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Submitted electronically via the Draft USDI v3 website

The Honorable Micky Tripathi
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20201

Re: United States Core Data for Interoperability Draft Version 3

Dear Dr. Tripathi:

Vizient, Inc. appreciates the opportunity to comment on the Office of the National Coordinator (ONC) Standards Bulletin 2022-1 (SB22-1) which discusses the latest, draft version 3 of the United States Core Data for Interoperability (USCDI) standard (Draft USCDI v3). Many of the topics in SB22-1, including USCDI v3, have a significant impact on our members and the patients they serve.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 50% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics and advisory services, as well as a contract portfolio that represents more than $100 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

In our comments, we respond to various issues raised in the SB22-1 and offer our recommendations to constructively improve USDCI v3 and to support efforts related to health equity. We thank ONC for the opportunity to share recommendations related to USCDI v3 and note our general support for several of the changes included in the most recent draft version. However, Vizient believes it is important that additional clarification on a range of data elements be provided before USCDI v3 is finalized. In addition, we offer recommendations for future iterations of USCDI and provide suggestions related to health equity for additional consideration.

Are there any improvements needed in the data classes or elements included in Draft USCDI v3?

As described below, Vizient offers several suggestions related to the data classes or elements included in Draft USCDI v3. Notably, Vizient is generally supportive of several of the changes included in USCDI v3 as we believe they will help support more robust and accurate data collection for hospitals and other providers.

Appropriate and meaningful data class and element names and definitions?

Regarding the medication element, Vizient requests additional information regarding whether there is a specific list of medications based on USCDI requirements or if specific RxNorm fields are required. Based on Vizient's review of Draft USCDI v3 and previous USCDI versions, this is unclear and additional context regarding this data element is not provided in the Draft USCDI v3. We encourage ONC to provide such clarity upon finalizing USCDI v3 and for ONC to consider adding a National Drug Code (NDC) field to this element.

Should other data elements classified as Level 2 be added USCDI v3 instead or in addition to those included in Draft USCDI v3? If so, why?

Vizient recommends adding the below Level 2 data elements to USCDI v3. In support of these additions, use cases are also provided for consideration:

- Medications
    - Medication Administration: This allows for further insight and analyses of which medications were administered within visits.
    - Negation Rationale: This will allow for analyses as to what medication orders are being placed and then subsequently cancelled on a regular basis in addition to why they are being cancelled.
    - Dosage: This information allows for sharing of detailed dose information to patients and other parties rather than simple medication name which can lead to additional insights on dosing patterns.
    - Discharge Medications: This distinguishes which medications were prescribed for a patient to start/continue from the point of discharge and minimize confusion with medications prescribed as an inpatient.
    - Medications Dispensed: The allows for differentiation of which ordered medications were actually dispensed (e.g., generic). This may be different from what was ordered or administered as it is the result of a pharmacy system responding to a medication order.
- Facility Level Data
    - Facility Identifier: This allows for more detailed information as to which setting and facility a patient is receiving their care from within an organizational structure.
- Laboratory
    - Laboratory results (date and timestamps): Date and time stamps would allow for trending of labs over time. This could be especially helpful when initially adding patient data into Fast Healthcare Interoperability Resources (FHIR) databases since the upload date would be similar for all results.
- Observations
    - Observation Value; Observation Code; and Observation Performer: These 3 elements combined could be used to detail what kinds of observations took place, what the observations resulted in, and who ended up performing those observations during the visit.
- Social History

    - Alcohol Use: Standardizing alcohol use documentation will allow for accurate comparisons and trending over time and across care settings.
    - Drug Use: Standardizing drug use and drug abuse screening results will allow for accurate comparisons and trending over time and across care settings. This can tie into the focus on Social Determinants of Health (SDoH) with accurate and quantifiable data to allow for accurate assessments of a patient's social needs.
- Vital Signs
    - BMI: Inclusion of BMI would allow for quicker querying of patients in FHIR via BMI rather than having to calculate BMI from the data elements Body height and Body weight. A potential benefit to patients is that addition of BMI would provide more health information, especially as certain patients may not do the calculations themselves (e.g., patients outside of the 2-20 years range for which BMI percentile is included currently).
    - Vital Sign Results: date and timestamps: The addition of dates and time stamps would allow for trending of vital signs over time from various visits rather than relying on the date that the vital sign results were uploaded. This information could be especially helpful when initially adding patient data into FHIR databases. For example, if 3 blood pressures from different visits across 3 different months were all uploaded at once into a FHIR server, they would all show the same date that they were uploaded rather than having a reference date from when they were actually recorded.
- Social Determinants of Health
    - Outcomes: Vizient agrees with the use case description submitted to ONC by the Gravity Project.[1] Overall, addition of the Outcomes element would allow for enhanced measurement of SDoH interventions, which may then also be used in the context of quality measurement. Also, the addition of an Outcomes element would allow for a more complete information, as currently available SDoH elements, which are included in different data classes, do not include outcomes (e.g., SDoH Assessment, SDoH Problems/Health Concerns, SDoH Goals, SDoH Interventions).

Data Elements for Future Consideration after USCDI v3

Vizient appreciates ONC's efforts to build upon USCDI by providing new versions and additional clarity. For future versions of USCDI, Vizient encourages ONC to consider further clarifying the following elements and classes:

- Class: Care Team Members
    - Add care team member specialty options as an element. This change would help hospitals group outcomes by care team member specialty and would provide more comparison opportunities for outcomes across health care organizations.
- Class: Encounter Information
    - Add diagnosis sequence and encounter status (e.g., scheduled, cancelled, closed) as elements. This addition would give insight to what diagnoses were

[1] https://www.healthit.gov/isa/taxonomy/term/1846/level-2

associated with the designated encounters, and whether the encounters had already been closed, pending for future appointment or cancelled.

- Class: Procedures
    - Add procedure sequence as an element. The addition of procedure sequence and procedure time (as noted below) would allow for measurement of various times associated with procedures, in addition to providing further clarification as to which steps took place from start to finish for each procedure.
    - Add Procedure time as an element. Examples of procedure time include scheduled case start and end time, patient in room and patient out-of-room, anesthesia start and end time, incision start and end time; and recovery start and end time. The addition of procedure time (with procedure sequence, as noted above) would allow for measurement of various times associated with procedures, in addition to providing further clarification as to which steps took place from start to finish for each procedure. Also, recovery time could be tracked and referenced as variations in practice are considered.
- Class: Patient Demographics:
    - Add 'Broadband Availability' or 'Cellular service/Smartphone Availability' as an element. The addition would help match actionable factors to clinical outcomes in underserved populations.
- Element: SDoH Assessment
    - Currently, this element's description references structured evaluation of risk tools, like the Protocol for Responding to & Assessing Patients' Assets, Risks & Experiences (PRAPARE), Hunger Vital Sign, Accountable Health Communities Health Related Social Needs screening tool, but the applicable vocabulary standards are: Logical Observation Identifiers Names and Codes (LOINC®) version 2.71 and SNOMED International, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, January 2022 Release. As a result, it is unclear how evaluation of risk tools (and which version of those tools) were identified for inclusion in this data element. While Vizient understands separate opportunities for comment and feedback may exist and that these particular comments may be beyond the scope of the USCDI v3 comments, we encourage more coordination between such stakeholders. Vizient believes such coordination is important, especially as more screening tools are available electronically.

Are there significant barriers to development, implementation, or use of any of the Draft USCDI v3 data elements that would warrant not including them in USCDI v3?

Vizient notes that, as of the time of our comments, we did not encounter barriers to add the selected elements. We encourage ONC to include the elements in the draft USCDI v3 in the final version.

SB22-1: ONC Request for Additional Feedback on the Following Data Elements

Sex assigned at birth
In SB22-1, ONC indicates it is seeking additional information regarding the data element, Sex (Assigned at Birth), as it has observed that changes to the concept may be in order based on industry activities. For example, as provided in SB22-1, the Health Level 7® (HL7®) Gender Harmony project (Gender Harmony) has been working to clarify the purpose and use of Sex

Assigned at Birth, including distinguishing it from other sex and gender related concepts, such as “gender identity” and “sex for clinical use.” Vizient agrees with the clarification that Sex Assigned at Birth is a distinct data element from Gender Identity. Vizient would additionally support the Gender Harmony project’s proposal of additional data fields but offers two additional recommendations for two elements.

Specifically, instead of “Administrative Gender” Vizient suggests “Current Anatomical Sex” to provide clarity for providers and patients. Vizient notes that since Gender is a social construct while Sex is deemed a clinical construct, this term should be modified to identify current sex of the patient for both clinical and administrative purposes. In addition, Vizient is concerned “Sex for Clinical Use” is confusing and may decrease the accuracy of collected data. Vizient notes that “Current Anatomical Sex” would be a clearer description and should replace “Sex for Clinical Use”. Standardization of all of these data elements and the ability to share them across platforms will better serve the patient and will provide accurate data on health equity issues for transgender patients.

Gender Identity
Vizient supports the addition of a Gender Identity data element including Male, Female, Non-Conforming Gender, and Other. In concert with the Sex Assigned at Birth element, the standardization of Gender Identity data will provide accuracy and clarity to the identification of transgender patients. Additionally, Vizient recommends data standardized field for collection person-identified pronouns (He/Him/His, She/Her/Hers, They/Them/Theirs, etc.).

Patient Address
Vizient appreciates ONC’s efforts to improve the quality and standardization of patient address. Neighborhood factors provide vital context for how access to care and health outcomes are inequitably distributed. Thus, more consistent and accurate patient address information will help support community and other efforts that aim to improve community-level SDoH.

Population Level Monitoring

As the COVID-19 pandemic has made clear, data plays a critical role in public health surveillance and response. USCDI v3 takes numerous steps to address public health reporting priorities by, for example, adding Specimen Type and Result Status to the Laboratory data class and elements like Occupation, Occupation Industry and Pregnancy Status. To build upon this effort, Vizient emphasizes the need for population level monitoring support. For example, large-scale population-level data exports are challenging. Even though strides have been made, like the FHIR Bulk Data API, Vizient encourages more collaboration and resources be provided to support bulk transmissions to third parties.[2] In addition, we recommend that third parties using such information be involved in ONC’s efforts to identify improvements and test effectiveness, especially as this will be an area where collaboration will need to be ongoing.

[2] https://www.healthit.gov/test-method/view-download-and-transmit-3rd-party

Conclusion

Vizient appreciates ONC's efforts to gain additional feedback regarding the SB22-1, particularly as it relates to USCDI v3. Vizient membership includes a variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. In closing, on behalf of Vizient, I would like to thank ONC for providing the opportunity to respond to SB22-1. Please feel free to contact me, or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these recommendations.

Respectfully submitted,

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