

# **United States Core Data for Interoperability: Version 3**

August 9, 2022





### **Agenda**

- Why USCDI matters
- Overview of USCDI Version 3
  - Additional data classes and elements
  - Key changes to existing data classes and elements





# **Core Principles**



Comprises a core set of data needed to support patient care and facilitate patient access using health IT

Establishes a consistent baseline of data for other use cases

Expands over time via a predictable, transparent, and collaborative **public** process





# **Why USCDI Matters**

- New standard in the ONC Cures Act Final Rule in 2020
- Required for new Certification Criterion (application programming interface (API) to access patient data, using FHIR® US Core
- USCDI defines "Electronic Health Information" for purpose of Information Blocking (for now)

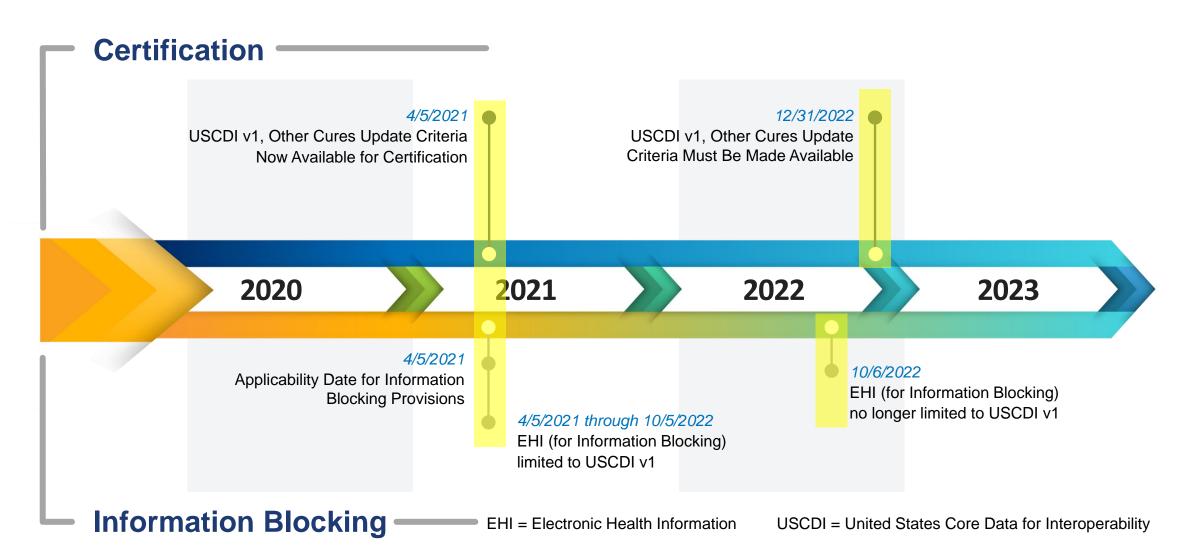




# Why USCDI Matters (Continued)

- The 2015 Edition Cures Update replaced the Common Clinical Data Set with USCDI v1. USCDI establishes a set of data classes and constituent data elements required to be exchanged in support of nationwide interoperability in these ONC Certification Criteria:
  - § 170.315(b)(1) Transitions of Care
  - § 170.315(b)(2) Clinical Information Reconciliation and Incorporation
  - § 170.315(e)(1) View, Download, and Transmit to a 3rd Party
  - § 170.315(f)(5) Transmission to Public Health Agencies Electronic Case Reporting
  - § 170.315(g)(6) Consolidated CDA Creation Performance
  - § 170.315(g)(9) Application Access All Data Request
  - § 170.315(g)(10) Standardized API for Patient and Population Services (new certification criterion that also refers to the USCDI)

# Why USCDI Matters: EHI and Information Blocking





## **USCDI Version 3**





<ul><li>Allergies and Intolerances</li><li>Substance (Medication)</li><li>Substance (Drug Class)</li><li>Reaction</li></ul>	Clinical Tests     Clinical Test     Clinical Test Result/Report	Health Status/ Assessments ★★  • Health Concerns →  • Functional Status ★	Patient Demographics/ Information ★ ★  • First Name  • Last Name	Procedures  • Procedures  • SDOH Interventions  • Reason for Referral ★	
Assessment and Plan of Treatment  • Assessment and Plan of Treatment  • SDOH Assessment	<ul> <li>Diagnostic Imaging</li> <li>Diagnostic Imaging Test</li> <li>Diagnostic Imaging Report</li> <li>Disability Status</li> <li>Mental Function</li> <li>Pregnancy Status</li> <li>Smoking Status</li> </ul>		<ul> <li>Middle Name (Including middle initial)</li> <li>Name Suffix ★★</li> <li>Previous Name</li> <li>Date of Birth</li> <li>Date of Death ★</li> <li>Race</li> </ul>	<ul><li>Provenance</li><li>Author Organization</li><li>Author Time Stamp</li></ul>	
Care Team Member(s)  Care Team Member Name  Care Team Member Identifier  Care Team Member Role  Care Team Member Location  Care Team Member Telecom	Encounter Information	Immunizations  • Immunizations	<ul> <li>Ethnicity</li> <li>Tribal Affiliation ★</li> <li>Sex ★★</li> <li>Sexual Orientation</li> <li>Gender Identity</li> <li>Preferred Language</li> <li>Current Address</li> </ul>	Unique Device Identifier(s) for a Patient's Implantable Device(s)  • Unique Device Identifier(s) for a patient's implantable device(s)	
Clinical Notes  Consultation Note Discharge Summary Note History & Physical Procedure Note Progress Note	Goals  • Patient Goals  • SDOH Goals	Laboratory  • Test  • Values/Results  • Specimen Type ★  • Result Status ★	<ul> <li>Previous Address</li> <li>Phone Number</li> <li>Phone Number Type</li> <li>Email Address</li> <li>Related Person's Name</li> <li>Related Person's Relationship</li> <li>Occupation</li> <li>Occupation Industry</li> </ul>	Vital Signs  Systolic blood pressure  Diastolic blood pressure  Heart Rate  Respiratory rate  Body temperature  Body height  Body weight	
	Health Insurance Information ★  • Coverage Status ★  • Coverage Type ★  • Relationship to Subscriber ★  • Member Identifier ★  • Subscriber Identifier ★  • Group Number ★  • Payer Identifier ★	Medications  • Medications ★  • Dose ★  • Dose Units of Measure ★  • Indication ★  • Fill Status ★	Problems  Problems  SDOH Problems/Health Concerns  Date of Diagnosis  Date of Resolution	<ul> <li>Pulse oximetry</li> <li>Inhaled oxygen concentration</li> <li>BMI Percentile (2 - 20 years)</li> <li>Weight-for-length Percentile (Birth - 24 Months) ★★</li> <li>Head Occipital-frontal Circumference Percentile (Birth - 36 Months)</li> </ul>	





### **Questions posed by AS TF**

- How to operationalize the changes from USCDI v2 to USCDI v3.
  - HL7 FHIR and C-CDA implementation guide updates
- Where does ONC sit in the regulatory process?
  - USCDI v1 per final rule required at end of 2022, EHI definition changes in October 2022
- Introduce dependency management with the SVAP process
  - Please provide more detail about this question
- Consider adoption as a block; not as pieces
  - From the criterion Standardized API for Patient and Population Services (g)(10): All data elements indicated as *mandatory* or *must support* by the standards and implementation specifications must be supported.





Questions?





# **USCDI** in Certification – C-CDA Example

- § 170.315(b)(1) Transitions of Care
  - Technical outcome The health IT can create a C-CDA (formatted to Release 2.1) that includes
    - Encounter diagnoses (according to either ICD-10-CM or SNOMED CT® codes), Cognitive status, and Functional status
  - C-CDA IG must be updated when new USCDI versions are published





# **USCDI** in Certification – FHIR US Core Example

- § 170.315(g)(10) Standardized API for patient and population services—
  - Technical outcome The health IT can use API technology to
    - Respond to requests for a single patient's and multiple patients' data according to FHIR and US Core for all USCDI data elements
    - Support all data elements indicated as mandatory and must support by the standards and implementation specifications
  - FHIR US Core IG must be updated when new USCDI versions are published



### **USCDI Version 3 Major Changes**

- Adopt all Draft USCDI v3 classes and elements proposed in :
  - Two new data classes (Health Insurance Information and Health Status)
  - 20 new data elements which include elements supporting equity, reducing disparities and public health data interoperability
- Expand terminology code systems (SNOMED CT) for sex, sexual orientation and gender identity to support inclusivity and alignment with Gender Harmony Project
- Add four new data elements in Medications data class
  - not proposed in Draft USCDI v3,
  - strongly supported by stakeholders
- Review of overall USCDI v3 process in the <u>ONC Standards Bulletin 22-2</u>





# New Data Classes and Elements in USCDI v3 (Compared to USCDI v2)

#### **Health Insurance Info**

- Coverage Status = 1
- Coverage Type = 1
- Relationship to Subscriber = +
- Member Identifier +
- Subscriber Identifier +
- Group Number +
- Payer Identifier 🛨

#### Health Status/Assessments ★

- Functional Status § = 1
- Disability Status = 1
- Mental/Cognitive Status ↑ §

#### Laboratory

- Specimen Type 🕂 🔍
- Result Status + @

#### **Medications**

- Dose § +
- Dose Unit of Measure § +
- Indication § +
- Fill Status § +

## Patient Demographics/ Information

- Date of Death §
- Tribal Affiliation = 1
- Related Person's Name §
- Relationship Type §
- Occupation Q
- Occupation Industry

#### **Procedure**

Reason for Referral §

New Data Classes = Equity Based Onderserved Public Health + Add'l USCDI Needs ONC Cert



# New Data Elements in Medication Data Class (Compared to Draft v3)

DATA ELEMENT	APPLICABLE VOCABULARY STANDARDS
Medication  Pharmacologic agent used in the diagnosis, cure, mitigation, treatment, or prevention of disease.	RxNorm Optional: NDC
<b>Dose</b> Amount of a medication taken each time	
Dose Unit of Measure	Unified Code for Units of Measure
Units of measure of a medication (e.g., milligrams, milliliters)	
Indication  Condition or diagnosis intended to be treated by a medication.	
Fill Status	
Indicator of whether a prescription was dispensed to a patient (e.g., dispensed, partially dispensed, not dispensed).	





## Other Changes to Data Classes and Elements

Change from:	Change to:	Reason for change
Health Status (Class)	Health Status/Assessments (Class)	Recognizes that class contains both statuses and structured assessments.
Patient Demographics (Class)	Patient Demographic/ Information (Class)	Recognizes class contains non-demographic patient information.  Occupation/Industry Related Person
Current and Previous Address (Elements) No applicable standards	Add US@ Specification as applicable vocabulary standard	Based on requested feedback on newly published, widely accepted standard.
Sex (Assigned at Birth) (Element)	Sex (Element)	Recognizes element often represents data outside of the relevance of an observation at birth, sometimes changes.
Weight-for-length Percentile (Birth - 36 Months) (Element)	Weight-for-length Percentile (Birth - 24 Months) (Element)	Practical use case limited to <=24 months, after which BMI Percentile is almost exclusively used.





### **Changes to Value Set Support**

### **Representing Social Determinants of Health - Screening Assessments**









1		Standard / Implementation Specification		Implementation Maturity	Adoption Level	Federally required		Test Tool Availability
5	Standard	LOINC®	Final		Feedback Requested	No	Free	No

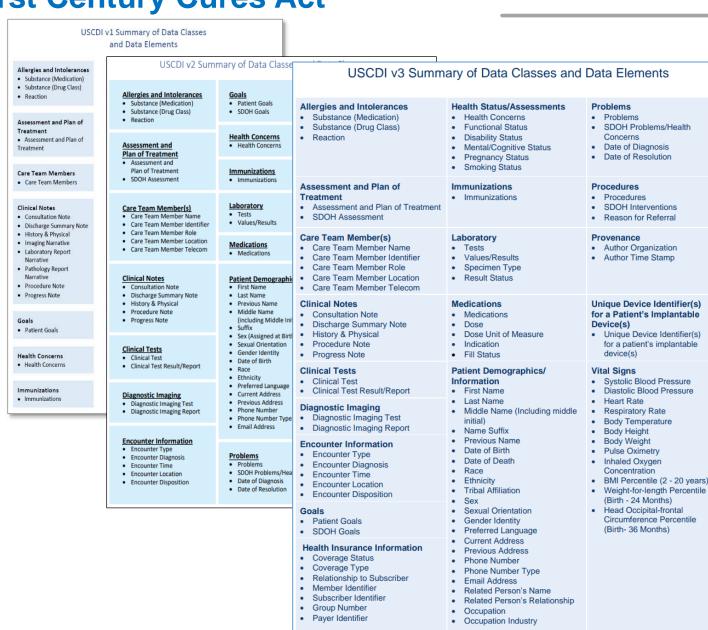
Limitations, Dependencies, and Preconditions for Consideration	Applicable Value Set(s) and Starter Set(s)
<ul> <li>SDOH Screening Assessments are screening questionnaire-based, structured evaluations (e.g., PRAPARE, Hunger Vital Sign, AHC-HRSN screening tool) for a Social Determinants of Health-related risk.</li> </ul>	<ul> <li>Social Determinants of Health Screening Assessments Value Set represents all of the individual domain assessment screening instruments identified by the Gravity Project</li> </ul>
<ul> <li>These are represented by LOINC panel codes for screening assessment that have been identified through the Gravity Project community consensus voting process</li> </ul>	
<ul> <li>The Gravity Project established and maintains current value sets which represent SDOH Screening Assessments across many SDOH domains, such as Food, Housing, and Transportation Security.</li> </ul>	
<ul> <li>The United States Core Data for Interoperability version 3 (USCDI v3) includes SDOH Assessments as a data element used to capture and exchange data on a patient's SDOH risks and needs. The value set included on this page is intended to guide development of the ability to capture this type of data in health IT.</li> </ul>	

#### The Office of the National Coordinator for Health Information Technology



### **USCDI Evolution Supports 21st Century Cures Act**

- USCDI v1 is required by Cures Act Final Rule and added four data elements: clinical notes, provenance, pediatric vital signs and address
- USCDI v2 added three data classes and 22 data elements in support of advancing health equity (SOGI and SDOH)
- Draft USCDI v3 addressed equity, disparities and public health data interoperability. Proposed two data classes (Health Insurance Information and Health Status) and 20 data elements
- USCDI v3 adopts draft USCDI v3 and four additional elements in the Medication data class







### **USCDI v4 Submission and Comment Process**

- ONC is accepting input for potential USCDI v4 data elements:
  - New data element submissions through <u>ONDEC</u>
  - Comments on existing data element pages (not previously accepted into USCDI)
  - Deadline is September 30, 2022.
- ONC plans on releasing Draft USCDI v4 in January 2023.





### **USCDI v4 Submission and Comment Process**

### **New Prioritization Criteria!**

- Represent important additions over previous USCDI versions
- Mitigate health and health care inequities and disparities
- Address the needs of underserved communities
- Address behavioral health integration with primary care and other physical care
- Address public health interoperability needs of reporting, investigation, and emergency response
- Require only modest standards or implementation guide developmental burden
- Require only modest developmental burden on health IT modules
- Create only modest implementation burden on providers and health systems
- Result in only modest aggregate lift for all new data elements