

# USCDI Version 5

August 15, 2024

# Agenda

- USCDI v5 publication
- New Data Elements in USCDI v5
- USCDI v6 Submission and Comment Period
- HTI-2 NPRM Comment Period

# 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

- ONC Cures Act Final Rule established USCDI v1 in 2020, and replaced the Common Clinical Data Set
- HTI-1\* establishes USCDI v3 as the new baseline data set for these criteria
  - Compliance date January 1, 2026
- HTI-2\*\* NPRM proposes to update baseline to USCDI v4
- Other data exchange programs include USCDI as the required data set:
  - CMS Patient Access and Payer-to-Payer API
  - TEFCA
  - California Data Exchange Framework (v2)

[\\*Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing](#)

[\\*\\*Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule](#)

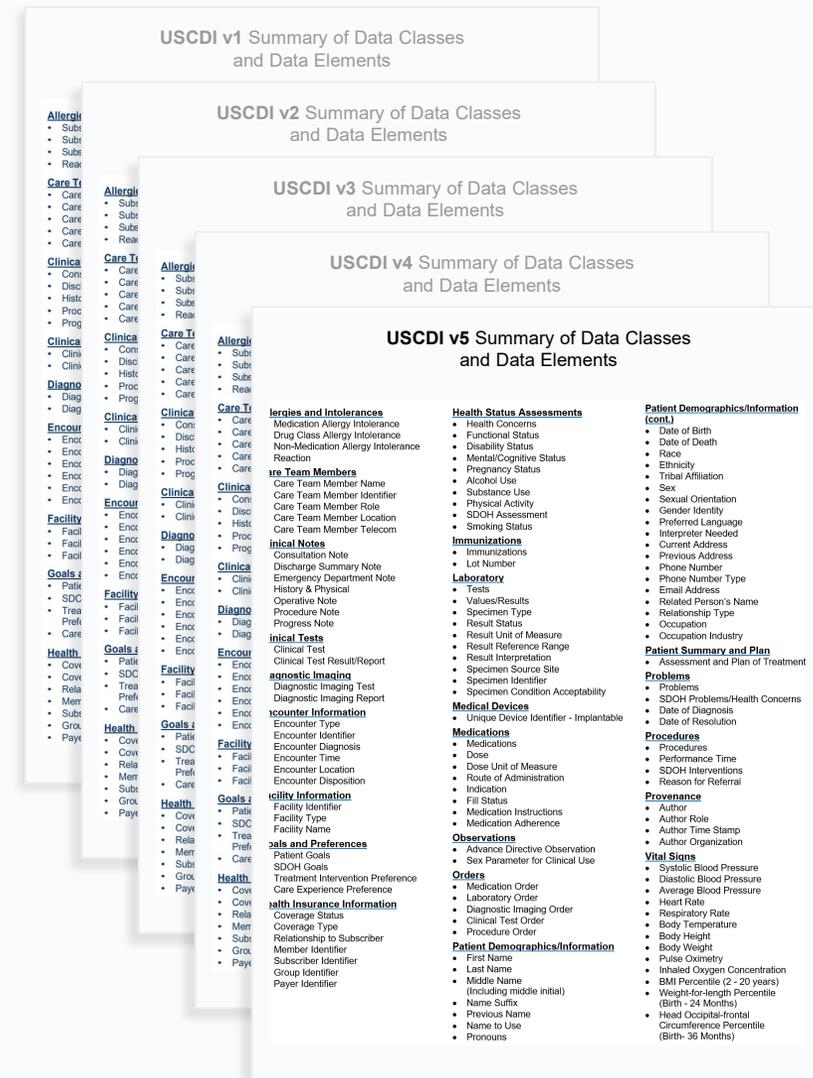
# Why USCDI Matters

- **Standards Version Advancement Process (SVAP)**
  - Allows health IT developers to:
    - Voluntarily update their products to newer versions of standards, including USCDI
    - Provide those updates to their customers
  - USCDI v4\* is available for update through SVAP
  - Updates to USCDI v3 are only available via HTI-1 conformance
  - US Core and Consolidated CDA that support USCDI v4\* also available through SVAP

\*The 2024 approved SVAP versions were announced June 20, 2024, and will be available for voluntary certification under the Certification Program on August 19, 2024. Tooling updates will be complete by December 31, 2024.

# USCDI: Transparent, Predictable, Collaborative

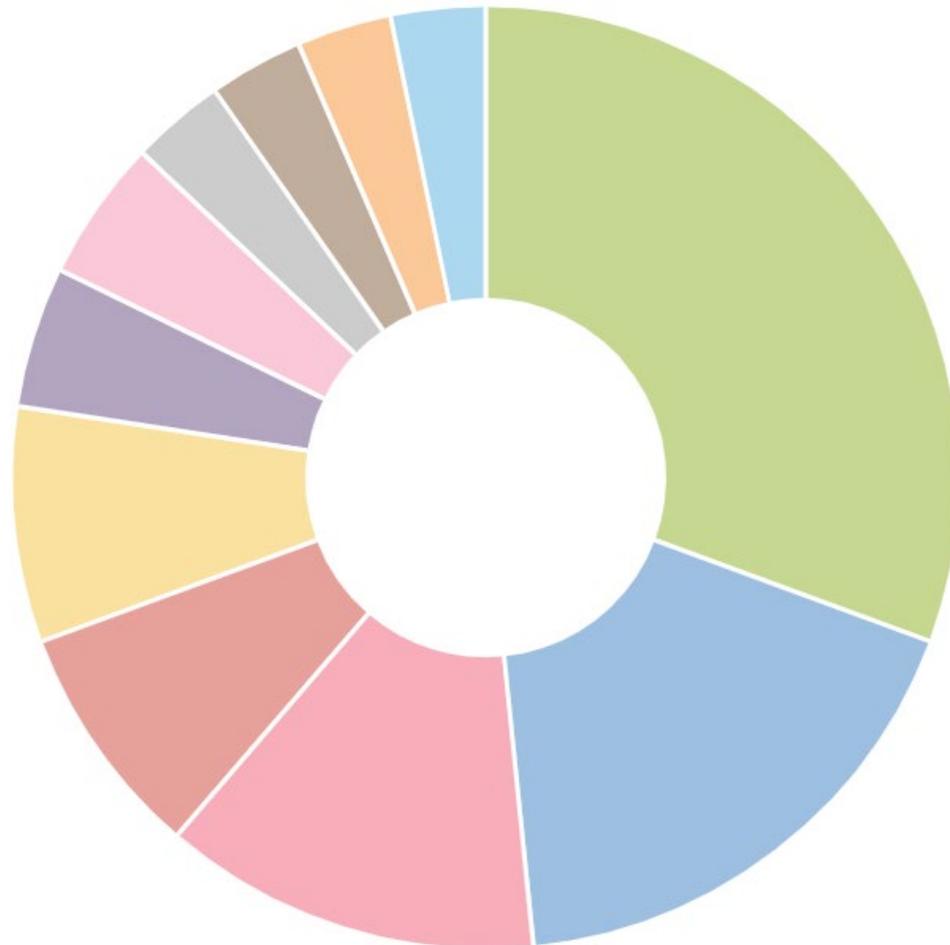
- **USCDI v1** is required by Cures Act Final Rule and added data classes clinical notes and provenance, and data elements pediatric vital signs and address
- **USCDI v2** added three data classes and 22 data elements in support of advancing health equity (SOGI and SDOH)
- **USCDI v3** added 24 data elements focused on factors promoting equity, reducing disparities and supporting public health data interoperability.
  - Required in HTI-1, effective January 1, 2026
- **USCDI v4** added Alcohol and Substance Use Assessments, Physical Activity, Treatment Intervention and Care Experience Preferences, and Medication Adherence data elements.
- **USCDI v5** adds 16 new data elements and two new classes, Orders and Observations. Data elements include Advance Directive Observation, Pronouns, Sex Parameter for Clinical Use, and Name to Use.





# USCDI v5 Submission and Comment Summary

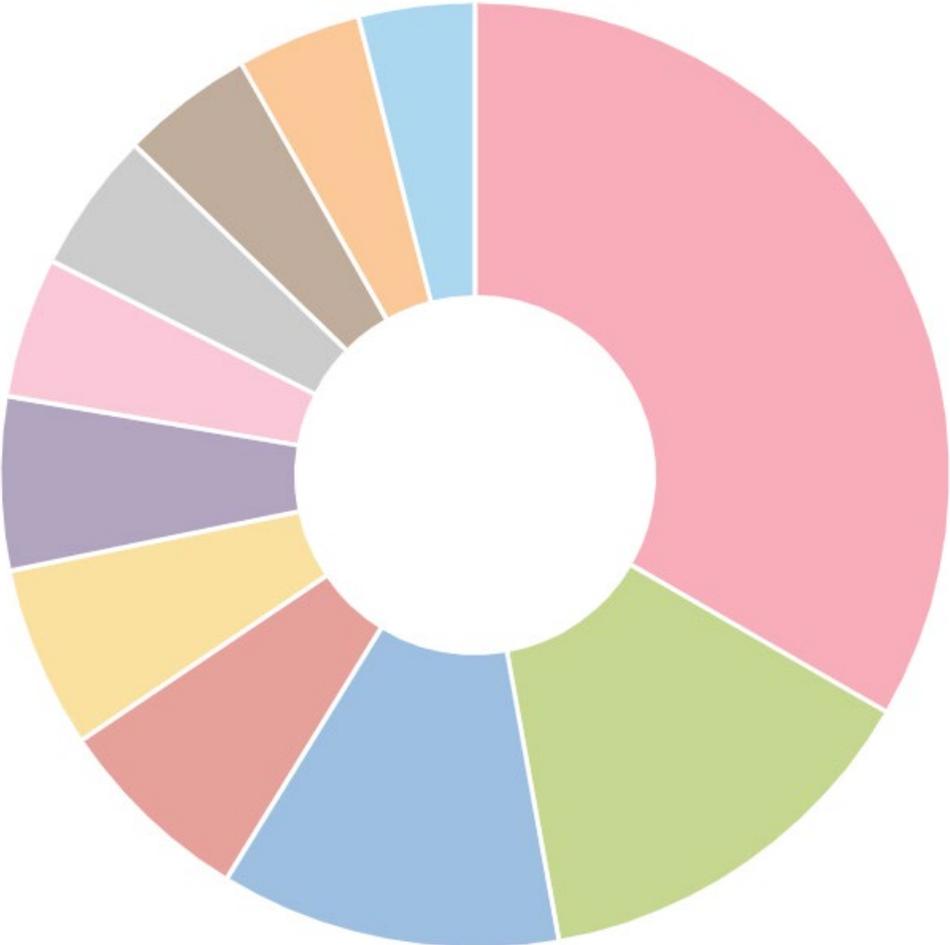
# ONDEC Submissions for USCDI Version 5



Submissions Received  
Total: **62**

Outcomes	19
Medical Devices	11
Health Status Assessments	5
Vital Signs	5
Encounter Information	3
Medications	3
Cancer Care	2
Genomics	2
Patient Demographics/Information	2
Provenance	2
Other...	8

# Public Comments on USCDI Version 5



Comments Received  
Total: **354**

Medications	49
Laboratory	41
Provenance	24
Patient Demographics/Information	22
Health Status Assessments	21
Pregnancy Information	17
Social Determinants of Health	17
Advance Directives	16
Immunizations	15
Clinical Notes	14
Other...	118

# New Data Elements for final USCDI v5

Clinical Notes	Immunizations	Medications
Emergency Department Note <b>H</b> Operative Note <b>H</b>	Lot Number <b>§</b>	Route of Administration <b>H</b>
New Data Class Observations	New Data Class Orders <b>§</b>	Patient Demographics/Information
Advance Directive Observation <b>H</b> Sex Parameter for Clinical Use <b>§ H</b>	Medication Orders Laboratory Orders Diagnostic Imaging Orders Clinical Test Orders Procedure Orders	Interpreter Needed = <b>H</b> Pronouns = <b>§ H</b> Name to Use = <b>§ H</b>
Provenance		
Author = <b>H</b> Author Role = <b>H</b>		

= Equity Based Underserved Public Health **§** ONC Cert **H** HITAC Recommended

# USCDI Version 5

## Allergies and Intolerances

- Medication Allergy Intolerance
- Drug Class Allergy Intolerance
- Non-Medication Allergy Intolerance
- Reaction

## Care Team Members

- Care Team Member Name
- Care Team Member Identifier
- Care Team Member Role
- Care Team Member Location
- Care Team Member Telecom

## Clinical Notes

- Consultation Note
- Discharge Summary Note
- Emergency Department Note
- History & Physical
- Operative Note
- Procedure Note
- Progress Note

## Clinical Tests

- Clinical Test
- Clinical Test Result/Report

## Diagnostic Imaging

- Diagnostic Imaging Test
- Diagnostic Imaging Report

## Encounter Information

- Encounter Type
- Encounter Identifier
- Encounter Diagnosis
- Encounter Time
- Encounter Location
- Encounter Disposition

## Facility Information

- Facility Identifier
- Facility Type
- Facility Name

## Goals and Preferences

- Patient Goals
- SDOH Goals
- Treatment Intervention Preference
- Care Experience Preference

## Health Insurance Information

- Coverage Status
- Coverage Type
- Relationship to Subscriber
- Member Identifier
- Subscriber Identifier
- Group Identifier
- Payer Identifier

## Health Status Assessment

- Health Concerns
- Functional Status
- Disability Status
- Mental/Cognitive Status
- Pregnancy Status
- Alcohol Use
- Substance Use
- Physical Activity
- SDOH Assessment
- Smoking Status

## Immunizations

- Immunizations
- Lot Number

## Laboratory

- Tests
- Values/Results
- Specimen Type
- Result Status
- Result Unit of Measure
- Result Reference Range
- Result Interpretation
- Specimen Source Site
- Specimen Identifier
- Specimen Condition Acceptability

## Medical Devices

- Unique Device Identifier - Implantable

## Medications

- Medications
- Dose
- Dose Unit of Measure
- Route of Administration
- Indication
- Fill Status
- Medication Instructions
- Medication Adherence

## Observations

- Advance Directive Observation
- Sex Parameter for Clinical Use

## Orders

- Medication Orders
- Laboratory Orders
- Diagnostic Imaging Orders
- Clinical Test Orders
- Procedure Orders

## Patient Demographics/ Information

- First Name
- Last Name
- Middle Name (Including middle initial)
- Name Suffix
- Previous Name
- Name to Use
- Pronouns
- Date of Birth
- Date of Death
- Race
- Ethnicity
- Tribal Affiliation
- Sex
- Sexual Orientation
- Gender Identity
- Preferred Language
- Interpreter Needed
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address
- Related Person's Name
- Relationship Type
- Occupation
- Occupation Industry

## Patient Summary and Plan

- Assessment and Plan of Treatment

## Problems

- Problems
- SDOH Problems/Health Concerns
- Date of Diagnosis
- Date of Resolution

## Procedures

- Procedures
- Performance Time
- SDOH Interventions
- Reason for Referral

## Provenance

- Author
- Author Role
- Author Time Stamp
- Author Organization

## Vital Signs

- Systolic Blood Pressure
- Diastolic Blood Pressure
- Average Blood Pressure
- Heart Rate
- Respiratory Rate
- Body Temperature
- Body Height
- Body Weight
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2 - 20 years)
- Weight-for-length Percentile (Birth - 24 Months)
- Head Occipital-frontal Circumference Percentile (Birth- 36 Months)



# New Data Elements and Classes USCDI v5

# Clinical Notes

Narrative patient data relevant to the context identified by note types.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
<p><b>Emergency Department Note</b> Narrative summary of care delivered in an emergency department.</p>	<p>Logical Observation Identifiers Names and Codes (LOINC) version 2.77</p> <ul style="list-style-type: none"><li>• At minimum: Emergency Department Note (LOINC code 34111-5)</li></ul>
<p><b>Operative Note</b> Narrative summary of a surgical procedure. Usage note: May include procedures performed, operative and anesthesia times, findings observed, fluids administered, specimens obtained, and complications identified.</p>	<p>Logical Observation Identifiers Names and Codes (LOINC) version 2.77</p> <ul style="list-style-type: none"><li>• At minimum: Surgical operation note (LOINC code 11504-8)</li></ul>

# Immunization

Record of vaccine administration.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
<b>Lot Number</b> Sequence of characters representing a specific quantity of manufactured material within a batch of a vaccine product	

# Medications

Pharmacologic agents used in the diagnosis, cure, mitigation, treatment, or prevention of disease.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
<p><b>Route of Administration</b> Physiological administration path of a therapeutic agent into or onto a patient. Examples include but are not limited to oral, topical, and intravenous.</p>	<ul style="list-style-type: none"><li>• SNOMED Clinical Terms® (SNOMED CT®) U.S. Edition, March 2024 Release</li><li>• National Cancer Institute Thesaurus (NCIt) v24.04e, FDA Structured Product Labeling (SPL) Terminology</li></ul>

# Observations

Findings or other clinical data collected about a patient during care.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
<p><b>Advance Directive Observation</b></p> <p>Information about a patient or provider authored document indicating its location, content, type, and verification status.</p> <p>Usage note: May include structured or unstructured data, whether a person has one or more advance directive documents, the type of advance directive, the location of the document, and whether it has been verified. Such documents may be used should a person be unable to communicate their wishes, preferences, or priorities to their provider.</p> <p>Examples include but are not limited to an indication that a living will is on file, a reference to the location of durable medical power of attorney, and the validating provider.</p>	
<p><b>Sex Parameter for Clinical Use</b></p> <p>Category based upon clinical observations typically associated with the designation of male and female.</p> <p>Usage note: There may be multiple instances of this data element for a single person, based on how the clinical observations (e.g., anatomic characteristics, recent hormone levels, or genetic testing) relate to or effect the clinical uses such as laboratory tests and results, diagnostic imaging, or preventive screening measures. Context specific values should be associated with these clinical uses.</p>	

# Orders

Provider-authored request for the delivery of patient care services.

Usage notes: Orders convey a provider's intent to have a service performed on or for a patient, or to give instructions on future care.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
<b>Medication Order</b> Provider-authored request for the dispensing of a therapeutic agent.	
<b>Laboratory Order</b> Provider-authored request for the performance of a laboratory test.	
<b>Diagnostic Imaging Order</b> Provider-authored request for the performance of a diagnostic imaging study.	
<b>Clinical Test Order</b> Provider-authored request for the performance of a non-laboratory or non-imaging test.	
<b>Procedure Order</b> Provider-authored request for the performance of a diagnostic or therapeutic intervention.	

# Patient Demographics/Information

Data used to categorize individuals for identification, records matching, and other purposes.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
<p><b>Interpreter Needed</b> Indication of whether a person needs language interpretation services.</p>	<ul style="list-style-type: none"><li>• Logical Observation Identifiers Names and Codes (LOINC) version 2.77</li><li>• SNOMED Clinical Terms (SNOMED CT) U.S. Edition, March 2024 Release</li></ul>
<p><b>Name to Use</b> Name that should be used when addressing or referencing a person.</p> <p>Usage notes: This information should be provided by the person. Can refer to a person's preferred name, nickname, or another name.</p>	
<p><b>Pronouns</b> Words that can replace a person's name when addressing or referring to a person.</p> <p>Usage note: This information should be provided by the patient.</p> <p>Examples include but are not limited to they/them/their, she/her/hers, he/him/his.</p>	

# Provenance

The metadata, or extra information about data, regarding who created the data and when it was created.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
<p><b>Author</b> Actor that created or revised the data. Usage note: The actor may be a provider, a patient, a device, an outside medical record, or something else. The source of the information can be used to form assessments about its quality, reliability, trustworthiness, or can indicate where to go to determine the origins of the information.</p> <p><b>Author Role</b> Category of actor that participated in the creation or revision of data. Usage note: The source of the information can be used to form assessments about its quality, reliability, trustworthiness, or can indicate where to go to determine the origins of the information. Examples include but are not limited to provider, patient, family member, and device.</p>	



# Changes to Existing Data Elements (USCDI v4)

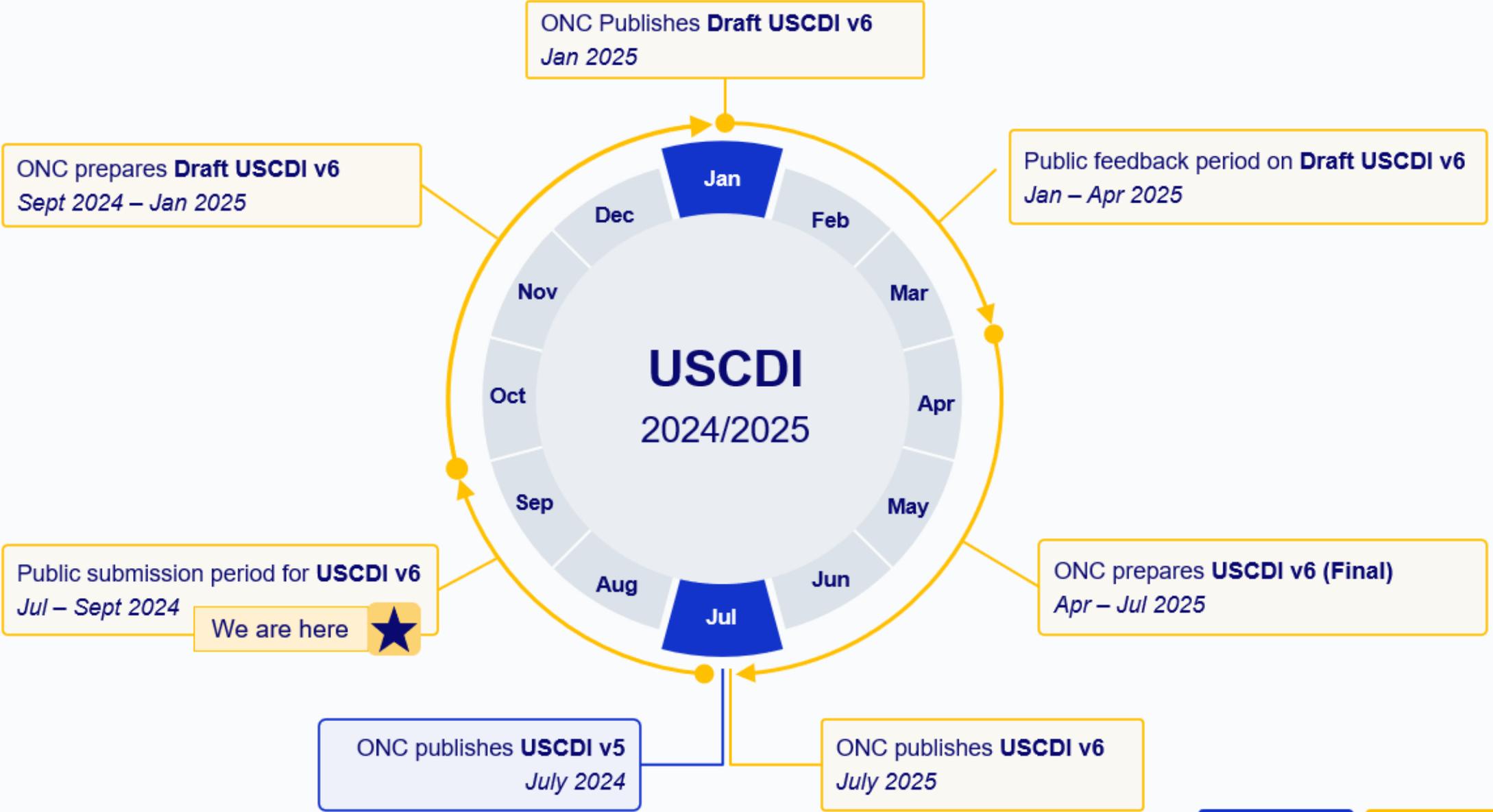
# Notable Changes to Existing Data Elements and Classes

Data Element	Change
Encounter Location	Add HSLOC as applicable vocabulary standard
Procedure	Change CDT standard reference
Immunizations	Technical correction-CVX, NDC standards
Medication Allergy Intolerance	Changed named to provide context
Drug Class Allergy Intolerance	Changed named to provide context
Non-Medication Allergy Intolerance	Changed named to provide context

Data Element	Change
Clinical Notes	Specified narrative content over structure



# USCDI Timeline



# USCDI Timeline

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## July 18, 2024

- USCDI v5 published
- Standards Bulletin published
- Data element level review
- [USCDI v6 submission](#) and comment cycle opening

## September 30, 2024

- USCDI v6 submission and comment cycle ends

## January 2025

- Anticipated Draft USCDI v6 publication
- HITAC ISWG convening to develop USCDI v6 recommendations

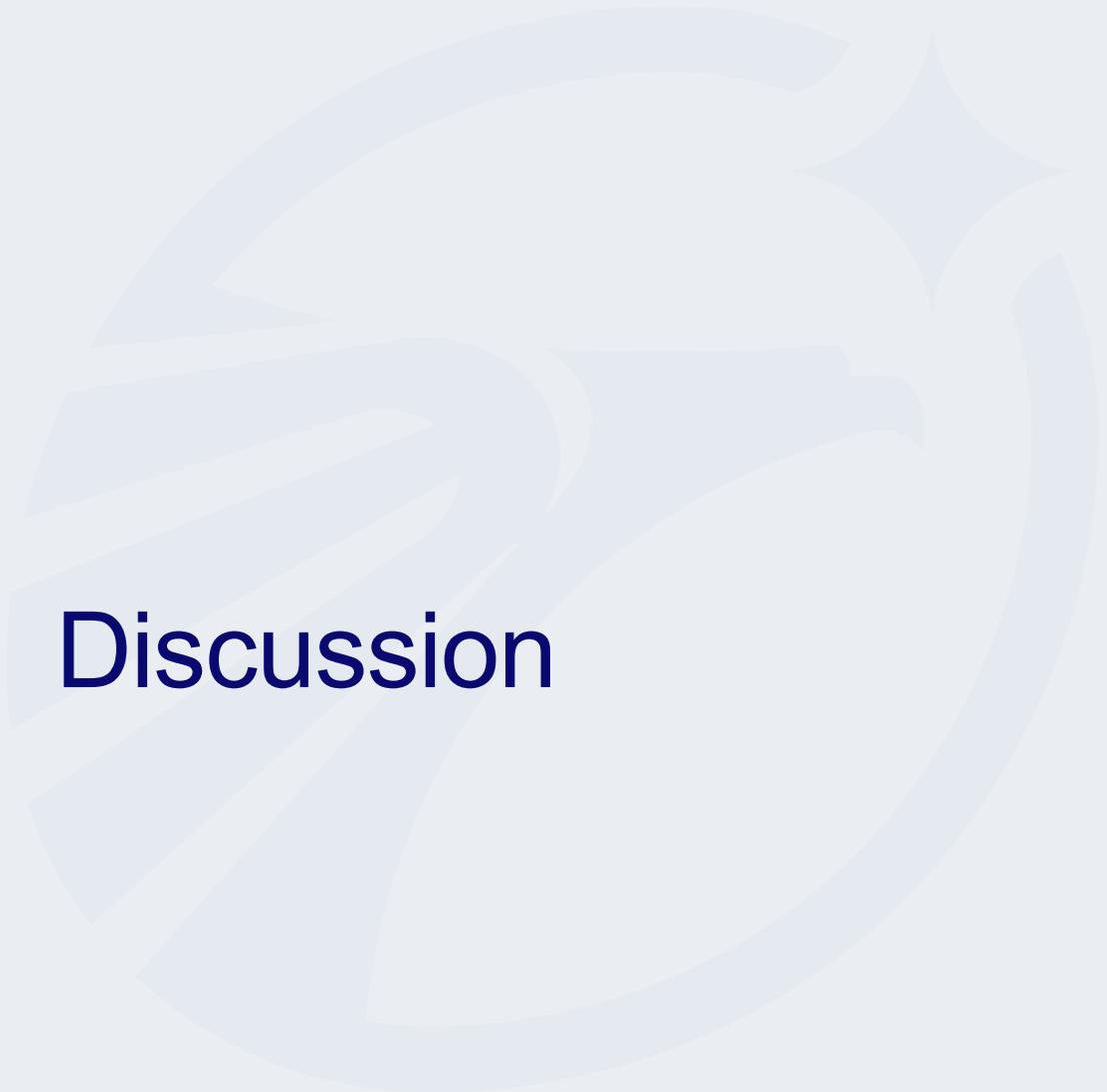
# Prioritization Criteria for New USCDI Data Elements

- Healthcare disparities and inequities
- Underserved communities
- Behavioral health
- Public health
- Aid in patient identification and patient matching
- Modest burden for
  - Standards and implementation guide developers
  - Health IT developers
  - Providers and health systems implementing updates

# HTI-2 Proposed Rule Comment Period

# Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule

- ONC's HTI-2 proposed rule implements provisions of the [21st Century Cures Act](#) and reflects ONC's focused efforts to advance interoperability and improve information sharing among patients, providers, payers, and public health authorities.
- Key proposals include:
  - Two sets of new certification criteria, designed to enable health IT for public health as well as health IT for payers to be certified under the ONC Health IT Certification Program. Both sets of certification criteria focus heavily on standards-based application programming interfaces to improve end-to-end interoperability between data exchange partners (health care providers to public health and to payers, respectively).
  - Technology and standards updates that build on the [HTI-1 final rule](#), ranging from the capability to exchange clinical images (e.g., X-rays) to the addition of multi-factor authentication support.
  - **Requiring the adoption USCDI version 4 by January 1, 2028.**
  - Adjustments to certain “exceptions” to the information blocking regulations to cover additional practices that have recently been identified by the regulated community, including a new “Protecting Care Access” exception, which would cover practices an actor takes in certain circumstances to reduce its risk of legal exposure stemming from sharing information.
  - Establishing certain Trusted Exchange Framework and Common Agreement™ (TEFCA™) governance rules, which include requirements that implement section 4003 of the 21st Century Cures Act.
- Proposals under review by the HITAC HTI-2 Proposed Rule Task Force 2024.
- [Read the Proposed Rule in the Federal Register](#)



# Discussion

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Reach out via phone or web

 202-690-7151

 Feedback Form: <https://www.healthit.gov/form/healthit-feedback-form>

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