

April 10, 2026

Mr. Steven Posnack, MS, MHS  
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Office of the National Coordinator for Health IT  
Department of Health and Human Services  
Hubert Humphrey Building, Suite 729  
200 Independence Avenue SW Washington, DC 20201

Submitted electronically to:

<https://isp.healthit.gov/united-states-core-data-interoperability-uscdi#draft-uscdi-v7>

Re: ONC's Draft United States Core Data for Interoperability (USCDI) Version 7

Dear Mr. Posnack:

Thank you for the opportunity to comment on Draft USCDI Version 7, published January 2026. We appreciate ONC's continued commitment to expanding standardized health data exchange through an open, transparent, stakeholder-driven process. The 30 proposed data element additions - including two new data classes (Adverse Events and Healthcare Information Attributes)- represent meaningful progress toward improved patient safety, nutrition care, and administrative interoperability.

These comments are submitted from the perspective of the Regenstrief Institute which maintains deep expertise in clinical terminology standards and their application to structured data exchange. Our feedback is grounded in a systematic gap analysis comparing Draft USCDI v7 requirements against the current LOINC v2.82 content set, with a focus on vocabulary readiness, implementation feasibility, and alignment with the SHIELD (Strengthening Health through Integration of Electronic Laboratory Data) initiative's public health informatics priorities.

## **I. General Support for the Draft USCDI v7 Direction**

We broadly support the direction of Draft USCDI v7. The expansion from 126 data elements in USCDI v6 to 156 in Draft v7 is a significant step, and we commend ONC for

the thoughtful approach of drawing 13 elements from existing exchange specifications (requiring no new standards development) and 9 from mature USCDI+ datasets. The alignment with national priorities - including patient safety, nutrition and wellness, and administrative burden reduction - is well-calibrated.

We particularly welcome the introduction of the Adverse Events data class, which fills a long-standing gap in standardized patient safety data exchange. The creation of the Healthcare Information Attributes class is also a pragmatic structural decision, consolidating contextual metadata (Indication, Performance Time, Diagnostic Report Date, Reason Not Performed) that was previously scattered or implicit.

## **II. Tobacco Use: Strong Direction, but Vocabulary Gaps Require Attention**

The evolution from "Smoking Status" to "Tobacco Use" is one of the most consequential changes in Draft v7. By broadening scope to include smokeless tobacco, cigars, pipe tobacco, waterpipes/hookah, nicotine pouches, nicotine gum, e-cigarettes, and other electronic nicotine delivery systems, ONC is correctly aligning USCDI with contemporary public health surveillance needs and the realities of modern tobacco product use.

However, our gap analysis of LOINC v2.82 against the expanded Tobacco Use requirements reveals material vocabulary shortfalls that could impede consistent implementation:

### **Areas for Further Development**

Waterpipe/hookah use: LOINC representation for waterpipe or hookah use - including status, frequency, duration, and age of initiation - has not yet been fully specified within the context of USCDI v7. Expanding coverage in this area would support more complete and consistent data capture.

Nicotine pouches: LOINC concepts for this emerging product category are not represented in LOINC. Given the increasing adoption of nicotine pouches, further development would help ensure appropriate representation.

Nicotine gum: Additional refinement would help distinguish medicinal nicotine replacement therapies from tobacco use products within LOINC, enabling more precise documentation and analysis.

These areas reflect evolving patterns of nicotine use and present an opportunity to strengthen alignment between USCDI v7 and current public health and clinical data needs.

### **Partial Coverage Areas**

E-cigarette/vaping: Only 2 LOINCs exist (105045-9 Electronic cigarette status; 112316-5 Vape product), but frequency, duration, quit dates, and age of initiation are absent. Frequency of use across all product types: Only 4 LOINCs address frequency, and most are cigarette-specific (e.g., 96842-0, 96103-7, 96101-1, 63773-6). Cigar and pipe products: Each has only 1 LOINC (age when stopped), with no codes for current use status or frequency.

### **Well-Covered Areas**

We note that traditional cigarette smoking is comprehensively covered (19 LOINCs), smokeless tobacco has reasonable baseline coverage (3 LOINCs), and duration/timing dimensions are well-represented (10 LOINCs). Additionally, 19 LOINCs exist for standardized assessment instruments (PhenX protocols, FTND), which provide a strong foundation.

### **Recommendation**

We recommend that ONC: (1) acknowledge the vocabulary gap in the final USCDI v7 guidance and signal to LOINC/Regenstrief that new code development is needed for waterpipe, nicotine pouch, and e-cigarette frequency/duration dimensions; (2) consider a phased implementation approach where elements requiring new vocabulary development have a longer compliance runway; and (3) provide explicit guidance on whether SNOMED CT concepts may serve as an interim bridge for product types where LOINC gaps exist. We further note that the current LOINC v2.82 exceeds Draft v7's stated minimum of v2.81, so implementers using current LOINC releases are already positioned for the well-covered dimensions.

## **III. Nutrition Assessment and Nutrition Order: LOINC Readiness Is Strong**

We support the addition of Nutrition Assessment (Health Status Assessments class) and Nutrition Order (Orders class) to USCDI v7. These elements align with national nutrition

and wellness priorities and have strong community backing from the PACIO Project and the Academy of Nutrition and Dietetics.

Our analysis of 21 nutrition-related LOINC codes in v2.82 confirms strong vocabulary readiness for Nutrition Assessment. The primary anchors are LOINC 75303-8 (Nutrition assessment Narrative), 75293-1 (Physical findings of nutrition assessment), and 75282-4 (Nutrition assessment panel), which together provide a robust core. The MNA-SF panel (107107-5) offers a named, standardized assessment tool aligned with USCDI v7's guidance to "use standardized tools when available." Multiple nutrition-specific document types (DOC.ONTOLOGY class) provide additional coverage for clinical notes.

We observe that the Nutrition Order element does not currently specify LOINC or any other vocabulary standard in the Draft v7 specification. We recommend that ONC clarify the expected vocabulary for Nutrition Order, potentially referencing LOINC for order identification and SNOMED CT for diet type concepts, consistent with the FHIR Nutrition Order resource structure.

#### **IV. Adverse Events: Welcome Addition with Vocabulary Considerations**

The new Adverse Events data class addresses a significant gap in standardized interoperability. The two-element structure - Adverse Event (with SNOMED CT as the applicable vocabulary) and Adverse Event Outcome (without a specified vocabulary)- is a reasonable starting point.

We offer two observations. First, the Adverse Event Outcome element lacks a specified vocabulary standard. Given that the examples cited (hospitalized, recovered, recovered with sequelae, death) closely align with the MedDRA and FDA adverse event outcome categories, we recommend ONC specify an applicable vocabulary - either SNOMED CT (which contains these concepts) or the HL7 FHIR Adverse Event outcome value set - to ensure consistent, comparable exchange. Without a specified vocabulary, implementers will default to free text, undermining the interoperability goals of USCDI.

Second, we note the potential for overlap or ambiguity between the Adverse Event element in this new class and the existing Reaction element in the Allergies and

Intolerances class. ONC should provide explicit guidance on the boundary between these elements, for example, clarifying that Allergies/Intolerances captures known patient sensitivities, while Adverse Events captures incident-level occurrences linked to specific clinical interventions.

## **V. Healthcare Information Attributes: Structural Clarity Needed**

The new Healthcare Information Attributes class consolidates contextual metadata - Diagnostic Report Date, Indication, Performance Time, and Reason Not Performed - into a single class. While we appreciate the intent to make these cross-cutting attributes first-class data elements, we note that this creates an ontological challenge: these elements are inherently contextual (they modify other data elements) rather than standalone. This kind of de-normalization highlights the importance of ONC also providing a specific coherent data model.

We recommend that ONC provide implementation guidance clarifying how these attributes are expected to be associated with their parent elements in FHIR-based exchange. For example, Reason Not Performed should be explicitly linked to the procedure, immunization, or medication it modifies, rather than exchanged as an isolated observation. Without this guidance, implementers may produce data that is technically USCDI-compliant but clinically disconnected.

## **VI. Health Insurance Information: Scope Concerns**

Draft v7 adds four new elements to Health Insurance Information: Coverage Period, Payer, Plan, and Plan Identifier. While these are important for administrative interoperability and prior authorization workflows (particularly in alignment with CMS-0057-F), we note that most of these elements lack specified vocabulary standards. Only Health Insurance Coverage Type references Source of Payment Typology (SOPT) v9.2.

We recommend ONC consider referencing existing payer and plan identifier systems - such as CMS National Plan and Provider Enumeration System (NPPES) identifiers or the CARIN Alliance's payer identifier work - to reduce implementation variability.

## VII. Alignment with SHIELD and Public Health Priorities

Several Draft v7 additions align well with the SHIELD initiative's goals of strengthening electronic laboratory data integration for public health. Specifically, the Specimen Collection Method element (Laboratory class), Immunization Status and Immunization Record Source (Immunizations class), and the Adverse Events class all support more complete and actionable public health case reporting and surveillance.

We encourage ONC to continue coordinating with APHL and the SHIELD community to ensure that USCDI data elements are represented in electronic laboratory reporting (ELR) and electronic case reporting (eCR) implementation guides, maximizing the bidirectional value of these additions for both clinical care and public health.

## VIII. Additional Observations

**LOINC Version Alignment:** Draft v7 references LOINC v2.81 as the applicable standard. We note that LOINC v2.82 is now available and includes new tobacco-related codes (e.g., 112316-5 Vape product, 112319-9 Tobacco use status, 111839-7 Smoking status) that are directly relevant to the expanded Tobacco Use element. We recommend ONC update the LOINC version reference to v2.82 in the final USCDI v7, or at minimum note that implementations using v2.82 are encouraged.

**Clinical Notes – Referral Note:** The addition of Referral Note (LOINC 57133-1) to Clinical Notes is a natural complement to the new Referral Order element in the Orders class. We support this pairing as it enables both the structured order and the narrative context to be exchanged.

**Device Type:** The addition of Device Type (SNOMED CT) alongside the existing Unique Device Identifier (UDI) is appropriate. However, we recommend guidance on how Device Type relates to the FDA's Global Medical Device Nomenclature (GMDN) and the Product Classification database, to support consistent categorization across clinical and regulatory contexts.

## **IX. Conclusion**

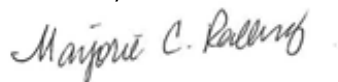
Draft USCDI v7 represents a meaningful and well-considered expansion of the national interoperability data set. We support its overall direction and commend ONC for the balance of ambition and pragmatism. Our comments are intended to strengthen the final version by identifying specific vocabulary gaps (particularly in Tobacco Use), requesting vocabulary specification where it is currently absent (Adverse Event Outcome, Nutrition Order, Health Insurance elements), and encouraging implementation guidance for the new Healthcare Information Attributes class.

Our comments for USCDI v7 (summarized on the pages following this letter), are intended to augment the USCDI with critical input and support its use in facilitating information exchange and interoperability goals.

If there are questions regarding our comments, please contact Marjorie Rallins, DPM, MS, Executive Director, Health Data Standards at [mrallins@regenstrief.org](mailto:mrallins@regenstrief.org) or 317-274-9415.

We appreciate and look forward to continued collaboration with ONC.

Sincerely,



**Marjorie Rallins, DPM, MS**  
**Executive Director**  
**Regenstrief Institute Health Data Standards**

**Enclosure: Regenstrief Institute Health Data Standards Response Summary**

## Regenstrief Institute Response Summary

Office of the National Coordinator for Health Information Technology (ASTP)

United States Core Data for Interoperability (USCDI) Standard (Draft Version 7)

Submitted electronically to:

<https://isp.healthit.gov/united-states-core-data-interoperability-uscdi#draft-uscdi-v7>

Data Class	Data Element	Position	Comment / Analysis	Recommendation	SHIELD Alignment
Adverse Events (NEW)	Adverse Event	Support	New class fills critical gap in patient safety data exchange. SNOMED CT (Sept 2025) is appropriate for encoding the event. Broad definition captures medication reactions, vaccination reactions, and procedural complications.	Support inclusion. Provide guidance distinguishing this element from the Reaction element in Allergies and Intolerances class to avoid implementer confusion.	Aligned – supports eCR and case reporting
Adverse Events (NEW)	Adverse Event Outcome	Support with caveat	<b>No vocabulary standard specified.</b> Examples (hospitalized, recovered, recovered with sequelae, death) align with MedDRA/FDA categories and HL7 FHIR Adverse Event outcome value set.	<b>Specify an applicable vocabulary</b> (SNOMED CT or HL7 FHIR Adverse Event outcome value set). Without one, implementers will use free text, undermining interoperability.	Aligned – standardized outcomes improve surveillance
Allergies & Intolerances	Allergy Intolerance Criticality	Support	Important for clinical decision support. No vocabulary specified, consistent with FHIR	Support. Consider referencing the FHIR criticality value set	Neutral

Data Class	Data Element	Position	Comment / Analysis	Recommendation	SHIELD Alignment
			AllergyIntolerance.criticality (low   high   unable-to-assess).	explicitly for consistency across implementations.	
Care Team Members	Healthcare Agent	Support	Individual legally authorized to make healthcare decisions. No vocabulary specified. Complements Advance Directive Observation in Goals and Preferences. Important for care coordination.	Support. Recommend clarifying relationships to existing Related Person data and the Advance Directive Observation element.	Neutral
Clinical Notes	Referral Note	Support	LOINC 57133-1 specified. Natural complement to new Referral Order in Orders class. Enables both structured order and narrative context exchange.	Support. Pairing with Referral Order is well-designed.	Aligned – supports care coordination reporting
Diagnostic Imaging	Diagnostic Imaging Reference	Support	The information to access a diagnostic imaging study (endpoint weblink, unique identifiers). No vocabulary specified but contextual/structural data.	Support. Ensure alignment with DICOMweb and IHE profiles for consistent image retrieval.	Neutral
Encounter Information	Appointment	Support	Planned healthcare event for future date/time. No vocabulary specified. Useful for care coordination and scheduling interoperability.	Support. Clarify relationship to Encounter elements once an Appointment results in an actual Encounter.	Neutral
Facility Information	Facility Telecom	Support	Contact information for facilities. Uses ITU-T E.123/E.164 standards, consistent with Care Team Member Telecom. Supports care coordination.	Support. No concerns.	Aligned – facility contact info supports lab/PH reporting

Data Class	Data Element	Position	Comment / Analysis	Recommendation	SHIELD Alignment
Healthcare Info Attributes (NEW)	Diagnostic Report Date	Support with caveat	Date/time report was made available. No vocabulary specified. This is inherently relational – it modifies a diagnostic report, not standalone.	Support. <b>Provide FHIR implementation guidance</b> on how this attribute links to its parent DiagnosticReport resource. Isolated exchange is clinically meaningless.	Aligned – report timing critical for PH surveillance
Healthcare Info Attributes (NEW)	Indication	Support	Sign, symptom, or condition justifying a care activity. SNOMED CT + ICD-10-CM 2026 specified. Relocated from implicit usage. Good to make explicit.	Support. Useful cross-cutting element. Clarify that it should be associated with the procedure/medication/order it justifies.	Aligned – indication context needed for lab orders
Healthcare Info Attributes (NEW)	Performance Time	Support	When a care activity was performed. No vocabulary (date/time). Relocated to new class. Examples include vaccine admin time, surgery start, specimen collection.	Support. Consistent with FHIR effective[x] patterns.	Aligned – specimen collection time critical for labs
Healthcare Info Attributes (NEW)	Reason Not Performed	Support with caveat	Explanation when an order/guideline is not carried out. No vocabulary specified. Usage note says applies to procedures, immunizations, medications.	Support. <b>Recommend specifying vocabulary</b> (SNOMED CT reason codes or HL7 negation reason value sets). Free text reduces analytical utility. Clarify FHIR linkage to parent resource.	Aligned – vaccination refusal tracking for IIS
Health Insurance Info	Health Insurance	Support	Time frame of policy. No vocabulary (date range). Important for prior	Support. Straightforward temporal data.	Neutral

Data Class	Data Element	Position	Comment / Analysis	Recommendation	SHIELD Alignment
	Coverage Period		authorization and administrative workflows per CMS-0057-F.		
Health Insurance Info	Health Insurance Payer	Support with caveat	Issuer of the policy. <b>No vocabulary standard specified.</b> Without a standard payer identifier, implementations will vary widely.	<b>Recommend referencing</b> NPPES or CARIN Alliance payer identifier standards to reduce variability.	Neutral
Health Insurance Info	Health Insurance Plan	Support with caveat	Insurance offering or package. <b>No vocabulary specified.</b> Plan names are not standardized across payers.	Recommend guidance on minimum expected structure (plan name + type at minimum).	Neutral
Health Insurance Info	Health Insurance Plan Identifier	Support	Identifier for the plan. No vocabulary. Structural identifier element.	Support. Consider referencing HIOS (Health Insurance Oversight System) plan identifiers used in ACA marketplace contexts.	Neutral
Health Status Assessments	Tobacco Use (REVISED)	Support with caveats	<b>Major revision</b> from Smoking Status. Expands to all tobacco products: smokeless, cigars, pipe, waterpipe/hookah, nicotine pouches, nicotine gum, e-cigarettes, ENDS. LOINC v2.81 + SNOMED CT specified. <b>Gap analysis of 66 LOINCs in v2.82 reveals: CRITICAL GAPS</b> – No LOINCs for waterpipe/hookah, nicotine pouches, or nicotine gum. <b>PARTIAL</b> – E-cig has only 2 LOINCs	Support the broadened scope. (1) <b>Update LOINC ref to v2.82</b> (includes 112316-5, 112319-9, 111839-7). (2) Signal to Regenstrief that new codes needed for waterpipe, nicotine pouches, e-cig frequency/duration. (3) Consider phased implementation for elements requiring new vocabulary. (4)	Aligned – tobacco surveillance is core PH

Data Class	Data Element	Position	Comment / Analysis	Recommendation	SHIELD Alignment
			(status + product); missing frequency/duration. Frequency coverage only 4 LOINC (6% of set), mostly cigarette specific. <b>WELL COVERED</b> – Traditional cigarette (19 LOINC), smokeless tobacco (3), duration/timing (10), assessment instruments (19).	Clarify SNOMED CT bridge role for gaps.	
Health Status Assessments	Nutrition Assessment	Support	Assessment of dietary intake. LOINC v2.81 specified. <b>LOINC readiness is strong</b> : 5 primary anchors (75303-8 narrative, 75293-1 physical findings, 75282-4 panel, 81674-4 fluid/nutrition panel, 107107-5 MNA-SF). Multiple DOC. ONTOLOGY document types for clinical notes. PRO and screening tools (NSRAS, CPHS, FACIT) provide optional enrichment.	Support. Recommend highlighting LOINC 75303-8 and 75282-4 as minimum implementation anchors, with 107107-5 (MNA-SF) as the preferred standardized assessment tool.	Neutral
Immunizations	Immunization Status	Support	State of an immunization event. No vocabulary specified in draft. FHIR uses a required value set (completed   entered-in-error   not-done).	Support. Consider referencing the FHIR Immunization Status value set for consistency.	Aligned – critical for IIS reporting
Immunizations	Immunization Record Source	Support	Source of immunization event information (e.g., administering facility, external record). No vocabulary specified.	Support. Aligns with IIS data quality needs. Consider referencing NCI Thesaurus or HL7 information source value sets.	Aligned – IIS data provenance

Data Class	Data Element	Position	Comment / Analysis	Recommendation	SHIELD Alignment
Laboratory	Specimen Collection Method	Support	Technique to obtain specimen (venipuncture, swab, biopsy, aspiration, catheter). No vocabulary specified; SNOMED CT procedure hierarchy would be appropriate.	Support. Recommend specifying SNOMED CT as the applicable vocabulary for specimen collection methods.	<b>Strongly aligned</b> – collection method critical for lab result interpretation and ELR
Medical Devices	Device Type	Support	Kind of device. SNOMED CT (Sept 2025) specified. Complements existing UDI element by adding categorical classification.	Support. Provide guidance on relationship to FDA GMDN and Product Classification for cross-context consistency.	Neutral
Medications	Medication Administration	Support	Event of patient consuming or being given medication. No vocabulary specified (event-level data). Examples: swallowing tablet, administering injection, infusion.	Support. Aligns with FHIR MedicationAdministration resource. Important for medication reconciliation and MAR interoperability.	Aligned – med admin data supports PH case data
Medications	Medication Dispense Quantity	Support	Amount dispensed or to be dispensed. No vocabulary (numeric + UCUM units). Complements existing Medication Dispense Status.	Support. Straightforward quantitative element.	Neutral
Orders	Medical Device Order	Support	Provider request for medical devices. No vocabulary specified. Examples: therapeutic footwear, insulin pump, CPAP.	Support. Consider referencing SNOMED CT or HCPCS for device order identification.	Neutral
Orders	Nutrition Order	Support with caveat	Request for therapeutic diet, nutrition support. <b>No vocabulary specified</b> in	Support. <b>Recommend specifying LOINC for order identification and SNOMED CT</b>	Neutral

Data Class	Data Element	Position	Comment / Analysis	Recommendation	SHIELD Alignment
			draft. Examples: cardiac diet, Mediterranean diet, enteral nutrition.	<b>for diet type concepts</b> , consistent with FHIR NutritionOrder resource.	
Orders	Referral Order	Support	Structured referral request to another provider/specialist. No vocabulary specified. Pairs well with new Referral Note in Clinical Notes.	Support. The order + note pairing is well-designed for referral workflows.	Aligned – referral tracking supports care coordination
Patient Demographics	Accommodation	Support	Modifications, tools, technologies, supports to access care. SNOMED CT (Sept 2025) specified. Important for disability access and health equity.	Support. Important for person-centered care and ADA compliance.	Neutral
Patient Demographics	Deceased Indicator	Support	Flag indicating whether patient is deceased. No vocabulary (boolean). Complements existing Date of Death.	Support. Simple, high-value element for data quality and patient matching.	Aligned – mortality tracking for PH
Patient Demographics	Patient Identifier	Support	Organization-assigned identifier (e.g., MRN). No vocabulary (identifier string). Supports patient matching and record linkage.	Support. Recommend guidance on identifier type coding (e.g., HL7 v2 identifier type codes).	Aligned – patient matching critical for PH
Problems	Condition Status	Support	How a condition presents/manifests (active, resolved, recurrence, remission). No vocabulary specified. FHIR uses Condition Clinical Status value set.	Support. Reference the FHIR Condition Clinical Status value set for implementer consistency.	Aligned – condition status needed for case classification

Data Class	Data Element	Position	Comment / Analysis	Recommendation	SHIELD Alignment
Procedures	Procedure Status	Support	Status of planned/performed activity (in-progress, completed, not-done). No vocabulary specified. FHIR uses EventStatus value set.	Support. Reference the FHIR EventStatus value set. Important for distinguishing planned vs. completed procedures.	Aligned – procedure completion status for case reporting