

April 28, 2022

Micky Tripathi, Ph.D., M.P.P.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Washington, DC 20416

Dear Dr. Tripathi,

On behalf of the 30 member companies of the HIMSS Electronic Health Record Association (EHRA), we appreciate the opportunity to offer our feedback to The Office of the National Coordinator for Health Information Technology (ONC) on its draft United States Core Data for Interoperability (USCDI) v3.

EHRA member companies serve the vast majority of hospital, post-acute, specialty-specific, and ambulatory healthcare providers using electronic health records (EHRs) and other health IT across the United States. Together, we work to improve the quality and efficiency of care through the adoption and use of innovative, interoperable health information technology.

Before providing specific feedback on individual data classes and data elements being proposed, we would like to address key challenges and opportunities to improve on the value and interpretation of the USCDI that are critical to address as the USCDI continues to evolve. In particular, as the USCDI grows and is positioned to be supported by any CHIT, EHRA members have growing concerns that various HIT, including EHRs, will be required to support more data than is necessary or reasonable based on the scope and purpose of the HIT.

We offer the following considerations regarding the proposed USCDI v3 elements.

Sincerely,



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Lumeris
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Medsphere
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Netsmart
Nextech

NextGen Healthcare
Office Practicum
Sevocity
STI Computer Services
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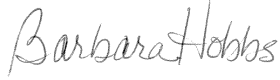
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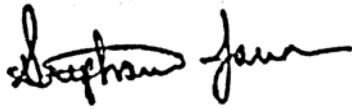
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Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.

Electronic Health Record Association

Comments on the United States Core Data for Interoperability (USCDI) draft v3

General Considerations

The USCDI has been defined as the core set of data for interoperability, and is thus a subset of all EHI/ePHI. All certified HIT is expected to support Version 1 through HL7 C-CDA and HL7 FHIR US Core. Newer versions of the USCDI also will be available for Certified HIT developers to claim support for through the Standards Version Advancement Process (SVAP) until a new certification rule raises the floor to a more current USCDI version. In addition, USCDI+ data sets are being developed as extensions for targeted areas such as Public Health and CMS Quality Measures. ONC has indicated that the scope of USCDI is not intended to expand to the full EHI (or ePHI).

Both premises, the scope of USCDI and its applicability to certified HIT, are increasingly being challenged by the expansion of the USCDI. The diversity of HIT that may be certified under ONC's program, how HIT is licensed and configured by individual healthcare organizations, and the need for interoperability standards that encompass all EHI will continue to contribute to challenges in identifying data elements that are appropriate for adoption in the USCDI.

Scope of USCDI Should Converge with EHI/ePHI

We are increasingly concerned that the long-term goal of the USCDI is not to address all EHI. However, it is essential that there is industry-wide consensus on the minimum set of data elements that constitute EHI. Without this consensus, the industry will not be able to build consensus on technical standards to exchange all EHI. Targeting long-term alignment with EHI could also enable developers to develop EHI export formats that are standards-based instead of proprietary.

We therefore urge ONC to reconsider the long-term scope of the USCDI and set the target for it to be ePHI as defined by the HIPAA Privacy Rule. While EHI is the defined scope of the 21st Century Cures Act, EHI has a variable scope considering that the definition of the Designated Record Set (DRS) under the HIPAA Privacy Rule allows for provider organizations to consider a different scope of electronic data that is to be shared based on their policy-based understanding of the DRS. That leads to friction. On the other hand, ePHI is invariable and will always encompass any individualized DRS scopes. ONC's Trusted Exchange Framework (TEF) has recognized this and uses ePHI as one of its key scoping definitions. We support that wider perspective.

Certified HIT comes in all shapes and sizes

There is an expectation (explicit or implicit) that EHRs are to support all USCDI since it is expected that, as new versions are published by ONC, there will be updates to the certification requirement. This expectation is reinforced by the USCDI's inclusion in the SVAP and RWT processes. However, not all HIT does or needs to be able to document all USCDI data, as they are not the original source. They may either receive it for display only, utilize services to access it from a source when needed, or they may not accommodate it all, depending on their user community's needs. It is therefore important that, as

newer versions of the USCDI are developed, not all the data elements and concepts of the USCDI are relevant to all certified HIT. This is more obvious in the USCDI v3 draft, and we expect that as USCDI further expands additional elements will be even less relevant to all certified IT.

Examples include:

- Pediatric Vital Signs (USCDI V1) are not applicable to all types of HIT (or even EHRs). While every healthcare provider is required to support the USCDI as part of obligations for implementation and use of Certified EHR Technology (CEHRT), not every healthcare provider treats children or has a need to record these elements.
- Discharge Summary and Discharge Diagnosis are not relevant to EHRs that are not intended for use in inpatient settings. These include traditional ambulatory-only EHRs and specialty EHRs intended for more narrow care settings. Such EHRs will never need to generate a discharge summary, and their users will never need to document a discharge diagnosis.
- Health Insurance Information and most “non-clinical” demographic data is typically collected and maintained in administrative/registration systems, not EHRs. Such data may need to be accessible in EHRs, but USCDI and supporting standards should not impose the requirement that EHRs collect and maintain such data.
- Clinical data is not maintained by scheduling and practice management systems and need not be accessible to them. As USCDI is starting to encompass data needed for administrative workflows, e.g., prior authorization, cost transparency, and other cross-clinical/administrative workflows, there is a need to align on common vocabulary and standards through USCDI. However, not all HIT wishing to be certified should be encumbered with having to maintain or even access and share all USCDI.

As USCDI expands to cover more administrative/financial data, this will become increasingly more obvious. If we are to limit USCDI to a core set that one reasonably can expect that all certified HIT would support, we believe we have almost reached that scope. But if we agree that EHI/ePHI is the real objective, then we must recognize that not all HIT presented to be certified should be expected to support all of the USCDI as versions advance.

Data Stratification

ONC must recognize that while there is a need to establish common standards for all eHI/ePHI, different types of HIT should be permitted to focus on different subsets of USCDI appropriate to their purpose, scope, and intended use. This requires the establishment of a data stratification method to ensure that not all HIT is required to support all USCDI, rather only such data as is appropriate for certified HIT given their scope and role.

To date, the EHRA has advocated for stratifying the USCDI. We suggest the following approach to address this issue across the USCDI and its supporting applicable standards/implementation guides that certification would specifically reference, as well as certification criteria.

USCDI

We suggest that the USCDI be viewed as a library of data concepts and classes, standardized through both vocabulary standards *and* supporting interoperability implementation guides that explain how data should generally be collected and used.

We suggest that the scope of USCDI should eventually contain all ePHI, as well as other core data for interoperability, where a minimum standard should be available to enable interoperability without special effort. This may be expressed as a constellation of data sets such as envisioned with USCDI+ but more expansive.

Standards/Implementation Guides

We suggest that FHIR US Core be recognized as the primary implementation guide establishing the necessary syntax and vocabulary bindings for interoperability. Where needed, other standards/implementation guides such as HL7 CDA C-CDA, HL7 v2, NCPDP SCRIPT, and X12 5010 may provide documentation and workflow guidance.

We note that, considering only FHIR US Core is available to SVAP, a fair amount of copying and some updating of FHIR profiles from other implementation guides such as Gravity or DaVinci is occurring or needed to ensure that FHIR US Core covers all USCDI. We suggest that ONC explore with HL7 how to better structure and relate the variety of implementation guides that have relevant content to support future versions of USCDI such that copying and re-work are limited if not eliminated.

Further, as implementation guides include profiles that may not (yet) be part of a USCDI version being contemplated, they must have clear interaction sets that can be used to reference specific subsets of the guides that would be relevant to that USCDI version. Such clarity and structure would also benefit the definition and boundaries of certification criteria both for USCDI and other capabilities (see, for example, our commentary on the ePA RFI)

Certification

We suggest that certification for APIs, as well as upcoming workflow guidance such as for ePA, be made more granular, recognizing that not all HIT needs to support all the USCDI. Currently 170.315.g (10) addresses access to a single set of FHIR US Core profiles rather than enabling subsets. While certain HIT may need certain data to be accessible when received, the format may vary and some of that data should not be expected to be maintainable. For example, one specialized EHR may receive a C-CDA document that includes a discharge diagnosis for a prior hospital stay. They should be able to display that as part of viewing the document as received, but they should not be required to parse that data from the document as discrete data and store it, nor maintain it as either original data on an encounter or applicable updates. This would also apply to many demographic data as they are frequently maintained in an administrative system, not a clinical system such as the EHR which frequently would keep a copy at the most, but not enable updates.

USCDI v2 to v3 Vocabulary Standards Updates

We support any updates to more current vocabulary standards versions for any data elements that were already included in USCDI v2. We do note that this does not imply that any certification is limited to only those versions, rather HIT being certified can use the most current version available at the time of certification as already provided through the certification program. Such a clarification, that the version referenced is not limiting what can be certified to, would be a helpful addition.

Detailed Response

As indicated in the General Considerations section, we believe that all EHI plus other core data to enable interoperability should be recognized in the USCDI in some fashion to indicate priority for standards or availability of standards to access and exchange those data. The following comments are not focused on whether it is appropriate to include the data element in the USCDI. Instead, the comments below focus on the clarity of definitions to facilitate consistent implementation of exchange with appropriate vocabulary and/or supporting standards and implementation guidance that can be referenced in certification.

Assessment and Plan of Treatment Data Class

The HITAC recommended the ability to receive “any” assessment and at least enable review/retention of the assessment in textual form, even though the receiving HIT may not be able to create such an assessment and plan of treatment. We support this proposal, recognizing that an EHR need not support the creation of an assessment and plan of treatment beyond the scope of that EHR.

Clinical Notes Data Class

The HITAC recommended that upon creation of a narrative clinical note, the note type be coded using a LOINC code from the LOINC Document Ontology that best captures the intent of the narrative clinical note to aid in searching and access. This recommendation included an indication that such a requirement should not imply that all HIT, and EHRs in particular, need to support the creation of narrative clinical notes for every entry in the LOINC Document Ontology. We support this recommendation in principle, with a clarification that health IT developers should be free to work with their clients to map existing EHR note types to LOINC codes as they see fit, rather than requiring the use of note types that might not be relevant to different groups' scope of practice.

Discharge Summary Data Element

The USCDI indicates that the Discharge Summary Clinical Note is a narrative note, yet the proposal specifies the inclusion of specific, discrete data. We recommend removing this specificity, as requiring providers to include specific discrete data in narrative notes imposes unnecessary clinician burden and concerns that the EHR is making them “click boxes.” The Discharge Summary Document Type templates already address how to include the data indicated. We also note EHRs that do not support inpatient or residential care have no need to create Discharge Summaries and should not be required to do so.

Clinical Tests Data Class

Clinical Test Data Element

We generally support the inclusion of a minimum set of non-imaging, non-laboratory tests. We note that not every EHR would maintain all tests as an original source based on the focus and specialization of the EHR, nor would other or all HIT need to receive such clinical test results. For example, laboratory HIT would be the original source for laboratory tests, but would not need to receive other clinical test results not relevant to the performance of the laboratory tests. We suggest clarifying that HIT supports the applicable values included in the set, and may support others as well.

Facility Level Data Class

Facility Identifier Data Element

The HITAC recommended supporting facility identifiers, including assigning authority, in particular for CCN (CMS Certification Number), NPI (National Provider Identifier), and PTAN (Provider Transaction Access Number). We note two concerns with the recommendation:

Facility identifiers must be associated with other clinical information or context to be valuable. For example, the facility where an encounter occurred, is planned to occur, or where a procedure was performed could be helpful information. However, exchanging a facility identifier without that context would confuse users. It is also not clear whether this is to represent an organization or more granular physical facilities.

While the NPI has meaning in the context of an EHR, the CCN and PTAN identifiers might not be used in EHRs, but rather in administrative and/or reporting systems. Therefore, not all HIT would need to support all identifiers based on context and purpose

We therefore suggest that this data element and the data class in general require more definition to clarify its purpose (organizational ownership/responsibility and/or physical location/building) and context (relationship and role to specific other data classes). We suggest that this data element, while likely widely used in its various forms, and, as the HITAC further suggests, is intended to reflect the organization that has overall responsibility for the encounter (visit, stay), is not ready for USCDI given the ambiguous and incomplete definition.

Health Status Data Class

We generally support the goal of aligning standards in this space but we note that there are many assessment instruments used across specialties and settings. We are concerned that different entities will not have a consistent understanding of the types of assessments that should be shared within each data element in this data class. Some are highly specialized and focused, and only applicable to certain settings. We suggest that ONC work with the provider community to identify a core set of assessments that are more widely adopted and used, thus increasing the value of sharing them. We also note that

even within the core set of assessments, certain providers and the EHRs they use may not find all of them relevant to their scope of practice and patient population.

Any assessment tool chosen for a value set must not be restricted by licensing requirements.

We suggest that as assessment tools are considered and adopted, the language(s) in which the tools are available are clearly documented in the ISA or USCDI. Considering the diversity of communities served, we also suggest that any tool selected should be available in a variety of languages.

Accommodation Data Element

The HITAC recommended adding Accommodation as a Health Status to complement Disability Status. We note that in ONDEC this exists as a comment, not yet Level 2. It is in particular unclear what vocabulary is intended to be used and how it is intended to be used with Disability Status. We suggest this data element, in combination with Disability Status, needs further definition and clarity before it is included in USCDI.

Disability Status Data Element

We suggest clarifying the boundaries between the disability, functional, and mental statuses more clearly using well-defined vocabulary for each to avoid overlap. We note that considering the vocabulary is not consistently used across providers at this stage, inclusion in USCDI becomes challenging as data exchanged will not have as much value for the receiving provider. Alignment and adoption of common vocabulary is critical to achieving that. We do recognize that documentation of this information is helpful, and we think that more standardization will drive better data value and use. As the submission indicated a key focus on using this status for disability benefits determination, we suggest considering this element for a disability benefits determination focused USCDI+ data set.

Functional Status Data Element

We suggest clarifying the boundaries between the disability, functional, and mental statuses more clearly, using well-defined vocabulary for each to avoid overlap. We note that because the vocabulary is not consistently used across providers at this stage, inclusion in USCDI becomes challenging as data exchanged will not be as useful for the receiving provider. Alignment and adoption of common vocabulary is critical to achieving that.

Mental Function Data Element

We generally support the inclusion of Mental Function but note that the terminology referenced is limited to cognitive status, while mental function encompasses more. We suggest that more feedback is required from stakeholders to properly scope this element, recognizing that various screener tools may focus on just cognitive status, other aspects, or both. Updating the name to Mental & Cognitive Status would aid in that clarification. We also suggest ONC clarify whether this element is intended to contain subjective observations and/or a standardized assessment.

Pregnancy Status Data Element

The HITAC recommended expanding the value set to include “intent to become pregnant.” We suggest that further review is required to determine whether two elements are needed to describe whether the patient is pregnant at a certain time vs. other categorizations that are either valid when the patient is or is not pregnant. The values suggested would be applicable for either one or the other state.

Additionally, we suggest including an Estimated Due Date to add context when the patient is pregnant. Only including the last recorded pregnancy status may create a misunderstanding if the pregnant patient was last seen by the sending organization some time ago.

Health Concern Data Element

We note that in USCDI v2 there was no clear definition of the Health Concerns data element, only at the data class level. As it is proposed to be moved under Health Status (which retained the definition of the USCDI v2 Health Concern data class), there is still no clear definition of how it is different from other Health Status data elements. We suggest either dropping the class altogether or providing a clear definition to understand relevant terminology and supporting standards/implementation guides.

We note that, generally, a health concern can be a kind of problem that is addressed separately and includes diagnoses. Health status findings need not be health concerns, problems, or lead to a diagnosis. Furthermore, Problems includes SDOH Problems/Health Concerns; thus this element either seems to already be sufficiently covered as part of Problem, or would be better addressed through a separate data class to highlight its unique characteristics.

Smoking Status Data Element

We support the re-classification of Smoking Status to be part of Health Status.

The HITAC recommended supporting various instruments to conceptualize smoking status and history. While we support the intent, it is not clear which specific alternative vocabulary is being suggested. We suggest considering this expansion in the next USCDI version to enable adequate review by the community.

Health Insurance Information Data Class

We are concerned about including the Health Insurance Information data class as key data is not yet sufficiently defined (see our detailed comments). While the current requirements to support all USCDI through certification, it requires EHRs in particular to enable support for this data that in fact may be provided by other HIT, e.g., an administrative/registration system. It is our understanding that one cannot certify to FHIR US Core version to enable support to all other relevant USCDI v3 data.

We note that health insurance information is typically documented as part of administrative workflows. EHRs may have at most a copy, or may rely on services to access the information as needed for display only. If the EHR does not record the health insurance information (as the system of truth), a FHIR based API to retrieve it makes no sense. Thus the meaning of “support” becomes critical as USCDI evolves. We

suggest ONC clarify that an element's inclusion in USCDI v2 or v3 does not require the EHR to certify its support of that element, even if that EHR intends to support other USCDI v2 or v3 elements under the SVAP. Until that is explicitly addressed, we recommend not including Health Insurance Information in USCDI to avoid overburdening EHRs with capabilities they need not have.

Coverage Status Data Element

We suggest updating the definition to indicate this is the status of the overall coverage (health plan, self-pay, etc.) and not that of the coverage associated with any particular encounter or claim.

Coverage Type Data Element

We suggest this element not be included until HL7, NCPDP, and X12 have aligned vocabulary and issued guidance as to which values are applicable in what context.

Member Identifier Data Element

While this element on its own is not necessarily a concern, see our general comments on health insurance information for our overall concern with the inclusion of this data.

Subscriber Identifier Data Element

While this element on its own is not necessarily a concern, see our general comments on health insurance information for our overall concern with the inclusion of this data.

Relationship to Subscriber Data Element

We note that there is no vocabulary defined for the relationships of interest. We suggest this element not be included until HL7, NCPDP, and X12 have aligned vocabulary and issued guidance as to which values are applicable in what context.

Group Number Data Element

While this element on its own is not necessarily a concern, see our general comments on health insurance information for our overall concern with the inclusion of this data.

Payer Identifier Data Element

While this element on its own is not necessarily a concern, see our general comments on health insurance information for our overall concern with the inclusion of this data. Additionally, it is important to determine which assigning authority is used to identify individual payers in order to ensure the correct interpretation of this value and document the other health insurance information within that payer's context. This will be essential to processes such as electronic prior authorization in order to enable the HIT to identify the right payer/health plan to interact with automatically.

Laboratory Data Class

The HITAC recommended that laboratory data, which is already widely shared and required to conform to CLIA regulations on lab reporting, be included in USCDI v3. In particular, the HITAC suggested the inclusion of Unit of Measure, various date and time stamps, and Reference Range. We generally support the inclusion of laboratory data that is already widely communicated as it advances USCDI to encompass all EHI for which standards have been established. However, this is a good example of why not all HIT that intends to be certified should be required to support all USCDI data including that which it does not manage.

Specimen Type Data Element

We support the inclusion of this data element but note that not all results include specimen type, as it may be implied from the test code and/or not included on the report received.

Result Status Data Element

We support the inclusion of this data element.

Test Kit Unique Identifier

The HITAC made a recommendation to include a Test Kit Unique Identifier. We note that while there is tremendous interest in this data for tests performed during the COVID pandemic as test kits were made available under an Emergency Use Authorization, it has been very difficult to record. We therefore suggest that the focus should be first on enabling a more streamlined method to acquire a Test Kit Unique Identifier before introducing this in USCDI.

Medications Data Class

The HITAC recommended starting including additional medication data that is already widely shared when communicating prescriptions. In particular, the HITAC suggested the inclusion of Dose, Strength, Formulation, Sig/Dosing Instructions, Route, and Status. We generally support the inclusion of medication data that is already widely communicated as it advances USCDI to encompass all EHI for which standards have been established. However, this is a good example of why not all HIT that intends to be certified should be required to support all USCDI data including that which it does not manage.

Patient Demographics Data Class

Date of Death Data Element

We support the proposal to add this data element.

Tribal Affiliation Data Element

We suggest only listing the value set from the submission, TribalEntityUS, not the FHIR and CDA standards references as those are beyond the scope of USCDI.

Occupation / Occupation Industry Data Elements

We suggest focusing on a single data element each for Occupation and Occupation Industry rather than introducing the more complex and extensive ODH implementation guide. The larger ODH IG should be considered in a future version after it has had an opportunity to be more widely deployed, used, and matured. For Occupation, the proposed value set (Occupation ONETSOC Detail ODH Value Set) is reasonable to start, and for Occupation Industry the Industry NAICS Detail (ODH) Value Set.

However, we are concerned that the current value sets are too granular for typical documentation and awareness use cases. The value sets should therefore either be extensible to enable the use of more coarse occupation descriptions, or introduce a leveling/hierarchy that enables the use of either more granular or coarse values as relevant to the context. The definition should recognize that capturing more than one occupation and occupation industry, while appropriate, should not be required for all HIT to support maintenance as they may only need one occupation of focus to provide necessary context.

Related Person's Name / Relationship Type Data Elements

We suggest clarifying whether this element is meant to represent a generally related person, or to address the relationships that a person may have in the context of a Care Team (e.g., guardian, caregiver), Health Insurance role (e.g., member, subscriber), administrative/financial purposes, or other contexts. We suggest that this related person is representing a general demographic relationship and is not intended to cover any of the other context-specific relationships. It could be used for patient matching or general awareness. For example, family members should not have to be listed here to be part of the Care Team or any other context. In another example, relationship types in the Patient Demographic data class should be distinct and separate from the roles a person may have as part of a care team, or other context-specific relationships, e.g., a guardian or caregiver are appropriate for a Care Team, thus not to be further referenced here, while a guarantor is appropriate for health insurance information, thus not to be further referenced here..

Current Address / Previous Addresses Data Elements

We support the adoption of the US@ specification for exchanging addresses.

Gender Identity Data Element

Considering that the proposed SOGI value set being addressed in the HL7 Gender Harmony Project has not been finalized and USCDI v2 does already include a value set, we suggest reconsidering the SOGI value set resulting from the HL7 Gender Harmony Project once finalized as a standard for a future version of USCDI.

Sex (Assigned at Birth) Data Element

Considering that the proposed value set being addressed in the HL7 Gender Harmony Project has not been finalized and USCDI v2 does already include a value set, we suggest reconsidering the value set resulting from the HL7 Gender Harmony Project once finalized as a standard for a future version of USCDI.

Procedures Data Class

Reason for Referral Data Element

The proposed definition of Reason for Referral is “An explanation or justification for why this service is being requested or was provided.” The definition of Procedures currently states “An activity that is performed with or on a patient as part of the provision of care. “ Considering the focus of the reason for referral on the request, not the actual performance of a procedure, we suggest that the reason for referral should be part of another data class. Also considering that a reason for a request is not limited to referrals or procedures, but also tests and other appointments, we suggest this become part of a new data class focusing on requests for services and include a Reason as a data element. We note that the example of a referral for transportation for SDOH interventions would be better described in that context as well.

Introduction of a Request for Services (including procedures, appointments, visits, tests, transportation, etc.) would require more definition and review; thus we suggest this update should be part of the next USCDI version. Until that time, we suggest not including Reason as the development/updates of relevant standards and implementation guides would have insufficient clarity on intent.