United States Core Data for Interoperability (USCDI)
ONDEC (ONC Data Element and Class) Submission
CAP Comments

The College of American Pathologists (CAP) appreciates the opportunity to comment on the draft of USCDI version 4. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine.

Data sharing through widely accepted standards is critical to ensure that health information is available and comprehensible across care settings for use in patient care, public health, and emergency (eg, pandemic) preparedness and response. For broader sharing of electronic health information, the USCDI is critical to establishing foundational standards to support patient care. The CAP is pleased that the draft version of USCDI v4 is a dramatic improvement on previous versions and will offer comments for how to further improve USCDI v4. The CAP emphasizes that there should be alignment of data element names and meaning between USCDI and FHIR to simplify and promote the accuracy of future data element mapping.

The ONC has issued a request for information as to whether a single USCDI data element *Time of Procedure* satisfies the community submissions to add timing elements to a variety of USCDI data classes. The CAP does not support the use of a single *Time of Procedure* data element for pathology and laboratory purposes, as it cannot clearly represent the laboratory times and dates that are required by regulation to be reportable. For example, it is unclear whether a single data element named *Time of Procedure* is indicating the time of the sampling procedure or the time of the analytic procedure. Separate laboratory data elements are necessary to represent regulatorily mandated laboratory dates and times in the USCDI. With respect to current USCDI submissions, this single *Time of Procedure* data element would not be sufficient to represent the Level 2 laboratory time data elements, which are necessary for interoperability and should be added into the USCDI.

USCDI v4 Elements:

- **Data Class:** Laboratory
- **Data Element:** Result Reference Range
- **CAP Comment:** The CAP applauds the ONC's decision to add this data element to USCDI v4, as this data element represents the upper and lower limit of test values expected for a designated population of individuals and is required by CLIA. However, the CAP would like to note that a simple text field for this data element (as in HL7 2.5.1) is inadequate for interoperability. The CAP recommends that this Result Reference Range data element be aligned with the FHIR observation.referenceRange element, which supports discrete low and high values, normalValue (expected value), and text based reference descriptions. For this data element, the CAP recommends UCUM for units and SNOMED CT for non-numerical values.

- **Data Class:** Laboratory
- **Data Element:** Result Interpretation

- **CAP Comment:** The CAP applauds the ONC's decision to add this data element to USCDI v4, as this data element represents the categorical assessment of a laboratory value (e.g. "high", "low", "critical", etc.) and is required by CLIA. The CAP recommends that the HL7 interpretation code system and value set—which was in the original submission for this data element—be added as a minimum vocabulary standard for this data element. The CAP would also recommend that the ONC include SNOMED CT as a vocabulary standard for this element.

- **Data Class:** Laboratory
- **Data Element:** Specimen Source Site
- **CAP Comment:** The CAP applauds the ONC's decision to add this data element to USCDI v4, as this data element indicates the body location where a specimen was obtained and is required by CLIA.

- **Data Class:** Laboratory
- **Data Element:** Specimen Condition and Disposition
- **CAP Comment:** The CAP applauds the ONC's decision to add this data element to USCDI v4, as this data element includes any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability relevant to the performance or non-performance of a test as required by CLIA. The CAP recommends that SNOMED CT—which was in the original submission for this data element—be added as the vocabulary standard for this data element.

- **Data Class:** Procedures
- **Data Element:** Time of Procedure
- **CAP Comment:** The ONC has issued a request for information as to whether a single USCDI data element Time of Procedure satisfies the community submissions to add timing elements to a variety of USCDI data classes. The CAP does not support the use of a single *Time of Procedure* data element for pathology and laboratory purposes, as it cannot clearly represent the laboratory times and dates that are required by regulation to be reportable. For example, it is unclear whether a single data element named *Time of Procedure* is indicating the time of the sampling procedure or the time of the analytic procedure, Separate laboratory data elements are necessary to represent regulatorily mandated laboratory dates and times in the USCDI. With respect to current USCDI submissions, this single *Time of Procedure* data element would not be sufficient to represent the Level 2 laboratory time data elements which are necessary for interoperability and should be added into the USCDI.

- **Data Class:** Facility Information
- **Data Element:** Facility Identifier
- **CAP Comment:** The CAP supports this data element and finds that this element can capture the necessary information about Laboratory Address and Location. The CAP recommends that this data element should include identifier information number for facilities. If the facility type is a medical laboratory then a CLIA number should be used to unambiguously identify the laboratory.

USCDI Level 2 Data Elements:

- **Data Class:** Laboratory
- **Data Element:** Laboratory results: date and timestamps
- **CAP Comment:**
    - One single *Time of Procedure* data element cannot clearly represent all the many times and dates associated with laboratory and pathology data, including this *Laboratory results: date and timestamps* data element, which is required in regulation and is intended to represent the most recent timestamp associated with completion of all components.
    - This data element should be renamed to *Laboratory Results Issued Date/Time* and should be included as a data element in USCDI v4. This data element should accommodate time zone differences.
    - This data element aligns with CLIA's required "Test Report Date" and also with FHIR's observation.issued data element.
- **Vocabulary Standard:** The CAP recommends replacing the listed standards for this data element with the value format from the OBX-19 field in HL7 2.5.1, which is a version of the Health Level Seven (HL7) standard that defines methods for transferring and sharing data between various healthcare systems and providers. HL7 2.5.1 OBX-19 is aligned with the ISO 8601 international standard for communicating date and time information.

- **Data Class:** Laboratory
- **Data Element:** Laboratory Test Performed Date
- **CAP Comment:**
    - One single *Time of Procedure* data element cannot clearly represent all the many times and dates associated with laboratory and pathology data, including this *Laboratory Test Performed Date* data element, which is required in regulation and represents the most clinically relevant time point in which to interpret the result and is distinct from result reporting date (*Laboratory Results Issued Date/Time*). In the case of observations taken directly from a subject, this data element is the actual date and time the observation was obtained. In the case of a specimen-associated study, this data element represents the date and time the specimen was obtained from a patient and collected into a container or obtained.
    - This data element should be combined with the *Specimen Collection Date/Time* Level 2 data element, titled *Specimen Collection Date/Time,* and included as a data element in USCDI v4. This data element should accommodate time zone differences.
    - This data element aligns with the FHIR observation.effective data element (if greater alignment with FHIR is desired, this data element could also be renamed "Laboratory Results Effective"). CLIA specifies the use of this data element if appropriate.
- **Vocabulary Standard:** The CAP recommends the value format from the SPM-17 field in HL7 2.5.1, which is a version of the Health Level Seven (HL7) standard that defines methods for transferring and sharing data between various healthcare systems and providers. The CAP supports the use of the HL7 2.5.1 standard because the standard was designed to help laboratories comply with CLIA requirements. HL7 2.5.1 SPM-17 is aligned with the ISO 8601 international standard for communicating date and time information.

- **Data Class:** Laboratory

- **Data Element:** Specimen Collection Date/Time
- **CAP Comment:**
    - One single *Time of Procedure* data element cannot clearly represent all the many times and dates associated with laboratory and pathology data, including this *Specimen collection date/time* data element, which is required in regulation and represents the date/time when clinical specimen was collected from subject patient.
    - This data element should be combined with the *Laboratory Test Performed Date* Level 2 data element, titled *Specimen Collection Date/Time,* and included as a data element in USCDI v4. This data element should accommodate time zone differences.
    - This data element aligns with the FHIR observation.effective data element (if greater alignment with FHIR is desired, this data element could also be renamed "Laboratory Results Effective"). CLIA specifies the use of this data element if appropriate.
- **Vocabulary Standard:** The CAP recommends the value format from the SPM-17 field in HL7 2.5.1, which is a version of the Health Level Seven (HL7) standard that defines methods for transferring and sharing data between various healthcare systems and providers. The CAP supports the use of the HL7 2.5.1 standard because the standard was designed to help laboratories comply with CLIA requirements. HL7 2.5.1 SPM-17 is aligned with the ISO 8601 international standard for communicating date and time information.

- **Data Class:** Laboratory
- **Data Element:** Test Kit Unique Identifier
- **CAP Comment:** The CAP supports the elevation of this data element into USCDI, because the data element uniquely identifies the type of test that was used to obtain the Test Result Value. It should be specified that this *Test Kit Unique Identifier* data element is required to be sent if available and that the inclusion of this data element in USCDI does not imply a requirement of collection.

USCDI Level 1 Data Elements:

- **Data Class:** Laboratory
- **Data Element:** Instrument Unique Identifier
- **CAP Comment:** The CAP supports the elevation of this data element into Level 2 and ideally into USCDI.

USCDI Comment Data Elements:

- **Data Class:** Laboratory
- **Data Element:** Test Result Harmonization Status
- **CAP Comment:** The CAP applauds the ONC's decision to add this data element at the Comment Level. The CAP's recommendations for the format and content of this data element will be forthcoming.
- **Technical Correction:** The CAP would also like to suggest a change in the content of the USCDI Web page that describes this data element. The text under "information from submission form" on that page includes all the text from multiple data elements. This obscures the text about the Test Result Harmonization Status element. The CAP would suggest that the text on other

data elements be deleted on that page so that the explanation of the harmonization status element is clear.

Please contact Han Tran at htran@cap.org as needed for any follow up on this commentary.