Defining EHI and the Designated Record Set in an Electronic World

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Introduction

In 2016, Congress passed and enacted into law the 21st Century Cures Act (Cures), a far-reaching, bipartisan bill intended to accelerate medical product development and bring new innovations and advances more quickly and efficiently to patients that need them. Key provisions of Cures sought to enhance health information interoperability and prohibit information blocking by "actors," including healthcare providers, health information networks, health information exchanges, and health IT developers. The Office of the National Coordinator for Health IT (ONC) Cures Act Final Rule, which was released in March 2020 and published in the Federal Register on May 1, 2020, implements the interoperability requirements laid out in Cures.

ONC Cures Act Final Rule

A key provision of Cures prohibits actors from "interfer[ing] with, prevent[ing], or materially discourag[ing] the access, exchange, or use of electronic health information."[1] The ONC Cures Act Final Rule defines electronic health information, "or EHI," as:

> *electronic protected health information (ePHI) as the term is defined for HIPAA in 45 CFR 160.103 to the extent that ePHI would be included in a designated record set as defined in 45 CFR 164.501, regardless of whether the group of records are used or maintained by or for a covered entity as defined in 45 CFR 160.103 but EHI shall not include (1) psychotherapy notes as defined in 45 CFR 164.501; or (2) information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.*[2]

Another important provision of Cures requires certified health IT developers, as part of the new 2015 Cures Edition certification criterion, to provide a means to export all EHI that a certified health IT system can store at the time of certification for: (1) a single patient and (2) all patients whose EHI is in the system. ONC indicated that uses of this export feature might include a patient requesting their own information or a healthcare provider choosing to migrate information to another health IT system. The EHI export certification criterion relies on the same definition of EHI as above.

Beginning October 6, 2022, actors will be expected to adhere to the full scope of EHI for purposes of information blocking compliance. Certification to the EHI export criterion is expected by December 31, 2023.

Designated Record Set under HIPAA

Understanding the definition and scope of EHI requires deep familiarity with the Designated Record Set (DRS) as defined under the HIPAA Privacy Rule, which established the concept of the DRS as the foundation of an individual's "right of access" to protected health information

[1] PL 114-255.
[2] 45 CFR 171.102.

(PHI). It further defined the DRS as a group of records maintained by or for a Covered Entity (CE) that is/are:

> *(1) medical records and billing records about individuals maintained by or for a covered healthcare provider;*
>
> *(2) enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan, or*
>
> *(3) used, in whole or in part, by or for the covered entity to make decisions about individuals.*

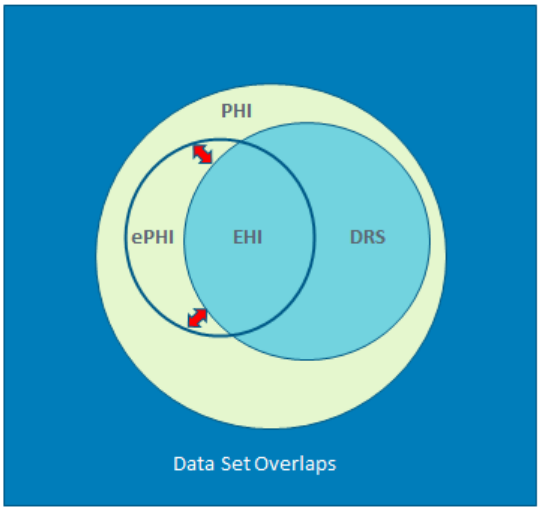
The term "record" means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.[3]

Subparagraph (3) of the definition of the DRS has generated much discussion among stakeholders, including the Task Force, as to whether the DRS only includes records used to make decisions about individuals and the feasibility of anticipating whether such records are in fact used for decision-making. However, in the preamble of the HIPAA Privacy Rule, the HHS Office for Civil Rights (OCR) suggests that the DRS includes records that are "normally used, and are reasonably likely to be used to make decisions about individuals."[4] OCR also notes that subparagraph (3) includes records that are "used to make decisions about any individuals, whether or not the records have been used to make a decision about the particular individual requesting access."[5]

Using the definition above, covered entities today generally interpret for themselves which records may be included in the DRS for compliance purposes. As a result, and as depicted in the diagram on the next page through the red arrows, there is variation and discrepancy in how healthcare organizations decide which types of records are included in their DRS. In turn, this has led to longstanding inconsistencies and confusion for CEs and Business Associates (BAs) over how to comply with federal regulations.

[3] 45 CFR 164.501.
[4] HIPAA Privacy Rule, 65 Fed. Reg. 82,606 (December 28, 2000).
[5] Id.

Data Universes under HIPAA and Infomation Blocking



Definition
- PHI – 45 CFR 160.103
- DRS – 45 CFR 164.501
- ePHI – electronic subset of PHI
- EHI – intersection of ePHI and DRS

Challenges
- ⇔ DRS to some extent is fluid by implementation, thus scope of EHI can change by provider, even though it may involve the exact same data set, ePHI, available.

Scope of Work

United in the belief that a consensus-based understanding of the definition of EHI for compliance purposes could benefit patient, providers, and developers, the American Health Information Management Association (AHIMA), the American Medical Informatics Association (AMIA) and the Electronic Health Record Association (EHRA) collaborated to examine the relationship between specific aspects of the ONC Cures Act Final Rule and the definitions of the DRS and EHI.

For over two years, a Task Force convened by these groups has sought to develop consensus recommendations among health information professionals, health informaticists, and health IT professionals on how to standardize expectations for data classes relevant to the DRS and EHI. The consensus recommendations in this report are intended to guide stakeholders on ways to operationalize these regulatory concepts in an electronic environment. Each of the host organizations contributed participants to a joint working group to further these goals, and worked within their organization to solicit additional input and contributions. The Task Force also sought feedback from provider organizations and other stakeholders.

This report describes the process the Task Force used to evaluate the definition of EHI and its relationship to the DRS, and outlines key considerations that stakeholders should take into account when operationalizing these concepts. The report also includes the Task Force's review of data classes commonly maintained in health IT and the DRS against the definition of EHI, an analysis that helped frame development of the key considerations and recommendations. Task Force members agreed that whether a particular data class is considered EHI will evolve over time as the definition of EHI (as well as the DRS) is not a static definition. Indeed, we recognize that the report from this Task Force represents a snapshot in time. For that reason, we consider the data classes reviewed by the Task Force as an exemplary "floor" for what might qualify as EHI. Actors will therefore need to keep in mind that should a patient, caregiver or third-party ask for information that is not a data

class examined in this report, it does not mean that the information requested is not necessarily part of the DRS or EHI.

Following is the process the Task Force used to examine the definition of EHI and its relationship to the DRS. As part of this process, the Task Force identified a number of key issues in relation to the definition of EHI.

Process

The Task Force began its work by examining data classes that are commonly contained in health IT and exchanged today to determine whether such data classes were also EHI. The Task Force then evaluated data elements that might be exchanged less frequently. These data classes were identified from:

1. ONC's US Core Data for Interoperability (USCDI) and ONC New Data Element and Class (ONDEC) website;[6]
2. Health IT developer lists of data classes maintained in their products; and
3. Best practices previously developed by AHIMA.[7]

Rather than develop new definitions for each examined data class, the Task Force applied existing USCDI and ONDEC definitions for consistency. For data classes that did not have a related USCDI or ONDEC definition, the Task Force provided examples of the respective data classes.

The date classes and data elements reviewed by the Task Force can be found in **Table 1**.

In October 2021, The Task Force released its initial draft of this report for public comment. Task Force members sought feedback from various stakeholders including providers, health IT developers, health information professionals, health information exchanges and health information networks, patient advocates and many others. Task Force members extensively reviewed all feedback provided by stakeholders. This updated report reflects the feedback provided by stakeholders as well as additional discussions undertaken by the Task Force members.

Table 1: Data Classes Reviewed by Task Force

Data class	Data elements	Definition of Data Class
USCDI v1 Data Classes		
Allergies	Substance (medication), Substance (drug class), Reaction	(See USCDI definitions.)
Assessment and Plan of Treatment	Assessment and Plan of Treatment, *SDOH Assessment**	(See USCDI definitions.)

[6] Available at: https://www.healthit.gov/isa/ONDEC.
[7] Available at: https://library.ahima.org/doc?oid=104008#.YS5ZG45Kg2w.

Care Team Members	Care Team Member(s) *Care Team Member Name, Care Team Member Identifier, Care Team member Role, Care Team Member Location, Care Team Member Telcom*	(See USCDI definitions.)
Clinical notes	Consultation Note, Discharge Summary Note, History & Physical, Procedure note, Progress note, Imaging narrative, Lab Report Narrative, Pathology Report Narrative	(See USCDI definitions.)
Goals	Patient Goals, *SDOH Goals*	(See USCDI definitions.)
Health concerns	Health Concerns	(See USCDI definitions.)
Immunizations	Immunizations	(See USCDI definitions.)
Laboratory	Tests, Values/results, **Specimen Type, Results Status****	(See USCDI definitions.)
Medications	Medications	(See USCDI definitions.)
Patient Demographics	First Name, Last Name, Middle Name (including middle initial), Suffix, Previous Name, DOB, Race, Ethnicity, Sex (assigned at birth), *Sexual Orientation, Gender Identity,* Preferred Language, Current Address, Previous Address, Phone Number, Phone Number Type, Email Address, **Date of Death, Tribal Affiliation, Related Person's Name, Related Person's Relationship, Occupation, Occupation Industry**	(See USCDI definitions.)
Problems	Problems, *SDOH Problems/Health Concerns, Date of Diagnosis, Date of Resolution*	(See USCDI definitions.)
Procedures	Procedures, *SDOH Interventions,* **Reason for Referral**	(See USCDI definitions.)
Provenance	Author Time Stamp, Author Organization	(See USCDI definitions.)
Smoking status	Smoking Status	(See USCDI definitions.)
Unique Device Identifiers for a Patient's Implantable Device	Unique Device Identifiers for a Patient's Implantable Device	(See USCDI definitions.)
Vitals	Systolic Blood Pressure, Diastolic Blood Pressure, Heart Rate,	(See USCDI definitions.)

	Respiratory Rate, Body Temperature, Body Height, Body Weight, Pulse Oximetry, Inhaled Oxygen Concentration, BMI Percentile (2-20 years), Weight for Length (birth-36 months), Head Occipital-Frontal, Circumference Percentile (birth-36 months)	
Additional USCDI v2 Data Classes		
Clinical Tests	Clinical Test, Clinical Test Result/Report	(See USCDI definitions.)
Diagnostic Imaging	Diagnostic Imaging Test, Diagnostic Imaging Report	(See USCDI definitions.)
Encounters	Encounter Type, Encounter Diagnosis, Encounter time, Encounter Location, Encounter Disposition	(See USCDI definitions.)
DRAFT USCDI v3 Data Classes		
Health Insurance Information	Coverage Status, Coverage Type, Relationship to Subscriber, Member Identifier, Subscriber Identifier, Group Number, Payer Identifier	(See USCDI definitions.)
Health Status	Health Concerns, Functional Status, Disability Status, Mental Function, Pregnancy Status, Smoking Status	(See USCDI definitions.)
ONC ONDEC Data Classes		
Level 2		
Biologically Derived Product	Product Code, Unique Identifier, Source Identifier, Division, Processing Facility	(See USCDI definitions.)
Exposure/Contact Information	Exposure/Contact Agent, Exposure/Contact Date, Exposure/Contact Direction, Exposure/Contact Source/Target Participant, Exposure/Contact Type	(See USCDI definitions.)
Facility-Level Data	Facility Name, Facility Address, Facility Contact Information, Facility Identifier, Facility Type, Facility GPS Coordinates, Facility Managing Organization Identifier	(See ONDEC definitions.)
Family Health History	Family Health History	(See ONDEC definitions.)
Functioning***	Functional Status, Disability Status, Mental Function	(See ONDEC definitions.)
Medical Devices or Equipment	Devices Used (applied)	(See ONDEC definitions.)
Nutrition and Diet	Oral Diet Type, Oral Diet Consistency, Oral	(See USCDI definitions.)

	Diet Texture Modifiers, Oral Nutrition Supplement, Enteral Nutrition Type, Enteral Nutrition Volume, Enteral Nutrition Rate, Enteral Nutrition Frequency, Enteral Nutrition Additive, Enteral Nutrition Flush, Eating/drinking Assistive Device, Oral Diet Nutrient Modifiers	
Observations	Observation Value, Observation Code, Observation Timing, Observation Subject, Observation Performer	(See ONDEC definitions.)
Orders	Type of Orders for Medical Care/Services	(See ONDEC definitions.)
Pregnancy Information	Multiple Gestation, Gestational Age, Corrected Estimated Due Date, Last Menstrual Period	(See USCDI definitions.)
Recorded Sex or Gender Class	Recorded Sex or Gender (RSG)	(See USCDI definitions.)
Referrals	Reason for Referral	(See USCDI definitions.)
Sex for Clinical Use	Sex for Clinical Use (SFCU)	(See USCDI definitions.)
Social Determinants of Health	Outcomes	(See USCDI definitions.)
Social History	Social History Observation, Alcohol Use, Drug Use, Sexual Activity, Refugee Status, Congregate Living	(See USCDI definitions.)
Substance use	Substance Use	(See USCDI definitions.)
Travel information	Travel History Location, Travel History Dates, Travel Plan Location, Travel Plan Dates	(See ONDEC definitions.)
Work Information	Job Employer Address, Job Employer Name, Job End Date, Job Start Date, Job Supervisory Level or Pay Grade, Job Work Classification, Job Work Schedule, Usual Occupation, Usual Occupation Duration, Usual Occupation Start Date	(See USCDI definitions.)
Level 1		
Advance Directives	Personal Advance Care Plan, Advance Directive Observation, Quality of Life Priorities, Care Experience Preference, Living Will, Durable Medical Power of Attorney	(See ONDEC definitions.)
Genomics	Gene Studied, Variant Data, Variant Interpretation, Variant Type	(See USCDI definitions.)

Ophthalmic Data	Refractions, Visual Acuity, Intraocular Pressure, Right Eye Intraocular Pressure, Left Eye Intraocular Pressure, Visual Acuity LogMAR Left Eye, Visual Acuity Uncorrected Right Eye, Visual Acuity Uncorrected Left Eye, Visual Acuity Corrected Right Eye, Visual Acuity Corrected Left Eye, Refraction, Visual Acuity LogMAR Right Eye	(See USCDI definitions.)
Security label	Security Label Purpose of Use (POU) Tag, Security Level Confidentiality Tag	(See USCDI definitions.)
Comment level		
Durable medical equipment	DME Orders	(See USCDI definitions.)
Explanation of benefit	Care Team role, Claim Service Start Date, Claim Service End Date, Claim Paid Date, Modifier Code-4, Modifier Code-3, Modifier Code-2, Modifier Code 1, Procedure Type, Procedure Code Type, Procedure Date, Procedure Code, Diagnosis Code Type, Diagnosis Type, Present on Admission, Is E code, Diagnosis Code, Line Copay Amount, Line Member Liability, Line Allowed Amount, Line Submitted Amount, Line Coinsurance Amount, Line Other Payer Paid Amount, Line Patient Deductible, Line Amount Paid to Provider, Line Allowed Amount, Drug Cost, Line Amount Paid by Patient, Line Discount Amount, Line Payment Amount, Line Member Reimbursement, Claim Referring Physician Network Status, Line Noncovered Amount, Payment Member Explanation, Line Payment Denial Code, Benefit Payment Status, Quantity Qualifier Code, Quantity Dispensed, Compound Code, National Drug Code, Allowed Number of Units, Revenue Center Code, Place of Service Code, Type of Service, Service to Date, Line Number, Service (from) Date, Total Amount, Claim Discount Amount, Claim other Payer Paid Amount, Member Liability, Copay Amount, Statement from Date, Co-insurance Liability Amount, Member Paid Deductible, Claim Non-covered Amount, Claim Payment Amount, Member Reimbursement, Claim Amount Paid to Provider, Amount Paid by Patient, Claim Total Allowed Amount, Claim Total Submitted Amount, Organization Identifier Type, Practitioner Identifier Type, Claim	(See USCDI definitions.)

	Operating NPI, Claim Operating Surgeon Name, Service Facility Address, Claim Supervising Physician Name, Claim Supervising Physician NPI, Claim Prescribing Physician Name, Claim Referring Physician Name, Service Facility Name, Claim PCP Name, Claim Performing Provider Name, Claim Billing Provider Name, Claim Attending Physician Name, Service Facility NPI, Claim PCP NPI, Claim Prescriber Contracting Status, Claim Performing Provider Network Status, Claim Performing Provider NPI, Claim Received Date, Claim Referring Service Network Status, Claim Attending Physician NPI, Claim Billing Provider Contracting Status, Claim Billing Provider NPI, Claim Identifier Type, Plan Reported Brand-Generic Code, Prescription Origin Code, Refill Number, DAW Product Selection Code, RX Service Reference Number, Days Supply, Adjudication Amount Type, Procedure Code Type, Claim Identifier Type, Adjudication Date, Statement Thru Date, Claim Payer Identifier Claim Payment Status Code, Claim Payee, Claim Payee Type, Claim Payer Name, Claim Other Payer Identifier(s), Claim Payment Denial, Patient Discharge Status, Claim Sub Type, Claim Type, Claim Processing Status, Claim Frequency Code, Claim Service Classification Type Code, Claim Bill Facility Type Code, Claim Inpatient Admission Type Code, Claim Inpatient Source Admission Code, Claim Diagnosis Related Group Version, Claim Adjusted to Identifier, Claim Adjusted From Identifier, Payer Claim Unique Identifier, Member Discharge Date, Member Admission Date	
Newborn's Delivery Information	Gestational Age at Birth, Apgar Score, Pregnancy Outcome, Birth Weight	(See ONDEC definitions.)
Organization Data	Organizational Identifier Components, Organization/Hospital Identifier	(See ONDEC definitions.)
Outcomes	Oncology Outcomes, Adverse Events	(See ONDEC definitions.)
Research Data	Study Name, Status	(See ONDEC definitions.)

Additional Data Classes Discussed		
Provider-provider messages with patient-identifiable information		Example: secure emails linked to a patient.
Provider-provider chat messages with patient-identifiable information		Example: secure chat messages linked to a patient.
Patient-provider messages		Example: secure emails linked to a patient.
Audit trail		Example: §170.315(d)(2) in the 2015 Edition certification criteria.
Clinical decision support history		Example: records that a particular drug interaction appeared to a clinician and the clinician's response to the interaction.
Event logs		Example: provider login times, logout times, system logouts.
Credentialing records		
Quality reports		
Consents (TPO, negotiated, HIE, medication)		
Census information		
Patient transportation		Example: moving a patient from one room of the hospital to another.
Transportation		For example, specific arrangements of motorized transportation of the patient to another facility.
Events (admission, discharge, transfer)		
Prior authorizations or authorizations		
Claims		
Billing codes assigned		Example: when coding a hospital account.

Hospital account and coverage		
A/R transactions		
Price estimates given to patient		
Lists of prices/charges		
Financial assistance applications		
Financial assistance decisions		
Eligibility information		
Charges, refunds, deductibles, interest paid/due		
Payments		
Denials		
Billing statements and summaries		
Collection information		
Pregnancy history, maternity, pregnancy status		
Patient relationships		Example: non-clinical participants in a care team, social support structures, family support structures.
Patient education		Documentation of education provided to the patient.
ADT notifications		
Account or collection notes		
Patient safety related information		

Correspondence with the patient or their guarantor		
Fetal monitoring strips		
Wearables		

**Data elements in italics indicates that an existing data class has had data elements added to it as part of USCDI v2.*
***Data elements in bold indicates that an existing data class has had data elements added to it as part of draft USCDI v3.*
****Functioning is included in draft USCDI v3 under the Health Status data class.*

Key Considerations: Status Conditions

The Task Force identified several key considerations to take into account when interpreting and applying the definition of EHI. Task Force members first identified that in some circumstances certain data classes may not be considered EHI depending on their "status." For example, some data classes may have a status condition such that it is not used in decision-making and therefore would not be considered EHI. Further discussion on how to differentiate those types of data classes will be important. Task Force members agreed that there is an inherent challenge in that use of a particular data class in decision-making is a key factor in the definition of EHI but not necessarily easy to track programmatically in an HIT system, leading to actors either casting a wide net as to what is considered EHI or relying on manual identification.

The Task Force identified several status conditions including:

- Unvalidated data
- Draft data
- Duplicative data
- Data that does not meet the ePHI definition

The first three conditions reflect discussion of a specific instance of that data class's inclusion within the DRS definition. Examples of each of these status conditions can be found below.

Status Conditions

Unvalidated Data

Examples of unvalidated data may include external records prior to clinical review or reconciliation, or device readings that have not been reviewed or checked by a clinician. Patient-generated data that is submitted to a clinician prior to clinical review or reconciliation may be another example of unvalidated data. Some readers may consider 'unvalidated' to include data received by an actor that has not been matched to a patient and therefore has not been included in the medical record. For the purposes of this document, we are not including this type of data in the definition of 'unvalidated' and would not consider this type of data to be in the DRS.

The HIPAA Privacy Rule makes clear that a covered entity is required to provide access to PHI regardless of whether the covered entity created the information or not.[8] However, the process of validating external records prior to incorporation into the medical record is a pervasive activity often performed to maintain the quality and integrity of incoming data. This action raises the question of whether external records that are unvalidated are considered EHI.

The Task Force agreed that whether validation is needed may depend on certain contexts, often times based on the level of trust. For example, data from consumer applications may require more arduous validation versus clinical applications. In contrast, a report from a clinician that does not work at the healthcare facility that is filed in the patient's record or results from an outside lab that are incorporated into a patient's record but are never validated is likely EHI because it could be relied upon for decision-making.

Task Force members agreed that validation should not be used as an excuse to not share data. In other words, not validating the data or delaying the validation of the data itself when such information could be used in decision-making does not necessarily mean the data is not considered EHI. Task Force members also agree that validation of the data should not take an unreasonable amount of time as to delay providing such information when requested if it is in fact EHI.

Additional exploration is needed to define what is considered "validation" and when validation processes should occur. Practically speaking, Task Force members noted that stakeholders should consider that there is a true cost associated with validating every piece of information at the discrete data level prior to incorporation into the record, including the feasibility of the action itself. Task Force members also suggested that greater proliferation of provenance data could help to reduce uncertainty in this area and provide greater context during validation.

Further work is also needed to examine how such validation processes may occur and who is responsible for such validation as it may be performed by clinical or administrative staff depending on the type of data class involved.

Draft Data

Unlike unvalidated data, the Task Force agreed that draft data expects or anticipates some further change. Draft data may include a clinical note in progress that may be written or edited but not yet signed. Draft data may also include reports that are in the process of being written or edited that have not been signed by the clinician. Pre-charting was also identified as draft data that therefore may not be considered EHI. Another example is data used for teaching workflows, provided a medical student begins the work and it is later taken over by other authors.

The Task Force reviewed guidance from the HHS Office for Civil Rights that stipulated "draft" PHI could be part of the designated record set if used for decision-making.[9] A recent frequently asked question (FAQ) from ONC regarding the Cures Act Final Rule appears consistent with this OCR guidance, stating that if draft clinical notes or incomplete test results are pending confirmation and are used to make decisions about the individual, such data would be considered part of the DRS and therefore EHI.[10]

[8] HIPAA Privacy Rule, 65 Fed. Reg. 82,732(December 26, 2000).

[9] Available at: https://www.hhs.gov/hipaa/for-professionals/faq/2067/is-a-clinical-laboratory-required-to-provide

Similar to the discussion involving unvalidated data, the Task Force agreed that if draft data is used for decision-making, it could be considered EHI.

Duplicative Data

There was consensus within the Task Force that if information is maintained in duplicate formats or systems, the holder may have the flexibility to choose from which system the EHI could be produced. For example, audio transcription files and transcribed text or lab result information may be in both a lab system and an electronic health record (EHR) and used for decision-making.

Guidance from the HHS OCR suggests that if the same data is maintained in more than one designated record set, a covered entity is obligated to only produce the information once in response to a request for access.[11] When pertaining to similar circumstances involving EHI, Task Force members agreed that the holder should be able to determine which system they would pull the EHI from when it is requested. However, the Task Force noted that when "all data" is requested, it might operationally be easier to provide duplicates whereas when specific data is requested, it might be simpler for an actor to produce from one source.

It is important to note that guidance from OCR also makes clear that an individual has a right of access to all PHI maintained about them by the covered entity (or its business associate) that is maintained in one or more designated record sets.[12] Similar guidance related to the Cures Act Final Rule offered by ONC suggests that an attempt by an actor to "artificially restrict or otherwise influence the scope of EHI may constitute an interference and could be subject to the information blocking regulation in 45 CFR part 171."[13] Therefore, having duplicative data in more than one system does not necessarily mean the data is not part of the designated record set and therefore not EHI. Rather, a reasonableness standard seems to be imputed with respect to what must be producible when EHI is requested.

Data Does Not Meet the ePHI Definition

ONC defines EHI as ePHI to the extent that ePHI would be included in a DRS, *regardless of whether the group of records is used or maintained by or for a covered entity.* Task Force members agreed that this seems to broaden the applicability of the definition of EHI. However, the definitions of ePHI and Individually Identifiable Health Information (IIHI), which helps to set the scope of ePHI, indicate that the context of collection and HIPAA definitions plays a role in defining EHI as well.

Therefore, the Task Force believes that information must be collected by a CE or BA of the CE when they are acting as CEs or BAs and not as employers or in other capacities. This addition context ensures that travel information collected by a non-CE/BA, such as a travel

[10] Available at: https://www.healthit.gov/curesrule/faq/non-final-clinical-information-such-draft-clinical-notes-or-incomplete-test-results-are-pending.

[11] Available at: https://www.hhs.gov/hipaa/for-professionals/faq/2043/does-an-individuals-right-under-hipaa/index.html.

[12] Available at: https:html .https://www.hhs.gov/hipaa/for-professionals/faq/2045/does-an-individual-have-a-right-to-access/index.htm

[13] Available at: https://www.healthit.gov/curesrule/faq/actor-required-fulfill-request-for-access-exchange-or-use-ehi-all-ehi-they-have-for-patient-or.

agency or information collected by a CE/BA acting as an employer, when the data would not be part a medical or billing record, does not qualify as EHI. However, that same travel information collected by a CE/BA as part of a medical/billing record or potentially used to make a decision about a patient would be EHI. Similarly, electronic information collected about the employee that relates to their employment such as lab results for drug screenings, immunization history, or similar information would not be considered EHI because it is not considered ePHI under the HIPAA Privacy Rule.

Similarly, data classes that are not patient identifiable such as information that lacks the 18 types of individual identifiers under the Safe Harbor standard of the HIPAA Privacy Rule or data that has been de-identified by expert determination consistent requirements of 45 CFR 164.514(b)(1) are not considered EHI. In both of these instances, because the data is not considered ePHI, it would not meet the threshold to constitute EHI. This analysis appears consistent with the preamble of the Cures Act Final Rule in which ONC states:

> *We agree that health information that is de-identified consistent with the requirements of 45 CFR 164.514(b) should not be included in EHI. It is not, however, necessary to specifically exclude such de-identified information from the EHI definition because information that does not identify an individual, and with respect to which there is no reasonable basis to believe the information can be used to identify an individual, is not individually identifiable information, so it would not be EHI. To note, once PHI has been de-identified, it is no longer considered to be PHI.*[14]

Additional considerations

The Task Force also discussed whether more granular distinctions might be useful to consider in the future when defining EHI. For example, input from provider groups suggested the age of the data might be an important factor in considering the value of exchanging it, even though data age is not considered in the definition of EHI or in the context of information blocking. Guidance from the HHS OCR reinforces the notion that the age of the information is not a consideration in terms of whether data is considered part of the designated record set given that under the HIPAA Right of Access, an individual has the right to access PHI maintained by a covered entity (or their business associate) even if it is old or archived.[15]

The Task Force also identified some data classes that were clearly EHI, but that might merit special policy considerations, including:

- Balancing the privacy of care team members when disclosing their names as part of the "care team" data class under USCDI v2.
- Recognizing the diversity of types of information contained in some data classes, such as noted in USCDI v1, and the difficulty of managing sensitive information within the note such as behavioral health information.

Upon identifying the aforementioned status conditions, the Task Force proceeded to assess the data classes identified in **Table 1** to determine whether certain status conditions may apply to the data classes, in which case the data class may not be considered EHI. The Task Force's analysis can be found in **Table 2**.

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[14] 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 85 Fed. Reg. 25,804 (May 1, 2020).

[15] Available at: https://www.hhs.gov/hipaa/for-professionals/faq/2044/does-the-individual-have-a-right-to-access-phi/index.htm.

Table 2: Application of Status Conditions to Data Classes

Data Class	Definition of Data Class	Is it EHI?	Status Conditions	Additional considerations
USCDI v1 Data Classes				
Allergies	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated.	
Assessment and Plan of Treatment	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated.	
Care Team Members	(See USCDI definitions.)	Yes	Unvalidated, duplicated.	EHI only when linked to an identified patient as a relationship. The Task Force discussed a common concern for the privacy of care team information (particularly last names), though this is outside the scope of the definition of EHI. Another consideration was maintenance of care team information over time for accuracy.
Clinical Notes	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated.	
Goals	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated.	
Health Concerns	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated.	
Immunizations	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated.	
Laboratory	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated.	
Medications	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated	Medication administrations and medication dispenses are proposed for future USCDI consideration.
Patient Demographics	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated.	
Problems	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated.	
Procedures	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated.	
Provenance	(See USCDI definitions.)	Uncertain		Provenance is a metadata class, which makes it unique in USCDI v1. The Task

				Force did not venture fully into the discussion given definitionally, USCDI v1 is currently considered EHI. However, the Task Force acknowledged that, like other metadata, it may not be EHI (as metadata, it is not necessarily health information). Regardless, in many cases the Task Force agreed it makes sense to share this metadata along with data in USCDI for context.
Smoking status	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated.	
Unique Device Identifier(s) for a Patient's implantable device	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated.	
Vitals	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated.	The Task Force also discussed fetal monitoring strips as a vital, noting that while considered vitals, this information is often captured using an external device and scanned into the chart. The Task Force also noted the complexity associated with this information living in the mother's record. Similarly, the Task Force discussed wearables as a vitals data element. We noted the wearable mode of capture may place particular emphasis on "draft" data before incorporation into the medical record. Task Force also noted that vitals may show up in other parts of the record and may not be calibrated and/or validated if patient-generated.

USCDI v2 Data Classes				
Clinical Tests	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated	This data class might encompass both the image and the report. Some of the conditions (for example, draft status) would not be applicable to an image but would be applicable to the report.
Encounter Information	(See USCDI definitions.)	Yes	Unvalidated, duplicated.	Encounters include past encounters as well as scheduled appointments.
Diagnostic Imaging	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated.	This data class might encompass both the image and the report. Some of the conditions (for example, draft status) would not be applicable to an image but would be applicable to the report.
USCDI v3 Data classes				
Health Insurance Information	(See USCDI definitions.)	Yes	Unvalidated, duplicated	
Health Status	(See USCDI definitions.)	Yes	Unvalidated, duplicated	
ONC ONDEC Data Classes				
Level 2				
Biologically Derived Product	(See ONDEC definitions.)	Yes	Unvalidated, duplicated	
Exposure/Contact Information	(See ONDEC definitions.)	Yes	Unvalidated, duplicated	
Facility Level Data	(See ONDEC definitions.)	Uncertain	Unvalidated, duplicated.	Facility data may be EHI only when linked to an identified patient as a relationship.
Family Health History	(See ONDEC definitions.)	Yes	Unvalidated, draft, duplicated.	
Functioning	(See ONDEC definitions.)	Yes	Unvalidated, draft, duplicated.	

Medical Devices or Equipment	(See ONDEC definitions.)	Yes	Unvalidated, duplicated	Medical devices may be EHI only when linked to an identified patient due to usage, implantation, etc.
Nutrition and Diet	(See ONDEC definitions.)	Yes	Unvalidated, draft, duplicated.	
Observations	(See ONDEC definitions.)	Yes	Unvalidated, draft, duplicated	
Orders	(See ONDEC definitions.)	Yes	Unvalidated, draft, duplicated.	
Pregnancy Information	(See ONDEC definitions.)	Yes	Unvalidated, draft, duplicated.	
Recorded Sex or Gender Class	(See ONDEC definitions.)	Yes	Unvalidated, duplicated.	
Referrals	(See ONDEC definitions.)	Yes	Unvalidated, draft, duplicated	
Sex for Clinical Use (SFCU)	(See ONDEC definitions.)	Yes	Unvalidated, duplicated.	
Social Determinants of Health (SDOH)	(See ONDEC definitions.)	Yes	Unvalidated, draft, duplicated, not ePHI.	SDOH is considered EHI if documented in the course of care or if accepted, received or stored by an actor and used for decision making.
Social History	(See ONDEC definitions.)	Yes	Unvalidated, draft, duplicated.	
Substance Use	(See ONDEC definitions.)	Yes	Unvalidated, duplicated.	
Travel Information	(See ONDEC definitions.)	Yes	Unvalidated, duplicated, not ePHI.	
Work Information	(See ONDEC definitions.)	Yes	Unvalidated, duplicated, not ePHI.	
Level 1				
Advance Directives	(See ONDEC definitions.)	Yes	Unvalidated, draft, duplicated.	Similar concepts include living will, medical power of attorney, etc. should be evaluated similar to advanced directives.
Genomics	(See ONDEC definitions.)	Yes	Unvalidated, draft, duplicated	There are other federal and state laws/ regulations that set specific privacy or purpose of use requirements for genomic data that would also need to be considered.

Ophthalmic data	(See ONDEC definitions.)	Yes	Unvalidated, draft, duplicated.	
Security Label	(See ONDEC definitions.)	Uncertain		The Task Force recognized the value of this for interoperability, as well as interest in this for legal reasons, or for a patient validating that labels they desired were accurately applied. However, there is skepticism that it is health information.
Comment level				
Durable Medical Equipment (DME)	(See ONDEC definitions)	Yes	Unvalidated, draft, duplicated.	Information generated or the order for DME will be EHI but not the equipment itself.
Explanation of Benefits	(See ONDEC definitions)	Yes	Draft, duplicated	Information is typically produced by payer so the provider might not have access to it.
Newborn's Delivery Information	(See ONDEC definitions)	Yes	Unvalidated, draft, duplicated	Information will likely exist in mother and newborn record.
Organization Data	(See ONDEC definitions)	Uncertain	Unvalidated, duplicated.	Organization data might be EHI only when linked to an identified patient as a relationship.
Outcomes		Yes	Unvalidated, draft, duplicated	
Research data	(See ONDEC definitions.) Example data elements: study name, status.	Yes	Unvalidated, duplicated, not ePHI.	There may be sensitive information implied even in a study name. **See FAQ:** https://www.hhs.gov/hipaa/for-professionals/faq/311/what-does-hipaa-say-about-research-participants-right-of-access/index.html
Additional Data Classes Discussed				
Provider-provider messages with patient-identifiable info†	For example, secure emails linked to a patient.	Yes	Unvalidated, draft, duplicated, not ePHI.	Task Force discussed difficulties with sharing this data class.
Provider-provider chat messages with patient-identifiable info+	For example, secure chat messages linked to a patient.	Yes	Unvalidated, draft, duplicated, not ePHI.	Task Force discussed difficulties with sharing this data class.

Patient-provider messages†	For example, secure emails linked to a patient. Could also include appointment reminders.	Yes	Unvalidated, draft, duplicated, not ePHI.	
Audit trail	For example, (d)(2) in certification.	No		It captures information about electronic health information, but is not health information.
Clinical decision support history	For example, records that a particular drug interaction appeared to a clinician and the clinicians response to the interaction.	No		Conceptually this is another type of audit trail.
Event logs	For example, provider login times, logout times, system logouts.	No		Not ePHI.
Credentialing records		No		
Quality reports		No		
Consents (TPO, negotiated, HIE, medication)		Yes	Unvalidated, draft, duplicated.	Medication or procedure consents are clearly EHI. We have more open questions regarding HIE consents which may not relate to treatment or billing decisions. Future discussion is needed as to whether clinically related consents versus administrative consents should be evaluated separately although for purposes of this exercise, the Task Force treated them as one data class.
Census information		No		Not ePHI.
Patient transportation	For example, moving from one room of the hospital to another.	No		Not ePHI.
Transportation	For example, specific arrangements of motorized transportation of the patient to another facility	No		Not ePHI. Separate from transportation insecurity, which would be a social determinant.
Events (admission, discharge, transfer)		Yes	Unvalidated, duplicated.	

Prior authorization or authorizations		Yes	Unvalidated, draft, duplicated.	
Claims		Yes	Unvalidated, draft, duplicated.	
Billing codes assigned	For example, when coding a hospital account.	Yes	Unvalidated, draft, duplicated.	
Hospital account and coverage		Yes	Unvalidated, draft, duplicated.	
A/R transactions		No		
Price estimates given to patient		Yes	Unvalidated, draft, duplicated.	
Lists of prices/charges		No		Not patient identifiable.
Financial assistance applications		Yes	Unvalidated, draft, duplicated.	
Financial assistance decisions		Yes	Unvalidated, duplicated.	
Eligibility information		Yes	Unvalidated, duplicated.	
Charges, refunds, deductibles, interest paid/due		Yes	Unvalidated, duplicated.	
Payments		Yes	Unvalidated, duplicated.	
Denials		Yes	Unvalidated, duplicated.	
Billing statements and summaries		Yes	Unvalidated, draft, duplicated.	
Collection information		Yes	Unvalidated, duplicated.	
Pregnancy history, maternity, pregnancy status		Yes	Unvalidated, duplicated.	
Patient relationships	For example, non-clinical participants in a care team, social support structures, family support structures.	Yes	Unvalidated, duplicated, not ePHI.	
Patient education	Documentation of education provided to the patient.	Yes	Unvalidated, draft, duplicated.	
ADT notifications	As required by Center for Medicare and Medicaid Services (CMS) Conditions of Participation.	Yes		There is an expectation that such notifications be documented in the medical record as required by CMS.
Account or collection notes				The Task Force was not familiar with this data class, it might depend on the content of the note.

Patient safety related information		No		The Task Force noted that some patient safety work might be confidential and therefore not included.
Billing correspondence between patient and their guarantor		Yes		The Task Force noted that while this is EHI, historically it may not have always been included in the DRS.

†Various types of provider communications (provider-provider messages, provider-provider chats, patient-provider messages, etc.) were discussed by the Task Force. In general, there were concerns that the wide variety of content that might be encompassed in a message makes it difficult to assess generically whether the content within is EHI or not. There was consensus among Task Force members that communications without individually identifiable patient information are not considered EHI. The Task Force also discussed an expectation that content within communications be incorporated into another data class (such as a note) if used in decision-making and under such circumstances would be considered EHI. If this were done consistently, that would offer confidence that provider communications did not include non-duplicative EHI. However, there was not confidence that this is widely adopted in practice today. Rather, there were concerns about the workflow burden of adopting such a practice and concerns about the downstream workflow impact of greater incorporation of data into notes, which can already suffer from "note bloat."

Conclusion

Our analysis demonstrates the complexity associated with defining EHI for multipurpose use, such as in ONC's certification program and compliance with information blocking. Whether a data class is considered EHI may depend on certain status conditions or characteristics. Other data classes might merit special consideration, such as behavioral health information. Throughout this process, Task Force members have agreed that what data classes are considered EHI will continue to evolve over time. However, we firmly believe that standardizing clinician and developer expectations around the definition of EHI will be critically important to successful operationalization of the Cures Act Final Rule.

The Task Force appreciates the feedback that it has received from stakeholders in the course of drafting this report. We welcome the opportunity to continue to work with stakeholders to further refine a consensus understanding of what data classes are considered EHI, including the federal government and private sector to further operationalize the definition of EHI as the stakeholder community adapts to the technical, regulatory, and business considerations related to the Cures Act Final Rule.

Appendix A: Task Force Members

AHIMA, AMIA, and EHRA would like to thank and acknowledge the following Task Force members who contributed their time and expertise to the development of this report.

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