Submitted Electronically

September 22. 2026

Thomas Keane, MD, MBA
National Coordinator for Health IT
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street SW
Washington, DC 20416

RE: United States Core Data for Interoperability Version 7

Dear National Coordinator Keane:

On behalf of the American Medical Informatics Association (AMIA), we appreciate the opportunity to provide feedback to the Office of the National Coordinator for Health Information Technology (ONC) on the final United States Core Data for Interoperability Version 7 (USCDI v7) and considerations for USCDI Version 8 (USCDI v8).

AMIA is the professional home for more than 6,000 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 advances health and wellness by moving research findings from bench to bedside and evaluating interventions, innovations, and public policy across settings and populations.

General Comments

AMIA recommends that the Office of the National Coordinator for Health Information Technology (ONC) publish a structured and transparent roadmap describing how technically mature USCDI+ data elements will be evaluated, prioritized, and advanced into future USCDI versions. The additions to USCDI v7 demonstrate the value of this pathway; however, stakeholders would benefit from clear readiness criteria, sequencing principles, opportunities for stakeholder input, and implementation expectations.

To promote nationwide implementation, AMIA further recommends that ONC pair newly introduced data elements with authoritative implementation guides, formal FHIR profiles, validated terminology mappings, testing and validation resources, and clearly defined conformance expectations. Providing these resources alongside new USCDI requirements will help reduce variation across implementations, limit unnecessary administrative burden, and improve the reliable exchange and use of standardized health information.

Data Classes

Adverse Events

- AMIA supports the new Adverse Events data class and its Adverse Event Condition and Adverse Event Outcome elements, which can strengthen care continuity, patient-safety monitoring, quality measurement, and analysis of preventable harm.
- AMIA supports renaming "Adverse Event" as "Adverse Event Condition" but recommends clarifying whether an event is suspected or clinically determined to be associated with a precipitating clinical intervention.
- Future USCDI versions should link the adverse event to the precipitating clinical intervention and capture its onset, resolution, reporter, causality assessment, severity, verification status, and any subsequent treatment provided in response.

Care Plans

- Clarify the scope of Care Plan and its relationship to Assessment and Plan of Treatment, Patient Goals, Health Concerns, Care Experience Preferences, and Treatment Intervention Preferences.
    - Consider a "Plan of Care" that accounts for diagnostic plan (tests) and follow-up plan.
- Explicitly include patient values, preferences, and goals and identify their source, e.g. patient, caregiver, etc.
- Provide implementation guidance for structured, narrative, and hybrid care plans so that information can be exchanged and aggregated without imposing inflexible or burdensome documentation requirements.

Clinical Notes

- AMIA continues to recommend adding Admission Note and Anesthesia Note as Clinical Notes data elements.
- Provenance should disclose whether clinical documentation was authored by a clinician; generated from a template or pick list; copied from another source; produced through voice recognition; or generated or materially revised using artificial intelligence. The record should also identify clinician review and approval.
- Until mature structured EDOH standards are available, ONC should expressly support documentation of environmental and occupational exposures in clinical notes, including heat, air and water quality, extreme weather, toxic chemical exposures, pollutants, and workplace environmental hazards. AMIA continues to recommend beginning work on Environmental Determinants of Health (EDOH). Environmental and social factors should be treated as complementary "Determinants of Health," with development informed by frameworks such as the United Nations Office for Disaster Risk Reduction (UNDRR) Hazard Information Profiles and emerging clinical value sets.

Diagnostic Imaging

- AMIA supports Diagnostic Imaging Reference as a computable foundation for access to imaging studies. We appreciate ONC's clarification that external image access also depends on

interoperability and exchange agreements with organizations hosting picture archiving and communication system (PACS) or imaging servers.

- A future USCDI version should identify whether an imaging report or prioritized result used an AI or algorithmic component, including the system identity and version, applicable FDA status, how AI was used, and an appropriately credentialed health professional human verification. Where appropriate, associated software or devices should be linked to the Unique Device Identifier (UDI).

Facility Information

- AMIA supports adding Facility Telecom. However, Facility Address continues to require guidance for mobile, emergency, home-based, and other non-traditional settings.
- Clarify how to represent EMS, mobile units, and organizations operating across multiple locations or without a fixed service address.
- Define address types used in exchange and add a structured Address Type element for mailing, service, billing, and other purposes.

Goals and Preferences

- Rename the class "PERSON'S GOALS AND PREFERENCES" to recognize that goals persist beyond an episode in which an individual is a patient.
- Differentiate person-generated goals, clinician-captured goals, interdisciplinary care-team goals, advance-directive information, and goals derived from clinical orders. Source and verification are essential to interpretation.
- Align Patient Goal with Treatment Intervention Preference and distinguish the person's desired outcomes from care-team goals documented in the Patient Summary and Plan.
- The addition of Healthcare Agent partially advances AMIA's recommendation to identify an authorized decision-maker when a patient cannot communicate. Future work should clarify how Healthcare Agent relates to the broader category of patient-authorized representatives and how the source and scope of authority are represented.

Health Status Assessments

- Add Environmental Risk Assessment under Health Status Assessments, beginning with implementable use cases such as heat-risk assessment.
- Support clinical, medication, workplace, and household risk factors that enable care teams to identify individuals susceptible to heat-related and other environmental harms.
- AMIA supports revising Smoking Status to Tobacco and Nicotine Product Use and expanding its scope to cigarettes, e-cigarettes (electronic nicotine delivery systems; ENDS), vaping devices, smokeless tobacco, and other nicotine products. Implementation guidance should distinguish product type, current and past use, amount, frequency, chronicity, and source of information so the element supports clinical care without collapsing materially different exposures. Since some ENDS products are advertised as being "zero nicotine" or "nicotine-free" but can still contain measurable amounts of nicotine, we recommend that all vaping device use be recorded regardless of advertised or reported nicotine content.

- AMIA supports v7's clarification that SDOH Goals, SDOH Problems/Health Concerns, and SDOH Interventions are examples of the broader Patient Goal, Problem, and Procedure elements. Implementation guidance should continue to align with the Gravity Project and avoid stigmatizing language.
- Identify the care-team member conducting an assessment, including role and credential, while incorporating privacy safeguards appropriate to sensitive information.

Laboratory

- AMIA supports Specimen Collection Method and the final addition of Specimen Collection Date and Time. Separating specimen-collection timing from procedure-performance timing will improve interpretation of laboratory results.
- Result Reference Range should identify the underlying procedure or test and provide the reference range and interpretation used by the generating laboratory or entity, rather than relying solely on a manufacturer-suggested range.

Medical Devices

- AMIA supports Device Type and Medical Device Order and appreciates the revised Medical Devices class definition aligning with the FDA definition of a medical device.
- Clarify the representation of permanent, implantable, temporary, home-use, and durable medical devices, including PICC lines, catheters, wound-vacuum systems, home monitors, and other devices used across settings.
- Clarify whether and how software functions, digital therapeutics, and other regulated digital medical products are represented and linked to Device Type, Medical Device Order, and Unique Device Identifier (UDI).
- For UDI, ONC should develop phased, use-case-driven implementation guidance that accounts for laboratory information systems and point-of-care systems and minimizes manual data entry.

Medications

- AMIA supports the separate inclusion of Medication Administration and Medication Dispense Quantity. Together, these elements help distinguish what was ordered, dispensed, and administered. AMIA recommends distinction between and the ability to record health professional administered, self-administered, or lay caregiver-administered medication mechanisms.
- Medication Dispense Quantity does not capture why a prescription was only partially dispensed. Future versions should include a standardized reason for partial dispensing, such as shortage, affordability, clinical decision, insurance limitation, or patient preference.
- Clarify the provenance and meaning of dispense and fill status, including whether information originates from a pharmacy, health information exchange, clinician, patient, or caregiver. Filling or dispensing a medication should not be interpreted as confirmation that the patient received or took it.

Patient Demographics/Information

- AMIA supports Accommodation, Patient Identifier, and Deceased Indicator.

  - AMIA welcomes the addition of Accommodation to USCDI v7. AMIA recommends that ONC adopt a standardized, repeatable, and interoperable representation for patient-specific accommodation needs, using or extending existing HL7 FHIR structures and a coded value set developed with meaningful participation from disability communities. The representation should identify the subject of the need, whether the patient or a related person such as a companion or caregiver; permit free text; distinguish a need from whether and how it was provided; and clarify the relationship between Accommodation and Interpreter Needed. AMIA also reiterates its recommendation that Disability Status be moved to Patient Demographics/Information.
- Add Participation in Clinical Trials to capture the unique clinical context of individuals currently or previously enrolled in research studies.
- Add Veteran Status as a Patient Demographics/Information element.
- Move Disability Status from Health Status Assessments to Patient Demographics/Information and support collection from all individuals through accessible, person-centered methods.
- Emphasize self-identified or patient-verified race and ethnicity and routinely update applicable vocabularies to avoid stigmatizing or outdated language.
- Looking ahead:
  - Preferred Language: AMIA encourages ONC to consider expanding language data in a future version of USCDI to distinguish the language a person prefers to use for healthcare from preferred language or language spoken at home. Expanded data should support multiple and encounter-specific preferences, proficiency, communication modality, identification of the subject to whom the information applies (the patient or a relevant person such as a parent, guardian, or caregiver), and sufficiently specific language identification under RFC 5646.
  - Interpreter Needed: AMIA encourages ONC to consider enhancing Interpreter Needed in a future version of USCDI by linking it to the language and communication modality required, and to the subject who needs interpretation, whether the patient or a relevant person. It should also support standardized exchange of whether and how interpreter services were provided, including modality, interpreter type, and outcome.

Problems

- AMIA supports adding Condition Status and moving Health Concern into the Problems class. Condition Status provides useful context but does not fully address the limitations of Date of Diagnosis and Date of Resolution.

Provenance

- The new Healthcare Information Attributes class improves the exchange of contextual information through elements such as Diagnostic Report Date and Time, Reason Not Performed, Indication, and Performance Date and Time. It does not, however, resolve AMIA's broader provenance concerns.

- For each applicable element, provenance should identify the actor, author, organization, device, software, patient, caregiver, or other entity that generated or supplied the information; the actor's role; relevant timestamps; and verification or modification status.
- Provenance standards should expressly support AI-generated and AI-assisted information and preserve a longitudinal history rather than only the latest snapshot.

Vital Signs

- Add source information that distinguishes vital signs collected by a clinician or other care-team member, reported by a patient or caregiver, or generated by an automated device or monitoring system, including but not limited to remote monitoring system. Include the role of the individual collecting or validating the measurement.

Conclusion

We respectfully commend ONC for your continued dedication to stakeholder engagement throughout the development of USCDI v7. We welcome the opportunity to support this collaborative process and contribute to the refinement of the standard.

The recommendations outlined in this submission are intended to ensure that USCDI v8 effectively reflects the diverse operational realities of healthcare organizations, enhances the quality and equity of patient care, and strengthens the foundation for meaningful, nationwide interoperability. We look forward to continuing dialogue and partnership as this important work progresses.

***

Thank you for your consideration. If you have questions or require additional information, please contact Tayler Williams, Senior Manager, Public Policy, at twilliams@amia.org.

Sincerely,

Eileen Koski, MPhil
Chair, Public Policy Committee