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April 25, 2022

Micky Tripathi, Ph.D. M.P.P.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: United States Core Data for Interoperability (USCDI) Version 3 Draft

Dear Dr. Tripathi,

Cerner Corporation appreciates the opportunity to submit public comment on the draft USCDI Version 3. As a leading supplier of clinical and management information systems and a market leader in health information interoperability, we believe our experience provides us with valuable insight in this subject area and are grateful for the ability to share that insight.

Cerner supports and appreciates the hard work and dedication of you and your staff behind the creation of the USCDI and the ONC New Data Element and Class (ONDEC) submission system and process for ongoing annual expansion of the USCDI. Cerner strongly supports ONC's drive for interoperability across healthcare stakeholders and recognizes the valuable role that the USCDI plays in that endeavor.

If you have any questions or if we can provide any additional information, please do not hesitate to contact me at (816) 201-1465.

Sincerely,

John Travis
Vice President & Regulatory Strategy Executive
Cerner Corporation

General Comments

As we have expressed in various other public comments related to the USCDI – including on the Cures Act final rule and for the draft USCDI V2 – we continue to be concerned about the rapid expansion of the USCDI given its use as a specification for Interoperability criteria in the ONC HIT Certification Program.

While each of the data elements that have been proposed as part of a draft USCDI release have their own understandable value for particular care venues and/or use-cases, the significance of the USCDI as a standard cited in the HIT Certification Program for criteria included in the Base EHR definition (particularly the Transitions of Care and Standardized API criteria at 45 CFR 170.315(b)(1) and (g)(10), respectively) appears not to be fully appreciated for its impact given that the full scope of the USCDI must be supported under current ONC regulation to certify to those criteria.

We appreciate that the USCDI has important roles to support both federal and stakeholder interests for enabling interoperability on data significant to those interests. However, on its current track, any such requirements do in fact become required capabilities of HIT certifying to the above-mentioned certification criteria or claimed by a certified HIT developer through the Standards Version Advancement Process (SVAP) making the USCDI a monolith from a requirements standpoint.

This is a problem for HIT developers who would be compelled to keep pace with support for new data elements that may be of little applicable value for the healthcare providers they serve. They may support the current scope of the USCDI V1 as it is an appropriate "core" or "common" clinical data set for interoperability, and it does comport well to the current interoperability requirements for both HL7® CDA® C-CDA[1] and HL7 FHIR® US Core for a clinical system. However, as it expands, the USCDI goes beyond this scope by incorporating data that is more aligned to revenue cycle types of applications as well as other forms and purposes of HIT beyond the direct patient care space.

Also, while it has been stated in certain forums (such as the HITAC Interoperability Standards Workgroup) that there is not a data capture requirement through use of such certified HIT for future versions of the USCDI, historical guidance from CMS for the Promoting Interoperability program suggests otherwise. Even if not, ONC guidance in Q&A with the HIMSS Electronic Health Records Association (EHRA) regarding requirements for the 2015 Edition Cures Update certification has at least asserted that HIT must support upstream

[1] References to HL7® CDA® C-CDA throughout this comment letter are intended to encompass both the HL7® Implementation Guide for CDA Release 2 Consolidation CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1 C-CDA 2.1, August 2015, June 2019 (with Errata) adopted as standard at 45 CFR 170.205(a)(4) and the HL7® CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2, October 2019 adopted as standard at 45 CFR 170.205(a)(5), as well as any future iterations of those guides.

recording of the data in addition to exchange via the specified mechanisms (HL7 CDA C-CDA and/or HL7 FHIR US Core).

We do not argue against USCDI expansion generally as the data elements have their own merit for the purposes and use cases that define their value. But we do believe it folly to continue to operate under the assumption that all such data must necessarily be supported by a singular type of HIT presented for certification to the interoperability criteria that currently require the whole of the USCDI.

Ultimately, the fact remains that under current ONC policy, healthcare providers in acute and ambulatory settings would be required to adopt technology supporting new versions of the USCDI should the current certification requirement be updated as part of any future revision to the specifications required for Certified EHR Technology (CEHRT) compliance. There is also the uncertain effect of other payment programs and reimbursement models that are beginning to cite the USCDI, such as the Centers for Medicare and Medicaid Innovation (CMMI) Accountable Care Organization (ACO) Realizing Equity, Access, and Community Health (REACH) Model which already has cited the USCDI V2 data elements as part of its requirements for participants. The adoption requirement for certified HIT for support of that participation is not clear given V2 data classes and data types are cited.

Recommendations for the future of the USCDI

Considering these concerns, we offer an alternate view of how the USCDI should be treated to allow the data set to continue to expand annually to encompass and provide standardization for a growing set of healthcare data without imposing unintended consequences for developers and users of CEHRT. Specifically, we recommend the following actions to shape the future of the USCDI:

Clarify the long-term intent of the USCDI to be the establishment of a common definition/scope for all Electronic Health Information (EHI).
As we progress towards the October 6, 2022, effective date for the Information Blocking regulation's scope expanding to all EHI, there continues to be a clear need for a defined data set representing the "all EHI" data scope. This is true both for the purpose of establishing a common understanding of what is or is not EHI, as well as providing standards for how to exchange that data in a consistent manner enabling seamless integration into downstream systems for availability at the point of care.

Building the USCDI towards this purpose will help to solve that problem in the long-term while also enabling the data set to be repositioned as a library of standardized data elements from which individual data classes or elements can be cited downstream as appropriate for specific use-cases or purposes.

Enable stratification of the USCDI when cited in regulation – particularly for the HIT Certification Program.

As we have expressed in our opening comments, the reality of the USCDI in its current state is that it is inextricably linked with the Base EHR and CEHRT concepts applicable primarily to healthcare providers in acute and ambulatory care venues. This is problematic as it does not recognize or appreciate the reality that certified HIT comes in many different shapes, sizes, and forms that have different needs/purposes, and it compels certified HIT developers (and the healthcare providers they serve) to support data that may be of little applicability to intended use. The result is workflow challenges and data overload for clinicians instead of simplifying care delivery as interoperability is intended to do.

The first such example of this was introduced in V1 with the pediatric vital signs data elements. Unless intended to serve pediatric providers, not all HIT (not even all EHR-based HIT) would have a need to support recording and exchange of such data and we now see this continued through data elements proposed in the USCDI draft V3, such as the Health Insurance Information data class. This is an example of data that, while undoubtedly valuable for many purposes, would not be recorded and maintained by all types of HIT. For example, even for a clinical EHR system, it would likely be only *accessible* in the system while being recorded and maintained externally, such as in a dedicated financial or registration system.

As a resolution for this, we recommend that any federal, state, or private sector programs that may cite the USCDI to meet their unique requirements do so by identifying the specific data classes (or even individual elements) that suit their needs, as opposed to citing the full data set. As highlighted before, we have already seen one example of this with the requirements for the USCDI V2 Patient Demographics data elements in the ACO Reach program.

For the HIT Certification Program in particular, the USCDI should transition from being a single standard cited as an "all or nothing" requirement for applicable criteria to a model where defined subsets of the USCDI can be cited for individual criteria based on what specific elements from the full USCDI data library are appropriate. This would both solve the issues with Base EHR/CEHRT criteria we called out, as well as open up opportunity for more specialized HIT to be able to be certified in the future in the Program.

Establish expectations whereby new versions of the USCDI are to go through a standards development process before being considered for the SVAP or citation in other regulation and/or programs.

Another trend we have observed through the first few iterations of the USCDI is the misconception that new versions are somehow mandatory to immediately support and

begin use of for regulatory purposes (generally in relation to CEHRT requirements). We are aware that this is untrue until such time as new versions may be named in regulation, but it is a prevalent market perception which also reflects a lack of understanding and appreciation for the standards development process that follows the adoption of new USCDI data elements – specifically for HL7 FHIR US Core and HL7 CDA C-CDA. In fact, standards development has only 3-4 months after publication of the USCDI proposed version updates to create a draft for ballot to ensure it is available in the spring of the following year for consideration of newly finalized USCDI versions in the SVAP. We note that as of April 25, 2022 (7 days before the 2022 SVAP Comment Period closing) neither the updated HL7 FHIR US Core nor HL7 CDA C-CDA providing specifications for USCDI V2 have been published by HL7.

To address these misconceptions and standards development cadence considerations, we recommend ONC explicitly modify the USCDI expansion process to note the expectation that standards development must be feasible and occur in the year following adoption of a new final version for any data classes and types not supported by standards at the time of USCDI inclusion.

Furthermore, ONC should provide recommendations to any direct downstream stakeholders who may cite new data classes and elements in programs to wait a minimum of one year before doing so to allow for standards development to have addressed any gaps in need. This would also apply to the SVAP. For example, following release of the final USCDI V3 in July 2022, the period from August 2022 through July 2023 should be dedicated to allowing for standards development and publication of implementation guides. We note that this is already the documented intended process for the HL7 FHIR US Core Implementation Guide's Future of US Core. However, official recognition and endorsement of this as part of the USCDI's growth path is needed for it to take hold.

Clinical Notes

Discharge Summary Note

In the draft USCDI V3 publication, ONC proposed a change to the Discharge Summary Note data element definition which imposes a requirement that such notes must include admission and discharge dates and locations, discharge instructions, and reason(s) for hospitalization. While we can understand the thought process behind this proposal given that the identified elements are already required to be supported as part of HIT certified to the View, Download, and Transmit to 3rd Party (VDT) criterion at 45 CFR 170.315(e)(1), it is inappropriate to impose the inclusion of explicit discrete elements as part of clinical notes that are specifically defined as narrative content intended for enabling exchange of free text clinical information.[2] Clinicians creating Discharge Summary Notes should be free to format

[2] https://www.federalregister.gov/d/2020-07419/p-489

those notes according to their expertise and discretion – including defining what information should be required based on a hospital's own application of the compliance with Conditions of Participation at CFR 482.24(c)(4)(vii).[3]

Furthermore, including these explicit data elements as requirements for an individual clinical note will create duplication of data when such notes are exchanged within a HL7 CDA C-CDA document. This is because, as mentioned above, these same elements are already required as standalone data to be included in HL7 CDA C-CDA documents certified for the VDT criterion at 45 CFR 170.315(e)(1). Accordingly, when a Discharge Summary Note containing the same data is exchanged as part of a C-CDA document using the Note Activity entry template defined in the HL7 CDA C-CDA R2.1 Companion Guide R2, the data will be duplicated.

We recommend that the proposed updates to the Discharge Summary Note definition not be adopted. Rather, if the elements (i.e., admission and discharge dates and locations, discharge instructions, and reason(s) for hospitalization) are considered important data for nationwide interoperability, they should be proposed for adoption as standalone USCDI data elements in next year's draft USCDI V4 publication. However, to be clear, adopting these as standalone data elements in the USCDI V3 would not be appropriate as industry stakeholders have not had opportunity to consider correct data class placement, definition, and potential vocabulary standards for them.

Clinical Tests

Clinical Test

In the USCDI V3 draft publication, ONC included a USCDI Clinical Tests Minimum Set value set for the Clinical Test data element. We appreciate the identification of a specific subset of codified clinical tests for clarity on the expectations and definition for the data element and are generally supportive of adopting this as standard.

However, it is important to note that not all HIT systems and healthcare providers will necessarily support the ordering and documentation of all identified tests depending on their types and specialties. A helpful clarification for the standard would be to state that it is intended as a definitional tool for the scope of the data element and individual healthcare providers and HIT systems are expected only to support what is applicable to their practice and/or technology.

[3] https://www.govinfo.gov/content/pkg/CFR-2017-title42-vol5/xml/CFR-2017-title42-vol5-part482.xml#seqnum482.24

Health Insurance Information

Coverage Status
While we believe there is real value in the adoption of a Coverage Status data element in the USCDI V3, there is some ambiguity with the element and its definition as proposed that require some modification to ensure clarity and consistency in its intended usage.

First and foremost, it is unclear whether the intent is for this element to be used for purposes of determining whether a particular claim will be paid, or simply as a status indication of whether a patient has some type of insurance coverage (or self-pay capability). We believe the intent is for the latter, in which case the use of "claim" as part of the definition is inappropriate as presence of insurance generally does not necessarily indicate coverage or guarantee payment for a specific claim.

Accordingly, while we do recommend the data element be adopted in the USCDI V3, we suggest that the following definition be used: "Active or inactive status of a particular financial instrument which may be used to reimburse or pay for health care products and services. Includes both insurance and self-payment." Additionally, we recommend the element be adopted with the HL7 FHIR® Financial Resource Status Codes value set as a vocabulary standard.

Coverage Type
In reviewing the proposed Coverage Type data element, we note that there is a conflict between possible interpretations of it which is reinforced by the existence of opposing industry standard value sets. This is also a fact that has been acknowledged by the HL7 Financial Management Group (FMG).

The first possible interpretation is that a coverage type is intended to be a representation of the type of health insurance plan that would be providing coverage. This view is represented by the Source of Payment Typology (SoPT) Payer value set which is also cited as the standard for the data element as proposed. The second possible interpretation is that a coverage type is intended to represent the actual type of coverage (not necessarily a particular health plan or health insurance coverage). This is represented by the HL7 FHIR® Coverage Type and Self-Pay Codes value set.

In our view, the latter is the more appropriate interpretation for the basic fact that there are other types of payers involved in healthcare payment than exclusively healthcare payers (e.g., such as liability carriers, auto Insurance carriers, etc.). However, this is a conflict that has not yet been fully worked out within the industry. Furthermore, in our experience there is also lack of uniformity in how HIT systems record these concepts of "type" without alignment to a specific value set which reflects a general lack of maturity.

Accordingly, we recommend against adopting this element in the USCDI until either this conflict in interpretation is resolved or the industry defines a suitable value set that can accommodate both categorizations of coverage types to be cited in the USCDI.

Subscriber Identifier
The proposed Subscriber Identifier data element is a straightforward concept that is appropriately defined. It is also not an element that could have a defined value set considering that the identifier scheme would be unique to each payer or health plan. Therefore, we recommend adopting this data element in the USCDI V3 as proposed but note that it will be critical that there be a link between the Payer Identifier and the Subscriber Identifier in downstream standards used to exchange Health Insurance Information data.

Relationship to Subscriber
The proposed Relationship to Subscriber data element is essential as part of the Health Insurance Information data class to ensure that there is a structured means by which to understand who the actual subscriber is (the patient themselves or a related person). We also appreciate that the proposed definition for the element is clear that it is intended to represent what the target patient's relationship is to the subscriber as opposed to the subscriber's relationship to the patient as there is some inconsistency in how that is handled across HIT systems today. For example, when the target patient is the child of the subscriber this element would identify the relationship as *child* instead of identifying the relationship in the reverse manner as *father or mother*.

However, it is important to adopt a standard value set to ensure consistent use and application of the data element in the real world. One possible value set to consider is the HL7 FHIR® Subscriber Relationship Codes value set. However, this is limited in its available values and may not appropriately account for all relevant relationships that are commonly captured in HIT systems today. A more appropriate standard value set would be the X12 Individual Relationship Code value set. This is already ubiquitous in the industry considering that it is what payers are obligated to use for HIPAA transaction standards. Therefore, we recommend that the data element be adopted with the proposed definition and cite the X12 value set as vocabulary standard.

Member Identifier
As with the proposed Subscriber Identifier data element, the proposed Member Identifier data element is straightforward and has an appropriate definition. It also is not in need of a standard value set to be cited as the identifier scheme would be unique to the payer.

The only potential complexity we see with this element is the case of patients who are part of Medicare Advantage plans who will have multiple Member Identifiers – one for the primary

insurer and a second for the Medicare Beneficiary Identifier (MBI). We note that this, much like with the Subscriber Identifier data element, creates a critical co-dependency with the Payer Identifier element. However, this is something that should be able to be appropriately accounted for within downstream exchange standards assuming requisite guidance is provided to standards developers.

Accordingly, we recommend that the Member Identifier data element be adopted as proposed with no standard value set cited.

Group Number
We have no concerns or recommended changes to cite for the Group Number element and believe it is appropriate to adopt as proposed.

Payer Identifier
The Payer Identifier data element, while seemingly straightforward on the surface, is an extremely complex concept that lacks any level of standardization in the industry today. For starters, there is no single definition or issuing authority for a common payer identifier. Instead, payers often assign themselves their own identifier, and there are many different assigning authorities, such as clearinghouses, that also issue their own proprietary identifiers. Examples of these include Change Healthcare and SSI. There are also other examples such as the National Association of Insurance Commissioners (NAIC) company code identifier which is more of a generic identifier for any type of insurance company, whether healthcare-focused or not.

There is also the critical question of whether the Payer Identifier element is intended to be applied solely at the highest level of the payer entity or at the level of an individual health plan (of which a payer entity would generally offer multiple). This would also be relevant, for example, as to whether this data element would be used as part of an electronic prior authorization process to enable connections with the correct payer/health plan. Based on the definition provided (and the presence of the separate Group Number data element in the proposed data class), we believe the intent is for this Payer Identifier element to represent specifically the highest-level payer entity, but that should be further clarified in the definition, if adopted.

Collectively, the lack of uniformity and ambiguity is problematic for the adoption of this data element, but these are not simple issues that can be remedied in short order by deferring the element's adoption to a future USCDI version. Furthermore, as we have noted in our comments on other data elements in the proposed Health Insurance Information data class, the Payer Identifier is a critical element with multiple co-dependencies. Therefore, despite these concerns, we do recommend that if the Health Insurance Information data class is adopted at all in the USCDI V3, that the Payer Identifier data element be included. And until a

single assigning authority has been established that covers all payers, there should be guidance published along with the data element stating that a minimum set of assigning authorities is established that collectively would cover all payers to provide appropriate context to recipients.

Health Status

Health Concerns and Smoking Status

We support the proposal to re-classify the Smoking Status data element under the newly proposed Health Status data class as part of the USCDI V3. This change aligns with the nature of the proposed Health Status data class which consists of elements that would generally be represented through variations of the HL7 FHIR Observation resource.

Regarding the Health Concerns data element, we are generally neutral as to the data class the element resides in given that downstream exchange standards will ultimately more directly dictate how particular elements are categorized. However, it is worth noting that Health Concerns are represented in HL7 FHIR via the Condition resource which would place them in stark contrast to the rest of the proposed Health Status data class which would be represented via the HL7 FHIR Observation resource.

Pregnancy Status

Having knowledge of a patient's pregnancy status is an important facet of grasping the full picture of their healthcare needs and providing the right care. Accordingly, we support the adoption of Pregnancy Status as a data element under the Health Status data class with the USCDI V3. Furthermore, we recommend adopting the element with the International Patient Summary (IPS) Pregnancy Status value set as the standard. This value set is cited in HL7 FHIR International Patient Summary Implementation Guide's Observation (Pregnancy: status) resource profile and offers a simple value set utilizing LOINC codes.

However, it is also important to remember that a pregnancy status is a point in time observation that may not be consistently maintained or updated for currency depending on how often a patient has an encounter with a particular provider. For example, a patient may see a specialist provider during their pregnancy and have their pregnancy status recorded as "Pregnant" but not see that provider to have the status observation refreshed as part of that provider's local health record until long after the completion of their pregnancy. In this case, an incorrect status could very easily be exchanged with downstream providers in perpetuity that reflected the one-time status when the patient was pregnant. Accordingly, we recommend that an additional data element of the Estimated Due Date (EDD) be adopted alongside Pregnancy Status to provide appropriate context and timing information for the status observation. This will help to ensure that, even if an incorrect status is exchanged like in the example above, the EDD will provide downstream consumers with the necessary

context to infer that the status is likely outdated and needs to be reviewed before incorporating into a patient's local health record.

In our experience, it is already common procedure to record an EDD alongside the Pregnancy Status observation so adoption of this additional element should not create a heightened burden for stakeholders. Additionally, there is already an existing Observation (Pregnancy: EDD) resource profile as part of the in HL7 FHIR International Patient Summary Implementation Guide (which is also referenced as part of the Observation (Pregnancy: status) resource profile) as well as an Estimated Delivery Date entry template as part of HL7 CDA C-CDA R2.1 Implementation Guide (which is similarly referenced within the Pregnancy Observation entry template).

As a final note, it will be important that the EDD data element be adopted with a definition clarifying that it is only relevant and expected to be recorded/exchanged if the patient's Pregnancy Status is recorded as Pregnant.

Functional Status

In reviewing the proposed Functional Status data element for adoption in the USCDI V3, we are concerned that the proposal is too broad and non-specific to yield a successful implementation of a new standardized data element in the USCDI. To be effective and useful to stakeholders, a data element for recording and exchanging of a patient's functional status must cite explicit functional status assessments that would be considered authoritative for data exchange. There could still be some flexibility to use additional assessments that may produce a functional status observation, but a standard set of assessments is needed to establish a consistent and effective definition for the data element across stakeholders.

This is critical not only for the purpose of ensuring a common understanding for the data element, but also for establishing usable value of the data element for healthcare providers. In our experience, "assessment" is a very loose term in healthcare and different care venues have different assessments that are meaningful to them. This also means that two different providers may not ascertain the same meaning even if they are viewing the same functional status assessment. This is not problematic in and of itself, but it does pose an issue when one considers making this a standard interoperability element as part of the USCDI because if there is no understanding of what individual providers utilize and derive value from in context of functional status assessments, then there is little tangible value in exchanging the data.

For the reasons outlined above, we strongly recommend against adopting this data element as part of the USCDI V3. To be clear, this is not because functional status data does not offer value for delivery of healthcare. Rather, the element simply is not mature enough for adoption in the USCDI given the inconsistency in use of standard forms of functional status

assessments and the lack of a standard set of same that would provide value across care venues to define as part of the USCDI data element.

Because of the difficulty of standardizing assessment methods in the near future, we recommend ONC's focus for the immediate term should be put to establishing a common/standard set of functional status assessments to adopt as part of the data element in a future version of the USCDI. A possible starting point to consider is the set of standardized patient assessment data elements (SPADEs) adopted as part of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 or the International Classification Function, Disability, and Health (ICF).

Mental Function

In reviewing the proposed Mental Function data element, we note that there is a lack of clarity from the definition provided as to whether the intent is for this element to capture data providing an indication of cognitive impairment in a patient (e.g., Alzheimer's or dementia) or psychological and psychiatric mental health conditions. It appears more likely that it is the former, however, like the concerns expressed for the Functional Status data element, there is not a standard set of assessments cited to make that abundantly clear.

Accordingly, consistent with the Functional Status data element, we recommend that Mental Function not be adopted as part of the USCDI V3. Instead, a specific set of assessments that can capture the intended observations for the data element across various care venues should be identified so that it can be reconsidered for a future USCDI version. As with our recommendations for the Functional Status data element, this is not because we believe that the data is not valuable in the delivery of healthcare. Rather, the necessary specificity and maturity simply is not available to justify adoption in the USCDI.

Disability Status

We are encouraged to see that for the proposed Disability Status data element there is an existing LOINC-coded value set – the Disability Status value set – consisting of a standardized six-question assessment that is already utilized as part of the Disability Status resource profile in the HL7 FHIR Implementation Guide: Electronic Case Reporting (eCR). This standard provides a recognized assessment that could be cited and used consistently across care venues to assess and communicate a patient's disability status that we noted is lacking for the Functional Status and Mental Function proposed data elements.

However, in our experience, disability status is not a data point commonly captured and exchanged across care venues, nor is there currently a tangible clinical use-case driving the collection of this data across venues. Therefore, we do not believe there is currently an appropriate level of value for the care venues impacted most directly by the USCDI to compel its adoption in the USCDI V3. In fact, the original submission for this data element specifically

cites automation of applications for disability benefits as a primary use-case for the data. That being the case, this data element is more appropriate to be adopted as part of a USCDI+ extension for an isolated use-case related to public sector benefits determination.

As a last point, although we recommend against its adoption in the USCDI V3, we also reiterate that if Disability Status were to be adopted as part of the core USCDI, the Disability Status value set should be cited as the standard.

Additional Comments
As a final recommendation applicable to the proposed Functional Status, Mental Function, and Disability Status data elements collectively, we recommend that once these elements are fine-tuned as suggested above, ONC consider adopting and re-classifying them under a data class dedicated to assessments in a future USCDI version. This would more appropriately capture how the data points originate and allow for expansion to a broader set of standardized assessment-based observations over time.

As we have expressed in our comments above, it would be critical that any data elements adopted as part of such a data class be done with explicit assessments/tools cited as standard for each. With that in mind, we suggest ONC consider looking towards the International Classification Function, Disability, and Health (ICF) as a source for defining such standards. The ICF, while primarily adopted in Europe to date, offers a proven and elegant way of expressing how a patient functions overall inclusive of the diverse types of status observations being considered here for the USCDI V3.

Laboratory

Specimen Type
We support the proposal to adopt Specimen Type as a new data element under the Laboratory data class in the USCDI V3 to assist in addressing public health priorities. There is clear value in having knowledge of the specimen from which a laboratory test result was derived, and such information is already commonly recorded and exchanged in healthcare today.

To further standardize the exchange of the specimen type with laboratory tests and results, we recommend ONC adopt this new data element with the HL7 v2 Specimen Type value set as the vocabulary standard. This is a widely recognized value set for exchange of specimen information that is cited in common exchange standards including the HL7 FHIR® R4 Specimen resource. Furthermore, it provides mappings to alternate code systems (including SNOMED-CT) that may be used in certain local systems.

Result Status
We support the proposal to adopt Result Status as a new data element under the Laboratory data class in the USCDI V3 to assist in addressing public health priorities. Understanding the status of a result is critical in correctly interpreting its meaning and exchanging the status as part of a result is already common practice in healthcare.

We also recommend adopting the HL7 Observation Status value set as the vocabulary standard for the data element to further standardize its exchange. This is the most appropriate value set as it is what the industry is currently coalescing around via its citation in the HL7 FHIR® R4 Observation resource along with various Profiles for the resource adopted under HL7 FHIR® US Core. It is also more appropriate than other value set options such as the HL7 Result Status value set cited in the HL7 CDA C-CDA R2.1 IG for representing result status in the Result Observation (V3) entry template as it is more expansive and tailors to the most commonly used and appropriate values.

Patient Demographics

Date of Death
We support the proposal to adopt Date of Death as a new data element in the Patient Demographics data class for the USCDI V3. Understanding a patient's deceased status is a simple and important data point for care providers to be aware of and should be recorded routinely as part of a patient's record when a death occurs. In our experience, there are instances in which a patient's summary of care documentation may be transmitted to a downstream provider after death without clear indication of the deceased status which can lead to confusion for care providers and other potential adverse scenarios.

Considering that this data element is a basic date observation, we agree that it can be adopted without citing any vocabulary standard.

Tribal Affiliation
In reviewing the proposed Tribal Affiliation data element, we note that there are three unique vocabulary standards identified: The HL7 FHIR® US Public Health Tribal Affiliation extension, the HL7 CDA Tribal Affiliation template, and the TribalEntityUS HL7 value set. Setting aside the fact that we have been unable to identify the existence of a Tribal Affiliation template in any published HL7 CDA specification, both the HL7 FHIR® and HL7 CDA standards represent content exchange standards as opposed to vocabulary standards. Therefore, given that the USCDI is content exchange standard-agnostic, adoption of either of those standards would be inappropriate for this (or any) USCDI data element.

Accordingly, if the Tribal Affiliation data element is adopted as part of the USCDI V3, the TribalEntityUS HL7 value set should be adopted as the sole vocabulary standard.

Related Person's Name and Relationship

In reviewing the proposed new data elements for Related Person's Name and Related Person's Relationship, we believe there is a potential conflict/redundancy between these data elements, as defined, and other USCDI data elements either already adopted in the USCDI V2 or also proposed as part of draft the USCDI V3.

The Care Team data class elements for Care Team Member's Name and Care Team Member's Role largely account for what would be captured and exchanged as part of Related Person data elements based on their proposed definitions which specifically identify that Related Persons would be those involved in the care of the patient. This would include such cases as a child or spouse who acts in a caregiver role for an elderly patient, a guardian who acts as a primary contact for a patient's care, and many other scenarios of non-clinical persons playing a role in a patient's care. While there is not an official definition adopted for the Care Team Member Name and Role data elements, it is implied that their definitions would be essentially equivalent to what is being proposed for Related Person's Name and Relationship.

Additionally, in cases where the related person may not be considered a true care team member given the relationship is solely financial in nature (which may or may not be considered a care team member depending on individual interpretations), the related person would still be accounted for under the Health Insurance Information data elements proposed in the draft USCDI V3 (most specifically through the Relationship to Subscriber element).

Although the proposed definitions do not reflect it, we recognize that there is a possibility that a patient could have individuals who may be considered a related person in certain scenarios even though they are not directly involved in their care or payment for care. This could include, for example, a family member. Furthermore, this is a concept that is already supported in HL7 FHIR via the RelatedPerson resource, where the RelatedPerson.name attribute would represent the Related Person's Name element, and the RelatedPerson.relationship attribute would represent the Related Person's Relationship.

Accordingly, we recommend that these data elements be adopted with two specific changes:

First, the definition must be updated to reflect the intent that these elements are utilized for representing only relationships which are not already accounted for under either the Care Team data class or the Relationship to Subscriber data element under the Health Insurance Information data class (assuming it is adopted in the USCDI V3). As expressed above, this is critical to avoid redundancy and duplication of data that can lead to confusion and overload.

Second, there is an error with the proposed vocabulary standards that needs to be addressed. As proposed in the draft, the CDC-defined HL70063 value set is defined as a vocabulary standard for the Related Person's Name data element. This appears to be a mistake as it would apply to the Related Person's Relationship data element (Related Person's Name could not have a vocabulary standard). However, we recommend that the FHIR Patient Relationship Type value set be adopted as the vocabulary standard for Related Person's Relationship in its place. This is a more robust value set that is already cited in the commonly used HL7 FHIR® RelatedPerson resource.

Occupation
We agree that recording and exchange of a patient's occupation has a clear purpose in clinical care and support its adoption as defined in the USCDI V3. A person's work and what that work may expose them to or place them at heightened risk of is a critical health factor that could be used more frequently in clinical care and for proactive and preventive care purposes. For example, knowing that a patient's occupation may potentially expose them to contaminants like asbestos or to smoke inhalation could help alert care providers to the need for particular screening and/or testing. The COVID pandemic has also exposed a need for better understanding a patient's occupation given that various occupations expose individuals to higher risk of contracting viral infections.

Regarding a vocabulary standard for the data element, we understand the value of standardizing responses to the extent possible and do not have any Issue with the proposed Occupation ONETSOC Detail value set. However, it is important to recognize the fact that a single value set is highly unlikely to suitably account for the full range of possible occupations a patient may identify. Accordingly, if the proposed value set is adopted for the element, there should be specific notation that the value set is intended to be extensible to allow for other custom entries to be defined and exchanged, as necessary.

Occupation Industry
We also support adoption of the Occupation Industry data element in the USCDI V3 as defined to serve as a categorizing element for Occupation. However, we also reiterate that the proposed value set would minimally need to be noted as extensible given the reality that a single value set will not be able to appropriately account for all possible industries an individual might identify.

Sex (Assigned at Birth)
While not formally proposed as part of the draft USCDI V3, ONC requested feedback with the draft on the existing value set for the Sex (Assigned at Birth) data element – specifically around potentially aligning the element with the HL7 Gender Harmony Project's new concept of Record Sex or Gender.

We appreciate the feedback request and the work that the Gender Harmony Project is doing, and we believe that the direction for how Sex (Assigned at Birth) is treated under their data model has merit. However, we recommend against adopting any changes to the Sex

(Assigned at Birth) value set with the USCDI V3 for a few reasons. First and foremost, the implications for a change to consider Sex (Assigned at Birth) a Recorded Sex or Gender as defined by the Gender Harmony Project are not entirely clear (see additional points bulleted below). Having a full understanding of the range of impacts to stakeholders by adopting such changes and taking those into account up-front is critical to avoid confusion and unintended consequences. Additionally, making such a change without corresponding updates to Certification Program requirements for the Demographics criterion (45 CFR 170.315(a)(5)) would seemingly place providers and developers at risk of non-compliance if they were to adopt the USCDI V3 standards in their systems/practices (and, at minimum, there would be extensive confusion and inconsistency).

Instead, we have outlined the following considerations and questions that would need to be addressed for stakeholders to understand the full scope of impacts to HIT systems, healthcare workflows/processes, and data exchange if changes to align to the Recorded Sex or Gender concept were to be adopted.

- What would the expected value set be for Sex (Assigned at Birth) if aligned as a Recorded Sex or Gender? Per the Gender Harmony Modeling Sex and Gender Representation, Release 1 HL7 Informative Document, the standard value set would consist of F, M, X, and < values that would be extensible for local implementations (such as individual states with different Birth Certificate value sets). Does this indicate that there would no longer be a single standard value set required for Sex (Assigned at Birth) under the USCDI and it would simply be fully extensible per use-case or local need?
- What would this change mean for exchange of existing documented Sex (Assigned at Birth) observations – does adopting Sex (Assigned at Birth) as a Recorded Sex or Gender mean that such legacy medical record documentation should be updated in some way?
- Is Sex (Assigned at Birth) as a Recorded Sex or Gender still to be considered a value that should be recorded on all patients (as able) and exchanged? Understanding those expectations for all sex and gender concepts is critical for both HIT developers and healthcare providers.
- If Sex (Assigned at Birth) were updated to align with the Recorded Sex or Gender concept, would that mean that other existing sex or gender concepts in HIT systems that fit under the Recorded Sex or Gender concept as defined in the Gender Harmony Modeling Sex and Gender Representation, Release 1 HL7 Informative Document (e.g., administrative sex, administrative gender, legal sex, etc.) would also be expected to re-align as Recorded Sex or Gender observations?
- Would this change indicate that Sex (Assigned at Birth) is no longer intended to be considered within HIT system logic for clinical determinations (e.g., as part of determining reference ranges or clinical decision support)? If so, we believe adopting additional changes to incorporate a Sex for Clinical Use (SFCU) concept (also cited in Gender Harmony's Modeling Sex and Gender Representation, Release 1 HL7 Informative Document) should be a hard dependency for this change to the Sex

(Assigned at Birth) concept – both for the USCDI as a data set and for HIT systems implementing the change.
    - Given the significance of the impact and the confusion that pertained to ONC's earlier updates for sex and gender related concepts in the 2015 Edition rulemaking, the prospect of adopting another net-new concept for sex raises an additional set of questions and concerns for implementers, such as: what existing sex or gender documentation within existing medical records should be updated to these new concepts and which data elements within such records should they populate? What sex or gender fields would then be appropriate to display face-up in a record and/or be used as the source of truth for identifying and addressing patients? What procedures should be followed for recording these fields (e.g., patient-reported vs. only based on documentation sources or an actual medical examination)?
- What value(s) should be used for billing and benefits determination by payers for items, services, procedures, diagnostic testing, or other clinical care that are sex-specific? Presumably, a patient's sex documented with their insurance company would be treated as another Recorded Sex or Gender (like Sex (Assigned at Birth) is) under the Gender Harmony model. However, as Gender Harmony's Modeling Sex and Gender Representation, Release 1 HL7 Informative Document points out, many patients may have a legitimate clinical need for care that is considered specific to a different sex than what is on file for their insurance. This is an important issue which is already posing serious challenges for stakeholders and needs to be at the forefront of any consideration for adopting new or revised sex/gender concepts and interoperability requirements.

There are many other questions that come into play – especially as we get into the considerations for adoption of the SFCU concept alongside any changes to Sex (Assigned at Birth). However, the above considerations are a good starting point that provide a lens into the complexities of appropriately handling of sex and gender in HIT systems, and the significant implications that even modest changes to established processes can carry for both HIT developers and healthcare providers using the systems.

Gender Identity

Like the Sex (Assigned at Birth) data element, ONC requested feedback on aligning the value set for the existing Gender Identity data element with the HL7 Gender Harmony Project's new recommended value set. We do support the idea of updating the Gender Identity value set to align with the Gender Harmony Project's recommendations for many of the same reasons that are outlined in Gender Harmony's Modeling Sex and Gender Representation, Release 1 HL7 Informative Document. However, there are some important considerations that must be accounted for before making such a change.

First, the adoption would create misalignment between the USCDI V3 and standards adopted under the Certification Program regulations for the Demographics criterion (45 CFR 170.315(a)(5)). Unless ONC made equivalent changes to those regulations (or offered

discretion for HIT developers and healthcare providers subject to compliance with the standards), this creates the potential for compliance risks for developers and providers who would make updates to align with the USCDI V3. This is something ONC must address if this change were adopted in the USCDI V3 (or any future USCDI version).

Second, given that Gender Identity has been recorded using the broader value set currently required for ONC's HIT Certification program and cited in the USCDI V2, there is a need for standardized mapping to be provided from that value set to the new one promoted by Gender Harmony to ensure preexisting documentation is accurately and consistently updated and/or mapped to the new values.

Third, while the new Gender Harmony value set offers distinct advantages over the existing one, the reduction in available values can also cause the loss of specificity and detail that can be important for clinicians and others involved in a patient's care. Accordingly, if the Gender Harmony value set is adopted in the USCDI V3, we recommend adding specific notation that the value set is intended to be extensible to allow local systems to utilize more granular value sets as needed. We also suggest that a concerted effort be made to promote inclusion of standardized means of exchanging contextual information such as comments for recorded values in downstream standards.

Current and Previous Address

Like the Sex (Assigned at Birth) and Gender Identity data elements, ONC requested feedback on the possibility of adopting the US@ Project specifications as standard for the existing Current Address and Previous Address data elements. While we do believe that this is the correct direction for the data set to establish consistency in the industry, given how new the standard is we recommend that ONC defer Its adoption for the USCDI V3 and formally propose its adoption for these elements in the draft USCDI V4.