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April 13, 2026

Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Washington, DC 20416

Attn: National Coordinator

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

Dear Dr. Keane,

Oracle Health is pleased to provide feedback on the draft United States Core Data for Interoperability (USCDI) version 7. As a leading provider of clinical and management information systems and a market leader in health information interoperability, we bring expertise and valuable insights to the field of standards development. We appreciate the opportunity to share our knowledge and contribute to advancing the field.

As we have commented on previous USCDI versions, we continue to believe it is critical to assess the data readiness and availability of sufficiently mature standards and associated implementation guides to enable consistent adoption by all relevant health information technology (HIT). This readiness includes the ability to scale at the national level without unreasonable risk for re-work when standards and implementation guides are not sufficiently mature and have insufficient adoption in operational settings.

Oracle Health supports and appreciates the hard work and dedication of you and your staff. We strongly support ONC's drive for interoperability across healthcare stakeholders and recognize the valuable role USCDI plays in that endeavor. We are committed to working with ONC and the industry to continue the progress in enabling interoperability.

Sincerely,

Alex Mugge
Sr. Director, Global Health Policy & Regulatory Intelligence

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General Comments

As we have commented previously in our responses since USCDI v2, we remain concerned with the ambiguity of existing and proposed USCDI data class and data element definitions and lack of mature standards for all proposed USCDI data classes and elements. We strongly urge ONC to address the following:

1. **Enable USCDI subsets to be supported by certified HIT**

With the proposed additional data elements it continues to be increasingly more difficult for specialty electronic health records (EHRs) and other HIT of interest to actually be certified to relevant criteria, particularly (g)(10) as we are also seeing an increased focus on FHIR-based API access. Currently, when data is added to USCDI and adopted in SVAP or the underlying certification program, all HIT to be certified must support every USCDI data class and element, which includes supporting both local storage and management of that data, as well as standardized exchange. We continue to urge ONC to reconsider that approach and adjust the certification program to allow HIT to only be certified to the specific scope of USCDI data elements that are relevant for their particular user base or overall purpose – i.e., the scope of data they *manage* that we propose to be defined as "supporting the ability for the pertinent data to be stored locally and for the system's end-users to view and interact with the discrete USCDI data while documenting and managing their clinical, administrative, and/or financial workflows." We suggest this can be managed by enabling software developers to identify and attest to the USCDI data they support while existing certification and information blocking provisions can provide an enforcement mechanism when HIT is found to manage data that yet has no ability to share that in accordance with the supporting standards such as HL7® FHIR® US Core.

2. **Health Information Attributes**

We note that including the proposed Health Information Attributes data class includes data elements without clarification which other data classes or data elements are expected to support the data elements in this Healthcare Information Attributes, i.e., they have no clear meaning on their own. While seemingly they may apply to all other data classes, that would not be accurate or would not use the terminology provided. Particularly:

a. Performance Time – This data element is moved from Procedures to Health Information Attributes. It may reasonably then apply to, e.g., the newly proposed Medication Administration data element in Medication, but not to the Dose or Route of Administration data elements within Medication. Another example would be that the Performance Time element should not apply to Facility Information data class while the Encounter Information data class already has an Encounter Time.
b. Indication – This data element is moved from Medications to Health Information Attributes. The definition was expanded beyond specifically Medications, yet it would not expand to all data classes or data elements in USCDI, e.g., Encounter

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Diagnosis seems to already cover Encounter Information while Provenance, Patient Demographics, others, and even Clinical Notes would not seem to need this data element.

c. Diagnostic Report Date – This data element is newly proposed to USCDI and would have been more appropriately included in Laboratory and Diagnostic Imaging, but not in Medications or Patient Demographics and many other data classes.
d. Reason not Performed – This data element is newly proposed to USCDI and would have been more appropriately included in Clinical Tests, Diagnostic Imaging, Procedures and a couple of other data classes, but not in Clinical Notes, Patient Demographics, or Encounter Information.

We suggest ONC add these data elements to the data classes, or data element definitions, where they are applicable. Alternatively, we recommend expanding the definition for each of these to indicate which data class, or data element definitions where they are applicable.

Generally, we suggest that USCDI would be substantially less ambiguous if it were to use FHIR resource, attributes and vocabulary bindings as its modeling language as it immediately establishes conceptual alignment with the primary target standard for data sharing. Where FHIR does not cover the intended concept yet it would clearly identify a gap in potential standards support, which would yield a data concept at Level 0 in OnDeck to advance and mature. This would not hinder use of USCDI outside of interoperability initiatives among HIT and would set those initiatives up for future adoption of data sharing using HIT.

3. Workflow Context

USCDI defines data classes very broadly allowing for interpretations that not only support the ability to view/access the data (e.g., presence of an order), but also to initiate/manage the workflow (e.g., the placement of an order, the reporting of the result in response to the order, etc.).

We suggest that ONC include an introductory statement to USCDI that the current purpose in the context of certification is for viewing/accessing USCDI data for documented orders, prescriptions, or performed procedures only. The statement should convey that supporting USCDI does not imply support for active workflow management for the placement, fulfillment, or performance of USCDI data classes, e.g., closed loop referrals, lab ordering to commercial laboratories, etc. orders, referrals, or appointments. Please note our separate comments under *Enable USCDI subsets to be supported by certified HIT* above on how to use USCDI more flexibly to enable certification for those USCDI data classes and elements that certified HIT actually manages, but is not required to manage by virtue of it being part of USCDI.

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4. Vocabulary

References to vocabulary are mostly to the overall code system to be used, not to the specific branches that are applicable. For some (e.g., Clinical Notes) there are references to very specific individual LOINC codes, and not having a more targeted middle ground set is causing challenges where they could be very helpful. For example, what are "all Clinical Tests" to be considered?

The HITAC provided a recommended starting set of specific LOINC-coded tests in their USCDI v3 recommendations (see Appendix B) but this was never formally adopted. We urge ONC to adopt these recommendations, thus reducing ambiguity to, e.g., the scope of Procedures or which SDOH assessment tools are recognized widely enough to be supported (not necessarily documented, but viewable when received). The lack of specific cited tools continues to cause significant confusion for both HIT developers and health care providers and misses an opportunity for further standardization of data exchange across care settings.

Overall, we suggest that vocabulary be more specifically bound in USCDI data elements – such as citing specific value sets established for the equivalent data concepts in the FHIR US Core IG Profiles.

USCDI v7 Proposed and Updated Data Classes and Elements

We provide the following feedback on the specific changes proposed to USCDI with the v7 draft.

1. Adverse Event and Adverse Event Outcome [Adverse Events]

We are concerned with the introduction of Adverse Event and Adverse Event Outcome as data elements in USCDI v7. As a typical EHR is used to document clinical events and related care delivered within a provider organization, it does not capture whether an event is classified as an adverse event or determine its ultimate outcome. Instead, a separate risk management system is generally used to track any pertinent data to an adverse event as part of a risk management process, and the originating provider may not always be aware that an adverse event has occurred, e.g., in the case of a delayed reaction to an immunization.

We therefore urge ONC not to adopt these data elements given that an EHR does not collect this risk management information and EHR users may not have information to accurately capture this data. As an alternative, downstream USCDI certification requirements that are primarily focused on EHRs today could be amended to apply only to the subset of USCDI data that a given HIT system is designed to capture and manage, consistent with our general comments. This would allow for more, relevant systems to be certified to the data classes and data elements they manage and can easily share data with other HIT that manages that same data, instead of forcing them onto supporting EHR capabilities that are not relevant to their purpose and users.

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2. Allergy Intolerance Criticality [Allergies and Intolerances]

We support the inclusion of the proposed Allergy Intolerance Criticality data element and recommend USCDI reference the HL7 value set AllergyIntoleranceCriticality.

3. Healthcare Agent [Care Team Members]

We generally support the inclusion of an healthcare agent as proposed, but note that the CareTeam Role data element effectively already covers this considering the FHIR US Core implementation using http://cts.nlm.nih.gov/fhir/ValueSet/2.16.840.1.113762.1.4.1099.30, which already includes roles similar to healthcare agent, e.g., legal guardian. However, "healthcare agent" or their synonyms healthcare proxy or medical power of attorney are not included. We recommend enhancing the Care Team Role data element definition and explicitly call out healthcare agent as a relevant role, while working with HL7 and NIH NLM to formally recognize it as a distinct function.

4. Referral Note [Clinical Notes]

We support the inclusion of the proposed Referral Note narrative data element and agree with the usage note on the Clinical Notes data class that this, and the other Clinical Notes, should not be confused as representative of the CDA C-CDA document types. However, considering that the same LOINC code is to be used for both the narrative note and the document type, this will continue to be interpreted as being the same. Accordingly, we urge ONC to work with HL7 to fully disambiguate these two concepts so they can be recognized as different based on appropriate encoding.

5. Diagnostic Imaging Reference [Diagnostic Imaging]

We agree with the need to enable sharing images across providers and with patients and other parties as appropriate. However, we suggest it is premature to advance a Diagnostic Imaging Reference into USCDI as there is no balloted and published implementation guide nor sufficient implementation and deployment that enables implementation at scale.

We recognize the progress made by the Argonaut Project, and within individual organizations, but as our response to the *Diagnostic Imaging Interoperability Standards and Certification* RFI also indicates, this issue must be resolved first with the source imaging systems (i.e., PACS/VNA) and much work still is left to enable adoption across the spectrum from the imaging systems to EHRs, patient apps, and other HIT. As we also indicated, further updates to the DICOMweb standard are necessary along with incentives in payment systems to drive the investment in infrastructure essential to enabling access to view or share/receive the images and integrate the image review capabilities within a clinician's workflow.

We therefore urge ONC not to include this data element in USCDI at this time but rather work with industry and CMS to advance the essential implementation guides and

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funding/payment considerations that will enable successful adoption, starting with the imaging services making the references available.

6. Appointment [Encounter Information]
We support the inclusion of the proposed Appointment data element.

7. Facility Telecom [Facility Information]
We support the inclusion of the proposed Facility Telecom data element. However, we remain concerned that the required context for Facility Information is not clearly defined in USCDI and must be inferred from the HL7 FHIR US Core or HL7 CDA C-CDA implementation guides, which are not consistently used when USCDI is used outside of interoperability initiatives. We recommend clarifying these contextual requirements directly within USCDI to ensure consistent interpretation and implementation.

8. Reason Not Performed [Healthcare Information Attributes]
We generally support the inclusion of the proposed Reason Not Performed data element. However, including it in the Healthcare Information Attributes data class does not provide adequate guidance on what healthcare information this data element is to be collected for, as further discussed in our General Comments section on this new data class.

We urge ONC to put this data element in the appropriate data classes it is relevant to, specifically Clinical Tests, Diagnostic Imaging, Laboratory, Medications, Orders, Procedures, and Vital Signs. Alternatively (but not preferred) include in the definition of the data element the specific data classes and/or elements to which it applies. Whichever path is taken, it is critical to dispel ambiguity regarding the intended usage and scoping of the data element.

9. Diagnostic Report Date [Healthcare Information Attributes]
We generally support the inclusion of the proposed Diagnostic Report Date data element. However, including it in the Healthcare Information Attributes data class does not provide adequate guidance on what healthcare information this data element is to be collected for, as further discussed in our General Comments section on this new data class as well.

We therefore urge ONC to put this data element in the appropriate data class(es), specifically Laboratory and Diagnostic Imaging.

10. Health Insurance Coverage Period, Health Insurance Payer, Health Insurance Plan, and Health Insurance Plan Identifier [Health Insurance Information]
We support the inclusion of the proposed Health Insurance Coverage Period, Health Insurance Payer, Health Insurance Plan, and Health Insurance Plan Identifier data elements.

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11. Nutrition Assessment [Health Status Assessments]
We support the inclusion of the proposed Nutrition Assessment data element.

12. Tobacco Use [Health Status Assessments]
We generally support expanding the Tobacco Use data element beyond exclusively smoked tobacco. However, several considerations should be addressed to ensure clear and consistent implementation.

First, the scope of the element requires careful definition. While the name "tobacco use" suggests a focus on tobacco products, the proposed definition includes examples that extend to non-tobacco nicotine use. We encourage alignment between the element's name and its definition once the scope is finalized.

Second, regardless of the ultimate scope, there is an important design question regarding how these observations should be structured in practice. Specifically, whether different forms of tobacco, nicotine, and potentially cannabis use, should be captured through a single broad question with a unified value set, or through distinct observations with dedicated value sets (e.g., for e-cigarette use). From an implementation perspective, separate observations with their own value sets would better align with existing system design and support clearer data capture and exchange.

13. Immunization Status and Immunization Record Source [Immunizations]
We support the inclusion of the proposed Immunization Status and Immunization Record Source data elements. However, we have concerns with the way the latter is defined and scoped.

Looking at the original submission for the Immunization Record Source data element from the CDC, it is clear that their desire was simply for a binary indication of whether the record was based on historical data (e.g., second-hand knowledge of the vaccination) or administered directly by the provider communicating the information. This would constitute a Boolean value that would most closely align with the Immunization.primarySource field on the FHIR R4 Immunization resource, which is currently labeled as Must Support on the FHIR US Core IG Immunization profile and defined as "Indicates whether the data contained in the resource was captured by the individual/organization which was responsible for the administration of the vaccine rather than as 'secondary reported' data documented by a third party. A value of 'true' means this data originated with the individual/organization which was responsible for the administration of the vaccine." However, the way the proposed data element is defined as "Examples include but are not limited to facility administering the immunization and an external record" suggests an expectation that the element identify the specific entity that performed the administration – which appears to be directly aligned with the Immunization.informationSource field added in the FHIR R6 edition of the Immunization resource (but not present in FHIR R4) – instead of the Boolean indication of historical vs. locally administered.

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Accordingly, we strongly recommend amending the proposed element to re-define it as "Indicates whether the data contained in the resource was captured by the individual/organization which was responsible for the administration of the vaccine rather than as 'secondary reported' data documented by a third party. A value of 'true' means this data originated with the individual/organization which was responsible for the administration of the vaccine" (or a closely aligned verbiage) for clarity of intended alignment with the FHIR Immunization.primarySource field and consider incorporation of an additional data element to align with the FHIR R6 Immunization.informationSource field in future USCDI iterations.

14. Specimen Collection Method [Laboratory]
We support the inclusion of the proposed Specimen Collection Method data element and recommend USCDI include SNOMED as the applicable vocabulary standard, e.g., using the value set in FHIR R4 (Valueset-specimen-collection-method - FHIR v4.0.1.) as an example set.

15. Specimen Condition [Laboratory]
While not marked, we note and appreciate the updated definition from Specimen Condition Acceptability to Specimen Condition and the associated description to be aligned with FHIR US Core definition.

16. Device Type [Medical Devices]
We support the inclusion of the proposed Device Type data element.

17. Medication Administration [Medications]
We generally support the inclusion of the proposed Medication Administration data element; however, the introduction as proposed raises various concerns.

First, we suggest focusing on administrations by a clinician. We note that beyond the scope of Medication Adherence data element, EHRs do not capture patient recordings of their self-administrations, and clinicians currently do not seek to include this level of detail in their EHRs.

Second, we note the definition of Medication Administration generally references "information about the event" and the examples focus on route and method of administration, while the submission includes dose, and the Medications data class also already includes a Route of Administration, thus adding to the ambiguity on what data is relevant to a Prescription, Dispense or Administration. We strongly recommend that the Medications data class be split into individual data classes for (1) Medication Request, (2) Medication Dispense, and (3) Medication Administration and identify for each of the relevant data elements. That may seem duplicative as some data elements appear in multiple; however, it substantially reduces complexities in understanding the data relevant to each concept.

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We also note that this is a good example for our general comment to use FHIR concepts to define USCDI. It also yields yet another example of the scope of USCDI not being applicable to all EHRs or other HIT and refer to our comments on that topic in the General Comments section of this letter.

18. Medication Dispense Quantity [Medications]
We support the inclusion of the proposed Medication Dispense Quantity data element.

19. Medical Device Order [Orders]
We generally support the inclusion of the proposed Medical Device Order, and we particularly support that ONC is not referencing a vocabulary standard as DME orders are typically descriptive in the absence of a national vocabulary standard. However, we note that this yields yet another example of the scope of USCDI not being applicable to all EHRs or other HIT and refer to our comments on that topic in the General Comments section of this letter.

20. Nutrition Order [Orders]
We generally support the inclusion of the proposed Nutrition Order data element in USCDI. However, we note that this yields yet another example of the scope of USCDI not being applicable to all EHRs or other HIT and refer to our comments on that topic in the General Comments section of this letter.

21. Referral Order [Orders]
We support the inclusion of Referral Order in USCDI, however we have concerns about the scope of this data element. We recommend that ONC limit the scope of Referral Order to exclusively medical specialist referrals, not to social and community services.

22. Accommodation [Patient Demographics/Information]
We note that the submission for this data element references the availability of a Disability Status specification (http://hl7.org/fhir/us/ecr/2021Jan/StructureDefinition-disability-status.html) which is currently used in eCase Reporting. However, the value set used in that profile indicates the disability, but not the modifications, tools, technologies, and other supports necessary to access care. The submission indicates there are no other applicable standards, while the reference in the proposed data element generally references SNOMED.

Considering there is no clearly defined standard for accommodations, while there is for Disability Status, we suggest to either change the perspective to including a Disability Status, following the profile as used for eCase Reporting, or to withdraw the proposal and collaborate with HL7 to establish an agreed to profile definition for Accommodation.

23. Deceased Indicator [Patient Demographics/Information]
We support the inclusion of the proposed Deceased Indicator data element.

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24. Patient Identifier [Patient Demographics/Information]
We support the inclusion of the proposed Patient Identifier data element.

25. Condition Status [Problems]
We support the inclusion of the proposed Condition Status data element.

26. Procedure Status [Procedures]
We support the inclusion of the proposed Procedure Status data element.