicable laboratory test.
- Medication - ONC should consider adding elements to address medication administration and medications dispensed, to include not only dosage but also route of administration. Clarification is needed for the element "Fill Status." Is such information to be generated by the patient, clinician, an exchange or pharmacy?
- Patient Demographics Information – Again, AMIA encourages ONC to ensure that vocabulary standards are updated routinely as standards change and evolve, to avoid stigmatizing language and ensure health equity and respect for all people.
- Problems – There are limitations on the capture of diagnosis information. ONC's inclusion of SNOMED International, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, March 2022 Release and International Classification of Diseases ICD-10-CM 2022 as vocabulary standards represent an important step, but in reality, the problem or reason for seeking medical attention is often not documented in the health record.
- Provenance - The information contained in this data class is a critical underpinning for all other data classes and elements. Beyond the elements of author time stamp and author organization, the role of the author should be identified. The author may or may not be an identified member of the care team, especially highlighting the possibility of patients and authorized family or caregivers as potential contributors of health data.
- Vital Signs - ONC should consider adding elements to identify the role of the individual taking the vital signs, differentiating between inputs that might be from a care team

member, or patient or family/caregiver, as separate from an automated device or home monitoring system.

- AMIA suggests that ONC add “Participation in Clinical Trials” as a data class for inclusion in USCDIv4. It is necessary to capture the unique clinical scenarios of participants enrolled in clinical research studies.
- ONC should continue to work with HL7 to ensure that USCDI elements map to corresponding FHIR Resources.

AMIA would be pleased to serve as a resource to ONC as it continues its important work to advance meaningful data collection. Thank you for your time and consideration of these comments.

Sincerely,

A handwritten signature in blue ink that reads "Gretchen P Jackson". The signature is written in a cursive, flowing style.

Gretchen Purcell Jackson, MD, PhD, FACS, FACMI, FAMIA
President and Board Chair, American Medical Informatics Association