Federation of American Hospitals

Charlene K. MacDonald
President and CEO

April 13, 2026

Via electronic submission through the Interoperability Standards Platform

Thomas Keane, MD, MBA
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 Street, SW
7th Floor
Washington, DC 20201

Re: United States Core Data for Interoperability (USCDI) – Draft Version 7 (Draft USCDI v7)

Dear Dr. Keane,

As the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States, the Federation of American Hospitals (FAH) appreciates the opportunity to provide comments to the Office of the National Coordinator for Health Information Technology (ONC) regarding the above-referenced USCDI, Draft Version 7 (Draft USCDI v7).

FAH supports the use of health information technology (health IT) to improve care delivery, strengthen care coordination, and empower patients and caregivers. We believe these goals are best achieved by advancing interoperability in a manner that is technically feasible, operationally aligned with real-world clinical workflows, and minimizes unnecessary burden on healthcare providers and health IT developers. We appreciate the continued leadership of the Trump Administration and ONC in advancing the USCDI, and we offer the following comments and recommendations on Draft USCDI v7.

Draft USCDI v7 includes 30 overall proposed data element additions across multiple data classes, informed by stakeholder feedback and aligned with evolving health care priorities. ONC has stated that this version strengthens support for patient safety, nutrition care, and administrative burden reduction. FAH appreciates and supports these goals. FAH also requests that ONC reconsider certain data elements to ensure that any new elements added to the USCDI baseline are supported by clear definitions, applicable vocabulary standards, and demonstrated feasibility within current clinical workflows so that these elements can meet their potential. FAH offers the following comments and recommendations to guide these efforts.

1. Prioritize High-Value Elements Already Captured in Clinical Workflows

Except as otherwise noted herein, FAH supports advancing data elements that are already widely captured in structured formats within clinical workflows and supported by certified electronic health record technology. Prioritizing these elements enables near-term interoperability gains with minimal implementation burden, while improving patient safety and care coordination. **We want to expressly note our support for inclusion of the following elements:**

- Device Type: Draft USCDI v7 proposes Device Type as a new data element within the Medical Devices data class, representing the kind of instrument, machine, appliance, implant, software, or similar medical device. This element is already represented in exchange specifications required in the ONC Health IT Certification Program and is largely supported by certified health IT.

- Accommodation: Draft USCDI v7 proposes Accommodation as a new data element within the Patient Demographics/Information data class, capturing modifications, tools, technologies, and other supports necessary to access care.

- Deceased Indicator: Draft USCDI v7 proposes Deceased Indicator as a new data element within the Patient Demographics/Information data class, indicating whether a patient is deceased or not.

These elements reflect data that is already routinely captured in clinical practice and, in the case of Device Type, is already largely supported by certified health IT. Their inclusion in USCDI would continue to facilitate interoperability gains consistent with current operational workflow and without introducing data variability that could undermine the interoperability goals.

With respect to the remaining proposed data elements not individually addressed, FAH generally supports advancing elements that are already represented in exchange specifications required under the ONC Health IT Certification Program and that are largely supported by certified health IT, provided that clear definitions and applicable vocabulary standards are established prior to finalization. For elements that are not yet widely captured in clinical workflows, FAH encourages ONC to consider advancing them through USCDI+ or future iterations after sufficient standardization and implementation readiness is demonstrated.

2. **Align USCDI Elements with Existing Law and Ensure Appropriate Definitions**

FAH fully supports interoperability. In achieving this goal, it is important to recognize, before advancing any USCDI elements, that each element must have the appropriate definitions, terminology standards, and implementation expectations. Without this clarity and standardization, USCDI elements are likely to be exchanged inconsistently, limiting interoperability value and increasing provider burden. Inconsistency could create a very significant impact on the interpretation of the measures and could have an impact on the care provided to patients. FAH concerns in this regard are most acute with respect to the proposed Adverse Event and Adverse Event Outcome data elements, which present not only definitional and standardization challenges, but also fundamental conflicts with existing federal statutory privacy protections governing patient safety activities:

Adverse Event and Adverse Event Outcome

Draft USCDI v7 proposes a new Adverse Event data class with two data elements: Adverse Event, defined as a change to patient condition that could be an unintended effect of clinical interventions, and Adverse Event Outcome, which documents the result of an adverse event. These definitions deviate from current understanding and practice and would create confusion for providers and patients.

FAH opposes the inclusion of Adverse Event and Adverse Event Outcome in the USCDI because the elements, as framed, conflate routine clinical documentation with determinations that arise from patient safety activities. In routine clinical care, events are not consistently labeled as "adverse events" at the point of documentation, and attribution is often ambiguous or not feasible without deeper analysis. Many clinical conditions (*e.g.*, electrolyte abnormalities, hypotension) are documented as clinical findings rather than explicitly classified as adverse events. Importantly, determining whether an event qualifies as an adverse event requires investigation and causal analysis, such as root cause analysis, performed outside the medical record through patient safety activities, risk management, or peer review channels. These determinations are not typically exchanged as discrete data elements within clinical workflows, and until the root cause analysis or other review has been performed, it typically is not clear whether an adverse event has even occurred let alone the causes of it.

Additionally, the proposed Adverse Event and Adverse Event Outcome data elements conflict with existing federal law, specifically the Patient Safety and Quality Improvement Act (Patient Safety Act). Records created for patient safety events and reported to a Patient Safety Organization (PSO) under the Patient Safety Act are privileged and confidential Patient Safety Work Product (PSWP) when created and maintained within a Patient Safety Evaluation System (PSES). Maintaining this confidentiality is critical because it allows health care providers to report and analyze events and trends on a systemic basis and share recommendations for best practices across the health care system, which improves patient safety on a system-wide basis. As a general matter, PSWP records are not part of a Health Insurance Portability and Accountability Act (HIPAA) covered entity's designated record set (DRS) that must be made available to patients upon request. Implementing the proposed data elements will likely have the unintended effect of chilling robust quality and safety analysis currently being performed as PSWP. Underlying clinical facts in the medical

record remain accessible and are not rendered PSWP by subsequent analysis so accessing the source data is not affected by withdrawing this proposal.

Separately, ONC's information blocking framework prohibits practices that are likely to interfere with access, exchange, or use of electronic health information (EHI). EHI is limited to electronic protected health information to the extent it would be included in a HIPAA DRS; patient safety activity records are not part of the DRS and therefore are not EHI. Where the information at issue is PSWP maintained outside the DRS, it falls outside EHI and non-exchange is not considered information blocking. Underlying clinical information in the medical record remains subject to appropriate access, exchange, and use. Further, channeling adverse event determinations into general Fast Healthcare Interoperability Resources (FHIR) exchange for sharing health data also would duplicate established federal pathways for reporting events involving FDA-regulated products, add substantial review and staffing burdens with limited incremental patient benefit, and undermine the confidentiality protections that enable candid safety analysis.

Congress established a comprehensive, federally authorized pathway for adverse event learning through Patient Safety Organizations (PSOs). The Patient Safety Act created a nationwide, preemptive privilege and confidentiality framework and operationalized it through PSOs and explicit disclosure permissions, enabling providers to share adverse event information through protected channels rather than the medical record. Importantly, PSOs and providers may disclose PSWP about the safety of FDA regulated products directly to FDA without waiving privilege, so adverse event information for these products already flows to the appropriate regulator through existing pathways, alongside nonidentifiable safety sharing that advances learning. Any USCDI definitions in this space should be harmonized with FDA pharmacovigilance and medical device reporting definitions to avoid duplicative or conflicting federal data collection requirements. PSOs and their participating providers have built collaborative safety initiatives that reduce harm across care settings, and CMS has reinforced this model by tying hospital engagement in PSO patient safety activities to the Patient Safety Structural Measure in the Inpatient Quality Reporting Program (IQR). Providers operating within this IQR framework are already achieving the objectives that ONC seeks to advance, such as comprehensive adverse event tracking, information sharing across care teams, and systematic reduction of preventable harm, through these established legally authorized channels. Moreover, providers are required to report this IQR measure successfully or will be penalized with a 25 percent reduction in the hospital's annual Medicare market-basket update.

Further, including Adverse Event and Adverse Event Outcome data elements in USCDI without sufficient clarity risks duplicating existing clinical data while introducing variability and interpretive inconsistency, and at the same time conflicts with established legal frameworks. **Given these substantive and legal conflicts, any move to advance these elements should not proceed via a USCDI update alone. If ONC wishes to consider them further, it should do so only through formal notice and comment rulemaking that squarely addresses the intersection with the Patient Safety Act's privilege and confidentiality regime, clarifies the boundary with HIPAA's DRS and EHI, and provides a robust opportunity for public input.**

3. Ensure Proposed Elements Reflect Reliable, Structured Data Capture in Practice

As discussed, FAH supports advancing data elements that are consistently captured, maintained, or reliable within current clinical workflows. In contrast, exchanging data that is incomplete or inconsistently maintained risks propagating inaccuracies, creating unnecessary repetition and documentation burdens on clinicians, and undermining trust in interoperable data. **For the reasons described below, FAH does not support inclusion of the following elements in Draft USCDI v7 at this time and respectfully requests ONC reconsider their advancement**:

- Diagnostic Imaging Reference: Draft USCDI v7 includes Diagnostic Imaging Reference as a new data element within the Diagnostic Imaging data class, representing information that can be used to access a diagnostic imaging study. FAH recommends that ONC prioritize standardization of Picture Archiving and Communication Systems (PACS) or Vendor Neutral Archive (VNA) platforms, and imaging exchange standards before expanding requirements for image access and exchange. While image viewing through patient portals is feasible, download and transmit capabilities present significantly greater technical and operational challenges. Imaging studies vary widely in modality and file size, from small radiographs to multi-gigabyte CT and MRI scans, creating challenges for bandwidth, storage, system performance, and transmission. Additional barriers, including identity provisioning, authentication, infrastructure limitations, and vendor variability, further complicate scalable exchange. A uniform regulatory approach to all imaging modalities risks imposing requirements that are not technically feasible or operationally scalable. A standards-first approach is needed to support consistent and effective imaging interoperability. **Before**

advancing this element, ONC should review public comment from the January 30, 2026, Request for Information on Diagnostic Imaging Interoperability Standards and Certification, and offer a subsequent proposal informed by public comment at a later date after developing a more formal structure for imaging interoperability.

- Procedure Status: Draft USCDI v7 proposes Procedure Status as a new data element within the Procedures data class, representing the status of a planned or performed activity. In practice, procedure status fields are frequently not updated after initial entry and often default to "active" regardless of the actual state of the activity. Exchanging status data that does not reliably reflect current clinical reality risks misleading receiving providers and undermining confidence in the usefulness of interoperable data.

- Reason Not Performed: Draft USCDI v7 proposes Reason Not Performed as a new data element within the proposed Healthcare Information Attributes data class, representing an explanation or justification provided when an order or practice guideline is not carried out. Draft USCDI v7 proposes this element to specify structured information about why an ordered test, procedure, immunization, or other planned intervention did not occur. While FAH appreciates the intent, reasons for non-performance are highly variable, frequently unstructured, and often captured in ancillary systems such as laboratory or imaging workflows rather than the EHR. In practice, a procedure was either performed or not, and the reasons it was not performed, which may range from patient refusal to scheduling conflicts, are not consistently documented in a manner that lends itself to standardized, structured exchange. Without clear constraints on scope and representation, this element risks introducing noise into the data exchange, compromising the quality of information that receiving providers rely upon, and generating inconsistent and difficult-to-interpret data.

- Diagnostic Report Date: Draft USCDI v7 proposes Diagnostic Report Date as a new data element within the proposed Healthcare Information Attributes data class, representing the date and time a report containing test results or clinical interpretation was made available to providers. Diagnostic reports already include multiple associated timestamps, and it is unclear how this proposed element differs from those existing data points or what specific interoperability gap it is intended to fill. Adding a potentially duplicative timestamp without clear differentiation from existing fields risks creating confusion rather than advancing interoperability.

4. Define Data Granularity and Vocabulary Standards Prior to Publishing

To support consistent and meaningful interoperability, ONC should establish clear expectations for data granularity and applicable vocabulary standards before finalizing new elements. Without this guidance, implementations are likely to rely on local practices or free-text documentation, limiting interoperability and downstream usability. **While FAH is open to the inclusion of the following elements, each requires further specification from ONC to ensure that the data exchanged is consistent, usable, and meaningful to receiving providers**:

- Nutrition Assessment: Draft USCDI v7 proposes Nutrition Assessment as a new data element within the Health Status Assessments data class, representing an assessment of a person's dietary intake. While Nutrition Assessment is a critical part of patient care, we request more clarity regarding the intended use, scope, and applicable standards for this proposed element, as there is significant room for interpretation in how different providers capture and represent this information. Specifically, additional guidance is needed to define the types of assessment and information expected to be captured and exchanged consistently across systems. For example, additional guidance could clarify whether this assessment should include dietary restrictions or history, physical examination findings, and/or functional assessments. Greater clarity on these details, along with the appropriate terminology standards, would be very beneficial.

- Specimen Collection Method: Draft USCDI v7 proposes Specimen Collection Method as a new data element within the Laboratory data class, describing the technique or procedure used to obtain a specimen. FAH recommends that ONC provide clarification on the expected level of detail and applicable vocabulary standards to reduce variability in representation.

- Tobacco Use: Draft USCDI v7 proposes to expand the existing Smoking Status data element within the Health Status Assessments to more comprehensively capture information about a patient's use of tobacco and nicotine products. FAH supports inclusion of tobacco use and notes it is already widely

captured within certified health IT. Standardizing representation will further enhance interoperability and support clinical and public health use cases. However, tobacco use can currently be captured in many different ways, and it is unclear what data should be sent and how data received from other providers will be usable or valuable without further specification. We recommend that ONC provide clear guidance on representation before finalizing this element to ensure it can be implemented consistently.

- Patient Identifier: Draft USCDI v7 proposes Patient Identifier as a new data element within the Patient Demographics/Information data class, defined as a sequence of characters assigned by an organization to uniquely refer to a patient. FAH recognizes that the use of unique patient identifiers would support more accurate patient matching across disparate health information systems. While we support inclusion of patient identifiers in USCDI, we request clarification on expected identifier types. Specifically, it is unclear whether this element is intended to require a medical record number or support alternative identifiers (*e.g.*, enterprise or regional identifiers) to ensure reliable and consistent patient identification across systems.

5. Additional Element-Specific Feedback

In response to ONC's request for feedback on any aspect of Draft USCDI v7, including suggestions for improvement in data class and element definitions, identification of significant barriers to development or implementation, and input on the optimal approach for representing specific data elements, FAH offers the following additional comments. **For some of the elements below, FAH supports inclusion but recommends clarifications or implementation considerations to maximize their interoperability value. For others, FAH does not support inclusion or recommends that foundational standards work be completed before the element is advanced.**

- Referral Note: Draft USCDI v7 proposes Referral Note as a new data element within the Clinical Notes data class, providing a narrative summary requesting an opinion, advice, or service from a clinician. FAH has concerns about inclusion of Referral Note as a distinct USCDI data element because referrals are typically initiated through orders and documented within existing progress notes. Requiring a discrete referral note solely for interoperability purposes would introduce unnecessary operational burden without improving care coordination.

- Facility Telecom: Draft USCDI v7 proposes Facility Telecom as a new data element within the Facility Information data class, representing phone or email contact information for a physical place of available services or resources. We support inclusion of Facility Telecom and recommend clarifying that facility-level contact information should serve as the default for interoperability. Individual clinician contact information is often unreliable in shift-based care environments, whereas facility-level contact points better support safe and effective coordination.

- Health Insurance Information (Coverage Period, Payer, Plan, Plan Identifier): Draft USCDI v7 proposes four new data elements within the Health Insurance Information data class: Health Insurance Coverage Period (the timeframe in which the policy is in force), Health Insurance Payer (the issuer of the policy), Health Insurance Plan (the health insurance offering or package), and Health Insurance Plan Identifier (a sequence of characters used to uniquely refer to an insurance plan). **We support inclusion of these elements, which are already widely captured and supported in certified health IT.** Standardized exchange of payer and plan information can reduce administrative burden and improve coordination across care settings. Different data for the same patient can also assist providers in identifying changes to coverage more expeditiously. We urge clarification of plan identifiers through examples of appropriate identifiers and by identifying the relationship between plan, by specific type of plan, and member identifiers.

FAH believes the continued evolution of the USCDI data set can advance interoperability, improve care coordination, and enhance the usability of exchanged health information. Prioritizing elements that are already captured in clinical workflows, supported by clear definitions, and aligned with standardized vocabularies will maximize interoperability value while minimizing implementation burden. However, not all proposed elements are equally suited for inclusion in the USCDI baseline. Elements that lack consistent capture, clear use cases, or standardized representation may be more appropriately advanced through USCDI+ or future iterations. Expanding USCDI without sufficient clarity risks introducing variability and unnecessary data that obscures more important data elements for patient care, reducing data reliability and diverting resources from higher-value interoperability priorities.

FAH appreciates the opportunity to comment on Draft USCDI v7. We look forward to continued partnership as we strive to advance interoperability to improve our nation's health care system. If you have any questions regarding our comments, please do not hesitate to contact Katie Tenoever of my staff at ktenoever@fah.org.

Sincerely,
/s/
Charlene K. MacDonald
President and CEO