

CMS Data Element Library HIT Workgroup Comments on the ONC 2021 [Interoperability Standards Advisory \(ISA\)](#)

November 9, 2020

The Centers for Medicare and Medicaid (CMS) Data Element Library (DEL), Health Information Technology Workgroup (HITWG) evaluated the online version of [2020 Interoperability Standards Advisory \(ISA\)](#) and offer the following comments based on an analysis against the data classes and related health IT vocabulary codes for the federally required post-acute care (PAC) assessment instruments.

[Section I – Vocabulary/Code Sets/Terminology Standards and Implementation Specifications](#)

- **General Comments:**

- **Inconsistencies between USCDI and ISA Listed Standards**

- In working with the [USCDI v1 \(July 2020 errata\)](#) and the online version of ISA, the HITWG identified some areas of inconsistencies between these two resources. Some standards identified for USCDI data elements did NOT match federally required standards listed in the ISA (see Appendix for complete listing). We understand there may be reasons for inconsistencies and provide the results of our analysis should it be helpful to ONC in identifying opportunities for harmonization between ISA and USCDI where appropriate.

- **Clarification of data and related standards**

- **Background:** Across several interoperability needs, the ISA makes the distinction between the terminology standard relevant for identifying observations (e.g. LOINC) and the one relevant for identifying observation values (e.g. SNOMED CT). See also [this explanatory text](#) in the current ISA. Recent recommendations and proposals to the USCDI have also sought clarity by more clearly linking Data Classes (and corresponding Data Elements) to structures in the data models for exchange (e.g. FHIR, CDA) and analysis. For example, within the domain of data about functioning, it is important to distinguish between Conditions (problems, diagnoses) and Observations (assessments). As such, the proposed USCDI data element for Functioning: Mobility is constrained to health data represented in data structures for observations. This proposed data element notes that: i) observations should be represented using terminologies supporting this conceptual model, such as LOINC, which is designed for this purpose, and ii) representing problems, goals, and other types of information related to

mobility functioning should use other data class structures as appropriate. Based on such constraints, CPT codes are not an appropriate code system for representing clinical observations.

- **Recommendation:** We recommend that all terminology interoperability needs be reviewed for further specification of what the data is for, and to label data type and corresponding vocabulary more clearly. For example, the “Representing Nutrition Assessment, Diagnosis, Interventions and Monitoring/Evaluation” need clearly contains several different information types. The terminologies listed (LOINC, SNOMED CT, CPT, eNCPT) have different roles across these types, but all are just listed as “standard”.

- **Clinical Notes: Representing Clinical Notes**

- **Recommendations: General**

- The “Type” should be clarified as it is not really a “Standard for observations”
- The two listed “Implementation Specifications” should be listed under the Content/Structure part of ISA and not the Terminology section as they do not represent terminology standards.
- The “Adoption Level” of LOINC should be 5 bubbles (high or widespread adoption). The HL7 Clinical Document Architecture (CDA) standard specifies that the clinicalDocument.code for any CDA document should come from LOINC. Implementation guides like the Consolidated CDA Templates for Clinical Notes, that are part of the Meaningful Use regulations and certification criteria, require LOINC codes to identify the document types.

- **Recommendations: Limitations, Dependencies, and Preconditions for Consideration**

- To align with the data elements found in the USCDI Clinical Notes data class, the HITWG recommends that a description be added for Procedure Notes. A LOINC code is provided, but there is no description for this data element.
- We concur with the recommendations of the LOINC Committee that Imaging Narrative, Laboratory Report Narrative, and Pathology Report Narrative be removed from this section as they represent narrative interpretations of ordered procedures (not clinical notes). Lab reports should be covered under the Laboratory section, Imaging reports under the Imaging section, and likely a new section is needed for other kinds of study procedure reports.

- **Cognitive Status: Representing Patient Cognitive Status**

- **Recommendations: Limitations, Dependencies, and Preconditions for Consideration**

- We recommend adding a link to the PACIO Workgroup (<http://pacioproject.org/>). PACIO has developed a FHIR Cognitive Status Implementation Guide (IG) which is being balloted as a standard for trial use

in October and November 2020. The IG leverages the FHIR exchange structures and LOINC-coded observations.

- If appropriate, please consider including Cognitive Status observation data elements that have been proposed in USCDI under the Functioning Data Class and Mental Function data element. See:

<https://www.healthit.gov/isa/uscdi-data/mental-function>

- **Recommendations: Applicable Value Set(s) and Starter Set(s)**

- The Regenstrief Institute is developing a value set that contains the LOINC terms for cognitive status assessment from the standardized PAC data elements. The value set is planned for publication in conjunction with the December 2020 LOINC release. The value set will be assigned a canonical URI and OID for identification, and will be made available via the [LOINC FHIR Terminology Server](#).
- Within the ISA, we recommend that the currently displayed listing of LOINC codes be replaced by the explanatory text above until this value set is available (expected December 2020). When the value sets are published, the ISA can point directly to them by OID and by canonical URI (which resolves to the LOINC FHIR Terminology Server).

- **Functional Status/Disability: Representing Patient Functional Status and/or Disability**

- **Recommendations: Limitations, Dependencies, and Preconditions for Consideration**

- We recommend revising existing information presented on the PACIO Workgroup (<http://pacioproject.org/>). PACIO has developed a FHIR Functional Status Implementation Guide (IG) which is being balloted as a standard for trial use in October and November 2020. The IG leverages the FHIR exchange structures and LOINC-coded observations.
- In the description provided for the CMS Data Element Library, we recommend expanding the list of supported assessments to include:
 - Functional Assessment Standardized Items (FASI) used for Home and Community-Based Services (HCBS)
 - Hospice Item Set (HIS) used for Hospice Care
- If appropriate, please consider including Mobility, Self-Care, and Domestic Life/IADL observation data elements that have been proposed for USCDI v2 under the Functioning Data Class. See: <https://www.healthit.gov/isa/uscdi-data/functioning#comment>

- **Recommendations: Applicable Value Set(s) and Starter Set(s)**

- The Regenstrief Institute is developing a value set that contains the LOINC terms for functional status assessment from the standardized PAC data

elements. The value set is planned for publication in conjunction with the December 2020 LOINC release. The value set will be assigned a canonical URI and OID for identification, and will be made available via the LOINC FHIR Terminology Server.

- Within the ISA, we recommend that the currently displayed listing of LOINC codes be replaced by the explanatory text above until this value set is available (expected December 2020). When the value sets are published, the ISA can point directly to them by OID and by canonical URI (which resolves to the LOINC FHIR Terminology Server).

- **Preferred Language: Representing Patient Preferred Language (Presently)**

- **Recommendations: Limitations, Dependencies, and Preconditions for Consideration**

- The Department of Health and Human Services Office of Minority Health has worked with CMS to standardize data elements pertaining to preferred patient language and use of an interpreter. We recommend that consideration be given to including these standardized items and corresponding LOINC codes in this ISA category.
 - What is your preferred language? LOINC® 54899-0
 - Do you need or want an interpreter to communicate with a doctor or health care staff? LOINC® 54588-9

- **Social, Psychological, and Behavioral Data: Representing Depression**

- **General Comment:**

- The title used for the Representing Depression ISA category is confusing in light of the PHQ-2 and PHQ-9 identified as exemplar content for this category. The PHQ-2 and PHQ-9 are depression screening tools, however the title itself could imply a depression diagnosis. Consistent with our overall comments about reviewing the ISA to further clarify the type of data (intended shape or element such as `observation.code`, `observation.value.code`, or `condition.code`), we also recommend that the title be revised to capture the constraint that this ISA category represents (depression screening/monitoring).

- **Recommendations: Limitations, Dependencies, and Preconditions for Consideration**

- We recommend adding a link to the PACIO Workgroup (<http://pacioproject.org/>). PACIO has developed a FHIR Functional Status Implementation Guide (IG) which is being balloted as a standard for trial use in October and November 2020. The IG leverages the FHIR exchange structures and LOINC-coded observations.
- Responses in the PHQ-9 questionnaires used by acute care providers have a different format and granularity than the responses to PHQ-9 questions

embedded in PAC standardized assessments. LOINC provides unique panel codes for the two versions of the PHQ-9:

- LOINC® 44249-1 PHQ-9 quick depression assessment panel [Reported.PHQ]
- LOINC® 54635-8 Resident mood interview (PHQ-9) [Reported PHQ-9 CMS]

If appropriate, please note the availability of the LOINC code explicit for the PHQ-9 on the PAC standardized assessments or address this as known issue.

APPENDIX – Comparison of USCDI Listed Standards to ISA Federally Required Listed Standards

| USCDI v1 (Errata July 2020) | | | ISA: Vocabulary/Code Set/Terminology Section | | | |
|----------------------------------|----------------------------------|---------------------|--|---|--|--|
| USCDI Data Class | Data Element | Listed Standard | Category | Listed Standards: Federally Required <i>Red Text = Variance from USCDI</i> | Listed Fed Req Stnds Consistent : USCDI to ISA | Listed Standards: Other |
| Allergies and Intolerances | Substance (Medication) | RxNorm | Representing Patient Allergies and Intolerances; Medications | * RxNorm * SNOMED CT | Yes | Medication Reference Terminology (MED-RT) |
| Allergies and Intolerances | Substance (Drug Class) | SNOMED CT | Representing Patient Allergies and Intolerances; Medications | * RxNorm * SNOMED CT (for Medication Class) | Yes | Medication Reference Terminology (MED-RT) |
| Allergies and Intolerances | Reaction | SNOMED CT | Representing Patient Allergic Reactions | SNOMED CT (Observation Values) | Yes | LOINC |
| Assessment and Plan of Treatment | Assessment and Plan of Treatment | None | Representing Assessment and Plan of Treatment | CPT | No | LOINC SNOMED CT |
| Care Team Members | Care Team Members | None | Representing Health Care Providers | National Plan and Provider Enumeration System National Provider Identifier (NPI) | No | National Uniform Claim Committee (NUCC) Health Care Provider Taxonomy |
| | | | Representing Provider Role in Team Care Settings | None | Yes | SNOMED CT |
| Clinical Notes | Consultation Note | LOINC® code 11488-4 | Representing Clinical Notes | LOINC (LOINC® code 11488-4) | Yes | * HL7® FHIR® Argonaut Clinical Notes Implementation Guide * HL7® FHIR® US Core Implementation Guide |
| Clinical Notes | Discharge Summary Note | LOINC® code 18842-5 | Representing Clinical Notes | LOINC (LOINC® code 18842-5) | Yes | * HL7® FHIR® Argonaut Clinical Notes Implementation Guide * HL7® FHIR® US Core Implementation Guide |

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|-----------------------------|-----------------------------|---------------------|---|---|--|--|
| USCDI Data Class | Data Element | Listed Standard | Category | Listed Standards: Federally Required <i>Red Text = Variance from USCDI</i> | Listed Fed Req Stnds Consistent : USCDI to ISA | Listed Standards: Other |
| Clinical Notes | History & Physical | LOINC® code 34117-2 | Representing Clinical Notes | LOINC (LOINC® code 34117-2) | Yes | * HL7® FHIR® Argonaut Clinical Notes Implementation Guide * HL7® FHIR® US Core Implementation Guide |
| Clinical Notes | Imaging Narrative | LOINC® code 18748-4 | Representing Clinical Notes | LOINC (LOINC® code 18748-4) | Yes | * HL7® FHIR® Argonaut Clinical Notes Implementation Guide * HL7® FHIR® US Core Implementation Guide |
| Clinical Notes | Laboratory Report Narrative | None | Representing Clinical Notes | None | Yes | * HL7® FHIR® Argonaut Clinical Notes Implementation Guide * HL7® FHIR® US Core Implementation Guide |
| Clinical Notes | Pathology Report Narrative | None | Representing Clinical Notes | None | Yes | * HL7® FHIR® Argonaut Clinical Notes Implementation Guide * HL7® FHIR® US Core Implementation Guide |
| Clinical Notes | Procedure Note | LOINC® code 28570-0 | Representing Clinical Notes - "Procedure Note" NOT listed | None | No ¹ | None |
| Clinical Notes | Progress Note | LOINC® code 11506-3 | Representing Clinical Notes | LOINC (LOINC® code 11506-3) | Yes | * HL7® FHIR® Argonaut Clinical Notes Implementation Guide * HL7® FHIR® US Core Implementation Guide |
| Goals | Patient Goals | None | Representing Patient Goals | None | Yes | * LOINC * SNOMED CT |

¹ "Procedure Note" NOT listed in this ISA category

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|-----------------------------|-----------------|---|--|---|--|---|
| USCDI Data Class | Data Element | Listed Standard | Category | Listed Standards: Federally Required <i>Red Text = Variance from USCDI</i> | Listed Fed Req Stnds Consistent : USCDI to ISA | Listed Standards: Other |
| Health Concerns | Health Concerns | None | Representing Patient Health Concerns | None | No ² | * LOINC * SNOMED CT |
| Immunizations | Immunizations | * CDC IIS: Current HL7 Standard Code Set, CVX -- Vaccines Administered * CDC National Drug Code (NDC) Directory – Vaccine NDC Linker Table | Representing Immunizations – Administered | * Clinical Vaccines Administered (CVX) * National Drug Code (NDC) | Yes | * Manufacturing Vaccine Formulation (MVX) * RxNorm * Current Procedural Terminology (CPT) |
| Laboratory | Tests | LOINC | Representing Laboratory Tests | * LOINC (Observations) * SNOMED CT (Values) | No | None |
| Laboratory | Values/Results | None | Representing Laboratory Values/Results | None | Yes | * LOINC * SNOMED CT |
| Medications | Medications | RxNorm | Representing Patient Medications | *RxNorm *NDC | No | None |

² "Representing Patient Health Concerns" is listed in ISA 2020 Reference Edition but does NOT appear in the Vocabulary/Code Set/Terminology Section of the ISA website

a) ISA Table of Contents (<https://www.healthit.gov/isa/isa-document-table-contents>) does NOT list "Representing Patient Health Concerns"

b) When reviewing ISA categories, navigation on left-side of screen DOES list "Representing Patient Health Concerns", but NO category page is available

| USCDI v1 (Errata July 2020) | | | ISA: Vocabulary/Code Set/Terminology Section | | | |
|-----------------------------|---|--|--|--|--|-------------------------|
| USCDI Data Class | Data Element | Listed Standard | Category | Listed Standards: Federally Required <i>Red Text = Variance from USCDI</i> | Listed Fed Req Stnds Consistent : USCDI to ISA | Listed Standards: Other |
| Patient Demographics | <ul style="list-style-type: none"> • First Name • Last Name • Middle Name (including middle initial) • Suffix | None | None | None | Yes | None |
| Patient Demographics | Previous Name | None | None | None | Yes | None |
| Patient Demographics | Birth Sex | HL7 Version 3 (V3) Standard, Value Sets for AdministrativeGender and NullFlavor | Representing Patient Sex (At Birth) | For Male and Female, HL7® Version 3 Value Set; for Administrative Gender Unknown, HL7® Version 3 Null Flavor (Observation Values) | Yes | LOINC (Observations) |
| Patient Demographics | Date of Birth | None | None | None | Yes | None |
| Patient Demographics | Race | <ul style="list-style-type: none"> * OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, October 30, 1997 * CDC Race and Ethnicity Code Set | Representing Patient Race and Ethnicity | <ul style="list-style-type: none"> * OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, October 30, 1997 * CDC Race and Ethnicity Code Set | Yes | None |

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|-----------------------------|--------------------|--|---|--|--|-------------------------|
| USCDI Data Class | Data Element | Listed Standard | Category | Listed Standards: Federally Required <i>Red Text = Variance from USCDI</i> | Listed Fed Req Stnds Consistent : USCDI to ISA | Listed Standards: Other |
| Patient Demographics | Ethnicity | * OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, October 30, 1997 * CDC Race and Ethnicity Code Set | Representing Patient Race and Ethnicity | * OMB Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, October 30, 1997 * CDC Race and Ethnicity Code Set | Yes | None |
| Patient Demographics | Preferred Language | Request for Comment (RFC) 5646, "Tags for Identifying Languages", September 2009 | Representing Patient Preferred Language (Presently) | Request for Comment (RFC) 5646 | Yes | None |
| Patient Demographics | Current Address | None | None | None | Yes | None |
| Patient Demographics | Previous Address | None | None | None | Yes | None |
| Patient Demographics | Phone Number | * ITU-T E.123 (02/2001) International Telecommunication Union E.123: Notation for national and international telephone numbers, e-mail addresses and web addresses * ITU-T E.164 International Telecommunication Union E.164: The international public telecommunication numbering plan | Representing Patient Contact Information for Telecommunications | * ITU-T E.123 (02/2001) International Telecommunication Union E.123: Notation for national and international telephone numbers, e-mail addresses and web addresses * ITU-T E.164 International Telecommunication Union E.164: The international public telecommunication numbering plan | Yes | None |

| USCDI v1 (Errata July 2020) | | | ISA: Vocabulary/Code Set/Terminology Section | | | |
|-----------------------------|-------------------|-----------------|---|--|--|-------------------------|
| USCDI Data Class | Data Element | Listed Standard | Category | Listed Standards: Federally Required <i>Red Text = Variance from USCDI</i> | Listed Fed Req Stnds Consistent : USCDI to ISA | Listed Standards: Other |
| Patient Demographics | Phone Number Type | None | Representing Patient Contact Information for Telecommunications | * ITU-T E.123 (02/2001) International Telecommunication Union E.123: Notation for national and international telephone numbers, e-mail addresses and web addresses * ITU-T E.164 International Telecommunication Union E.164: The international public telecommunication numbering plan | No ³ | None |
| Patient Demographics | Email Address | None | Representing Patient Contact Information for Telecommunications | * ITU-T E.123 (02/2001) International Telecommunication Union E.123: Notation for national and international telephone numbers, e-mail addresses and web addresses * ITU-T E.164 International Telecommunication Union E.164: The international public telecommunication numbering plan | No ⁴ | None |
| Problems | Problems | SNOMED CT | Representing Patient Clinical "Problems" (i.e., Conditions) | SNOMED CT | Yes | |

³ The Applicable Value Set(s) and Starter Set(s) for this category include examples of phone number type per ITU-T E.123 (02/2001)

⁴ The Applicable Value Set(s) and Starter Set(s) for this category include examples of email address per ITU-T E.123 (02/2001)

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|---|---|---|--|---|--|--|
| USCDI Data Class | Data Element | Listed Standard | Category | Listed Standards: Federally Required <i>Red Text = Variance from USCDI</i> | Listed Fed Req Stnds Consistent : USCDI to ISA | Listed Standards: Other |
| | | | Representing Patient Medical Encounter Diagnosis | * SNOMED CT * ICD-10-CM | No | |
| Procedures | Procedures | * HCPCS * CPT-4 * SNOMED CT <i>Optional:</i> ICD-10-PCS; CDT | Representing Medical Procedures Performed | SNOMED CT CPT-4 HCPCS ICD-10-PCS | No | |
| | | | Representing Dental Procedures Performed | CDT | No | |
| Provenance | Author Time Stamp | None | Representing Data Provenance | None | No | HL7® FHIR® Provenance Resource |
| Provenance | Author Organization | None | Representing Data Provenance | None | No | HL7® FHIR® Provenance Resource |
| Smoking Status | Smoking Status | SNOMED CT | Representing Patient Tobacco Use (Smoking Status) | SNOMED CT (Observation Values) | Yes | LOINC (Observations) |
| Unique Device Identifier(s) for a Patient's Implantable Device(s) | Unique Device Identifier(s) for a Patient's Implantable Device(s) | UDI identifier as described by applicable FDA regulation. (found at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/) | Representing Unique Implantable Device Identifiers <i>Listed in ISA Content/Structure Section</i> | Unique device identifier as defined by the Food and Drug Administration at 21 CFR 830.3 | Yes | * HL7 Cross-Paradigm Implementation Guide: UDI Pattern, Release 1 * NCPDP SCRIPT Standard, Implementation Guide, Version 2017071 * NCPDP Telecommunication Standard Implementation Guide, Version F2 * NCPDP Product Identifiers Standard Implementation Guide Version 1.4 * HL7® FHIR® US Core Implantable Device Profile * HL7® CDA® R2 Implementation Guide: C-CDA Supplemental Templates for Unique |

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|-----------------------------|--------------------------|-----------------|--|---|--|---|
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| | | | | | | Device Identifier (UDI) for Implantable Medical Devices, Release 1 - US Realm |
| Vital Signs | Diastolic Blood Pressure | None | Representing Patient Vital Signs | LOINC | No | ISO/IEEE 11073 Health informatics - Medical / health device communication standards |
| Vital Signs | Systolic Blood Pressure | None | Representing Patient Vital Signs | LOINC | No | ISO/IEEE 11073 Health informatics - Medical / health device communication standards |
| Vital Signs | Body Height | None | Representing Patient Vital Signs | LOINC | No | ISO/IEEE 11073 Health informatics - Medical / health device communication standards |
| Vital Signs | Body Weight | None | Representing Patient Vital Signs | LOINC | No | ISO/IEEE 11073 Health informatics - Medical / health device communication standards |
| Vital Signs | Heart Rate | None | Representing Patient Vital Signs | LOINC | No | ISO/IEEE 11073 Health informatics - Medical / health device communication standards |

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| Vital Signs | Respiratory Rate | LOINC | Representing Patient Vital Signs | LOINC | Yes | ISO/IEEE 11073 Health informatics - Medical / health device communication standards |
| Vital Signs | Body Temperature | UCUM | Representing Patient Vital Signs | LOINC | No | ISO/IEEE 11073 Health informatics - Medical / health device communication standards |
| Vital Signs | Pulse Oximetry | None | Representing Patient Vital Signs | LOINC | No | ISO/IEEE 11073 Health informatics - Medical / health device communication standards |
| Vital Signs | Inhaled Oxygen Concentration | None | Representing Patient Vital Signs | LOINC | No | ISO/IEEE 11073 Health informatics - Medical / health device communication standards |
| Vital Signs | BMI Percentile (2 - 20 Years) | None | Representing Patient Vital Signs | LOINC | No | ISO/IEEE 11073 Health informatics - Medical / health device communication standards |
| Vital Signs | Weight-for-length Percentile (Birth - 36 Months) | None | Representing Patient Vital Signs | LOINC | No | ISO/IEEE 11073 Health informatics - Medical / health device communication standards |
| Vital Signs | Head Occipital-frontal Circumference Percentile (Birth - 36 Months) | None | Representing Patient Vital Signs | LOINC | No | ISO/IEEE 11073 Health informatics - Medical / health device communication standards |