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 (Cures) Act, 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.

[1] PL 114-255.

[2] 45 CFR 171.102.

Designated Record Set under HIPAA

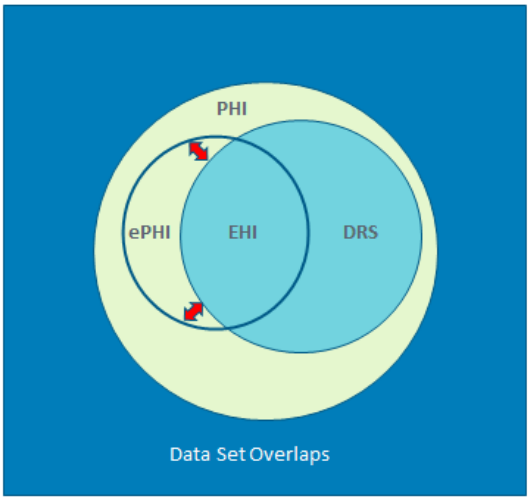
Understanding the definition and scope of EHI requires deep familiarity with the Designated Record Set (DRS) as defined under the HIPAA Privacy Rule, which established the concept of the DRS as the foundation of a patient's "right of access" to protected health information (PHI). It further defined the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

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 below 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.

Data Universes under HIPAA and Information 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.

[3] 45 CFR 164.501.

Scope of Work

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

Over the last year, 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. 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[4];
2. Health IT developer lists of data classes maintained in their products; and
3. Best practices previously developed by AHIMA[5].

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 reviewed by the Task Force can be found in **Table 1**.

[4] Available at: https://www.healthit.gov/isa/ONDEC.

[5] Available at: https://library.ahima.org/doc?oid=104008#.YS5ZG45Kg2w.

Table 1: Data Classes Reviewed by Task Force

DATA CLASS	DEFINITION OF DATA CLASS
USCDI v1 Data Classes	
Allergies	(See USCDI definitions.)
Assessment and plan of treatment	(See USCDI definitions.)
Care team members	(See USCDI definitions.)
Clinical notes	(See USCDI definitions.)
Goals	(See USCDI definitions.)
Health concerns	(See USCDI definitions.)
Immunizations	(See USCDI definitions.)
Lab tests and results	(See USCDI definitions.)
Demographics	(See USCDI definitions.)
Problems	(See USCDI definitions.)
Procedures	(See USCDI definitions.)
Provenance	(See USCDI definitions.)
Smoking status	(See USCDI definitions.)
Implanted device identifiers	(See USCDI definitions.)
Vitals	(See USCDI definitions.)
USCDI v2 Data Classes	
Encounters	(See USCDI definitions.)
Diagnostic imaging	(See USCDI definitions.)
ONC ONDEC Data Classes	
Facility data	(See ONDEC definitions.)
Family health history	(See ONDEC definitions.)
Health insurance	(See ONDEC definitions.)
Orders	(See ONDEC definitions.)
Observations	(See ONDEC definitions.)
Medical devices or equipment	(See ONDEC definitions.)
Social determinants of health	(See ONDEC definitions.)
Social history	(See ONDEC definitions.)
Specimen	(See ONDEC definitions.)
Travel information	(See ONDEC definitions.)
Advance directives	(See ONDEC definitions.)
Biologically derived product	(See ONDEC definitions.)
Ophthalmic data	(See ONDEC definitions.)
Security label	(See ONDEC definitions.)
Substance use	(See ONDEC definitions.)
Work information	(See ONDEC definitions.)
Functional assessments	(See ONDEC definitions.)

Organization data	(See ONDEC definitions.)
Referrals	(See ONDEC definitions.)
Research data	(See ONDEC definitions.) Example data elements: study name, status.
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 consents)	
Census information	
Patient transportation	Example: moving a patient from one room of the hospital to another.
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.

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:

1. Unvalidated data
2. Draft data
3. Duplicative data
4. 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 set 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, as is data used for teaching workflows if a medical student writes materials that are later validated.

Additional exploration is needed to define what "validation" means and when validation processes may occur. Whether validation is needed may depend on certain contexts. For example, data from consumer applications may require different validation workflows as compared to 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 but never validated would likely be considered EHI because it is the type of information that would be relied upon for decision-making and therefore part of the DRS.

Further work is also needed to examine how such validation processes may occur and who is responsible for such validation. The Task Force recognized that validation may be performed by clinical or administrative staff depending on the type of data class involved. Task Force members also agreed that having processes for validation should not be used as an excuse to not share data.

Draft Data

Similar to unvalidated data, draft data may include a clinical note in progress, for example 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.

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. In such circumstances, the holder should be able to determine which system they would pull the EHI from when it 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 45 CFR 171.102. 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 still play 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 additional context ensures that travel information collected by a non-CE/BA, such as a travel 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, 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 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.*[6]

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.

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 version 2.
- 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.

[6] 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 85 Fed. Reg. 25,804 (May 1, 2020).

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 **Table2**.

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.
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.	
Lab tests and results	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated.	
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.	
Implanted device identifiers	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated.	
Vitals	(See USCDI definitions.)	Yes	Unvalidated, draft, duplicated.	

USCDI V2 DATA CLASSES				
Encounters	(See USCDI definitions.)	Yes	Unvalidated, duplicated.	Encounters includes 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.
ONC ONDEC DATA CLASSES				
Facility 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.	
Health insurance	(See ONDEC definitions.)	Yes	Unvalidated, duplicated.	
Orders	(See ONDEC definitions.)	Yes	Unvalidated, draft, duplicated.	
Observations	(See ONDEC definitions.)	Yes	Unvalidated, draft, duplicated.	
Medical devices or equipment	(See ONDEC definitions.)	Uncertain	Unvalidated, duplicated.	Medical devices may be EHI only when linked to an identified patient due to usage, implantation, etc.
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.	
Specimen	(See ONDEC definitions.)	Yes	Unvalidated, draft, duplicated.	
Travel information	(See ONDEC definitions.)	Yes	Unvalidated, duplicated, not ePHI.	
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.
Biologically derived product	(See ONDEC definitions.)	Yes	Unvalidated, duplicated.	
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.

Substance use	(See ONDEC definitions.)	Yes	Unvalidated, duplicated.	
Work information	(See ONDEC definitions.)	Yes	Unvalidated, duplicated, not ePHI.	
Functional assessments	(See ONDEC definitions.)	Yes	Unvalidated, draft, duplicated.	
Organization data	(See ONDEC definitions.)	Uncertain	Unvalidated, duplicated.	Organization data might be EHI only when linked to an identified patient as a relationship.
Referrals	(See ONDEC definitions.)	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.
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.	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.	Uncertain		Conceptually this is another type of audit trail, but the proximity to decision making prompted discussion.
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 consents)		Yes	Unvalidated, draft, duplicated.	
Census information		No		Not ePHI
Patient transportation	For example, moving from one room of the hospital to another.	No		Not ePHI.
Events (admission, discharge, transfer)		Yes	Unvalidated, duplicated.	
Prior auth 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.	

†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 intends to continue its work following the release of this report. This will include seeking feedback from stakeholders regarding key findings of this report, further discussions with stakeholders to refine a consensus understanding of what data classes are considered EHI, including follow-up actions by the federal government and/or private sector to further operationalize the definition of EHI. This includes further exploration of whether common characteristics across covered entities could yield a common interpretation of the designated record set that can serve as a template to improve consistency. For that reason, the Task Force does not consider these findings to be "final." Rather, we welcome input and feedback from stakeholders as we intend to evolve these findings to adapt to technical, regulatory, and business considerations.

AHIMA, AMIA and the EHR Association look forward to working with other stakeholders in the healthcare community in seeking to advance a common understanding of the definition of EHI and iterate on the findings in this report.