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Submitted Electronically

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U.S. Department of Health and Human Services
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Re: Draft USCDI Version 5

Dear Dr. Tripathi:

Thank you for the opportunity to provide comments on ONC's draft of the United States Core Data for Interoperability Version 5 (USCDI v5).

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

We have provided some general feedback on the USCDI, as well as more detailed recommendations on areas of ambiguity in the Draft USCDI v5 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 make it easier for them to quickly adopt updated versions of the USCDI in their products. However, as we express in our feedback, elements in the Laboratory, Observations, and Orders data classes are likely to jeopardize this consistent "modest aggregate" lift due to variance in interpretation and should be clarified prior to publication.

We would be happy to answer any questions you might have on 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,

Dave Fuhrmann
Research and Development
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General USCDI Feedback

Considerations for Expanding USCDI

Selection of Appropriate Data Classes and Elements

Many of the elements proposed in the Draft USCDI v5 are natural steps in furthering interoperability and extending data exchange from USCDI v4. For example, the new data elements added to the Clinical Notes and Immunizations classes (i.e., Emergency Department Note, Operative Note, and Lot Number) exhibit mature specifications for standardized representation and exchange through common interoperability mechanisms like FHIR and C-CDA.

Limiting Scope of Proposed Data Classes

The addition of classes as wide-reaching as Observations and Orders poses significant implementation challenges because different types of Observations and Orders conform to a variety of standardization frameworks. For example, grouping all orders together makes it difficult to capture and exchange relevant discrete information, since the information that applies to one type of order frequently does not apply to other types. As we detail in our comments below, data elements within Observations and Orders would be better suited for inclusion in relevant preexisting classes, rather than as standalone classes, once they reach appropriate maturity. In future expansions of the USCDI, we recommend new data classes have a higher degree of specificity and that their constituent elements align more closely with respect to their information models and applicable standards.

Feedback on Specific Data Classes and Elements

Laboratory Data Class

Test Kit Unique Device Identifier

Our understanding is that the Test Kit Unique Device Identifiers element is being proposed to further interoperability by allowing users to identify comparable results from different labs and organizations. However, test kit UDIs lack the industry maturity necessary to accomplish this goal in the following ways:

- While test kits are commonly barcoded to capture UDIs, existing integrations between the instrument and the LIS, and the LIS and the EHR, do not capture or transact this information. Updating each of these systems and transactions will take time.
- UDIs would not be expected to drive any functionalities in the EHR or LIS beyond being used as a reference point to know if results from two labs were tested using the same kit. This would make it difficult to incentivize the adoption of UDIs in EHR and LIS systems.
- Matching on the UDIs alone may not allow results across labs to automatically interoperate. UDIs do not provide context on other factors, such as the type of specimen, and thus require coordination with other identifiers to establish clinical equivalence of results.
- UDIs do not sufficiently roll up to a single functional test. For example, Abbot Architect iSystems has multiple IgG kits that perform the same function but have different UDIs – the only difference between these kits is the number of tests each can perform. In this case, results across the Abbot IgG kits would not be identified as comparable and would unnecessarily be separated simply because the kits could perform different numbers of tests.

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ONC should work with lab interoperability workgroups, such as The Sequoia Project's Laboratory Tiger Team, to develop a comprehensive solution for trending lab results before including a Test Kit UDI element in the USCDI.

Observations Data Class

Advance Directive Observation

The definition of "properties" in the description of this data element is vague. While the element's usage note gives examples of properties, we suggest defining a list of properties to assist in standardizing the exchange of information. ONC should align this list of properties for exchange with those defined in the related C-CDA standards, which exhibit a high degree of industry maturity and are widely used in Epic software. These properties include the document's status, date and time, text name of signee, type of advance directive, and location of the actual document.

ONC should move this data element under the Goals and Preferences class to position it alongside similar elements, namely Treatment Intervention Preference.

Sex Parameter for Clinical Use

Epic software supports a patient-level Sex Parameter for Clinical Use today, and we agree that exchanging this information is important for clinical care. However, in our experience, many other systems do not have the capability to use or exchange this concept. Additionally, there is unresolved discussion in the industry around the use and value of patient-level versus contextual Sex Parameter for Clinical Use values. ONC should defer inclusion of Sex Parameter for Clinical Use until the concept is more mature and broadly adopted.

Orders Data Class

We strongly discourage ONC from creating a single data class for all orders. Orders vary in their information models and applicable vocabulary standards (e.g., medication orders use RxNorm, laboratory orders use LOINC). For example, the discrete information for prescriptions, like dose and route information, would only be applicable for medication orders, rather than all orders. The same can be said for laboratory orders, diagnostic imaging orders, and so on. Flattening all these variant discrete fields into one data class avoids the nuance that makes orders information valuable and usable for clinicians, EHR developers, and a variety of other users. Additionally, given that an inpatient admission will frequently contain thousands of heterogenous orders and that a procedure catalogue for a single customer will often contain tens of thousands of entries, this catch-all approach would burden providers with enormous lists of orders without discrete data or actionable steps. Taken all together, this long list of orders would make it extremely difficult to parse out the information of relevant order types, since users would have to wade through vast quantities of irrelevant information to do so. The variance and volume of orders information renders their inclusion in a catch-all data class disruptive to ONC's goal of furthering meaningful interoperability.

Instead, ONC should position the orders suggested in the draft into separate, preexisting data classes, which would allow them to be addressed individually. For example, diagnostic imaging orders should be included in the Diagnostic Imaging class, laboratory test orders in the Laboratory class, intervention orders and referrals and consultations in the Procedures class, and do-not-resuscitate orders in the Goals

and Preferences class. This approach would allow for the definition of standards that apply to each unique order type, meaning the relevant discrete information for each type of order could be appropriately exchanged. It would also allow users to efficiently access information on a specific type of order, as opposed to having to search through all orders information. For these reasons, ONC should reassign any subsequent data elements of this class to appropriate, preexisting classes to facilitate a more meaningful exchange of orders information and decrease potential user burden.

Patient Demographics/Information Data Class

Pronoun

Epic supports the addition of this data element and agrees with ONC's approach of delegating related value set definitions to standards bodies like HL7.

Interpreter Needed

ONC's goal to "specify a patient's need for language services" is not comprehensively fulfilled through this element's yes-or-no configuration. For example, if a patient is receiving care somewhere their preferred language is not the primary language but is common enough that most providers speak it (e.g., fluent Spanish speakers in the southwestern United States), asking whether an interpreter is needed says more about the context of the visit than the patient's individual needs. Similarly, ambiguity arises in the case of patients who speak multiple languages or children who speak different languages than their parent or guardian (e.g., in what language should a translator be provided? Can a translator be provided in another language if one for a patient's preferred language is not available?). It is also unclear how this element accounts for changes to a patient's language proficiency over time.

More information related to a patient's (or their caregiver's, in the case of minors) language proficiency across multiple languages is necessary to address these regional and temporal concerns and ensure high care quality in all cases. ONC should instead include a broader Spoken Language Proficiency element, which would capture a patient's proficiency level across all the languages they speak. The mechanisms with which to exchange more complex language proficiency information already exist in the form of HL7's Language Communication CDA class: ONC should consider aligning their approach with this preexisting standard.

Provenance Data Class

The expense and complexity of including author and author role elements as metadata for all USCDI data elements exceeds the anticipated value of doing so; provenance metadata for author information is not always available or populated within EHRs. For example, data received via interfaces do not always have an associated author and may instead be attributed at the organizational level. Similarly, provenance data for author information is not always transferred when organizations convert data from one EHR system to another. Due to the information's lack of accessibility, we estimate it would take Epic approximately 20,000 hours of development to implement provenance information as proposed.

Instead, we recommend a targeted approach to inclusion of author and author role elements, once sufficient implementation guidance is available:

- First, ONC should only require the implementation of provenance for classes where that information is particularly valuable – specifically, Medications and Notes. There are many classes

(e.g., Patient Demographics/Information, Care Team, Allergies and Intolerances) for which collecting provenance metadata for author information would not be clinically valuable. There are also many high-volume classes (e.g., Vital Signs) where tacking on provenance entries to every data element would inflate storage and overall complexity. By contrast, the Medications and Notes classes offer clear clinical value in establishing provenance metadata and are not high-volume enough by themselves to raise storage concerns.

- Next, ONC should publish implementation guides that specify exactly who or what should be determined the author for each data element (e.g., organizations, singular users, multiple users). Limiting the scope of provenance metadata to the Medications and Notes classes helps mitigate this ambiguity, since medications and notes are typically signed, and we assume the signer would be the author. However, guidance will still be needed for such cases as historical medications, patient-reported medications, protocol medications, multiple note authors, and note addendums.

Once ONC limits the scope of provenance metadata for author information to clinically relevant classes and publishes the necessary implementation guidance, the author and author role elements can be considered for the USCDI.