The Office of the National Coordinator for Health Information Technology

Draft U.S. Core Data for Interoperability (USCDI) and Proposed Expansion Process

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Introduction

The 21st Century Cures Act (Cures Act) defines interoperability in the context of health information technology (health IT) as health IT that—

> (A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;
> (B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and
> (C) does not constitute information blocking as defined in section 3022(a).

The Cures Act sets an expectation that all of a patient's health information that is stored electronically will be able to be exchanged. This expectation requires that the industry collectively work towards defining the data that needs to be exchangeable, prioritizing the development of technical standards and implementation guidance to support the exchange of such data, and, ultimately, implementing those capabilities in health IT at the point of care.

The Draft US Core Data for Interoperability (USCDI) and its proposed expansion process aim to achieve the goals set forth in the Cures Act by specifying a common set of data classes that are required for interoperable exchange and identifying a predictable, transparent, and collaborative process for achieving those goals. This document provides ONC's first draft of the data classes that would be in the USCDI and lays out the process and structure by which the USCDI will be updated and expanded. The USCDI and its expansion process are intended to be collaborative vehicles around which ONC and the industry can coalesce to identify the critical data needed to enable interoperability and achieve the goals outlined in the Cures Act, we invite stakeholders to submit feedback on the proposed process and initial assignment of the data classes.

Common Clinical Data Set (CCDS)

In 2015, the US Secretary of Health and Human Services issued the 2015 Edition Health IT Certification Criteria (2015 Edition) final rule.[1] The 2015 Edition built upon previous rulemaking to facilitate greater interoperability and enable health information exchange through new and enhanced certification criteria, standards, and implementation specifications. In comparison to the previous editions, the 2015 Edition focused on identifying health IT components necessary to establish an interoperable nationwide health information infrastructure, fostering innovation and open new market opportunities, and allowing for more provider and patient choices in electronic health information access and exchange.

To achieve these goals, the 2015 Edition adopted the 2015 Edition Common Clinical Data Set (CCDS) definition. The CCDS evolved from the initial "Meaningful Use Common Dataset" that ONC adopted in 2012. The CCDS included new and updated vocabulary and content standards for clinical data exchange,

[1] 80 FR 62601, 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications, https://www.federalregister.gov/documents/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base?utm_content=previous&utm_medium=PrevNext&utm_source=Article.

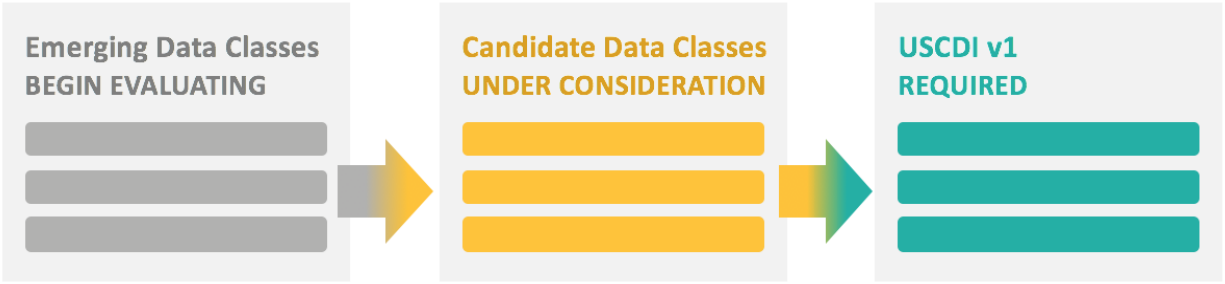
including: immunizations, unique device identifiers (UDIs), assessment and plan of treatment, goals, and health concerns.[2] It further expanded accessibility and availability of data exchanged by updating the definition of Base Electronic Health Record (EHR) to include enhanced data export, transitions of care, and application programming interface (API) capabilities, all of which required that at a minimum the CCDS be available.

Draft Trusted Exchange Framework

The Draft Trusted Exchange Framework is intended to enable Health Information Networks (HINs) to securely exchange electronic health information with each other to support a wide range of stakeholders. The draft Trusted Exchange Framework sets up an ecosystem wherein Qualified HINs connect to each other to support the use case of broadcast and directed query for treatment, payment, operations, individual access, public health, and benefits determination purposes. To enable the broadest set of use cases, Qualified HINs and their participants are required to be able to exchange the USCDI when such data is available (i.e. if a participant or Qualified HIN does not capture or have access to a specific data class, they are not expected to be able to exchange that data class). By requiring Qualified HINs and their Participants to be capable of exchanging the USCDI, the Trusted Exchange Framework will, over time, be able to support the Cures Act requirement of all electronic health information from a patient's record being available.

Proposed U.S. Core Data for Interoperability (USCDI) Expansion Process Overview

As part of ONC's continued efforts to expand the availability of a minimum baseline of data classes that must be commonly available for interoperable exchange, the draft USCDI builds off the CCDS definition and includes two additional data classes: Clinical Notes and Provenance. This document provides the process, data policy context, and structure by which a predictable schedule to expand the USCDI can be accomplished through collaboration with the industry. Once a data class has been proposed by the industry, it will follow a gradual process where it will be promoted to emerging status, then candidate status, and, ultimately, included in the USCDI. Once a data class is officially included in the USCDI, it will be required for nationwide exchange.



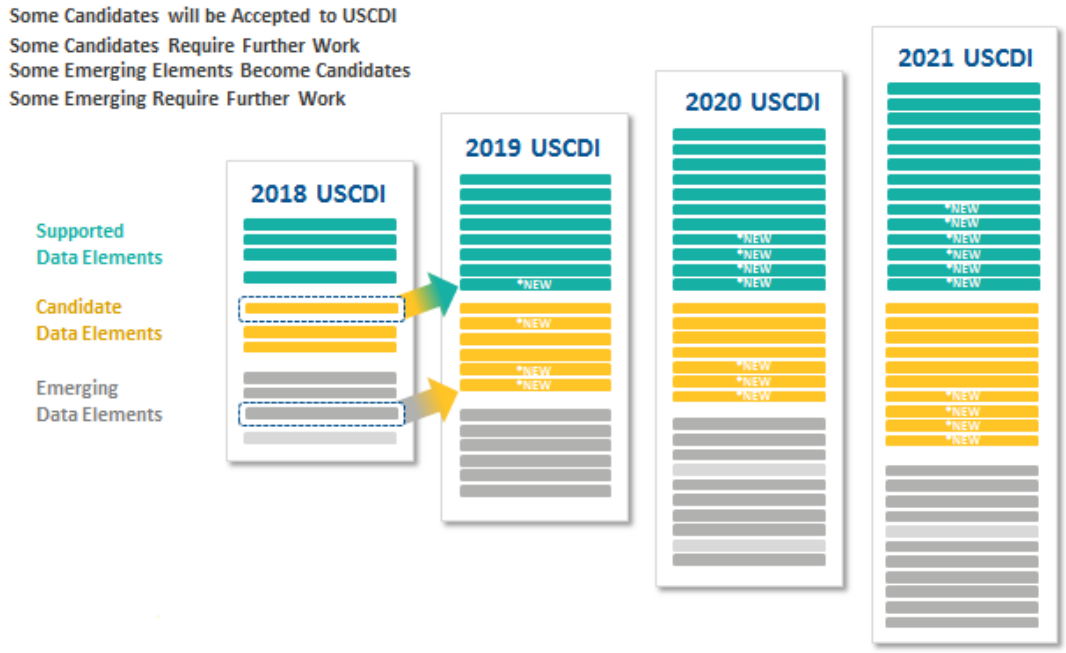
The proposed USCDI expansion process is expected to be conducted on an annual basis. Each cycle will be conducted and coordinated by ONC in an open and transparent manner that includes the opportunity for public comment. During each year's cycle, data classes would be considered for

[2] 2015 Edition Certification Companion Guide. https://www.healthit.gov/sites/default/files/2015Ed_CCG_CCDS.pdf

promotion from emerging to candidate status and from candidate status to USCDI. Once a data class is promoted to candidate status, it will be on track to be formally included in a future version of the USCDI for nationwide exchange.

The timing by which a data class moves from candidate status to USCDI will ultimately depend on the industry as a whole – including the public and private sectors – coalescing around the necessary technical specifications to make it possible to exchange the data class nationwide. Thus, industry stakeholders should take ONC's decision to include a data class as a candidate for USCDI status as a formal ONC data policy directive to focus and prioritize technical specification analysis and development to prepare the data class for inclusion in the USCDI. ONC recognizes that this technical work could take 12, 18, or 24 months to complete and expect that certain candidate data classes may remain in this status for 2 to 3 years. Once a data class is formally added to the USCDI, we will allow adequate time for the industry to implement and upgrade their technology to support the data specified in the USCDI.

Graphic 1: USCDI Expansion Process



Draft USCDI Version 1

The draft USCDI Version 1 (v1) reflects the same data classes referenced by the 2015 Edition CCDS definition and also includes Clinical Notes and Provenance. Clinical Notes is composed of structured (pick-list and/or check the box) and unstructured (free text) data. The free text portion of the clinical note may include the assessment, diagnosis, plan of care and evaluation of plan, patient teaching and other relevant data points. Provenance describes the metadata, or extra information about data, that can help answer questions such as when and who created the data. These two data classes were included in the draft USCDI v1 based on significant feedback from the industry post-2015 Edition rulemaking and during the Trusted Exchange Framework and Common Agreement stakeholder sessions about them being highly desirable as part of interoperable exchanges. Clinical notes was most often

relayed by clinicians as the data they sought but were often missing when they engaged in interoperable exchange. Similarly, understanding the provenance of the data being exchanged was also referenced by stakeholders as a fundamental need to improve the trustworthiness and reliability of the data being shared. All data classes in draft USCDI v1 can be supported by commonly used standards, including the Health Level Seven (HL7®) Consolidated Clinical Data Architecture (C-CDA) Version 2.1 and the Fast Healthcare Interoperability Resources (FHIR®) standards. A final USCDI v1 will be published in 2018. Furthermore, once the final Trusted Exchange Framework and Common Agreement (TEFCA) is published, Qualified HINs and their Participants will be required to update their technology to support all of the data classes included in USCDI v1 in accordance with the requirements in the final TEFCA.[3]

The following table includes the data classes in draft USCDI v1. We request comment on the addition of Provenance and Clinical Notes to the list of required data classes, specifically on industry readiness to support these data classes and the types of clinical notes that should be required.

Table 1: Draft USCDI Version 1 Data Classes

Draft USCDI Version 1 Data Classes	
1. Patient name	2. Sex (birth sex)
3. Date of Birth	4. Preferred Language
5. Race	6. Ethnicity
7. Smoking Status	8. Laboratory tests
9. Laboratory values/results	10. Vital signs
11. Problems	12. Medications
13. Medication Allergies	14. Health concerns
15. Care Team members	16. Assessment and plan of treatment
17. Immunizations	18. Procedures
19. Unique device identifier(s) for a patient's implantable device(s)	20. Goals
21. Provenance	22. Clinical Notes

USCDI Candidate and Emerging Data Classes Under Consideration

The data classes in the candidate and emerging status sections below were sorted based on feedback ONC has received from stakeholders via multiple avenues. These classes span a wide variety of use cases and target populations — including behavioral health, long term and post-acute care (LTPAC), individual access, public health, emergency medical services (EMS), pediatrics, social determinants of health, transitions of care, provider directory services, and clinical quality measures (CQMs). Moreover, this

[3] The Draft Trusted Exchange Framework proposes that QHINs and their Participants must update their data format and/or API to include new data classes added to the USCDI not less than 12 months after the data class has been officially added. We request comment on the feasibility of this timeframe. See Part B, Section 2.3 of the Draft Trusted Exchange Framework. https://www.healthit.gov/sites/default/files/draft-trusted-exchange-framework.pdf

sorting reflects ONC's best attempt to reflect this feedback and the priority to which stakeholders have assigned the data classes. Further, the sorting was informed by our own frame of reference assessment in terms of whether the data class already had some technical specification support via the C-CDA and/or FHIR standard(s).

We request public comment on the initial assignment of the data classes in the candidate and emerging sections as well as additional characteristics or attributes that should be considered in determining a data class' status, especially, whether a data class should be promoted to candidate status. We also request comment on additional data classes that should be added to either list, removed, or moved from one status to another.

Candidate Status

Data classes that achieve candidate status will be considered the "next up" data classes for inclusion in the USCDI. As a result, if additional technical specification development is necessary in order for these data classes to be exchanged nationwide, we expect the industry (as a whole) will prioritize and devote the resources necessary to position these data classes for promotion to the USCDI as soon as practicable. Generally, to be considered for candidate status, a data class must be clearly defined and have proven real-world applicability across a broad and diverse array of use cases, and substantial work in technical standardization has been or is actively being done by the industry. For example, Family Health History was adopted as an optional certification criterion in the 2015 Edition, has a clearly defined standard, and is valuable across a multitude of care specialties to assess what conditions a patient may be at an increased risk for. We will also consider data classes that have been identified by a majority of stakeholders as being particularly urgent to enhance public health, patient safety and care quality, such as Pregnancy Status.

The following table provides the list of data classes currently under consideration for candidate status, as well as a timeline for their inclusion in subsequent versions of the USCDI. A number of these candidates will be added to the USCDI v2, which will be released in 2019, while others will be phased in over 2020 (v3), 2021 (v4), and beyond based on readiness of technical standards, industry resources, and need. We have attempted to prioritize the data classes below based on feedback we have received from stakeholders, but request further comment.

Table 2: USCDI Candidate Status Data Classes

Year	Data Class	Description	Are technical[4] specifications available?
2019 (v2)	**Admission and Discharge Dates and Locations**	The dates and location of admission and discharge.	Yes (FHIR and C-CDA)
	Cognitive Status	Cognitive function, including a person's current and baseline attention, orientation and ability to register and recall new information and an individual's mental status.	Yes (FHIR and C-CDA)

[4] Technical Specifications Referenced: FHIR (STU3) and C-CDA (v.2.1)

Year	Data Class	Description	Are technical[4] specifications available?
	Encounter	An interaction between a patient and care provider(s) for the purpose of providing health care service(s) or assessing the health status of a patient.	Yes (FHIR and C-CDA)
	Discharge Instructions	Any directions that the patient must follow after discharge to attend to any residual conditions that need to be addressed personally by the patient, home care attendants, and other clinicians on an outpatient basis.	Yes (FHIR and C-CDA)
	Family Health History	Information about all guardians and caregivers (biological parents, foster parents, adoptive parents, guardians, surrogates, and custodians), siblings, and case workers; with contact information for each.	Yes (FHIR and C-CDA)
	Functional Status	Functional status data includes a person's current and baseline performance completing activities of daily living (ADLs), such as eating, bathing, walking, stair climbing, and may address altered gait and balance and decreased range of motion.	Yes (FHIR and C-CDA)
	Gender Identity	Gender identity refers to a person's self-perception as male or female, and may not be congruent with one's birth sex (or administrative gender).	Yes (FHIR)
	Pediatric Vital Signs	Pediatric age-specific norms for weight, height/length, head circumference, and BMI to calculate and display growth percentiles and plot them over time on standardized growth curves as appropriate.	Yes (FHIR)
	Pregnancy Status	Indicates whether or not a patient is pregnant.	Yes (FHIR and C-CDA)
	Reason for Hospitalization	Reasons why the patient was hospitalized.	Yes (FHIR and C-CDA)
2020 (v3)	**Care Provider Demographics**	Identification of care provider demographic information for each care team member as it relates to the patient (i.e., name, address, gender, date of birth).	Yes (FHIR and C-CDA)
	Care Team Members Contact Information	Identification of contact information for each care team member as it relates to the patient.	Yes (FHIR and C-CDA)
	Care Team Member Roles/Relationships	Identification of roles/relationships for each care team member as it relates to the patient (e.g., provider to patient, provider to provider).	Yes (FHIR and C-CDA)

Year	Data Class	Description	Are technical[4] specifications available?
	Diagnostic Image Reports (DIR)	A document that contains a consulting specialist's interpretation of image data. It conveys the interpretation to the referring (ordering) physician and becomes part of the patient's medical record. It is for use in Radiology, Endoscopy, Cardiology, and other imaging specialties.	Yes (FHIR and C-CDA)
2021 (v4)	**Individual Goals and Priorities**	Attribute within Goals that describes the intended health objective(s) set by an individual with a specific end point, for example, weight loss, restoring an activity of daily living, exercise goal, prevention based activities etc.	Yes (FHIR and C-CDA)
	Practitioner Responsible for Care	Attribute within the care team to designate the responsible clinician and their contact information.	Yes (FHIR and C-CDA)
	Provider Goals and Priorities	Attribute within Goals that describes the intended objective(s) for a patient, group or organization, set by the care provider, for example, weight loss, restoring an activity of daily living, obtaining herd immunity via immunization, meeting a process improvement objective, etc.	Yes (FHIR and C-CDA)
	Reason for Referral	Describes the purpose for the referral of the individual.	Yes (FHIR and C-CDA)
	Referring or Transitioning Provider's Name and Contact Information	Identification of referring or transitioning care provider and contact information.	Yes (FHIR and C-CDA)

Emerging Status

The following are data classes under consideration as emerging. These data classes have been identified by stakeholders as critical to achieving nationwide interoperability, but their overall priority for initial promotion to candidate status is unclear. In accordance with stakeholder feedback, ONC will consistently propose new data classes to be added to emerging status, thereby providing the industry with sufficient notice of what advancements lay ahead and allowing them appropriate time to react and prepare. Emerging status data classes are listed below in alphabetical order. We request comment on this list, including additional data classes not included or data classes that should be promoted to candidate status. Note that indented items in the Data Class column indicate that the item is a subset of a larger data class.

Table 3: USCDI Emerging Status Data Classes

Data Class	Description	Are technical[5] specifications available?
Advance Care Planning	Discussions that individuals have with their families and health care providers about end-of-life care.	Yes (FHIR and C-CDA)
Advance Directive	A legal document that states the kinds of medical care a person does or does not want under certain specific conditions.	Yes (FHIR and C-CDA)
Power of Attorney and name of person	An instrument (a written document; a formal or legal document in writing, such as a contract, deed, will, bond, or lease) authorizing a person to act as the agent or attorney of the person granting it.	Yes (FHIR and C-CDA)
Physician Orders for Life Sustaining Treatment (POLST) Form	A form translates end-of-life wishes based on a person's values, beliefs and goals for care using a shared medical decision-making process to create actionable medical orders that all health care providers, emergency personnel and treatment facilities must follow.	Yes (FHIR and C-CDA)
Alive Status/Date of Death	Indicates whether an individual is deceased or alive and date of death, if appropriate.	Yes (FHIR and C-CDA)
Care Provider Education/Licenses	Identification of care provider education and license information (e.g., NPI, state license, specialty information, Tax Identification Number (TIN).	Yes (FHIR and C-CDA)
Communication Facilitators	A person, i.e. a translator, or device, i.e. a hearing aid, that facilitates communication between a patient and their care provider.	Yes (FHIR and C-CDA)
Minor Consent	Consent refers to the minor's authority to keep information about certain medical services private and distinct from other content of the health record, such that it is not exposed to parents/guardians without the minor's authorization; the permission to receive medical treatments as required by institutional policy or jurisdictional law; and the authority granted to a designated an adult to provide and arrange for, medical care for a minor. Consent could vary based on state laws.	Yes (FHIR)
Disability Status	A physical or mental impairment that substantially limits one or more of the major life activities of such an individual.	Yes (FHIR and C-CDA)
Durable Medical Equipment	Medically necessary equipment that your doctor prescribes for use in patient's home, including wheelchairs, walkers, and hospital beds.	Yes (FHIR and C-CDA)
ESI/Electronic endpoint (for each organization, individual, relationship, system)	The technical details of an endpoint that can be used for electronic services.	Yes (FHIR)

[5] Technical Specifications Referenced: FHIR (STU3) and C-CDA (v.2.1)

Data Class	Description	Are technical[5] specifications available?
Health Insurance Information	Information pertaining to a patient's health insurance, information could include, but not limited to: name of insurance plan, coverage, identification number, and enrollment date.	Yes (FHIR and C-CDA)
Minor Status for Emancipation	Emancipation refers to a legal process that specifies when and under what conditions minors can become legally recognized as adults, independent from their parents.	No. Does not exist
Personal Representative	A person allowed access to protected health information on behalf of an individual they are representing, such as a child's parent or legal guardian, or a family member providing care for an aging relative.	Yes (FHIR)
Social, psychological, and behavioral data	Conditions in the places where people live, learn, work, and play that affect a wide range of health risks and outcomes.	Yes (FHIR and C-CDA)
Education	Captures an individual's current educational attainment (highest grade achieved).	Yes (FHIR and C-CDA)
Overall Financial Resource Strain	Encompasses both the subjective sense of strain as the result of economic difficulties and the specific sources of strain, including employment insecurity, income insecurity, housing insecurity, transportation insecurity, and food insecurity.	Yes (FHIR and C-CDA)
Social Connection/Support and Isolation	Measures an individual's level of social connection and support based on marital status, telephone contact, get togethers with friends, attendance at religious services, and engagement in social clubs.	Yes (FHIR and C-CDA)
Exposure to Violence	Measures an individual's exposure to intimate partner violence based on a 4-question HARK (Humiliation, Afraid, Rape, Kick) tool.	Yes (FHIR and C-CDA)
Employment Status	Measures whether an individual is currently employed, as well as the type of employment and the conditions this implies, including exposure to health risks.	Yes (FHIR and C-CDA)
Depression	Measures screening assessment results from the PHQ-2 and -9 Depression Screening instruments	Yes (FHIR and C-CDA)
Stress	Measures an individual's level of stress, in general.	Yes (FHIR and C-CDA)
Physical Activity	Measures moderate to strenuous activity in last 7 days, or on average per week.	Yes (FHIR and C-CDA)
Alcohol Use	Measures alcohol use and consumption based on the Alcohol Use Disorder Identification Test - Consumption [AUDIT-C] hazardous alcohol consumption screener.	Yes (FHIR and C-CDA)
Veteran's Status/Military History	Indicates the current or former military service of the individual. This may be included with employment status and history or captured separately.	No. Does Not Exist
Reconciled Medication List	Attribute within Medications that lists all the medications that the patient is taking, reconciled with allergy intolerances and problem list, as well as prescribed dosage, instructions, and intended duration.	Yes (FHIR and C-CDA)

Data Class	Description	Are technical[5] specifications available?
Special Instructions or Precautions for Ongoing Care	Special instructions and/or precautions for ongoing care, as appropriate, which must include, if applicable, but are not limited to: treatments and devices (oxygen, implants, IVs, tubes/catheters); precautions such as isolation or contact; special risks such as risk for falls, elopement, bleeding, or pressure injury and/or aspiration precautions.	Yes (FHIR)
Travel Status/History	Travel history (any travel, foreign and domestic) and dates of travel. It could also include future travel.	No. Does not exist
Weight- Based Dosing Calculation	The use of body weight (mg/kg) or body surface area (BSA) (mg/m^2) to calculate the appropriate dosage of a medication.	No. Does not exist

Comments

ONC developed the proposed expansion process and timeline based on feedback received from the industry, but require additional comments on how to objectively order data classes that are at a similar level of technical readiness but require prioritization based on industry bandwidth to build the technical specifications, number of use cases supported, and high level of need. We invite stakeholders to provide us with feedback on the initial assignment of the data classes in USCDI v1 and in both the candidate and emerging data classes, as well as additional characteristics or attributes that should be considered in determining a data class' status, especially, whether a data class should be promoted to candidate status. We also request comment on additional data classes that should be added to any of the three categories, removed, or moved from one status to another.

The comment period is now open for 45 days. Because of resource limitations, we are only accepting comments electronically at exchangeframework@hhs.gov. Attachments should be in Microsoft Word, Excel, Word Perfect, or Adobe PDF. The deadline for comment submission is 11:59 p.m. E.T. on February 18, 2018.

ONC will review, analyze, and post on our website at a future date all public comments that are received by 11:59 p.m. E.T. on February 18, 2018.[6]

[6] See https://beta.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement