April 13, 2026

Submitted Electronically

Thomas Keane, M.D., MBA
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

Re: Draft USCDI Version 7

Dear Dr. Keane:

Thank you for the opportunity to provide comments on ONC's draft of the United States Core Data for Interoperability Version 7 (USCDI v7).

As a leading developer of interoperable health information technology, Epic supports ONC's goal of aligning the industry's efforts and thoughtfully adopting standards to improve health information exchange. Consensus on standards like USCDI contributes to enhanced data exchange in nationwide interoperability networks like the Trusted Exchange Framework and Common Agreement (TEFCA).

We have provided some general feedback on USCDI, as well as more detailed recommendations on areas of ambiguity in Draft USCDI v7 that should be resolved before it is published and adopted by the industry. We support ONC's approach to prioritize new data elements that, when combined, are a "modest aggregate" lift for developers and implementers. Modest inclusions create a manageable scope for health IT developers and healthcare providers, and make it easier for them to quickly adopt updated versions of USCDI. However, elements in the Adverse Events, Diagnostic Imaging, Encounter Information, Healthcare Information Attributes, and Medications data classes warrant clarification prior to publication to ensure consistent implementation across the industry.

We would be happy to answer any questions you might have regarding our feedback and to continue to work with ONC and standards development organizations to improve standards-based data exchange in healthcare.

Thank you for your consideration.

Sincerely,

Danielle Friend

Danielle Friend
Research and Development
Epic

General USCDI Feedback

Feedback on Existing USCDI Standards

Project US@ Technical Specification

We urge ONC to reconsider the standard associated with patient address in prior versions of USCDI. The standard has not achieved successful implementation across the industry — converting non-compliant addresses to US@ format is not computationally feasible, and without an automated solution the burden falls on registrars and clinical staff to apply the specification manually during address entry.

Considerations for Expanding USCDI

Selection of Appropriate Data Classes and Elements

Many of the elements proposed in Draft USCDI v7 reflect thoughtful prioritization and natural progression from prior versions of USCDI. We appreciate ONC's identification of certain proposed data elements as US Core Must Support, which helps developers and implementers quickly identify where existing implementation guidance already supports exchange and where additional work may be needed.

However, several proposed data elements raise implementation concerns that we address in detail below. In particular, elements whose definitions lack sufficient specificity — such as Medication Administration, Nutrition Assessment, and Appointment — risk inconsistent implementation across the industry. As ONC continues to expand USCDI, we recommend that new data elements have clearly bounded definitions before finalization, and that ONC confirm implementation readiness across the industry before establishing compliance timelines. We also note that the Diagnostic Imaging Reference data element raises fundamental questions about the appropriate role of USCDI in addressing imaging interoperability, which we address separately below.

Feedback on Specific Data Classes and Elements

Adverse Events Data Class

We strongly discourage ONC from creating an Adverse Events data class. The Adverse Event and Adverse Event Outcome data elements could apply to two distinct domains, neither of which supports inclusion in USCDI.

In the context of routine clinical care, adverse events are not a mature concept for discrete documentation or exchange. They are not consistently captured or characterized as "adverse events" across EHR systems today. There is no mature, standardized data structure or vocabulary standard for adverse events in routine clinical care, and without these foundations the element does not meet the criteria for USCDI inclusion. Where adverse events are documented, they appear across varying workflows and are already captured through existing USCDI data classes such as Problems, Encounter Information, and Clinical Notes.

In the context of clinical research, adverse events are documented in specialized workflows, and we recognize the clinical value of exchanging this information within that context. However, not all care

settings participate equally in clinical trials — smaller practices and rural healthcare facilities, for example, may have limited or no involvement. We are concerned that even in the context of research, the use case fails to meet the intent of USCDI as a core, universally applicable dataset.

We recommend that ONC not include the Adverse Events data class in the final USCDI v7. The broad clinical care definition lacks the maturity necessary for consistent exchange, while the clinical research context is too narrow to meet USCDI's intent as a universally applicable dataset.

Allergies and Intolerances Data Class

Allergy Intolerance Criticality

We support the addition of this data element. Epic software captures and exchanges allergy information today, and this element reflects a clinically meaningful distinction that is well-suited for inclusion in USCDI.

Care Team Members Data Class

Healthcare Agent

We support the addition of this data element. Epic software captures and exchanges this information today, and its maturity warrants its inclusion in USCDI.

Clinical Notes Data Class

Referral Note

We support the addition of this data element, though encourage ONC to clarify the distinction between the Referral Note data element and the existing Reason for Referral data element. As currently defined, both elements appear to describe the clinical justification for a referral, and without clearer boundaries between them, implementers may exchange duplicative information or interpret the elements inconsistently.

Diagnostic Imaging Data Class

Diagnostic Imaging Reference

We refer ONC to our feedback on the Diagnostic Imaging Interoperability Standards and Certification RFI (RIN 0955-AA11), submitted March 16, 2026, which addresses the role of USCDI in diagnostic imaging exchange in detail; we do not support inclusion of this data element until ONC has pursued the foundational steps outlined in that feedback. As we expressed in that feedback, while USCDI is a powerful tool for raising the floor for interoperability, there are workflow and technical considerations for the exchange of diagnostic imaging data that ONC must first address.

Diagnostic imaging data, whether pixel data or imaging manifests, is chiefly stored in DICOM archives such as PACS and VNA systems. These systems do not participate in the ONC Health IT Certification Program. Requiring a system that does participate in the certification program to facilitate imaging data exchange on behalf of PACS and VNAs introduces significant workflow and standards considerations that have not yet been adequately addressed. As described in section D of our feedback for RIN 0955-AA11, if ONC were to consider expanding certification to PACS and VNAs, it should include multiple new criteria written specifically for the different entities involved in image exchange and align adoption of consensus

standards across all participants. Until USCDI is more flexible for different types of implementers, this data element should not be included in USCDI.

Additionally, the goal must be the electronic exchange of full diagnostic-quality images. The proposed definition, "The information that can be used to access a diagnostic imaging study," is generic and may lead to different interpretations of what access entails. For example, "access" could mean launching a web viewer, providing metadata to fetch the images, or simply including an accession number — leaving access to an entirely separate workflow outside the scope of USCDI. Providing a reference or link, without the infrastructure and standards to ensure the referenced images can be retrieved securely at diagnostic quality, will not meaningfully advance diagnostic imaging interoperability.

We recommend that ONC defer inclusion of this data element until it has pursued the foundational steps outlined in our RFI feedback, including building consensus around open standards such as FHIR ImagingStudy and DICOMweb WADO-RS, establishing appropriate incentives, and leveraging TEFCA for early adoption. Once those prerequisites are in place and ONC has adopted a more flexible approach to USCDI that can accommodate the diverse ecosystem of imaging vendors, inclusion can be meaningfully evaluated.

Encounter Information Data Class

Appointment

We recommend that ONC address significant definitional and structural concerns with this data element prior to finalizing its inclusion.

First, ONC should establish Appointment as a distinct data class rather than a single data element. Treating Appointment as a single data element does not account for the complexity inherent in appointment data and will lead to inconsistent implementation across the industry. We recommend ONC specify the constituent sub-elements of a distinct Appointment data class, such as service type (e.g., follow-up, physical), provider, date, time, and duration, and assess their maturity before inclusion.

Second, we recommend that ONC acknowledge that the appropriate scope of appointment data will vary by exchange context and that this variation is expected and appropriate. For example, a FHIR-based API query may return a broad set of appointments including historical records, while a transition of care document may warrant only future or pending appointments. Rather than prescribing a single approach, ONC should recognize that implementations will vary across these contexts and offer flexibility given the different purposes each exchange mechanism serves.

Facility Information Data Class

Facility Telecom

We recommend the final USCDI v7 specify which contacts to use by default. For example, the same healthcare facility might make use of multiple phone numbers or email addresses depending on the context:

- The phone number or email address used to field patient inquiries
- The phone number or email address used to coordinate referrals or transitions of care
- The phone number used for after-hours or urgent clinical contact

Any of these are reasonable to include, but the final USCDI v7 should specify which to use by default for consistent interpretation by the industry. Alternatively, USCDI could include multiple telecom types as distinct data elements or adopt a flexible approach that allows multiple telecom contacts to be exchanged alongside metadata describing the purpose of each.

Healthcare Information Attributes Data Class

Reason Not Performed

We recommend that ONC not include this data element in the final USCDI v7.

Where Reason Not Performed is currently implemented in EHR systems, it is scoped to specific, well-defined contexts. Most notably, in quality measurement, a limited set of standardized reasons including medical, patient, and facility exceptions are used to document why a measure action was not taken. Epic has implemented this concept in that context, but there is no generic or universal capability to document reasons not performed, suggesting that it is not mature enough for inclusion in USCDI.

If the intent of this element is to support quality measurement, we encourage ONC to consider whether USCDI is the appropriate vehicle. Quality measurement programs already address this concept through existing reporting standards, and those may be better suited to this use case than a universally applicable USCDI data element.

Health Insurance Information Data Class

We recommend that ONC clarify the definitions of the Health Insurance Payer and Health Insurance Plan data elements to specify that each refers to a name. As currently written, both definitions are broad enough to encompass sub-attributes such as identifiers, contact information, and plan terms, which are already addressed by the Health Insurance Payer Identifier and Health Insurance Plan Identifier data elements included elsewhere in Draft USCDI v7.

Health Status Assessments Data Class

Nutrition Assessment

We appreciate ONC's recognition of the important role nutrition information plays in patient health and wellbeing. We recommend, however, that ONC specify which assessment types are intended to be captured and exchanged within this data element prior to finalizing its inclusion. As currently proposed, the element is broad enough to encompass virtually any clinical interaction touching on a patient's nutritional status, from validated screening tools to informal provider-patient conversations. Without clearer scoping, implementers will map widely varying workflows and data sources to this element, resulting in exchanges that are inconsistent and difficult for receiving systems to interpret or act upon.

In practice, nutrition-related information is collected across a wide range of workflows in EHR systems, including structured flowsheets, forms with discrete question-and-answer fields, and unstructured clinical documentation. Organizations may maintain numerous distinct workflows for documenting nutrition-related information, and without greater specificity, the element will not produce reliable, comparable data across systems.

We recommend ONC identify a specific set of assessment types or validated instruments that should be exchanged within the Nutrition Assessment data element. Doing so would benefit both implementation,

by giving developers and implementers a defined scope to map to, and interoperability utility, by ensuring that receiving systems can meaningfully interpret and use the data they receive.

Tobacco Use

We support the revision of this data element to reflect the broadened scope of tobacco and nicotine products, which better aligns with current clinical documentation practices.

Immunizations Data Class

Immunization Status

We recommend that ONC clarify the definition and intended scope of the Immunization Status data element prior to finalizing its inclusion. The definition of this data element does not specify which status values are in scope for exchange. We recommend that ONC confirm the applicable value set and address potential overlap with the Reason Not Performed data element also proposed in Draft USCDI v7. If a "not performed" or equivalent status is included in the Immunization Status value set, that concept would be duplicative of Reason Not Performed and ONC should reconcile these elements to avoid conflicting or redundant exchange expectations.

Immunization Record Source

We recommend that ONC clarify the definition and intended scope of the Immunization Record Source data element prior to finalizing its inclusion.

The definition of this data element does not clearly distinguish whether the element is intended to represent where an immunization was administered or where it was documented. This distinction has meaningful implications for implementation, since the administering facility, the documenting organization, and the source registry are three unique concepts that would be captured and exchanged differently.

This ambiguity is further complicated in certain care settings where the source of immunization documentation may fall entirely outside the clinical encounter. For example, if a patient uses an at-home nasal spray flu vaccine, it becomes unclear whether the record source is the patient, the dispensing pharmacy, or the provider who recommended the vaccine. We recommend that ONC clarify that this element is scoped to immunizations administered within clinical care settings and consider whether existing Provenance data elements already address the sourcing information this element appears intended to capture.

Laboratory Data Class

Specimen Collection Method

We support the addition of this data element, which is clinically valuable and widely captured and exchanged today.

Medications Data Class

Medication Administration

We recommend that ONC clarify the definition and intended scope of this data element prior to finalizing its inclusion. As currently proposed, the definition — "information about the event of a patient

consuming or otherwise being administered a medication" — encompasses multiple pieces of data rather than specifying the discrete information expected to be exchanged, which will lead to inconsistent implementation across systems. ONC should identify the specific data components in scope for exchange, such as route, site, dose, date/time, provider, etc.

We recommend that ONC separately evaluate the maturity and applicability for Medication Administration in different care settings. Medication administration documentation is most mature and consistently captured in inpatient settings. In ambulatory and other care settings, medication administration is documented far less consistently, and the standards and workflows necessary to support reliable exchange are not yet uniformly in place. If USCDI offered flexibility to adopt data elements for targeted care settings only, adoption in inpatient settings seems appropriate.

Medication Dispense Quantity

We support the addition of this data element, though recommend that ONC clarify its definition prior to finalizing its inclusion. As currently written, the definition conflates two distinct concepts when referring to "the amount of medication dispensed or to be dispensed." The quantity to be dispensed is a single value associated with a prescription — i.e., the prescribed quantity. In contrast, the quantity actually dispensed does not have a one-to-one relationship with a prescription. A single prescription may result in multiple dispense events over time, each with its own dispense quantity. This occurs not only in the case of refills, but also in common real-world workflows such as partial fills due to inventory constraints or upon patient request. These data points serve different clinical and operational purposes and should be defined and referenced separately.

This distinction also points to a broader structural recommendation. The US Core Implementation Guide and CDA standards have already begun separating prescription and dispense information, using MedicationRequest for prescription data and MedicationDispense for dispense data. We recommend ONC align the USCDI data class structure with this existing approach by splitting the Medications data class into two distinct classes – one for Medication Prescriptions and one for Medication Dispenses – and grouping Dispense Status and Dispense Quantity together under the new Medication Dispenses class. This will reduce ambiguity about where dispense-related data elements belong and align USCDI with the standards infrastructure already implemented by certified health IT developers.

Orders Data Class

Medical Device Order

We recognize the value of this data element and the clinical need for consistent exchange of this information across organizations. However, we recommend that ONC clarify the intended scope of this element prior to finalizing its inclusion, and specify a required vocabulary standard.

The complexity of implementation will vary significantly depending on device type. Medical device orders for implantable devices represent a well-understood concept with more consistent documentation practices across the industry. Orders for other durable medical equipment, however, are documented in more varied ways across organizations and EHR implementations, and the vocabulary standards and workflows necessary to support consistent exchange of those orders are not uniform. We recommend ONC acknowledge this variation in its definition or implementation guidance and limit the scope of this element to implantable devices with mature documentation practices.

Patient Demographics/Information Data Class

Deceased Indicator

We support the inclusion of this data element. Today, Epic software captures and exchanges both a patient's deceased status and date and time of death when it is documented in clinical workflows. Its inclusion in USCDI reflects the maturity and clinical value of this data for interoperable exchange.

We note, however, that USCDI inclusion alone will not fully address the broader challenge of ensuring that patients' deceased status reaches EHR systems reliably. Mortality information often originates outside clinical encounters, through vital records systems and similar sources; data in EHRs may be incomplete absent those systems' abilities to propagate the information to EHRs via consensus standards. We urge ONC to coordinate with relevant federal and state government agencies, including public health authorities and state-level vital records offices, to promote more comprehensive and timely exchange of mortality information.

Problems Data Class

Condition Status

We recommend that ONC clarify the definition of this data element. The current definition's use of "presents or manifests" is ambiguous as a descriptor of status and could be interpreted more broadly than intended. For example, a condition such as hypertension "manifests" through elevated blood pressure readings; this is entirely distinct from whether the condition is currently active or has been resolved. Additionally, the examples provided — which include concepts such as active, inactive, and recurrence — are not mutually exclusive (e.g., a condition can be an active recurrence, satisfying both categories), and it is unclear whether a condition is expected to carry a single status value or whether multiple statuses can apply simultaneously. We recommend ONC revise the definition and examples to align with existing standards representations of condition status, such as the clinical status value set defined in the FHIR specification, to ensure consistent interpretation across implementing systems.