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Health informatics — HL7 Personal Health Record System Functional Model, Release 2 (PHR-S FM)

Informatique de santé — Modèle fonctionnel d'un système de dossier de santé personnel, version 2 (PHR-S FM)

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Foreword

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This document was prepared by HL7 (as ANSI/HL7 PHRSFM, R2-2021) and drafted in accordance with its editorial rules. It was assigned to Technical Committee ISO/TC 215, *Health informatics* and adopted under the "fast-track procedure".

This first edition of ISO 16527 cancels and replaces the ISO/HL7 16527:2015, which has been technically revised.

The main changes are as follows:

— updates to many functional requirements, including those relevant to:

  — patient advance directives, consents and authorizations;

  — PHR account management, activation, deactivation and account transfers;

  — allergies, intolerances and adverse reactions;

  — problem list management and integration from multiple sources;

  — care plans, treatment guidelines and protocols;

  — clinical decision support;

  — nutrition and dietary information;

— health calendar;

— annotation of externally sourced information;

— record corrections and amendments;

— reduction of data duplication – same data from multiple sources;

— customized data views and reports;

— Record Infrastructure including:

    — record entry management,

    — lifespan and lifecycle events – fully compatible with ISO/HL7 10781 – Electronic Health Record System Functional Model, Release 2.1;

— Trust Infrastructure including:

    — authorization,

    — authentication,

    — access control and audit – fully compatible with ISO/HL7 10781 – Electronic Health Record System Functional Model, Release 2.1.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 Notes to Readers

The HL7 Personal Health Record System Functional Model (PHR-S FM) was approved as a Draft Standard for Trial Use (DSTU) in July 2008. In September 2010 the PHR-S FM was presented to ISO TC215 as a New Work Item Proposal (NWIP) ballot and received comments from the international community. The comments from that ballot were used to update and improve the draft standard. The standard was updated, re-balloted, and the comments reconciled in September 2013 resulting in Release 1, and again in 2019 resulting in Release 2.

0.2 Changes from Previous Release

This personal health –focused standard (PHR-S FM) was developed in harmony with the clinically-focused HL7 EHR System Functional Model (EHR-S FM). When the EHR-S FM's layout was enhanced from Release 1 format to Release 2 format, the HL7 Personal Health Record Work Group determined to update and harmonize the PHR-S FM from Release 1 format to Release 2 format as well. The PHR-S FM will follow the format of the EHR-S FM with respect to the replacement of the Information Infrastructure Section with two individual sections: the Record Infrastructure section and the Trust Infrastructure section.

0.3 Background

0.3.1   Personal Health Record (PHR) Versus a Personal Health Record System (PHR-S)

The PHR WG makes a clear distinction between a PHR and a PHR System (PHR-S). The PHR is the underlying record (e.g., data, information, pictures, sounds, graphs, or videos) that the software functionality of a PHR-S maintains. There has been much discussion surrounding the definition of a personal health record. The PHR-S FM does not attempt to define the PHR but rather to identify system features and functions necessary to create and effectively manage PHRs. The PHR-S FM offers examples of data elements, but is not intended to provide details necessary to specify a data model.

The overarching theme of a PHR-S involves a patient-centric tool that is controlled, for the most part, by the individual PHR Account Holder. A PHR-S should be immediately available electronically and able to link to other systems. The PHR-S provides functionality to help an individual maintain a longitudinal view of his or her health history, and may be comprised of information from a number of sources – e.g., from providers and health plans, as well as from the individual. Data collected by the system is administrative and/or clinical, and the tool may provide access to health-related forms (e.g., Advance Directives) and advice (e.g., diet, exercise, or disease management). A PHR-S might also help the individual collect behavioral health, public health, patient-entered and patient-accessed data (including medical monitoring devices), medication information, care management plans and the like, and might be connected to providers, laboratories, pharmacies, nursing homes, hospitals and other institutions and clinical resources. This PHR-S-FM is universal and therefore generic by design. There may be additional constraints in certain realms or regions. For example, in the US Realm, the management of laboratory results is subject to the Clinical Laboratory Improvement Amendments (CLIA) federal regulation.

At its core, the PHR-S should provide the ability for the individual to capture and maintain demographic, insurance coverage, and provider information. It should also provide the ability to capture health history in the form of a health summary, problems, conditions, symptoms, allergies, medications, laboratory and other test results, immunizations and encounters. Additionally, personal care planning features such as Advance Directives and care plans should be available. The system must be secure and have appropriate identity and access management capabilities, and must use standard nomenclature, coding and data exchange standards for consistency and interoperability. A host of optional features have been addressed over the course of this initiative, including secure messaging, graphical presentation of test results, patient education, guideline-based reminders, appointment scheduling and reminders, drug-drug interactions, formulary management, health care cost comparisons, document storage and clinical trial eligibility.

The effective use of a PHR-S is a key point for improving healthcare in terms of effective self-management, patient-provider communication and quality objectives.

0.3.2 Designation of Sections

The PHR-S FM (i.e., all chapters) contains normative, informative, and reference sections. In the Conformance Clause chapter, the normative content defines how a functional profile achieves conformance to the PHR-S FM.

Health Informatics — HL7 Personal Health Record System Functional Model, Release 2 (PHR-S FM)

1 Scope

1.1 PHR-S Functional Model Scope

The HL7 PHR-S FM defines a standardized model of the functions that may be present in PHR Systems.

It is beyond the scope of the PHR system to control the use (or intended use) of PHR data. On the contrary, it is within the scope of the PHR system to manage the authorization of an individual (or other application). Those parties are then responsible for using the data for appropriate (or intended) purposes. The system manufacturers ought to specify "intended and permitted use of PHR data" in their Terms of Service and Terms of Use agreements.

This Functional Model Is Not:

- A messaging specification
- An implementation specification
- A conformance specification
- A specification for the underlying PHR (i.e., the record itself)
- An exercise in creating a definition for a PHR
- A conformance or conformance testing metric
- A requirement specification for a single PHR system (see Anticipate Uses below

The information exchange enabled by the PHR-S supports the retrieval and population of clinical documents and summaries, minimum data sets, and other input/outputs.

2 Normative References

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TR 14292:2012 *Health informatics -- Personal health records -- definition, scope, context and global variations of use*

3 Terms and Definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
base functional profile
existing functional profile from which new (child) functional profiles are created/derived

3.2
conformance
fulfillment of a product, process, or service of specified requirements

3.3
conformance criteria
requirements indicating the behavior, action, or capability that constitutes implementation of the function

3.4
conformance clause
section of a specification that defines the requirements, criteria, or conditions to be satisfied in order to claim conformance

3.5
conformance statement
description of the function in a PHR system that has been implemented. It reflects the degree to which a PHR system has met the functional profile's requirements and may include optional functions and information

3.6
derived functional profile
functional profile that is created from a base functional profile, also known as a child functional profile

3.7
extension
ability for a PHR-S to incorporate additional functionality beyond what is defined in a functional profile (e.g.,, the text within a PHR is often displayed on a screen -- but that same text could be read aloud by an (external) speech synthesis computer program (even though speech synthesis is not part of the PHR system, per se).

3.8
functional profile
subset of the PHR-S FM in which functions have been designated (sometimes in varying degrees) for certain PHR systems or sources or level of functionality

3.9
informative functional profile
registered functional profile that has successfully completed formal public scrutiny via the HL7 consensus process

3.10
inherited criterion
conformance criteria listed in a header function that will be inherited by all its children functions, and conformance criteria listed in a parent function that are inherited by all its children functions

3.11
registered functional profile
functional profile that has successfully completed HL7 EHR WG registration process and review

3.12
situational criterion
criterion that is required if the circumstances given are applicable

4 The Functional Model

4.1 Overview and Definition

The PHR-S FM is divided into four sections: Personal Health, Supportive, Record Infrastructure, and Trust Infrastructure. Functional profiles can be developed which identify various functions from one or more of these four sections in order to describe a given system, and allows for further characterization of that profile by the assignment of priorities to each function in the profile (see Figure 1). While the PHR-S FM should contain all

reasonably anticipated PHR-S functions, it is not intended to comprise the entire list of all functions that may be found in any specific PHR-S. Again, functional profiles will be developed to constrain the functions for an intended use (see Section 5.1). This document defines the PHR-S Functional Model and describes the general use of profiles and priorities (see **Reference Material** for examples of stakeholders that might create profiles).

Figure 1: PHR-S Function List Sections

As previously mentioned, the PHR-S FM is divided into four main sections: Personal Health, Supportive, Record Infrastructure, and Trust Infrastructure. Within the main sections are a number of subsections (parent-child relationships). Each subsection is comprised of a number of individual functions. Functions describe the behavior of a system in consumer-oriented language and are intended to be recognizable to all key stakeholders of a PHR-S. Each function contains a Function Name, Function Statement, and Conformance Criteria (which are "normative" in an ANSI-accredited standard) as well as other associated information such as Description (which is reference information and is not a normative part of the ANSI-accredited standard).

The numbering of the functions maintains parent-child relationships between the sections and subsections (e.g., "PH.1.1 Account Holder Profile" is the parent of child "PH.1.1.1 Identify and Maintain a Patient Record"). In many cases the parent is fully expressed by the children (see Figure 2). In the aggregate, the PHR-S Functional Model is intended as the superset of functions from which a subset can be derived by a Stakeholder Community to illustrate what they need in a PHR-S for their setting. Only a subset of this inclusive set of functions (one or more PHR-S Functional Profiles) will apply to any particular PHR-S implementation.

	PH.1.0	Account Holder Profile
Personal Health	PH.2.0	Manage Historical Clinical Data And Current State Data
	PH.3.0	Wellness, Preventive Medicine, and Self Care
	PH.4.0	Manage Health Education
	PH.5.0	Account Holder Decision Support
	PH.6.0	Manage Encounters with Providers
Supportive	S.1.0	Provider Management
	S.2.0	Financial Management
	S.3.0	Administrative Management
	S.4.0	Other Resource Management
Record and Trust Infrastructure	RI.	Record Infrastructure
	TI.	Trust Infrastructure

Figure 2: PHR-S Functional Outline

There is one type of mandatory inheritance in the PHR-S FM. All criterion listed in a parent function will be applicable to all the children of that parent function.

4.2 PHR-S Functional Outline

4.2.1 The Functions and Their Use

The PHR-S Functional Model can be used to:

- Promote a common understanding of PHR functions upon which developers, vendors, users and other interested parties can plan and evaluate PHR functions.
- Provide the necessary framework to drive the requirements and applications of next level standards, such as PHR content, coding, information models, constructs and interoperability for information portability between sub-systems of a PHR-S and across more than one PHR-S.
- Establish a standards-based method by which each realm (country) can apply these PHR-S functions to care settings, uses, and priorities.
- Inform those concerned with new, additional, or other use of PHR data and national infrastructure what functions can be expected in a PHR-S.

4.2.2 Personal Health Section Functions

Description of Personal Health section functions: The Personal Health (PH) section functions are the subset of PHR-S functions that manage information and features related to self-care and provider based care over time. PH section functions can yield a summary record of an individual's care, including ad hoc views of the overall PHR.

Example of a Personal Health section function: A function to ensure that the individual PHR Account Holder's demographic information is captured and maintained so that the individual is unambiguously identified.

Actors for Personal Health section functions: As the subject of PHR information, the PHR Account Holder is the principal user of PH section functions.

4.2.3 Personal Health Support Section Functions

Description of Supportive section functions: The Supportive section functions are the subset of PHR-S functions that assist the PHR Account Holder with administrative and financial requirements. Also included are PHR-S functions that provide input to systems that perform clinical research, promote public health and seek to improve the quality and outcome of health care delivered.

Example of a Supportive section function: A function that will electronically query local immunization registries to ensure that a person is currently registered and determine the person's immunization status.

Actors for Supportive section functions: The PHR Account Holder is the principal user of Supportive section functions, but under certain circumstances, health care providers might be expected to perform various Supportive section functions.

4.2.4 Record Infrastructure Section and Trust Infrastructure Section Functions

Description of Record Infrastructure section functions and the Trust Infrastructure section functions: These two sections are copied from the EHR-S FM R2 since the record and trust requirements of health information exchange between the personal and clinical settings overlap heavily. They offer functionality that supports the Personal Health and Supportive section functions. These functions ensure that the PHR-S provides information privacy and security, interoperates with other information systems (including PHR and EHR systems), and helps make PHR-S features accessible and easy to use.

Example of a Record Infrastructure section function: A function to ensure that PHR data, such as an immunization record, can only be viewed and updated after an individual or system authenticates the user's identity within the PHR-S.

Actors for Record Infrastructure section and the Trust Infrastructure section functions: These functions are generally performed transparently by the PHR-S on behalf of (and without intervention of) PHR-S Account Holders and other users.

4.3 Common Major Concepts Across the Model

4.3.1 Consistency in the Conformance Criteria

Within the authoring group, there was an intentional effort to create language consistency in the conformance criteria. The "Action-Verb" Hierarchy (see 6.4 The Action-Verb Structure) was established to help create semantic harmony within the conformance criteria so that, for example, if the Personal Health section has a conformance criterion using the Action-Verb "Update," that term has the same meaning as in the Supportive section's conformance criteria.

The levels in the Hierarchy are granular and have been arranged in a parent-child relationship. For example, the Hierarchy reveals that the "Capture" of information covers local data entry ("Enter") and importation of data from an external source ("Import"). Similarly, under the "Maintain" section of the Hierarchy, the term "Store" could invoke Action-Verbs listed below it. If the parent term is not used, then the respective verbs in the child will be cited individually in the criterion. If the term "Manage" is used, all of the applicable Action-Verbs included in the Hierarchy are encompassed in that criterion. Authors are responsible for determining whether one or more of the sub-verbs are appropriate for a given function and must write conformance criteria that constrain the use of the Action-Verb Hierarchy according to the intent of the profile being created.

4.3.2 PHR Account Holder Privacy

It is the bias of this Model that consumer privacy rights be protected to the fullest extent possible. However, as an international model that attempts to describe functionality for many PHR system sub-types (e.g., integrated PHR/EHR systems, stand-alone PHR systems, or vendor-provided Web-based systems), statements concerning consumer control over information are frequently tempered by the phrase (with some variations) "in accordance with user role, organizational policy, or jurisdictional law." This phrase does not extend license to institutions to violate individual rights, but acknowledges that legitimate exceptions may exist to the general rule of PHR Account Holder control over their PHR information. In all cases, the model requires that the privacy policy of a PHR system be fully transparent to PHR Account Holders, and that a PHR-S has the ability to capture a PHR Account Holder's consent on how his or her personal information may be used and disclosed (see functions in TI.1.8, Patient Privacy and Confidentiality for additional detail.)

4.3.3 Functionality versus Implementation

It is important to note that many functions provide the capacity for functionality (e.g., provide for standards-based interoperability), but do not give implementation details. A function, when implemented, must be implemented within the context of the entire PHR-S FM. For example, implementation of many functions throughout the model are expected to conform to the security and audit functions found within TI.1 (Security) and TI.2 (Auditable Records), and functions performed "by the PHR Account Holder" may be actually performed by others as delegated by the Account Holder (see TI.1.2, Entity Authorization).

4.3.4 Relevant Standards

Relevant Standards include:

- ISO/TR 14292 "Personal health records - definition, scope, context and global variations of use"

4.3.5 Consents, Authorizations, and Preferences

Consumers may desire to declare a consent, authorization, or preference differently in the PHR-S context than in the EHR-S context. The method of handling consents, authorizations, or preferences is not addressed by the PHR-S FM. Rather, such issues ought to be addressed during implementation. For example, such functionality could be implemented in a "services-aware" fashion if desired (for example, as a smart-cloud-type-query). Differences between multiple versions of consents, authorizations, or preferences may be best

adjudicated by humans. The state of the art may not yet be adequate to handle such adjudication computationally.

4.3.6   Scope of Downstream Uses of PHR data

The PHR-S FM currently only envisions privacy, security, and confidentiality measures that extend to the initial PHR data-exchange recipient and not to (possible) subsequent recipients of the PHR data that might be passed on by the initial data-exchange recipient.

This PHR-S FM is universal and therefore generic by design. There may be additional constraints in certain realms or regions. For example, in the US Realm, the management of laboratory results is subject to the Clinical Laboratory Improvement Amendments (CLIA) federal regulation.

4.4 Type of Profiles

Characterization of a PHR profile based on its attributes:

- Scope and nature of content

Some PHR systems do not contain any patient clinical data, but just have consumer health information, personal health journals, or information about benefits and/or providers.

Of those PHR systems that have clinical information, some are populated by EHRs, some are disease specific, some include just specific subsets (e.g., laboratory reports), and some are comprehensive.

- Source of information

Data in PHR systems may come from the consumer, patient, caregiver, healthcare provider, payer, or all of these.

- Custodian of the record

The person or organization that manages or maintains the physical record. This may be the consumer or patient, an independent third party, a healthcare provider, an insurance company, or an employer.

- Data storage

Data may be stored in a variety of locations, including an Internet-accessible database, a provider's EHR-S, the consumer/patient's home computer, a portable device such as a smart card or thumb drive, or a privately maintained database.

- Degree of Interoperability

PHR system may be stand-alone or be interoperable with other EHRs/PHRs or somewhere in between.

- Party controlling access to the data

While consumers or patients always have the right to access their own data, they do not always determine who else may access it. For example, PHRs that are "views into a provider's EHR" follow the access rules set up by the provider. In some cases, consumers do have exclusive control.

5   Conformance Clause

5.1 Introduction (Reference)

The following is the HL7 EHR Work Group (EHR WG) -approved Conformance Clause for the PHR System Functional Model (PHR-S FM). As important background on conformance, please note the following:

- This conformance clause defines what it means to conform to the PHR-S FM.
- Conformance to the PHR-S FM is defined for functional profiles. A PHR system (PHR-S) does not directly conform to the PHR-S FM, rather it conforms to one or more functional profiles.
- Conformance criteria are associated with every function in the PHR-S FM.
- This conformance clause does not specify testing or validation procedures to determine whether a PHR-S conforms to a functional profile or whether a functional profile conforms to the PHR-S FM.

The technical and management staff of the U.S. National Institute of Standards and Technology (NIST), Information Technology Laboratory provided input and support for the development of this conformance clause.

5.2 Scope and Field of Application (Normative)

This *conformance clause* defines the minimum requirements for *functional profiles* claiming conformance to the PHR-S FM. It also identifies how PHR systems achieve conformance to the Functional Model (FM), which is via the system's conformance to a particular functional domain profile, multiple functional profiles, or combination of domain and companion profiles. This clause specifies:

- The purpose, structure, and use of conformance criteria that are to be included in the PHR-S FM and conforming functional profiles,
- The rules for defining conforming functional profiles of the PHR-S FM,
- The relationship between functional profiles and PHR systems,
- Sample conformance clauses and use case scenarios,
- Guidance on the conformance requirements that a functional profile might levy on PHR systems,
- Guidance on the purpose and use of a PHR system Conformance Statement.

While the conformance requirements for functional profiles can be found in this clause, they necessarily reference the PHR-S FM and other sources.

This conformance clause does not specify testing or validation procedures to assess a functional profile's conformance to the PHR-S FM. It also does not specify testing or validation procedures to determine whether a PHR system conforms to a functional profile or matches its Conformance Statement.

5.3 Concepts (Normative)

5.3.1   Functional Profiles

Creating a functional profile is a method for defining subsets of the PHR-S FM. A functional profile is a specification which uses the Functional Model to indicate which functions are required, desired, or implemented for certain PHR systems (e.g., systems characterized by their attributes such as source, custodian, technical approach, or level of functionality) or for other purposes (e.g., systems based on scope or nature of information such as chronic conditions). See the figure in Section 5.8 for representative examples.

Functional profiles can be created by healthcare community stakeholders with interest in using and/or providing a functional profile for a PHR system (e.g., Integrated Delivery Network, or an Employer or Payer system). Functional profiles can represent the functionality required and desired for the level of functionality and interoperability or reflect the functionality incorporated in a vendor's PHR system. Once a functional profile is defined it can be implemented by PHR systems or it may trigger the creation of derived functional profiles. A *derived functional profile* is a functional profile that is created from an existing functional profile, inheriting functions from the base (existing) functional profile.

(NOTE: During the process of creating a Functional Profile, it may be important to understand and accommodate clinical processes, work flows and/or interaction(s) of healthcare actors. The international standard 'ISO 13940 System of Concepts to Support Continuity of Care' provides an outline of key principles and processes in the provision of healthcare. We would highly recommend reviewing this standard as part of your functional profile development work.)

There are two types of functional profiles: the Domain Functional Profile and the Companion Functional Profile. The Domain Functional Profile is the common type of profile used to describe a PHR system for a specific community of stakeholders and/or sponsors (such as, diabetes-specific, asthma-specific, EHR-linked or payer-linked). Also, a Domain Functional Profile of a PHR system can be for use in a selected realm to meet the rules, regulations and standards applicable for that realm. The Companion Functional Profile is a type of profile that must be paired with one or more Domain Functional Profiles. The purpose of a Companion Functional Profile is to add unique features to a PHR System, such as for research, records management and evidentiary support, usability, or preventative care. For example, many PHR systems for consumers do not

need to support clinical research. For a clinic that is supporting advanced research, the need may exist for a PHR system that is capable of all of the expected functions for routine patient self-monitoring activities, but also has unique features to support additional data collection needs for research reporting and clinical trials.

The Conformance Clause portion of this standard also supports the creation of other (potentially) unique types of Companion Functional Profiles, whose goal can be to meet the common (or overarching) needs of regulation-based or realm-specific requirements.

A formal process exists for registering and balloting functional profiles. Functional profiles that are submitted to the HL7 EHR Work Group with an attestation of conformance to Section 5, Conformance Clause, of the HL7 PHR-S FM Standard and successfully complete review by the Work Group are designated as "*Registered functional profiles*". Registered functional profiles that undergo formal public scrutiny via the HL7 consensus process as an Informative EHR Work Group ballot at the Work Group level will be designated as *HL7 Informative functional profiles*. HL7 Informative functional profiles are eligible to undergo full HL7 membership ballot via the HL7 consensus process.

5.3.2 Conformance Model (Normative)

A PHR-S does not conform directly to the PHR-S FM; rather, a PHR-S conforms to a functional profile (i.e., a subset – more specifically, a tailored subset) of the PHR-S FM. Conformance to the PHR-S FM is defined for functional profiles. A functional profile conforms either directly to the PHR-S FM or to another conforming functional profile. Thus, functional profiles claim conformance to the PHR-S FM and PHR systems claim conformance to one or more conforming functional profiles. A PHR system can also claim conformance to a domain functional profile, in combination with one of more companion functional profiles. A PHR system cannot claim conformance solely to a companion functional profile. Figure 3 illustrates this relationship.
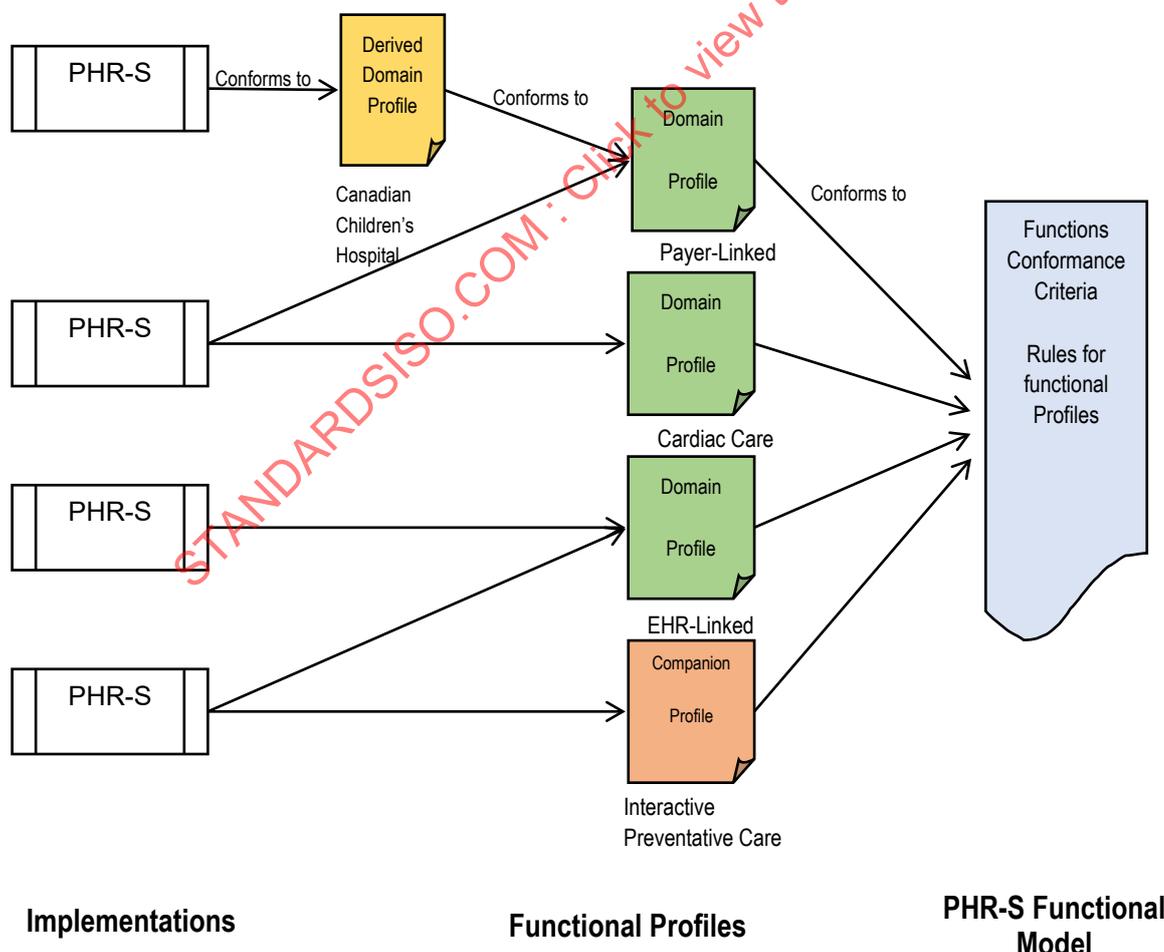
Figure 3: Conformance Relationships

5.3.3   Profile Traceability (Normative)

Functional profiles allow for added specificity and extensibility to the FM with changes allowed to the base FM functions and criteria. Section 6 of this chapter defines rules for these changes. It is also required that any changes and additions be tracked. Two added columns in profiles accomplish this. One column will document the unique source FM row number for each item in the new profile (or source profile for a derived profile). The second column will provide codes for the type of changes from the source FM (or source profile). Together, these two traceability columns will keep track of the origins of the functions or criteria – and whether it is modified or unchanged from that within the FM or the source profile. This may be important when questions arise as to where did it come from, why did you choose or modify it, etc. It can also be helpful to have traceability back to the FM functions and criteria if and when revisions to a profile or a derived profile are needed to reflect care setting, regulatory, technology changes – or when a newer version of the FM is offered.

5.4 Normative Language (Normative)

The following keywords (i.e., normative verbs) **SHALL** be used to convey conformance requirements.

- **SHALL –** to indicate a mandatory requirement to be followed (implemented) in order to conform. Synonymous with 'is required to'.
- **SHALL NOT –** to indicate a prohibited action. Synonymous with 'prohibited'.
- **SHOULD -** to indicate an optional recommended action, one that is particularly suitable, without mentioning or excluding others. Synonymous with 'is permitted and recommended'.
- **MAY** - to indicate an optional, permissible action. Synonymous with 'is permitted'.

5.5 Conformance Criteria (Normative)

5.5.1   Introduction

Every function in the PHR-S FM is associated with a set of *conformance criteria*. These conformance criteria form the basis for determining whether the function has been implemented.

5.5.2   Criteria in the Functional Profile

Functional profiles also have conformance criteria associated with every function in the functional profile. The functional profile's criteria are either (1) adapted from the PHR-S FM criteria with care-setting and application specific information or (2) if no care-setting or application specific criteria are present, inherited directly from PHR-S FM. Functional profiles **MAY** change PHR-S FM criteria to match the needs and priorities of the functional profile's constituency, e.g., by making it more specific, or changing it from 'may' or 'should' to 'shall'. The functional profile **SHALL NOT** be made less restrictive than the PHR-S FM by changing 'shall' criteria to 'may' or 'should' criteria. (A companion functional profile **MAY** be less restrictive that the FM by ignoring 'shall' criterion). Functional profiles **MAY** also add additional criteria.

5.5.3   'Dependent SHALL' Criteria

Conformance criteria that contain the keyword 'shall' **and** a dependency on situational conditions are called 'dependent shall' criteria. The 'dependent shall' **SHALL** contain the phrase "according to user role, organizational policy, and/or jurisdictional law" or other appropriate grammatical tie-in words (e.g., 'based on' rather than 'in accordance'). A 'dependent shall' criteria is used to highlight only these (i.e., user role, organizational policy, and/or jurisdictional law) conditions. A 'dependent shall' criterion is a mandatory criterion for functional profiles and situational for PHR systems. Specifically,

- All functional profiles **SHALL** inherit the criterion, if the function appears in the functional profile.
- A PHR system **SHALL** implement the Dependent SHALL criterion only if the criterion is applicable per the stated dependency in the PHR-S FM. (Note: If the Dependent SHALL criterion is not applicable to the profile but is still desired, the developer of the profile is permitted to include and implement the criterion.)

5.5.4   Referencing Other Criteria or Functions

There is often a link between functions and their criteria with other functions and criteria. For example, a given function may depend on another function or on a specific criterion associated with another function.

A criterion in the functional profile that references another function in the functional profile **SHALL** reference that function by indicating its Function ID and Function Name, as "X.n.n (Name)" (e.g., "PH.1. 5 (Manage Consents and Authorizations)". If the referenced function is required to be implemented, then all the 'shall' criteria of this referenced function apply. If the referenced function is a parent function that has child functions (i.e., sub-functions), the reference must be explicit regarding whether the child functions are included in the reference, all or selected ones. See the examples below:

- The system SHALL/SHOULD/MAY conform to TI.1.1 (Entity Authorization).
- The system SHALL/SHOULD/MAY conform to TI.2 (Audit) and all child functions.

- The system SHALL conform to S.1 Personal Health Support and separate function(s) The system SHALL conform to S.1 Provider Information. The system SHALL conform to S.2 Financial Management and all child functions.

A criterion in the functional profile that references a specific criterion in another function **SHALL** reference that function by rewriting the referenced criterion as one of its own and indicating the function and criterion number from where it came (e.g., F#, CC3).

5.6 PHR-S FM Structure and Extensibility (Normative)

5.6.1 Hierarchical Structure

Functions **MAY** be contained (i.e., nested) within other functions. A nested function is a 'child' to its 'parent' (i.e., the function that contains it). A child **SHALL** always have a parent. A function that is not a parent to another function is considered a 'leaf'. Figure 4 illustrates this hierarchical structure.

The PHR-S FM is represented as a hierarchical list of functions, consisting of functional parents, functional header children and functional leaf functions. Headers include an ID, Name and "H" in the column labeled "Type". Headers **MAY** contain conformance criteria only if the criteria apply to all its descendent functions (children, grandchildren, etc.). All parent functions **SHALL** be designated as a header ("H") function. Leaf functions contain at a minimum the following: ID, Name, Statement, Description, and Conformance Criteria and have an "F" in the "Type" column.

Conformance criteria listed in a header function **SHALL** be inherited by all its children functions. Similarly, conformance criteria listed in a parent function **SHALL** be inherited by all its children functions. Conformance Criteria have a "C" in the "Type" column.
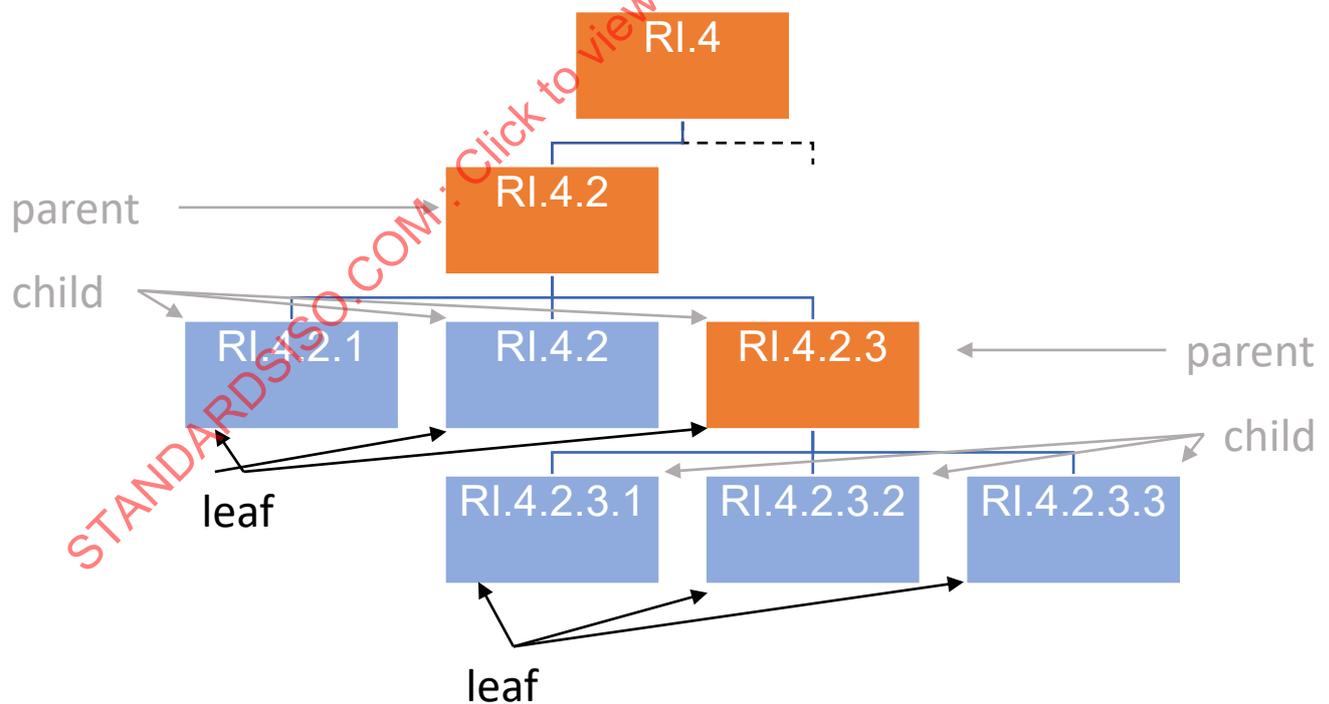
Figure 4: Portion of the PHR-S FM hierarchical structure

(Note: The numbering schema above reflects functions in the Personal Health section. For instance, PH.1.1 is the function 'Identify and Maintain a PHR Account Holder Record.)

Functional profiles either:

- Select functions from the PHR-S FM for inclusion in the functional profile,
- Deem a function in the PHR-S FM as not applicable, thus do not select it for inclusion in the functional profile,

- Add a new child function when it has been determined that there is no applicable function in the PHR-S FM to represent a functional need in the functional profile.

5.6.2   Naming Convention

Functional profiles **SHALL NOT** change the name or statement of a function except to allow for alignment to realm specific nomenclature, including language distinctions and implication of non-english translations. In these cases, the International Organization for Standardization (ISO) country code (ISO 3166 Country Codes) **SHALL** be appended to the function ID in the functional profile. It is recommended that the HL7 Affiliate for the respective realm coordinate with the profile development process to maintain a mapping of the Functional Model function name and/or statement and the realm-adjusted name and/or statement.

5.6.3   Priorities

Functional profiles indicate the importance and/or immediacy of a functional profile by associating a priority with a function. Three priorities have been defined: Essential Now, Essential Future, and Optional.

- Essential Now indicates that the implementation of the function is mandatory, as of the profile issuance date.
- Essential Future indicates that the implementation of the function is currently optional but will be mandatory at some future time, which is specified by the functional profile.
- Optional indicates that the implementation of the function is optional.

Any or all of these priorities **SHALL** be used in a functional profile. If the Essential Future priority is used, then functional profiles are required to define the timeframe associated with implementing functions. A timeframe **MAY** be a date, time allotment (e.g., year 2014, or four months after functional profile publication), or event (e.g., subsequent publication of this functional profile). A functional profile **MAY** define multiple timeframes for the Essential Future priority. If multiple timeframes are defined, then the timeframe **SHALL** be used to qualify each occurrence of the Essential Future priority (e.g., EF-2015, EF-2016).

5.6.4   Extensibility

To accommodate changes in technology as well as functional profiles' needs, the PHR-S FM is designed for extensibility with respect to functions and their related criteria. Incorporation of additional functions in the functional profile beyond what is defined in the PHR-S FM is accommodated through a set of rules for adding new functions as defined in Section 5.7.3.

Incorporation of additional criterion, changing the sequence of criterion and providing greater profile-specific detail, beyond what is defined in the FM, is accommodated through a set of rules for adding new criterion or changing existing criterion as defined in Section 5.5.2.

5.7 Functional Profile Conformance (Normative)

5.7.1   Introduction

A functional profile claiming conformance to the PHR-S FM **SHALL** meet all requirements specified in section 5.7.2 Rules for Domain Functional Profiles or 5.7.6 Rules for Companion Functional Profiles.

5.7.2   Rules for Domain Functional Profiles

Domain functional profiles that adhere to the Rules for Functional profiles **MAY** claim conformance to the version of the PHR-S FM from which it was derived.

Functional profiles claiming PHR-S FM conformance **SHALL**:

1. Identify the PHR-S FM with version/date from which the functional profile is derived,
2. Include a description, version and issuance date of the functional profile,

3. Contain a conformance clause which
    a. Defines the requirements that PHR systems must satisfy in order to claim conformance to the functional profile.
    b. Defines the requirements that functional profiles derived from the functional profile (i.e., derived functional profiles) must satisfy in order to claim conformance to the functional profile.
    c. Specifies that functions designated with the priority 'Essential Now' **SHALL** be implemented by conformant PHR systems.
    d. Specifies that functions designated with the priority 'Essential Now' **SHALL** be included in any derived functional profiles.
    e. If Essential Future is used, defines the meaning of 'Essential Future', including specifying the timeframe for when these functions are required to be implemented.
    f. Requires that at least one function, regardless of its priority, be implemented in order for a PHR system to claim conformance to the profile.
4. Identify functions from the PHR-S FM that are applicable to the functional profile. For each function, indicate its priority (i.e., Essential Now, Essential Future or Optional).
5. For each function, derive conformance criteria based on the PHR-S FM's conformance criteria.
    a. In the functional profile, there **SHALL** be at least one criterion for each function that is mandatory (a 'shall' criterion).
    b. If there are 'shall' criteria (for the function in the PHR-S FM), then those criteria **SHALL** also exist for the function (in the functional profile). Additionally, if the function is split (in the functional profile), then the parent's 'shall' criteria **SHALL** appear in at least one child of that function.
    c. If, as yet there is no 'shall' criterion (for the function in the PHR-S FM), then at least one of the 'should' or 'may' criterion **SHALL** be made mandatory, i.e., a 'shall' criterion.
    d. Adhere to the rules for referencing functions or criteria in Section 5.5.4.
6. For any function in the PHR-S FM where one or more criteria are 'dependent shall' criteria, the functional profile for that function **SHALL**
    a. Replicate verbatim each 'dependent shall' in the functional profile, regardless of whether the dependent situation applies or not.
    b. When the dependent situation applies, create 'shall' criteria that apply the dependency to the 'dependent shall' criterion, resulting in one or more new, constrained versions of the 'dependent shall' criterion.
    c. State the specific scope of practice, organizational policy, and/or jurisdictional law which applies or state why these dependencies do not apply.
7. Adhere to the rules for creating new functions in functional profiles in Section 5.7.3.
8. Be structured in accordance with the structural requirements defined for the PHR-S FM in Section 5.6.
9. Complete the two traceability columns, see Section 5.3.3, for any changes to functions or criteria, and include the following codes for type of change: (1 – sequence, 2 – optionality, 3 – content, 4 – new). Multiple codes are allowed to document the type of changes. For example, criterion #3 that is moved to #1, changed from SHOULD to SHALL, and with realm specifics on standards required would be coded as "1, 2, 3".
10. Be structured in accordance with the structural requirements defined for the FM in Section 5.6.1
11. Use the Glossary Action-Verbs for modifying or creating new conformance criterion.

Functional domain profiles claiming conformance to the PHR-S FM **MAY:**

1. Create additional functions according to the rules specified in Section 5.7.3.
2. Contain conformance criteria more specific and limited in scope than those of the PHR-S FM.
3. Replace the text 'standard(s)-based' found in some criteria with specific standards and/or specifications named at the most discrete level of designation.
4. Change a 'should' criterion to a 'shall' or a 'may' criterion.
5. Change a 'may' criterion to a 'shall' or a 'should' criterion.
6. Ignore a 'should' or 'may' criterion in the PHR-S FM (i.e., not include it in the functional profile).
7. Add additional conformance criteria beyond those in the PHR-S FM.
8. Make the order of the conformance criteria significant (e.g., put all 'shall' criteria first).
9. Enforce common resolution of ambiguous semantics of the PHR-S FM.
10. Make the functional profile public (e.g., published on a web site) so interested parties can see/use it.
11. Submit the functional profile for registration review by the HL7 EHR Work Group.

Functional domain profiles claiming conformance to the PHR-S FM **SHALL NOT:**

1. Specify any requirements that would contradict or cause non-conformance to the PHR-S FM.

2. Modify the name or statement of any function in the PHR-S FM, except to allow for alignment with realm specific nomenclature as specified in Section 5.6.2.
3. Change a mandatory conformance criteria to an optional criteria (i.e., replace the 'shall' within the criteria to 'should' or 'may') of any function in the PHR-S FM.
4. Modify any requirements of a function not selected for the functional profile (i.e., all unselected functions default to the PHR-S FM's criteria. If a profiling group wants to change something, they **SHALL** promote it into their functional profile).

5.7.3 Rules for Creating New Functions in Functional Profiles

If a function is not adequately specified for a functional profile or does not exist, the functional profile **SHALL** only create new children; the new children can be parents or leaves. Figure 5 illustrates the addition of a new child function.
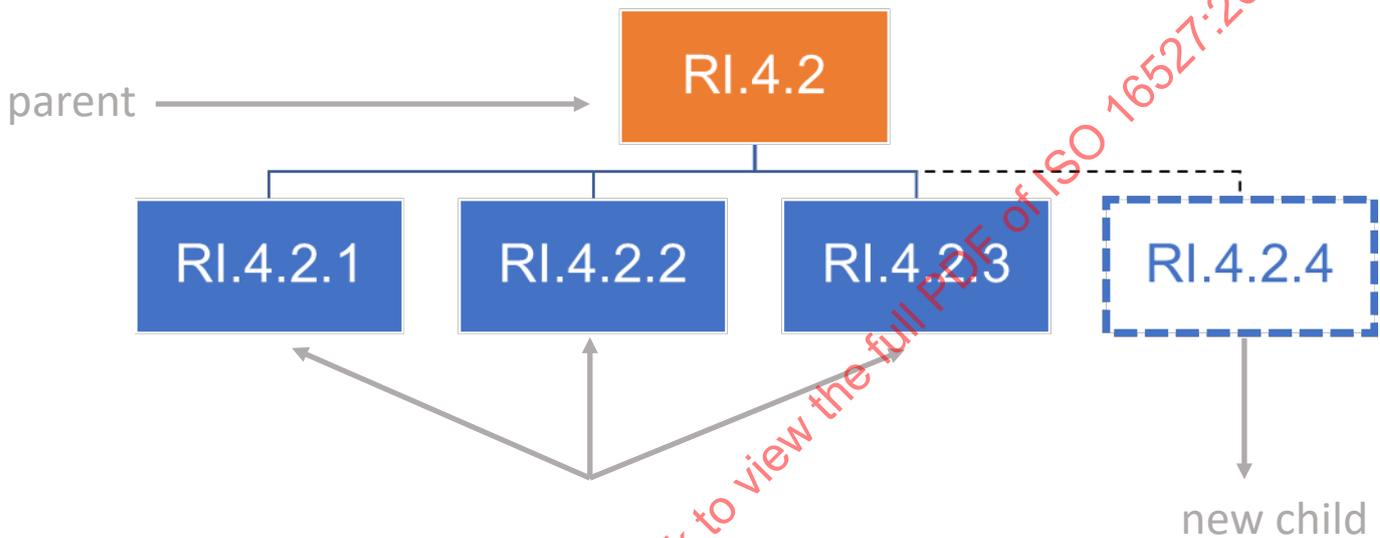
Figure 5: Creating a new function

The following rules specify the method for creating new functions.

1. Whenever possible, conformance criteria **SHOULD** be used to avoid creating a new function. This may be done, for example, in cases where the original function's conformance criteria are too broad: divide the PHR-S FMs or base functional profile's inherited conformance criteria into two criteria in the functional profile, one being mandatory and the other optional. If this is not possible, the creation of a new child function and associated criteria is allowed if necessary to clearly define the profile requirements.
2. When a 'leaf' function exists but is too broadly specified in the PHR-S FM or base functional profile for conformance criteria to adequately constrain it, then the function **MAY** be split as follows:
   a. The original 'leaf' function is retained as the parent of its newly created children functions,
   b. The original 'leaf' function's conformance criteria **SHALL** be distributed among its children functions.
3. When no candidate function exists to express the requirements of a functional profile, a new child function **MAY** be created (e.g., adding a new kind of summary list under the summary list's parent).

Parent functions **SHALL NOT** be split. This preserves the structure of the underlying PHR-S FM in the functional profiles
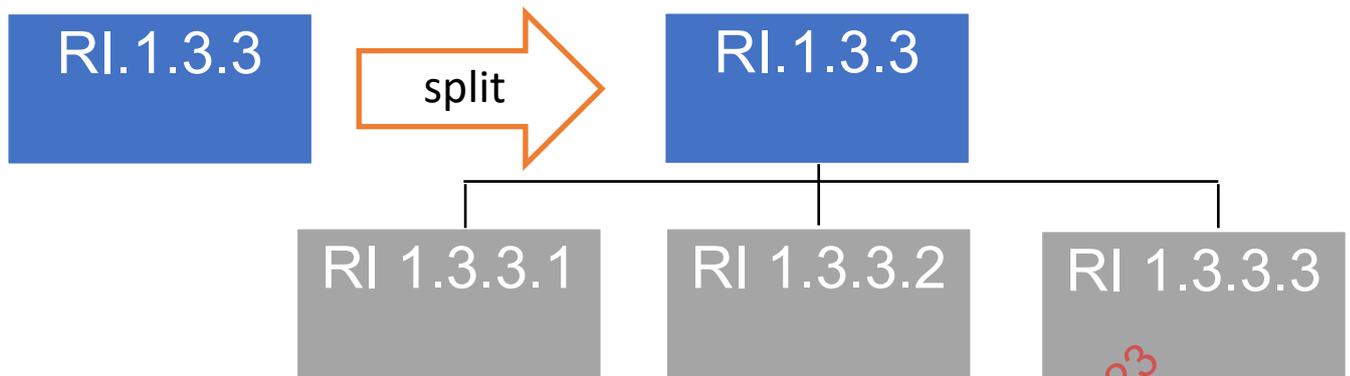
Figure 6: Splitting a function

If new children functions are created by a functional profile that is balloted or registered, these new functions will be captured by the HL7 EHR Work Group and tracked for review. The EHR Work Group **WILL** use these new functions and related criterion as input and candidates for changes to the FM (e.g., inclusion, relaxation of conformance criteria). The EHR Work Group MAY maintain a file of functions and criterion reviewed and rejected for inclusion in a future version of the FM.
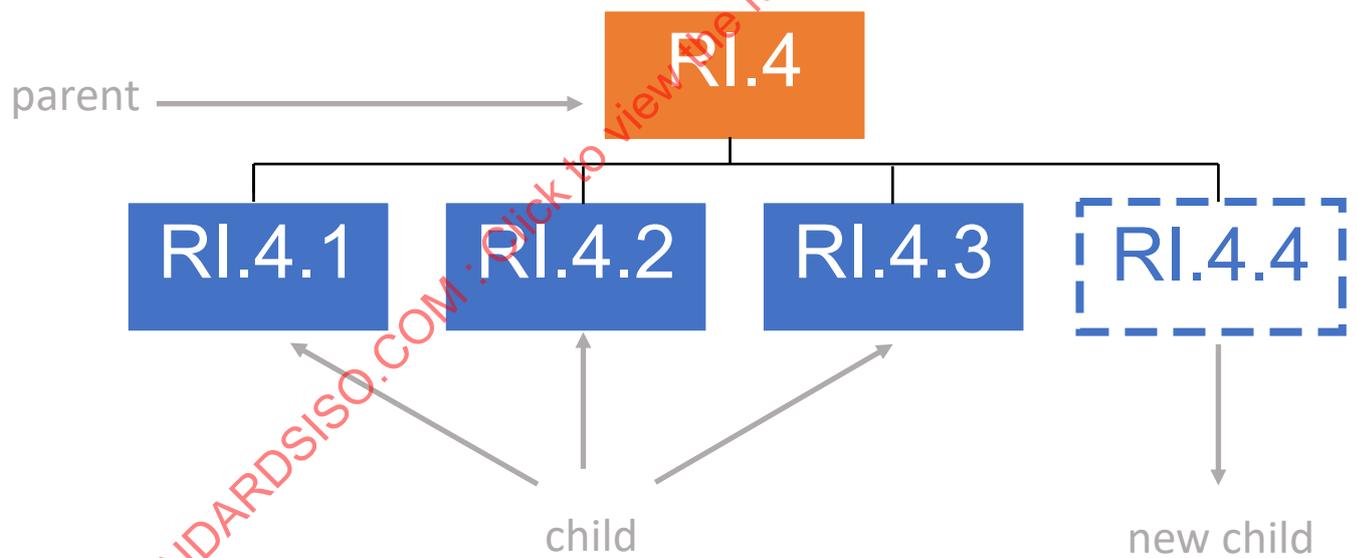
Figure 7: Adding a New Child Function

5.7.4 Rules for Derived Functional Profiles

Derived functional profiles claiming conformance to one or more base functional profiles **SHALL**:

1. Adhere to all the rules for functional profiles as specified in Section 5.7.2.
2. Adhere to the rules for creating new functions as specified in Section 5.7.3, if not prohibited by the base functional profile.
3. Identify the base functional profiles from which it is derived.
4. For each function inherited from a base functional profile, retain and not change mandatory conformance criteria to optional conformance criteria.

5.7.5   Conformance Statement

Functional profiles **MAY** want to require that a conformance statement be produced for systems claiming conformance to the profile. A *Conformance Statement* provides information about a PHR system, by presenting in a uniform manner the functions that have been implemented by the PHR system. A blank (i.e., yet to be completed) Conformance Statement typically takes the form of a questionnaire or checklist, to be completed for each PHR system.

A Conformance Statement provides a concise summary of a functional profile. It follows a standard layout, thus providing PHR system vendors and users a quick overview of the functional profile's functions. Moreover, it can also be used to highlight optional functions and capabilities supported by the PHR systems as well as document any extensions (i.e., additional functionality beyond what is in the functional profile) or specializations that have been made. A PHR system's Conformance Statement provides information that can be used in assessing the PHR system's conformance to a specific functional profile. Additionally, organizations wishing to acquire a PHR system **MAY** produce a Conformance Statement to indicate the functions that are required and/or desired in a PHR system.

Functional profiles **MAY** want to include a blank Conformance Statement in order to promote consistency among completed Conformance Statements. Conformance Statements can be useful in determining the chances of interoperability between two PHR systems, by comparing the functions supported by each PHR system. Additionally, for conformance testing purposes, it can be used to facilitate the selection of tests that would be applicable to a particular PHR system being tested. For example, if a PHR system did not implement functions designated as 'Essential Future', this would be evident in the Conformance Statement and the tests for these functions (which are unimplemented) would not be performed.

5.7.6   Rules for Companion Functional Profiles

Companion functional profiles that adhere to the Rules for Functional profiles **SHALL** claim conformance to the version of the PHR-S FM from which it was derived. Companion functional profiles will follow the section 5.7.2 Rules for Domain Functional Profiles and the section 5.7.4 Rules for Derived Functional Profiles, except for the exceptions and addition described below.

Companion functional profiles claiming FM conformance **SHALL**:

1. Adhere to section 5.7.3 for adding new functions,
2. Contain a conformance clause which
   - Defines at least one domain functional profile for which the companion functional profile can be linked that PHR systems must satisfy in order to claim conformance, or state any specific domain functional profiles that can or cannot be linked to the companion functional profile,
   - Defines the requirement(s) that companion functional profiles derived from the base companion functional profile (i.e., derived functional profiles) must satisfy in order to claim conformance to the companion functional profile.
3. Include **only functions being modified** from the Overarching section of Annex E as Essential Now and identify functions from other sections of Annex E of the FM that are applicable to the companion functional profile. For each identified function, indicate its priority (i.e., Essential Now, Essential Future, or Optional).
4. For each function, derive conformance criteria based on the FM's conformance criteria.
   - In the functional profile, there **SHALL** be at least one criterion for each function that is mandatory (a 'shall' criterion).
   - If there are 'shall' criteria (for the function in the FM), then those criteria **MAY** also exist for the function (in the companion functional profile) that it changes. Additionally, if the function is split (in the functional profile), then the parent's 'shall' criteria **MAY** appear in at least one child of that function.
5. For any function in the FM where one or more criteria are 'dependent shall' criteria, the companion functional profile may elect to ignore the criterion, but **if selected** for that function **SHALL** follow the rules for "Functional profiles claiming PHR-S FM conformance **SHALL**" list in section 5.7.2.

Companion functional profiles claiming conformance to the FM **MAY**:

1. Ignore a 'shall', "should' or 'may' criterion in the FM (i.e., not include it in the functional profile).
There are no exceptions to section 5.7.4 for Derived Companion Functional Profiles

5.8   Use Cases and Samples (Reference)

5.8.1   Functional Profile Use Cases

5.8.1.1   Example 1: PHR Source (based on custodian)

It is determined that a new source-based functional profile is needed to reflect the specific requirements and expectation of a system from this particular stakeholder source (e.g., a hospital, medical group, payer, or health record bank) – see Figure 9. To help ensure widespread use and uniformity, the functional profile authors elect to undergo the registration review followed by the HL7 consensus process (i.e., submitting the registered functional profile for an "Informative" committee level ballot). If successful, the result will be designated an HL7 Informative Functional Profile.

After looking at current list of HL7 PHR informative functional profiles, the decision to create a new functional profile is made. Each function in the PHR-S FM is examined and those that are relevant to the PHR source chosen – e.g., a Provider-Linked PHR from an Integrated Delivery Network. From these functions, a small set of 'core' functions is selected as being essential and mandatory. For each function, conformance criteria are developed either adapting the PHR-S FM conformance criteria or in a few cases, using the PHR-S FM criteria as is. To complete the functional profile, a description of the functional profile is written that includes its intended use and audience, as well as a conformance clause. The functional profile is made public by publishing it on various web sites. Additionally, the functional profile is submitted to HL7's EHR WG for registration review, comment and ballot.

5.8.1.2   Example 2: Level of Functionality derived functional profile

A Community of Interest (e.g., a regional health information exchange network, or a care management community who targets a specific chronic condition) or a particular stakeholder may want a functional profile. The Community of Interest or stakeholder may want a profile based on the level of functionality that they want for their patient population, to reflect the expectation of the PHR system's sophistication and/or capabilities – see Figure 8.

The Community of Interest or stakeholder does not want to create a new functional profile from scratch. After looking at the list of HL7 Registered PHR Functional Profiles, they find an existing functional profile that is very close to what they want. Using this functional profile as the base, they accept all the functions designated as 'Essential Now', reject functions designated as 'Future' and add several more functions. For each function, they review the conformance criteria and adapt the criteria to reflect their situational information.

5.8.1.3   Example 3: Vendor functional profile

A vendor of a PHR system wants to claim conformance to the PHR-S FM.

The vendor identifies and lists all the functions that are in his product. The vendor adds a description and a conformance clause (see samples in section 5.8.2). This is the vendor's functional profile. If the vendor has actually implemented all the functions listed, then this is equivalent to 'Essential Now' and these functions are mandatory. Vendor features that are not in the PHR-S FM may be added as added functions or added criteria – within the rules of sections 5.7.2 and 5.7.3 above. If functions that are currently implemented and those that will be implemented in the future are listed, then the functional profile is comprised of 'Essential Now' and 'Essential Future' and/or optional functionality. Finally, the vendor adds conformance criteria for each function inheriting directly (without change) the criteria in the PHR-S FM. This is appealing in that, the vendor has the opportunity to list the current functionality and, if desired, indicate future plans. In essence, this is similar to a vendor Conformance Statement (a concept with which most vendors are already familiar). A vendor may create multiple functional profiles.
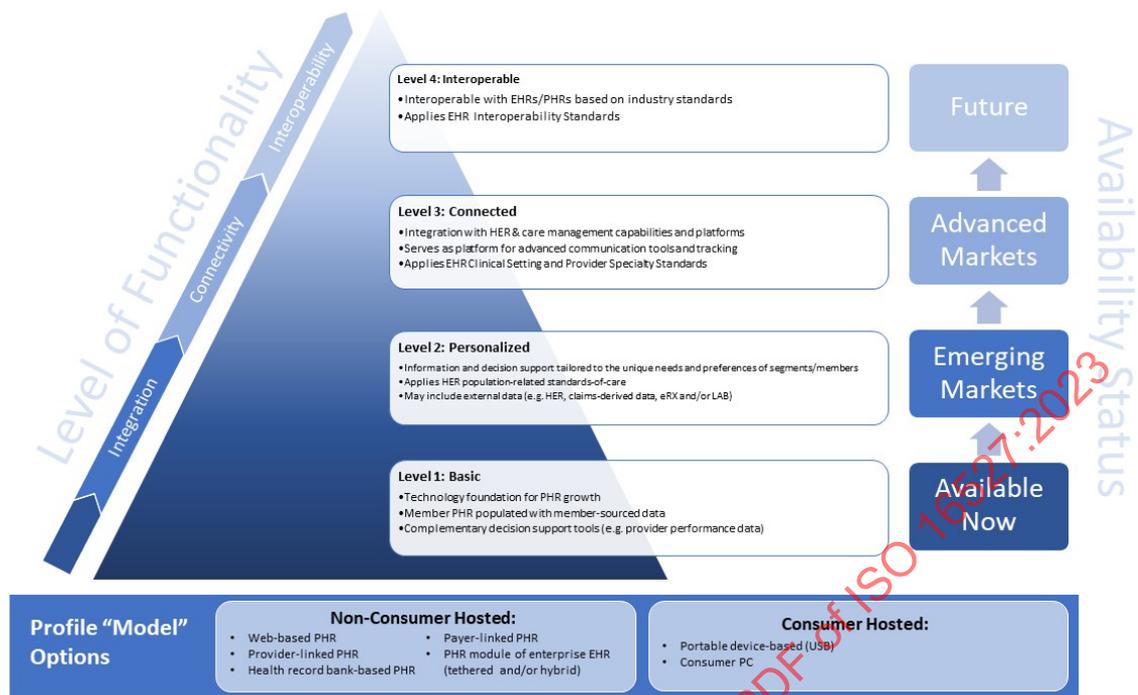
Figure 8: Examples of Functional Profile Options by "Model" and/or Level of Functionality

5.8.2   Sample Domain Functional Profile Conformance Clauses

5.8.2.1   Developing a Conformance Clause

To aid functional profile developers in developing a conformance clause for their domain functional profile, as required by Section 5.7.2 rule #3, the following fictional examples are offered. Note: in these examples, the keywords 'SHALL', 'SHOULD', and 'MAY' are capitalized and bold. This is a convention to draw attention to the keywords.

5.8.2.2   Sample 1: conformance clause for a Provider-linked PHR functional profile

This domain functional profile defines the conformance requirements for PHR systems and derived functional profiles. To conform to this functional profile, all 'Essential Now' functions **SHALL** be implemented. 'Essential Now' functions are considered mandatory functions. A PHR system is conforming if it implements all the functions designated as 'Essential Now' and the mandatory conformance criteria associated to that function. A derived functional profile is conforming if it follows the Rules for functional profiles.

Mandatory conformance criteria are indicated by the keyword 'shall'. Optional conformance criteria are indicated by the keywords 'should' or 'may'.

PHR systems **SHALL** provide a Conformance Statement structured according to the rules and policies defined in this functional profile.

5.8.2.3   Sample 2: conformance clause for a vendor system functional profile

Conformance is defined for My-PHRsystem. All functions in this functional profile are mandatory, are deemed as 'essential now', and **SHALL** be implemented in order to conform to this functional profile.

5.8.2.4   Sample 3: conformance clause for a Community of Interest functional profile

Conformance is defined for BuyMyDiabetesPHR. To conform to this functional profile, all functions labeled as 'essential now' **SHALL** be available and have been implemented. Functions labeled 'essential future' are optional, in that they are present for informational purposes only and **MAY** be implemented in future functional profiles.

5.9 Interpreting and Applying Conditional 'SHALL' (Reference)

5.9.1   Construction of Conformance Criteria Using the Conditional 'SHALL' Overview

Conformance criteria in the FM and those created can be structured in the simple format an Actor followed by normative verb followed by action or property. For example: The system **SHALL** capture demographic information as part of the patient record.

However, there are two conditional forms for which if the condition is true, then the following text must apply. One is If/Then. If condition, then Actor followed by normative verb followed by action. If the condition is not met (i.e., false) then ignore the rest of the sentence. For example, IF data is exchanged with internal or external systems, THEN the system **SHALL** conform to function TI.5.4 (Interchange Standards).

The other is a 'Dependent Shall' format. Actor followed by normative verb followed by action/interaction followed by 'according to scope of practice, organizational policy or jurisdictional law'. For example, "The system **SHALL** enable EHR-S security administrators to grant authorizations to principals according to scope of practice, organizational policy, or jurisdictional law."

The following example of a PHR-S FM 'dependent shall' criterion will be used to illustrate concepts throughout this section.

> PHR-S FM criterion: *The PHR-S **SHALL** provide the ability for PHR-S security administrators to grant authorizations to principals according to user role, organizational policy, and/or jurisdictional law.*

5.9.2   General Concepts

The purpose of the 'dependent shall' is to allow functional profiles to constrain a PHR-S FM 'shall' criteria based on situational conditions such as policy and legal implications. Specifically, the 'dependent shall' criteria in the PHR-S FM are 'shall' criteria plus a dependency, where the dependency is defined by:

- <u>User role</u> which applies to the various PHR Account Holder's possible or alternative roles – which may be or are setting specific or not, or may be related to whether the PHR is about them or is for their dependent.
- <u>Organizational policy</u> which refers to a plan or course of action intended to influence and determine decisions, actions, and other matters of a group of persons organized for a particular purpose within an association and structure through which individuals cooperate systematically to conduct business.
- <u>Jurisdictional law</u> which refers to the territorial range of authority or control with the power, right, or authority to interpret, apply, and declare the body of rules and principles governing the affairs of a community and enforced by a political authority; a legal system.

The structure of the 'dependent shall' criteria in the PHR-S FM is the same as the 'shall' criteria except with the addition of the phrase "according to user role, organizational policy and/or jurisdictional law" or other appropriate grammatical tie-in words (e.g., "based on" rather than "according to"). Note that all three dependencies are present in the PHR-S FM 'dependent shall' criteria. It is the functional profile that narrows it to any one dependency or any combination of the three. Moreover, in the functional profile, the specific user role, organizational policy, and/or jurisdictional law which necessitates evoking the 'dependent shall' is explicitly identified.

> For example: (derived from the PHR-S FM criterion above)

PHR-S FM criterion: *The PHR-S **SHALL** provide the ability for PHR-S security administrators to grant authorizations in accordance with the U.S. Health Insurance Portability and Accountability Act of 1996.*

The difference between a 'shall' criterion and a 'dependent shall' criterion is shown in the table below.

	'SHALL' Criterion	'Dependent SHALL' Criterion
Must be present in the functional profile?	Yes, either verbatim or modified (e.g., constrained or refined)	Yes, verbatim. If a dependency exists, add additional criteria reflecting the dependency.
Must be implemented by PHR systems?	Yes.	Situational – implemented only when the dependency exists. Specifically, the PHR system does not implement the 'dependent shall' criterion (as copied from the PHR-S FM), but does implement additional 'shall' criteria created to reflect the dependency.

Table 1: Differences between 'shall' and 'dependent shall'

5.9.3   Rationale for 'Dependent SHALL'

The reason for using a 'dependent shall' in the PHR-S FM is to highlight certain criteria and bring them to the attention of the reader – both developers of functional profiles as well as other users. 'Dependent shall' criteria are considered to be special cases, where there are one or more dependencies that affect these criteria, across multiple care settings. Using the 'dependent shall' ensures that developers of all functional profiles address the criterion and consciously decide whether the criterion in question is applicable, based on the stated dependency.

Regardless of whether a dependency exists or not, the 'dependent shall' is copied verbatim into the functional profile. The reasons for this are:

- Adherence to the rule that a 'shall' criterion is always inherited by the functional profile.
- Consistency with handling the 'dependent shall' under all conditions (i.e., when there are dependencies and when there are not).
- Retention of the 'dependent shall' so that it is present for derived profiles.
- Retention of the 'dependent shall' so that it remains effective for this profile if future requirements change (i.e., the dependency may not be applicable at this present time, but may be applicable in the future due to changes in user role, organizational policy or jurisdictional law.

5.9.4   How to Apply the 'Dependent SHALL'

The way to interpret and apply a 'dependent shall' criterion in a functional profile is as follows:

- Copy the criterion into the functional profile.
- Review the criterion and determine if any of the dependencies are applicable to the functional profile.
- If a dependency exists:

If one or more dependencies are applicable to the functional profile (e.g., there are jurisdictional legal requirements), add one or more 'shall' criteria that refine and further constrain the 'dependent shall' with respect to the dependencies.

For the new criteria, add an explanation and/or citing for the dependency. For example, "Jurisdictional legal requirements for this functional profile are defined by U.S. Federal Regulations HIPAA Security Rule 45 CFR Parts 160, 162 and 164". The explanation or citing may be in an appendix. It is likely that multiple criteria will reference the same explanation or citing.

Examples:

Functional Profile criteria

1. *The PHR-S SHALL provide the ability for PHR-S security administrators to grant authorizations to principles in accordance with HIPAA*.*

2. *The PHR-S SHALL provide the ability for PHR-S security administrators to grant authorizations for roles in accordance with 42 CFR Part 2*.*

*Dependency Explanation: For a U.S. realm functional profile, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as well as other jurisdictional legal requirements or other more stringent requirements would be applied to 'dependent shall' criteria in the functional profile.

PHR-S FM	Dependency Applies?	Applicability	Functional Profile
Dependent SHALL	Yes	Mandatory	Copy SHALL from the PHR-S FM
		Mandatory	Add additional criteria to reflect the dependencies. Use 'shall'.
		Mandatory	Add explanation or citing.
		Optional	Add additional criteria derived from 'dependent shall'. Use 'shall', 'should' or 'may'.

Table 2: Summary of actions when dependency exists

- If no dependency exists:
  If no dependency is applicable to the functional profile (i.e., there are no user roles, organizational policies, or jurisdictional legal requirements that apply), then document the rationale for deciding that no dependencies apply. This explanation may be in an appendix. It is likely that this explanation will apply to multiple 'dependent shall' criteria.

PHR-S FM	Dependency Applies?	Applicability	Functional Profile
Dependent SHALL	No	Mandatory	Copy SHALL from the PHR-S FM
		Mandatory	Add explanation
		Optional	Add additional criteria derived from 'dependent shall'. Use 'shall', 'should' or 'may'.

Table 3: Summary of actions for when no dependencies apply

- Add additional criteria – regardless of whether a dependency exists or not.
  It is always permissible for a functional profile to add new criteria. Add new criteria that are derived from the 'dependent shall'. Use any keyword: 'shall', 'should' or 'may' (see Section 5.4) in these new criteria.

Examples:

1. *The PHR-S **SHOULD** provide the ability for PHR-S security administrators to grant authorizations to principals.*

2. *The PHR-S **MAY** provide the ability for PHR-S security administrators to grant authorizations for roles.*

3. *The PHR-S **SHOULD** provide the ability for PHR-S security administrators to grant authorizations within contexts.*

4. *The PHR-S **SHALL** provide the ability for PHR-S security administrators to grant authorizations for roles for organizations with ten employees or more.*

6 Glossary

6.1 Preface (Reference)

Portions of this Glossary Clause are classified as NORMATIVE, including the Action-Verb Structure Section (8.4). See section by section labels. The Glossary is provided as guidance for preparing and interpreting HL7 Electronic Health Record and Personal Health Record System Functional Models (EHR-S FM and PHR-S FM respectively) and Functional Profile specifications and conformance statements. The goal is to promote clarity and consistency when interpreting and applying language of the FMs.

This Glossary is intended to be international in application. However, each realm may want to adjust terms to their own language.

6.2 Introduction (Normative)

The Health Level Seven International (HL7) EHR-S and PHR-S FM Glossary is an HL7 reference document that provides a set of definitions and guidelines in order to ensure clarity and consistency in the terms used throughout the FMs and in related FPs. The Glossary includes the definition of important terms used in the expression of EHR and PHR system functionalities, and comprises a consensus-based list of Action-Verbs and specific guidelines for constructing conformance criteria (CC).

Action-Verbs play a critical role in phrasing conformance criteria. Extensive efforts were made to categorize and normalize Action-Verbs and to develop guidelines for creating clear and consistent CCs throughout the FMs and in related FPs. Continuity with previous FM versions is provided by including Glossary terms that have been deprecated, accompanied by suggestions for preferred replacement terms. Vigorous efforts were deployed to reduce the ambiguities inherent in the use of human language; care was used to respect the fundamental meaning of words and to avoid domain specific usage of terms.

6.3 Overview (Reference)

HL7's EHR Work Group has unified glossaries for both the EHR-S and PHR-S FMs to ensure consistency. Each FM has a unique focus and coverage in the health information domain with specific system functional requirements, yet readers are often the same people. It is expected that FPs created within the context of either FM will align with this Glossary. However, this Glossary will not provide definitions for all the terms used in FPs. FPs will typically use context-specific, realm-specific, or specialized terms associated with their area of focus, and may need to incorporate a complementary glossary for these special terms.

In the case where FPs are merged, care should be exercised to ensure that the same Action-Verbs are used with the same meaning, and that identical meanings are conveyed with the same Action-Verb. It is recommended that existing FPs be re-examined and updated to closely align with the current set of Action-Verbs.

Some common terms and Action-Verbs have not been included in this Glossary. For example, terms like 'computer', 'keyboard', 'archive' and 'compact' are considered general computer field terms that do not need to be defined here. Some other terms reflect functionalities inherent in any computer system and are not defined here, e.g. compute. Readers who desire definitions of terms not covered in the Glossary are invited to consult trusted dictionaries or encyclopedias. Where definitions of terms are taken from recognized sources, specific references are included.

6.4 The Action-Verb Structure (Normative)

The Action-Verbs to be used for writing conformance criteria in the EHR-S FM and the PHR-S FM are organized in two hierarchies, each with its own specific set of Action-Verbs to:

- Secure and operationalize systems;
- Manage data and the health record.

Each hierarchy consists of Action-Verbs that collectively represent a logical set of actions.

6.4.1 Secure (System) Hierarchy

The Secure System hierarchy provides Action-Verbs for controlling access (authenticating and authorizing users), tracking activities (logging and auditing), and sustaining operations. This hierarchy has one parent, Secure (System), and three (3) intermediate children: Control Access, Track, and Sustain (Operations).

Secure (System)				
Control Access		Track		Sustain (Operations)
Authenticate	Authorize	Log	Audit	

Table 4: Action-Verbs supporting the Secure System Hierarchy

- Control Access: to limit the use of a system to only those who are permitted
- Track: to govern; control; administrate; oversee; inspect; examine; assess; observe; monitor; police; enforce; check
- Sustain (Operations): to keep the system running correctly (e.g., sustain operations; quality; integrity; throughput; mirror; reliability; failover; failsafe; versioned; virus-free; leak-free; up-to-date; safeguard)

6.4.2 Data Management Hierarchy

The Data Management hierarchy provides Action-Verbs for the complete range of data handling actions by a system. The hierarchy has one parent, Manage (Data), and six (6) children with subsets: Capture, Maintain, Render, Exchange, Determine, and Manage-Data-Visibility.

Manage (Data)										
Capture	Maintain			Render			Exchange	Determine		Manage Data Visibility
Auto-populate Enter Import Receive	Store Archive Backup Decrypt Encrypt Recover Restore Save	Update Annotate Attest Edit Harmonize Integrate Link/Unlink Tag/Untag	Remove Delete Purge	Extract	Present	Transmit	Export Import Receive Transmit	Analyze	Decide	De-Identify/ Re-Identify Hide/ Unhide Mask/ Unmask

Table 5: Action Verbs supporting the Data Management Hierarchy

The first three subsets cover the capture, maintenance and rendering of data as follows:

- Capture:
  - Auto-populate fields of data based on partially filled information
  - Enter data manually
  - Import data from an external source (which may be a device)
  - Receive data from another system (which may be a device)
- Maintain:
  - Store:
    - Archive data to external media
    - Backup data on backup storage media
    - Encrypt data for security and privacy purposes
    - Decrypt data to reverse encryption
    - Recover/Restore data from backup
    - Save data on local media
  - Update:
    - Annotate data with notes
    - Attest data to verify and approve
    - Edit data by modifying it
    - Harmonize data across multiple sources
    - Integrate data together
    - Link data to other data
    - Unlink data to remove prior linkage(s)
    - Tag data with labels
    - Untag data to remove prior label(s)
  - Remove:
    - Delete/Purge to remove data from storage media or directory(ies)
- Render:
  - Extract data based on certain criteria
  - Present data on an attached device
  - Transmit data to external systems or devices

The next subset pertains to the Exchange of data from one part or system to another or others.

- Exchange:
  - Export (transfer) data in a format that can be used by other systems
  - Import data from an external source (which may be a device)
  - Receive data from another system (which may be a device)
  - Transmit data to another party/system

The next subset provides verbs for the determination of actions in processing data:

- Determine:
  - Analyze data using rules and analytical steps
  - Decide appropriate actions as a result of that analysis

The final subset allows the construct of statements restricting the visibility of data and reversing those actions:

- Manage-Data-Visibility:
  - De-Identify data as to prevent associating the data to a specific person
  - Re-Identify data to reverse a prior de-identification
  - Hide data so that only authorized users can see that the data exist
  - Unhide data to reverse a prior hide operation
  - Mask data so that users can see that the data exist but only authorized users can actually view the actual data
  - Unmask data to reverse a prior mask operation

6.4.3 How Action-Verbs are defined

Action-Verbs are defined in the following manner:

For an Action-Verb that has a parent, the Action-Verb's definition will start with the immediate parent verb and then a restatement of the meaning of the Action-Verb, followed by at least one (1) example labeled as such. Examples will use the Action-Verb being defined with explanatory descriptions where relevant. Such as:

- PRESENT (Action-Verb): To RENDER (the parent Action-Verb) data by delivering the data to local users in a meaningful and appropriate way. For example, the system may PRESENT an alert automatically when a newly-arriving laboratory value is received that is out of normal range.

For a top level Action-Verb, the definition will include the next immediate level of children, followed by at least one (1) example labeled as such. Examples will use the Action-Verb being defined with explanatory descriptions where relevant. An illustrative example follows:

- MANAGE (DATA) (Action-Verb): To handle data by capturing, maintaining, rendering and exchanging data, determining actions about data, and managing data visibility. For example, the system shall provide the ability for a user to MANAGE patient and family preferences as they pertain to current treatment plans.

The following table lists the full set of eligible Action-Verbs and their logical construction:

Action-Verb	Construction
Analyze	To DETERMINE actions in the flow of processing data by comparing, correlating, or weighting certain data and by applying clinical or business rules, hence leading to a decision (see DECIDE). For example, the system may ANALYZE patient information using a drug-interaction database and a set of clinical rules. Another example is that the system may ANALYZE various protocols relative to a patient's condition. Another example is that a person may ANALYZE a proposed update to a patient's home address and DECIDE to reject the proposed update.
Annotate	To UPDATE data by attaching comments or notes to the data without editing the data. For example, an Attending physician may ANNOTATE the information entered by the Resident physician before signing the report.
Archive	To STORE data by moving the data to long-term storage media and deleting or purging data on the original online storage, according to scope of practice, organizational policy, and/or jurisdictional law. For example, the system at the Oak Street Hospital automatically ARCHIVES patient-related data that is older than eight years by encrypting and compressing it, moving it to long-term storage, purging it, identifying the data by month and year, and creating a pointer to the archived data. Another example is that a system may automatically ARCHIVE outpatient clinic schedules that are being replaced.
Attest	To UPDATE information by ATTESTing that an EHR record (or part of an EHR record) is genuine.. For example, a resident physician may ATTEST that the information contained in an EHR record was created by her. Another example is that an attending physician may annotate a resident's version of the record and then ATTEST to those changes. . Note: Attestations may be applied, affixed or bound to an EHR record, for example, via a digital signature, certification, or other verifying mark.
Audit	To TRACK system-initiated or user-initiated activities by analyzing logs based on policies or rules. For example, the system may automatically AUDIT the daily log for multiple-failed-logon-attempts. Another example is that an administrator may AUDIT the excessive use of extraordinary (i.e., "break-the-glass") access to certain patient information in the Emergency Department.
Authenticate	To CONTROL ACCESS to a system by validating the identity of a user, another system or a device before authorizing access. For example, the system may AUTHENTICATE Dr. Jones by validating his identity using a UserID and a biometric device. Another example is that the system rejects Sara Smith's attempt to AUTHENTICATE to the system after three failed password entries.
Authorize	To CONTROL ACCESS to a system by applying permissions to use certain functionality or to view certain data. For example, the system may AUTHORIZE Dr. Jones, an Emergency Department physician, to view Emergency Department patient records (note: We assume that the administrator has entered a set of permissions for all Emergency Department physicians). Another example is that the system does not AUTHORIZE deletion by Sara Smith of a patient record that has already been signed.
Auto-populate	To CAPTURE data by inputting it automatically using previously-existing data, providing a default value, or deriving it from other data, or by following various data-entry business rules. For example, the system may AUTO-POPULATE the city, state/province, and country fields when a user enters a zip-code. Another example is that the system may AUTO-POPULATE a newborn's home address with the mother's home address.
Backup	To STORE data by placing a copy of the data onto an electronically-accessible device for preservation in case the original is lost, corrupted, or destroyed. For example, a system may BACK UP the incremental changes made to a patient's record by storing it locally on a daily basis. Another example is that an administrator may BACK UP a complete copy of certain data by storing it at an offsite facility.
Capture	To MANAGE data by auto-populating, entering, importing, or receiving the data, either through human intervention or automated means. For example, a system may CAPTURE patient's data entered by a physician through the keyboard or sent by the physician using a mobile device. Another example is that the system may CAPTURE laboratory results by automatically receiving laboratory data or by keyboard entry for locally performed tests.
Control Access	To AUTHENTICATE users and/or systems and AUTHORIZE access to functionality and/or data. For example, the system may CONTROL ACCESS to the patient's data

Action-Verb	Construction
	by authenticating Dr. Jones' identity and authorizing him to update his patient's records. Another example is the system may CONTROL ACCESS to the system by refusing a hospital visitor the ability to authenticate to the system. NOTE: the set of CONTROL ACCESS Action-Verbs requires data specifying permissions. This permission data is managed via the MANAGE data Action-Verbs set.
Decide	To DETERMINE actions in the processing of data by choosing a certain alternative based on an analysis, and acting accordingly. For example, the system may DECIDE to render a notification to off-duty nurses to report for duty based on clinic rules and the receipt of a tornado alert. Another example is that the system may DECIDE to RENDER an alert to a clinician that a prescribed drug is contraindicated with the patient's listed allergies, based on the analysis conducted.
Decrypt	To STORE data by converting encrypted data back into its original form, so it can be understood. For example, the system may DECRYPT clinical data received from an authenticated external laboratory system.
De-identify	To MANAGE-DATA-VISIBILITY by removing identifiers from data in such a way that the risk of identifying an individual is very small under the circumstances, as specified by scope of practice, organizational policy, and/or jurisdictional law. For example, a system may DE-IDENTIFY data for a researcher who wants to perform an analysis of drug effectiveness on diabetic patients. Another example is where a hospital may DE-IDENTIFY data for a set of patients to transmit to a university professor looking for illustrative cases for educational work.
Delete	To REMOVE data by making it inaccessible to the application. For example, a user may DELETE an existing patient-appointment at the request of the patient. . Note: In the case where the data becomes invalid but needs to remain in the system, the word "TAG" is preferred over the word "DELETE" or the word "Nullify". This type of action is considered a data "Tagging" process and not a data deletion process. For example, a health information management professional may desire to TAG a certain clinical term as obsolete, but the term needs to remain in the system for backward compatibility purposes.
Determine	To MANAGE data by analyzing it and making a decision based on the analysis. For example, the system may DETERMINE the possible severity of a patient's allergic reaction to a proposed drug by analyzing the patient's profile against a drug database and deciding whether the clinician should be presented with an alert or not. Another example is that a system may DETERMINE the next steps in a workflow based on an analysis of a patient's laboratory results, the patient's profile, and the clinical rules of the clinic, this analysis leading to a decision as to the appropriate next steps in the clinical process.
Edit	To UPDATE data by correcting, amending, appending, or augmenting the data. For example, the physician may EDIT the patient's home address by correcting the civic number from 368 to 638 Oak Street. Another example is that a physician may EDIT existing notes about an injury by appending an x-ray picture of a broken bone.
Encrypt	To STORE data by transforming the data into a form that is difficult to understand by unauthorized people or systems. For example, the system may ENCRYPT sensitive information such as the patient's financial information.
Enter	To CAPTURE data by inputting it manually (for example, via a keyboard) or through other input devices. For example, the user may manually ENTER the patient's street address via the keyboard. Another example is that the user may ENTER the patient's body weight via an electronic weight scale.
Exchange	To MANAGE data by importing, receiving, exporting, or transmitting the data between systems. For example, the PHR Account Holder may exchange family history information with the PHR systems of other family members.
Extract	To RENDER data by locating, retrieving and possibly assembling data based on certain criteria and for certain purposes. For example, a system may EXTRACT for a clinician all the x-ray reports regarding the patient's chest. Another example is that the system may automatically EXTRACT allergy history when the physician enters a prescription. Another example is that a system may EXTRACT for a researcher the number of pneumonia-like cases treated at the Emergency Department within a specific time period. Another example is that a system may EXTRACT and aggregate information using a cohort of patients who have pneumococcal disease and categorize that cohort by specific age-ranges.

Action-Verb	Construction
Harmonize	To UPDATE data by aligning and reconciling it with other information in the system, or with the data of another system (or systems). For example, the system may HARMONIZE a patient's new home address with the data of systems of other members of the care-team.
Hide	To MANAGE-DATA-VISIBILITY by making specific information invisible so that the existence of the information is not expressed except to authorized users; viewers of the patient record receive no indication that the hidden information exists or does not exist. For example, the system may HIDE the existence of a patient's psychiatric record from all viewers except for the patient's psychiatrist. Note: the verb "unhide" is an acceptable verb to reverse the action of hiding.
Import	To CAPTURE data into a local system by proactively accessing data from an external source and then downloading and integrating the data into the local system. For example, the system may IMPORT the latest drug trial data every Friday evening. Another example is that the user may IMPORT various sets of best practices related to juvenile diabetes.
Inactivate	To maintain control of data by removing access to the data in such a way as the data is no longer active for a certain reason. For example, the PHR Account Holder may no longer employ a list of local oncologists, while the PHR Account Holder is stationed in another country for a while.
Integrate	To UPDATE data by merging other data with the existing data in a controlled manner. For example, a user may INTEGRATE summaries of health care services that were provided in another jurisdiction into the patient's local record. Another example is that an EHR system may INTEGRATE a single-sign-on application with the EHR system's existing user-authentication services. Another example is that an EHR system may INTEGRATE multiple third-party modules to enhance its capabilities.
Link	To UPDATE data by associating one piece of data with another piece of data. For example, the system may LINK a patient's encounter note with the patient's laboratory results. Another example is that a system may LINK attestable changes to a patient's record to the author's identifying information.
Log	To TRACK system-initiated or user-initiated activities (including access to data and/or functionality, attempts to access data and/or functionality, actions performed on data and/or functionality, and changes to system characteristics or versions) by storing a chronological trace of these activities. For example, the system may LOG the fact that modifications were made to a patient's record by storing the date, time, and identity of the user who modified the record as well as what changes were made to that record. Another example is that the system may LOG the fact that updates were applied to a drug-interaction database table, by storing the date and time at which it was updated.
Maintain	To MANAGE data by storing, updating, and/or removing the data within a system. For example, a system may provide the ability for a clinician to MAINTAIN data by keeping or discarding it. Another example is that a system may provide the ability for a clinician to MAINTAIN data by correcting or annotating it.
Manage (Data)	To handle data by capturing, maintaining, and rendering data, determining actions about data, and managing data visibility. For example, the system may provide the ability for a user to MANAGE patient and family preferences as they pertain to current treatment plans. Another example is that a clinician's system may provide the ability for the clinician to MANAGE patient data by creating a patient's record, updating a clinical note, utilizing clinical decision support tools, and transmitting the patient's billing information.
Manage-Data-Visibility	To MANAGE data by de-identifying/re-identifying, masking/unmasking or hiding/unhiding that data. For example, the system may provide the ability for an administrator to MANAGE-DATA-VISIBILITY in terms of who is allowed to view what specific patient data.
Mask (verb)	To MANAGE-DATA-VISIBILITY by obscuring (masking) specific data elements in order that this information is not available except to authorized users; viewers of the patient record can see that the data exists but cannot see actual contents. For example, the administrator may MASK the pregnancy status of all patients who are below the age of eighteen except for the obstetric unit staff.. Note: the verb "unmask" is an acceptable verb to reverse the action of masking.
Present	To RENDER data by delivering the data to local users in a meaningful and appropriate way. For example, the system may PRESENT to a physician (upon

Action-Verb	Construction
	manual request) a list of patients who are scheduled for care today, ordered by time-of-day, with the patient's known diagnosis using the physician's preferred terminology and language of choice. Another example is that the system may PRESENT an alert automatically when a newly-arriving laboratory value is received that is out of normal range. Another example is that a system may PRESENT to a physician a patient's lung respiration sounds. Another example is that a system may PRESENT patient-instructions using an audio and video system. Note: It is reasonable to assume that any data that is presented ought to be formatted, filtered, translated, transformed, mapped, and/or normalized, etc., as appropriate.
Pseudonymize	To MAINTAIN data by creating a pseudonym for its subject. For example, the name "Robert Q. Jamison" might be replaced with a pseudonym such as "John Smith" in a health care document before sharing it with others.
Purge	To REMOVE data by making it unrecoverable at the storage and/or media-level. For example, the system may PURGE the patient record for John Smith according to a rule that targets all records that are older than seven years. (Note: Destroy and Purge are synonyms; PURGE is the preferred term.)
Receive	To CAPTURE data from an external source by taking in that data without manual / real-time user intervention. For example, the system may RECEIVE various emails for a clinician who will later review them. Another example is that the system may RECEIVE from authenticated and authorized external systems laboratory results for a given patient. Another example is that the system may RECEIVE a facsimile transmission from an external device.
Recover	To STORE data by rebuilding original data using backups of data. For example, the system may RECOVER last week's data following a hard disk failure, using an offsite backup copy. (See BACKUP.)
Re-identify	To MANAGE-DATA-VISIBILITY by combining data in such a way that the patient's identity is re-established according to scope of practice, organizational policy, and/or jurisdictional law. For example, the system may RE-IDENTIFY de-identified data by providing a key that allows authorized users to re-establish the link between a given patient and that patient's de-identified data.
Remove	To MAINTAIN data by making the data inaccessible or unrecoverable according to scope of practice, organizational policy, and/or jurisdictional law. For example, a system may, at a physician's request, REMOVE by purging patient information that was received by mistake. Another example is that a system may, upon request by an administrator, REMOVE by deletion the schedule of outpatient clinic opening hours.. NOTE 1: The data may be deleted either by removing the data's pointer from the directory or by overwriting the data in such a way that the original data is unrecoverable. . NOTE 2: In the case where the data becomes invalid but needs to remain in the system, the word TAG is preferred over the word REMOVE or "Nullify". This type of action is considered a data "Tagging" process and not a data deletion process. For example, a health information management professional may desire to TAG a certain clinical term as obsolete, but the term needs to remain in the system for backward compatibility purposes.
Remove Access	To MAINTAIN data by disallowing access to the data in such a way as the data can no longer be retrieved.
Render	To MANAGE data by extracting, presenting and transmitting data to users or systems. For example, the system may RENDER a list of patients with a given disease that has been extracted from the clinic's active patient records. For example, the system may RENDER laboratory results by presenting them on a computer screen. Another example is that the system may RENDER data by transmitting a drug prescription to a pharmacy.
Restore	To STORE data to the production system by using previously archived data. For example, the system may RESTORE patient-encounter data for a returning patient whose data had been archived due to inactivity. Another example is that the system may RESTORE, for evidentiary support, patient data that had been archived after the patient expired. (See ARCHIVE.)
Save	To STORE data by placing it onto an electronically-accessible device for preservation. For example, a clinician may SAVE a given patient's demographic data or a newly-prescribed medication. Another example is that an administrator may SAVE an updated list of physicians that have practice privileges at the local hospital.

Action-Verb	Construction
Secure (System)	To ensure system reliability and integrity by controlling access to system functionality and/or data, tracking activities, and sustaining system operations. For example, the system may provide the ability for an administrator to SECURE a system by setting configuration parameters for controlling access, tracking, and sustaining system operations. Another example is that the system may SECURE access to a patient's record by controlling access to its content, tracking users who have modified the patient's record, and sustaining the record's availability on a continual basis.
Send	To OUTPUT data from the PHR Account Holder's system by exporting it in such a way as to (passively, automatically) route it to another system. For example, a PHR Account Holder's system may (passively, automatically) send weekly reports to a diabetes specialist's system regarding the PHR Account Holder's current weight.
Store	To MAINTAIN data by backing up, decrypting, encrypting, restoring and saving that data onto electronically accessible devices. For example, a clinician may STORE a given patient's demographic data or a newly-prescribed medication. Another example is that an administrator may configure a system to STORE progressive copies of certain data on a regularly-scheduled basis for backup purposes. Note: data may be stored as plain text or in encrypted or compressed form.
Sustain (operations)	To SECURE a system by promoting actions that enable the system to perform predictably and as intended. For example, a system may SUSTAIN (OPERATIONS) by applying business rules that enforce role-based access to the authorization management portion of the system, thus protecting the PHR Account Holder's data according to pre-determined security and privacy rules.
Synchronize	To OUTPUT data from the PHR Account Holder's system by exporting it in such a way as to coordinate certain data with another system (or systems). For example, the PHR Account Holder may coordinate the medications prescribed by two physicians with a list of home remedies so that each relevant, authorized stakeholder has a current list of the PHR Account Holder's medications/remedies.
Tag	To UPDATE data by marking it for special use. For example, a nurse may TAG the previous week's records for patients that presented with a severe cough and fever. Another example is that a general practitioner may TAG certain data for review by an oncologist. Another example is that an administrator may TAG an interchange standard version as being deprecated.. Note: see "flag" if the meaning is to signal a situation.. Note: the verb "untag" is an acceptable verb to reverse the action of tagging.
Track	To SECURE a system by logging and auditing system-initiated and/or user-initiated activities. For example, the system may TRACK the amount of time that the system was unavailable last month. Another example is that the system may provide the ability for an administrator to TRACK the number of active users of a newly-installed set of system functionality.
Transmit	To RENDER data by delivering the data to devices or other systems in a meaningful and appropriate way. For example, the system may (without human intervention) TRANSMIT an alert to a physician's beeper. Another example is that the system may (upon human intervention) TRANSMIT a given patient's encounter summary to an external facility. Another example is that the system may TRANSMIT data to another facility after mapping local codes to national codes.. Note: It is reasonable to assume that any data that is transmitted ought to be formatted, filtered, translated, transformed, mapped, and/or normalized, etc., as appropriate.
Unhide	To MANAGE-DATA-VISIBILITY by making visible the existence of previously hidden information (see HIDE). For example, the system may provide the ability for a patient to UNHIDE his psychiatric record, and hence the existence of that part of his record becomes visible to all authorized clinicians.
Unmask	To MANAGE-DATA-VISIBILITY by making masked information visible. For example, the administrator my desire to UNMASK certain patient financial information for the admission Department. For example, a system may provide the ability for an emergency department physician to UNMASK a patient's pregnancy status that was presented by the system as "******", to reveal a status of "Pregnant".
Untag	To UPDATE data by removing marking for special use. For example, a nurse may UNTAG the previous week's records for patients that presented with a severe cough and fever that had been previously tagged. Another example is that a general practitioner may UNTAG certain data after completion of review another provider.

Action-Verb	Construction
Update	To MAINTAIN data by annotating, editing, harmonizing, integrating, linking and tagging the data. For example, a clinician may UPDATE a patient's medication dosage. Another example is that the system may UPDATE a patient's record.

Table 6: Action Verbs and their Logical Construction

6.4.4 Deprecated Action-Verbs

The use of verbs that are specific in definition and use allows for greater understanding and consistency of conformance criteria throughout the model.

In this Glossary, the term "deprecated" is used to identify Action-Verbs that were used in conformance criteria (in previous FM Releases) but are not part of the updated hierarchy of Action-Verbs. It is recommended that deprecated Action-Verbs not be used in Conformance Criteria.

The following table lists a set of deprecated verbs and possible alternatives:

Deprecated Action-Verb	Possible Alternative(s)
Access	Instead, use CONTROL-ACCESS if the context is one of controlling access to the system. Use RENDER or PRESENT or another relevant Action-Verb when the context is one of accessing data.
Affirm	Instead, use TAG (with an appropriate qualifier). Affirm, Assert, Declare, Indicate, and State are synonyms.
Alert	Instead, use "RENDER or PRESENT or TRANSMIT an alert to a person or another system (including a device)". An Alert typically occurs after analyzing some data and arriving at a decision that someone must be alerted. See DETERMINE for some examples.
Amend	Instead, use EDIT.
Append	Instead, use the term EDIT. This means editing data by adding new data to existing data.
Assert	Instead, use TAG (with an appropriate qualifier). Affirm, Assert, Declare, Indicate, and State are synonyms.
Augment	Instead, use EDIT, ANNOTATE, or LINK with the appropriate qualifiers. Augmentation is the addition of information to existing healthcare data.
Calculate	Instead, use "DETERMINE and STORE" or "DETERMINE and PRESENT", as appropriate in the context.
Compute	Instead, use "DETERMINE and STORE" or "DETERMINE and PRESENT" as appropriate in the context.
Configure	Instead, use "MANAGE configuration parameters for…". For example, the user may desire to STORE configuration parameters regarding the preferred type of human language. Another example is that an administrator may UPDATE configuration parameters that control external access to the system by restricting access during the weekends.
Conform	To comply... Note: The verb 'Conform' is used with a special meaning in the FM and is not part of the Action-Verb model. It is a special instruction for including the functional requirements of one function in another function. For example: "The system SHALL conform to function TI.1.1 (Entity Authentication)".
Correct	Instead, use EDIT.
Create	Instead, use "DETERMINE and STORE" or "DETERMINE and RENDER" or "DETERMINE and PRESENT" as appropriate to the context.
Declare	Instead, use TAG (with an appropriate qualifier). Affirm, Assert, Declare, Indicate, and State are synonyms.
Deprecate	Instead, use TAG with an appropriate qualifier. Deprecation of certain information may be required when that data becomes invalid, but needs to remain in the system. For example, a health information management professional may desire to TAG a certain clinical term as deprecated, but the term is retained in the system for backward compatibility purposes.
Destroy	
Disable-Access	Instead, use "CONTROL ACCESS by removing permissions to use specific functionality and/or manage specific data".
Disclose	Instead, use "RENDER and TAG" with a label that identifies the data's purpose as "for disclosure use only".
Display	Instead, use PRESENT.
Document	Instead, use ENTER, or "TAG with" appropriate references, or "LINK to" sources.

Deprecated Action-Verb	Possible Alternative(s)
Eliminate	Instead, use DELETE or PURGE as applicable.
Export	Use RENDER instead.
Flag	Instead, use "RENDER an alert", or "PRESENT an alert", or "TRANSMIT a notice", if the intent is to signal a situation (i.e. flag a situation).
Generate	Instead, use "DETERMINE and STORE" or "DETERMINE and PRESENT" or "DETERMINE and RENDER" as appropriate to the context.
Grant-Access	Instead, use CONTROL ACCESS.
Identify	Instead, use other Action-Verbs adapted to the context. . For example, instead of '…to uniquely identify a patient…', one should say '…to MAINTAIN a unique identifier for a patient…' Another example is: instead of '…to help identify the patient...', use '…help DETERMINE the identity of the patient.'.
Input	Instead, use CAPTURE, ENTER, RECEIVE, IMPORT or AUTO-POPULATE, depending on the context and scope of actions described.
Label (verb)	Use "TAG with a label".
Merge	Instead, use INTEGRATE.
Modify Access	Instead, use: "MANAGE data regarding permissions"
Notify	Instead, use "RENDER or PRESENT or TRANSMIT a notification to a person or another system (including a device)".
Nullify	Instead, use "TAG as nullified".
Obsolete	Instead, use "TAG as obsolete".
Order	Instead, use "ENTER the parameters for an order".
Permit Access	Instead, use "AUTHENTICATE a user and AUTHORIZE access based on permissions assigned to that user".
Persist	Instead, use "STORE"
Print	Instead, use RENDER, PRESENT, OR TRANSMIT, depending on the context.
Prioritize	Instead, use "TAG with a priority level", or "DETERMINE priorities".
Provide access to	Instead, use CONTROL ACCESS, or PRESENT, as appropriate to the specific context.
Query	Instead, use ANALYZE or RENDER (or its children Action-Verbs), because queries or searches are implied when rendering or analyzing data.
Reactivate	Instead, use TAG with an appropriate qualifier. Reactivation of certain information may be required when that data, previously deprecated or made inactive, becomes valid again. For example, a health information management professional may desire to TAG a certain clinical term as reactivated.
Reconcile	Instead, use ANALYZE and DECIDE, or DETERMINE, or HARMONIZE depending on the context and the meaning intended.
Record	Instead, use STORE (or its children Action-Verbs).
Reject	Instead, use ''PRESENT or RENDER a message of rejection" or "TAG as rejected".
Replace	Instead, use EDIT, or "DELETE the old and SAVE the new", or "TAG as obsolete and SAVE the new", based on the context.
Report	Instead, use "RENDER a report", or "PRESENT a report".
Repudiate	Instead, use "TAG as repudiated or rejected".

Deprecated Action-Verb	Possible Alternative(s)
Retain	Instead, use STORE (with the possible addition of language that includes the notion that retention management may be needed to accommodate scope of practice, organizational policy, or jurisdictional law). For example, the system may provide the ability to STORE personal health information, and DELETE that data only as allowed by the organization's data-retention policies.
Revoke-Access	Instead, use "CONTROL ACCESS by eliminating permissions to use system functionality or to manage data".
Search	Instead, use ANALYZE or RENDER (or its children action-verbs), because queries or searches are implied when rendering or analyzing data. For example, instead of saying "The system SHALL provide the ability to search patient records based on previous names", one could say "The system SHALL provide the ability to PRESENT a list of records with possible patient name matches using previous patient names".
Select	Instead, use "ENTER a selection".
Sign	Instead, use "TAG-with-authenticated-signature". For example, a system may TAG a patient note with an authenticated signature when the physician completes the patient's note.
State	Instead, use TAG with an appropriate qualifier. Affirm, Assert, Declare, Indicate, and State are synonyms.
Support	Instead, use "PRESENT templates to do XYZ", or DETERMINE, or other Action-Verbs depending on the context and functionality to specify.
Suspend-Access	Instead, use "CONTROL ACCESS by temporarily withholding permissions to use system functionality or to manage data".
Synthesize	Instead, use "ANALYZE and STORE" or "ANALYZE and PRESENT".
Trigger	Instead, depending on the context, use "DECIDE on a course of action based on an analysis of certain data and rules", or "DECIDE and RENDER some information (for example, an alert or a notification) based on the analysis of certain data and rules".
View	Instead, use PRESENT.

Table 7: Deprecated Action-Verbs and Possible Alternative(s)

6.5 Guidelines for Use (Reference)

Contributors to the contents of the EHR-S and PHR-S FMs must be thoroughly familiar with this 'Guidelines For Use' Section. It is critical to the integrity of the FMs that key terms have a consistent meaning throughout each FM specification.

6.5.1 General Guidance

Throughout the EHR-S and PHR-S FMs, terms used for stating Conformance Criteria (CC) must respect meanings as conveyed in the definitions provided in this Glossary. Using the Action-Verbs rigorously will result in clearly written Conformance Criteria (CC) and help ensure consistent communication of functional requirements. Furthermore, combining various functional models and functional profiles is facilitated when a controlled set of terms is used consistently. Therefore, use of synonyms (as replacements) or local jargon should be avoided.

In the FMs, Statements and Descriptions should be written in 'business-like language' defining, in business and user terms, system capabilities that support user needs. CCs should be written from the system's perspective, with rigor and consistency across functional areas, using Action-Verbs and the guidelines; CCs should not be duplicates of the Statements and Descriptions. However, scope-wise, both Statement/Description and corresponding CCs must address the same functionalities.

CCs represent a fundamental component of the FMs by defining its functionalities in precise terms. Significant efforts were invested in developing a set of Action-Verbs with precise definitions that must be used in the construction of CC. The next section provides specific guidance on how CC should be composed.

Since various realms may require the use of certain terms (for example, a term that is embedded in national law), this FM Glossary maintains a realm-independent perspective. The long-term intent is to construct CCs that are computable and easy to validate as to their grammar and contents when it is relevant (i.e., use list of approved Action-Verbs).

6.5.2 Constructing Rigorous Conformance Criteria

Rigor, clarity and consistency in crafting CCs are of paramount importance. The following rules are to be followed whenever possible:

- It is generally preferable to use separate CCs instead of trying to include multiple actions in a single criteria, unless such a combination provides for an economy of statements and is unambiguous.
- Where an action can be performed both automatically by the system and manually upon initiation by the user, CCs should be composed with the "provide the ability to" phrase incorporated.

Selected verbs in conformance criteria should be at the proper level of granularity. If a parent verb in a hierarchy is used, then it means that the actions of all the children verbs under it <u>are pertinent and applicable</u>.

- For example, instead of saying MAINTAIN clinical data which would imply storage, update and deletion of data, one would say STORE and UPDATE data if deletion of data was not allowed.
- For example, if a given CC expects EDIT and TAG to be reasonable application of the function, but that ANNOTATE, HARMONIZE, INTEGRATE, LINK are unreasonable, then the word MAINTAIN should be avoided in lieu of the more precise "EDIT and TAG".
- An example of multiple Action-Verbs: "The system SHALL provide the ability to CAPTURE, STORE, EDIT, and TAG-as-deprecated entries in an xxx registry or directory to keep it current."

The general grammar to use in developing rigorous CCs has the following structure:

- "The system [SHALL | SHOULD | MAY] [provide the ability to] [Action-Verb] [functionality object(s)] [participant(s)] [qualifier(s)] ['according to user preference, scope of practice, organizational policy, and/or jurisdictional law']".
- The system is the subject of all the Conformance Criteria.
- [SHALL | SHOULD | MAY]. It is mandatory that one – and only one – of these three qualifier verbs be used.
  Meanings are defined in EHR-S FM Conformance Clause document and are repeated here for convenience:
  - SHALL – to indicate a mandatory functional requirement to be followed (implemented) in order to conform. Synonymous with 'is required to'.
  - SHOULD – to indicate an optional yet recommended functional requirement, one that is particularly suitable, without mentioning or excluding others. Synonymous with 'is permitted and recommended'.
  - MAY – to indicate an optional (permissible) functional requirement. Synonymous with 'is permitted'.
- [provide the ability to]: optional phrase used to convey when the functional requirement may be either initiated by user action or automatically by system rules. System rules may be configurable.
- [Action-Verb]: mandatory. The Action-Verb must come from the standardized list enumerated in this Glossary and respect the definitions provided. When another verb would appear preferable, it is suggested to look for that verb in the Glossary definition section where it may be listed with suggestions for a replacement verb and composition. This guide provides numerous examples.
- [functionality object(s)]: mandatory. Identifies the object(s) of the functional requirement.
- [participant(s)]: optional. Covers users (or external systems) that participate or are affected by the specified function.
- [qualifier(s)]: optional. This might relate to time, interval, condition(s). Can include (for example): "automatically", "manually", "in real time", "according to the business rules"
- ["according to user preference, scope of practice, organizational policy, and/or jurisdictional law"]: optional, when the action could be governed by relevant practices, policies and/or laws.

Note that "The system SHALL…" means that the system is required to perform the relevant function when all factors and specified conditions are met.

Some examples of rigorous CCs follow:

- The system SHALL provide the ability to PRESENT the list of scheduled patients according to selected criteria such as provider name, dates, time of day, nature of visit, etc. using language of choice.

- IF a provider attempts to prescribe a drug using the system, THEN the system SHALL DETERMINE whether interactions exist between the newly prescribed drugs and the medications on the patient's current medication list, and RENDER an appropriate response to the provider, according to scope of practice, organizational policy, and/or jurisdictional law.

The verb 'Conform' is used with a special meaning in the FM and is not part of the Action-Verb model. It is a special instruction for including the functional requirements of one function in another function.

- For example: The system SHALL conform to function TI.1.1 (Entity Authentication).

7 PHR System Conformance Claim via Self-Attestation

Claiming Conformance to a Functional Profile

When a software vendor/developer wishes to claim (for their product) conformance to a version of a PHR-S Functional Profile the document claiming conformance should include the following information:

- The Name and Version of the standard with which the software product is conformant.
- A full listing of the functions and conformance criteria with which the software product is conformant.

In this manner any individual/organization evaluating the software product may easily determine its claimed functionality.

The documentation detailing the process of determining conformance using a tool shall include the name of the tool, the version of the tool and the date(s) of testing (e.g., "The software was tested using Tool-X on Conformance Criterion-Y").

The process of claiming conformance to one or more Functional Profiles shall not be construed as creating a new Functional Profile.

If an end user suspects that a particular PHR-S product is not in compliance with a conformance criterion claimed in the software statement of conformance, the end user should first address the issue with the software vendor/manufacturer. The end user (provider) may also communicate their findings with the HL7 EHR Work Group. The EHR Work Group shall not be responsible for validation of any statement of conformance or for intervention with a software vendor/manufacturer when a discrepancy is reported by an end user, but at its discretion may contact the PHR-S vendor/manufacturer regarding the identified issue(s).

8 Glossary Supplement: Record Lifecycle Events and Descriptions (Normative)

Developed (in part) by the HL7 EHR/Security WG Vocabulary Alignment Project

Incorporated in:

    HL7 FHIR Core R4 and FHIR Record Lifecycle Event Implementation Guide (RLE IG)

    ISO 21089:2018 Trusted End-to-End Information Flows

    ISO/HL7 10781:2020 EHR System Functional Model Release 2.1

    ISO/HL7 16527:2020 PHR System Functional Model Release 2

8.1 Record Lifecycle Events (See RI.1.1.1)

Access/View Record Lifecycle Event - occurs when an agent causes the system to obtain and open a record entry for inspection or review.

Add Legal Hold Record Lifecycle Event - occurs when an agent causes the system to tag or otherwise indicate special access management and suspension of record entry deletion/destruction, if deemed relevant to a lawsuit or which are reasonably anticipated to be relevant or to fulfill organizational policy under the legal doctrine of "duty to preserve".

Amend (Update) Record Lifecycle Event - occurs when an agent makes any change to record entry content currently residing in storage considered permanent (persistent).

Archive Record Lifecycle Event - occurs when an agent causes the system to create and move archive artifacts containing record entry content, typically to long-term offline storage.

Attest Record Lifecycle Event - occurs when an agent causes the system to capture the agent's digital signature (or equivalent indication) during formal validation of record entry content.

Decrypt Record Lifecycle Event - occurs when an agent causes the system to decode record entry content from a cipher.

De-Identify (Anononymize) Record Lifecycle Event - occurs when an agent causes the system to scrub record entry content to reduce the association between a set of identifying data and the data subject in a way that may or may not be reversible.

Deprecate Record Lifecycle Event - occurs when an agent causes the system to tag record entry(ies) as obsolete, erroneous or untrustworthy, to warn against its future use.

Destroy/Delete Record Lifecycle Event - occurs when an agent causes the system to permanently erase record entry content from the system.

Disclose Record Lifecycle Event - occurs when an agent causes the system to release, transfer, provision access to, or otherwise divulge record entry content.

Encrypt Record Lifecycle Event - occurs when an agent causes the system to encode record entry content in a cipher.

Extract Record Lifecycle Event - occurs when an agent causes the system to selectively pull out a subset of record entry content, based on explicit criteria.

Link Record Lifecycle Event - occurs when an agent causes the system to connect related record entries.

Merge Record Lifecycle Event - occurs when an agent causes the system to combine or join content from two or more record entries, resulting in a single logical record entry.

Originate/Retain Record Lifecycle Event - occurs when an agent causes the system to: a) initiate capture of potential record content, and b) incorporate that content into the storage considered a permanent part of the health record.

Pseudonymize Record Lifecycle Event - occurs when an agent causes the system to remove record entry content to reduce the association between a set of identifying data and the data subject in a way that may be reversible.

Re-activate Record Lifecycle Event - occurs when an agent causes the system to recreate or restore full status to record entries previously deleted or deprecated.

Receive/Retain Record Lifecycle Event - occurs when an agent causes the system to a) initiate capture of data content from elsewhere, and   b) incorporate that content into the storage considered a permanent part of the health record.

Re-identify Record Lifecycle Event - occurs when an agent causes the system to restore information to data that allows identification of information source and/or information subject.

Remove Legal Hold Record Lifecycle Event - occurs when an agent causes the system to remove a tag or other cues for special access management had required to fulfill organizational policy under the legal doctrine of "duty to preserve".

Report (Output) Record Lifecycle Event - occurs when an agent causes the system to produce and deliver record entry content in a particular form and manner.

Restore Record Lifecycle Event - occurs when an agent causes the system to recreate record entries and their content from a previous created archive artefact.

Transform/Translate Record Lifecycle Event - occurs when an agent causes the system to change the form, language or code system used to represent record entry content.

Transmit Record Lifecycle Event - occurs when an agent causes the system to send record entry content from one (EHR/PHR/other) system to another.

Unlink Record Lifecycle Event - occurs when an agent causes the system to disconnect two or more record entries previously connected, rendering them separate (disconnected) again.

Unmerge Record Lifecycle Event - occurs when an agent causes the system to reverse a previous record entry merge operation, rendering them separate again.

Verify Record Lifecycle Event - occurs when an agent causes the system to confirm compliance of data or data objects with regulations, requirements, specifications, or other imposed conditions based on organizational policy.

Annex A
(Normative)

Function List

Three formats of the PHR-S FM function list are included for the reader's convenience at https://standards.iso.org/iso/16527/ed-1/en. They are:

- PHR-S_FM-R2_FunctionList.html

- PHR-S_FM-R2_FunctionList.pdf and

- PHR-S_FM-R2_FunctionList.csv

NOTE   Some systems will need a style sheet to render the .html version of the function list. It is also available at https://standards.iso.org/iso/16527/ed-1/en and listed as "functional-model."

Annex B
(Informative)

Glossary of Terms for the EHR-S FM

Term	Definition	Reference
Access	1) obtain, open, inspect, review and/or make use of health data or information 2) specific type of interaction between a subject and an object that results in the flow of information from one to the other	CPRI, modified ISO 21089:2018 GCST
Access control	1) means to ensure that access to assets is authorized and restricted based on business and security requirements 2) means to ensure that the resources of an electronic system can be accessed only by authorized entities in authorized ways 3) prevention of an unauthorized use of a resource, including the prevention of use of a resource in an unauthorized manner	ISO/IEC 27000:2009 ISO/IEC 2382-8:1998, modified ISO 21089:2018
Accountability	1) property that ensures that the actions of an entity may be traced uniquely to that entity 2) obligation of an individual or organization to account for its activities, for completion of a deliverable or task, accept responsibility for those activities, deliverables or tasks, and to disclose the results in a transparent manner	ISO/IEC 2382-8:1998 ISO 7498-2:1998, modified ISO 18308:2011 ISO 21089:2018
Accuracy	(data) extent that recorded data reflect the actual underlying information	ISO 21089:2018
Accurate	correct; conformity to truth or to a standard or model	Olsen, Jack E., Data Quality: The Accuracy Dimension, Morgan Kaufmann Publishers, San Francisco, CA, 2003 Merriam-Webster Dictionary
Active order	Active – In a state of action. Order – Request for a specific action.	America Heritage Dictionary, Second College Edition, 1991
Activity	See health care activity	
Actor (in the healthcare system)	1) human, organization, or a system entity that can participate in an action 2) with respect to an action, entity that participates in or observes that action	ISO/IEC 15414:2015, modified ISO 21089:2018
Advanced Directive	a legal document (such as a living will) signed by a competent person to provide guidance for medical and health-care decisions (such as the termination of life support or organ donation) in the event the person becomes incompetent to make such decisions	Merriam-Webster
Adverse reaction	a negative or unexpected reaction to a drug or medical procedure (a reaction can range from mild to life-threatening)	
Adverse sensitivity	a condition expected to result in undesirable physiologic reaction to an amount of a substance that would not produce a reaction in most individuals	
After Action	(review/report) a detailed critical summary or analysis of a past event (such as a clinical intervention) made for the purposes of re-assessing decisions and considering possible alternatives for future reference	

Term	Definition	Reference
Agent	1) (conscious) entity that takes conscious actions, such as an individual, organization, business unit 2) (delegated) entity that has been delegated (e.g. authority, a function) by and acts for another (in exercising the authority, performing the function) 3) (healthcare) individual, organization, business unit, medical device (e.g. instrument, monitor) and software (e.g. application) which a) performs a role in the provision of healthcare services and/or b) is accountable for actions related to, and/or c) ascribed in, the health record 4) (programmed) entity that takes programmed actions, such as software or a device 5) (responsible) entity that bears some form of responsibility for an activity taking place, for the existence of an entity, or for another agent's activity	ISO 21089:2018 (1,2,4,5) CEN 12265:2014, modified (3)
Aggregate (Population Health context)	the consolidation of information from cohorts of individuals, families, or other groupings that is associated because of similar social, personal, health care, or other needs or interests. Note: aggregate-level data is sometimes de-identified in the Population Health context.	
Aggregate Data	data that has been collected from two or more sources and combined into a single dataset	
Aggregation	process to combine standardized data and information [SOURCE: JCAHO, modified]	ISO 21089:2018 JCAHO
Alert (used as noun)	an indication from a system or device that a condition exists requiring assessment and possible action.	
Allergy	an exaggerated immune response or reaction to a substance that is generally not harmful. The manifestation of an allergy includes a variety of physiologic responses (e.g. rash, itching, hypotension, anaphylaxis) and can be dependent on the route of exposure (inhalation, skin contact, ingestion).	MedLine Plus US National Institute of Health/National Library of Medicine
Anonymize	1) process that removes the association between the identifying data set and the data subject 2) remove personally identifying particulars or characteristics from record content so that the original source or data subject cannot be known	ISO 21089:2018 (2)
API	application program interface: set of routines, protocols, and tools for building software applications. An API specifies how software components should interact.	
Appropriate	suitable or proper in the circumstances	
Architecture	1) structure of components, their inter-relationships, and the principles and guidelines governing their design and evolution over time 2) set of principles on which the logical structure and interrelationships to an organization and business context are based. Note: Software architecture is the result of software design activity 3) set of design artefacts or descriptive representations that are relevant for describing an object such that it can be produced to requirements (quality) as well as maintained over the period of its useful life (change)	The Open Group Architectural Framework (TOGAF):2009 (1) ISO 21089:2018 (2) Zachman - Enterprise Architecture: 1996 (3)

Term	Definition	Reference
Archive	1) process of moving one or more EHR extracts to off-line storage in a way that ensures the possibility of restoring them to on-line storage when needed without loss of meaning. Wherever possible, archived data should be technology-independent so that future users do not have dependencies on obsolete technology from the past 2) create, update or move an archive artifact with health record content for long-term, typically offline storage, external to the source system	ISO 18308:2011 (1) ISO 21089:2018 (2)
Assessment	1) (in medicine and nursing) an evaluation or appraisal of a condition 2) the process of making such an evaluation 3) (in a problem-oriented medical record) an examiner's evaluation of the disease or condition based on the patient's subjective report of the symptoms and course of the illness or condition and the examiner's objective findings, including data obtained through laboratory tests, physical examination, medical history, and information reported by family members and other health care team members.	Mosby's Medical Dictionary:2009
Associate	To maintain data by updating it in such a way as to draw connections between disparate data; to establish/maintain a relationship between two or more entities	
Assurance	1) (surety) grounds for surety, certainty or confidence about something 2) (security) grounds for confidence that an entity meets its claimed level of protection, including security objectives 3) (system services) development, documentation, testing, procedural and operational activities carried out to ensure a system's services do in fact provide the claimed level of function, performance and usability	ISO/IEC 15408-1:2009, modified (1) OMG, modified (2,3)
Atomic Data Elements	indivisible units of data	
Attest, Attestation	1) affirm, certify and/or authenticate a specific unit of information is true and genuine 2) (authenticity/accuracy) declare that record entry content exists, is authentic, accurate and true and therefore that it can be trusted 3) (completion) declare that record entry content exists and is complete for the purpose intended 4) (evidentiary) provide or serve as clear evidence of and thus certify and record applicable administrative (or "legal") responsibility for a particular unit of information	ISO 21089:2018 (2,3,4)
Audit	1) mechanism employed to record and examine activities of an agent 2) systematic and independent examination of accesses, additions, or alterations to electronic health records to determine whether the activities were conducted, and the data were collected, used, retained or disclosed according to organizational standard operating procedures, policies, good clinical practice, and/or applicable regulatory requirement(s), and to recommend necessary changes in controls, policies or procedures	ISO 21089:2018 (1)

Term	Definition	Reference
Audit Trail	1) (evidence of information operations) record that captures details such as additions, deletions, or alterations of information in an electronic record without obliterating the original record. An audit trail facilitates the reconstruction of the history of such actions relating to the electronic record. 2) (evidence of resource utilization) record of the resources which were accessed and/or used by whom 3) (evidence of system use/activities) chronological record of system activities that is sufficient to enable the reconstruction, reviewing and examination of the sequence of environments and activities surrounding or leading to an operation, a procedure, or an event in a transaction from its inception to final results	ISO 7498-2:1998 (2) GCST (3)
Authentic	1) (object, entity, record) is what it purports to be; genuine and of undisputed origin; bona fide; based on facts, accurate and reliable 2) genuine; true; having the character and authority of an original; duly vested with all necessary formalities and legally attested; competent, credible, and reliable as evidence 3) object state or status, deemed present (authentic) or non-present (not authentic), on the basis of a given data object's responses to conformance testing on three questions: a. what does the object provider purport the object to be? b. what is the specification for that object? c. what means are offered to verify that 1=2?	ISO 21089:2018 (1) Downing v. Brown, 3 Colo. 590 (2) thelawdictionary.org (2) Altiglieri, et al, in "Diagnosing and Treating Legal Ailments of the Electronic Health Record: Toward an Efficient and Trustworthy Process for Information Discovery and Release" in The Sedona Conference Journal, Summer 2017, p. 233 (3)
Authenticate, Authentication	1) process proving something is real, true, or genuine 2) (data) process of verification of the integrity of data that have been captured, stored or transmitted 3) (data source) process of corroboration that the source of data received is as claimed 4) (identity of entity) process to provide assurance regarding the claimed identity of an entity (e.g. subject, user, author) 5) (health record entries) process to verify that an entry exists, is complete, accurate and final 6) (object) process to assure the identity of an object 7) satisfaction of the requirement of authenticating or identifying an item of evidence, where the proponent must produce evidence sufficient to support a finding that the item is what the proponent claims it is	ISO 21089:2018 (1,2,3) ISO/IEC 10181-2:1996, modified (4) JCAHO, modified (5) ASTM E1762: 2013, modified (6) US Federal Rules of Evidence (7)
Authority	body that has legal powers and rights	ISO/IEC 2382-8:1998
Authorize, Authorization	1) granting of rights, which includes granting of privileges to access data and functions 2) prescription that a particular behaviour must not be prevented	ISO 7498-2:1998, modified (1) ISO/IEC 15414:2015 (2)
Authorized User	user who may, in accordance with the Security Policy, perform an operation	ISO/IEC 15408:1999
Automatically	qualifier used to indicate that the action will be done by the system, independently of any user intervention	
Auto-Populate	system process that automatically fills in input fields with data that are already known/available within the systems database	

Term	Definition	Reference
Availability	1) (accessibility/usability) property of being accessible and useable upon demand by an authorized entity 2) (non-concealment) prevention of the unauthorized withholding of information or resources	ISO 7498 2:1998 (1) ITSEC (2)
Background Process	system processes running behind the scene without human initiation, interaction or intervention. Sometimes employed to perform certain maintenance activities.	Oracle Database Administrator Guidance, modified
Backup	a copy of data for the specific intent of ensuring its preservation and possible restoration in case the original is lost, corrupted, or destroyed	
Behavioral Healthcare	range of services for individuals at risk of, or suffering from mental, addictive, or other behavioral health disorders	SAMHSA
Best practice	practices that incorporate the best objective information currently available regarding effectiveness and acceptability	SAMHSA
Bind, Binding	process of associating two related elements of information. Examples: a) one may bind an author's (digital) signature to the corresponding health record content created by that author; b) one may bind certain metadata to an electronic document; c) one may bind a certain laboratory results (report) to a corresponding laboratory order.	
Boundaries	border or limit	
Business Rule	statement that defines or constrains some aspect of the business, intended to assert business structure, or to control or influence the behavior of the business. Examples include (but are not limited to) coding, billing, claim filing and reimbursement, resource management (personnel, beds, supplies, equipment), workflow optimization, and clinical decision support.	The Business Rules Group:2013
Business Unit	discrete and accountable function or sub-function within an organization. Example: A business unit can include a department, service or specialty within a healthcare provider organization.	ISO 21089:2018
Care	provision of accommodations, comfort and treatment to an individual subject of care (patient); also implying responsibility for safety	JCAHO
Care Guidelines (synonymous with Health Care Guidelines)	1) recommendations offered by a care giver to a patient 2) recommendations recognized by care providers as being appropriate. In general, care guidelines are based on expert knowledge of assessing, treating and/or managing a particular medical condition.	US Agency for Health Research and Quality
Care Plan, Treatment Plan	tool used by clinicians to plan and coordinate care for an individual patient that aids in understanding and coordinating the actions that need to be performed for the subject of care (patient)	
Care Process	task or set of tasks that is/are clinically-oriented; typically comprised of care planning, care delivery, and follow up tasks	
Care Team	group of individuals who provide health care to an individual for a given health care episode, health care setting or with regard to a health condition	
Cascade	something arranged or occurring in a series or in a succession of stages typically such that each stage derives from or acts upon the product of the preceding	

Term	Definition	Reference
Chain-of-Trust Agreement	statement of requirements that certain administrative procedures will be implemented to guard the integrity, confidentiality and availability of sensitive data, where the sender and receiver agree to protect the data electronically transmitted between them	
Change Log, Change Histry	record of revisions/updates that have occurred over time; a log that can serve as an audit record for activity in a file or record system	
Chronicity	attributes or dimensions that could be associated with a chronic condition, including: a) time period (e.g., childhood, pubescence, constant); b) duration of condition (e.g., brief, extended, sustained, habitual); c) duration of episode (e.g., sleeping hours, self-limiting, consistent); d) level (e.g., mild, moderate, or severe condition or pain); e) and/or periodicity or frequency (e.g., a seasonal allergy).	
Clinical Decision Support	1) use of data to discover, guide and/or justify the proper course of care (or interventions) to support health and health care activities 2) type of system or algorithm (logic) that assists health care providers in making clinical decisions	
Clinical Document, Clinical Documentation	1) documents (records) created in the course of supporting health and providing health care serices; may be used in support of clinical decisions 2) documentation of clinical observations and services, with the following characteristics: a) persistence (a clinical document continues to exist in an unaltered state, for a time period defined by local and regulatory requirements); b) stewardship (a clinical document is maintained by a person or organization entrusted with its care); c) potential for authentication (a clinical document is an assemblage of information that may be legally authenticated); d) wholeness – (authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document); e) human readability (a clinical document is human readable)	
Clinical image	non-textual, pictorial depiction of clinical information (e.g., a radiograph, picture, video, or waveform)	
Clinical information	data related to the health/health care of an individual collected from or about an individual receiving health care services. It may include a caregiver's objective measurement or subjective evaluation of a patient's physical or mental state of health; descriptions of an individual's health history and family health history; diagnostic studies; decision rationale; descriptions of procedures performed; findings; therapeutic interventions; medications prescribed; description of responses to treatment; prognostic statements; and descriptions of socio-economic and environmental factors related to the patient's health.	CPRI:1996 ASTM 1769:1997
Clinical Practice Guideline (CPG)	statement that includes recommendations intended to optimize patient care. It is informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.	Board on Health Care Services, US Institute of Medicine (IOM), National Academies of Science:2011
Clinical process	the set of interrelated or interacting health care activities performed by one or more health care professionals	ISO 18308:2011
Clinician	health professional who delivers health services directly to a patient/client	ISO 12773-1:2009
Clinical tasks	discrete health and health care actions whose results are recorded in clinical documents	

Term	Definition	Reference
Code set(s)	group of keys or indices used for encoding data elements, such as tables of terms, medical concepts (e.g., medical diagnostic codes or medical procedure codes)	HIPAA:1996, modified ISO 21089:2018
Coding system	organized, managed collection of codes, each of which has associated designations, meanings and in some cases relationships, properties or rules	HL7 Vocabulary Work Group, modified
Coding Scheme	collection of rules that maps the elements of one set on to the elements of a second set. Note: The two sets considered here are: a) a set of 'code meanings' (or 'coded set'), and b) a set of 'code values' (or 'code set'). Those sets are not, per se, part of the coding scheme.	ISO 18308:2011 ISO/IEC 2382-4:1999
Coded	references a vocabulary, code set or value set (e.g., SNOMED, LOINC)	
Cohort	1) group of individuals who share a common exposure, experience or characteristic 2) study group of individuals, some of whom are exposed to a variable of interest, in which subjects are followed over time. Cohort studies can be prospective or retrospective.	American Medical Association
Compendium	(in the context of Pharmacy) collected body of information detailing the standards of strength, purity, and quality of drugs	
Complete Health Record	final, assembled and authenticated, health record for an individual. A health record is complete when a) its contents reflect the diagnosis, results of diagnostic tests, therapy rendered, condition and progress (of the subject of care), and condition (of the subject of care) at discharge, and b) its contents, including any required clinical résumé or final progress notes, are assembled and authenticated, and all final diagnoses and any complications are recorded without use of symbols or abbreviations.	JCAHO ISO 21089:2018
Completeness	(record) extent to which relevant records are present and the fields in each record are populated appropriately	ISO 21089:2018
Concept	unit of knowledge created by a unique combination of characteristics	ISO 18308:2011 ISO 1087-1:2000
Confidentiality	1) (not disclosed) property that information is not made available or disclosed to unauthorized individuals, entities or processes 2) (controlled release) condition in which information is shared or released in a controlled manner 3) (labeling) status accorded to data or information indicating that it is sensitive for some reason, and that therefore it needs to be protected against theft or improper use and must be disseminated only to individuals or organizations authorized to have it 4) (need to know) restriction of access to data and information to individuals who have a need, a reason and permission for access	ISO 13606-4:2019, modified (1) US National Research Council (2) US Office of Technology Assessment (3) JCAHO (4)
Conform	to comply. Note: The verb 'Conform' is used with a special meaning in the FM and is not part of the Verb Hierarchy. Instead it is a special instruction for including the functional requirements of one function in another function. For example: "The system SHALL conform to function TI.1.1 (Entity Authentication)…".	
Conformance	fulfillment of specified requirements by a product, process, or service.	HL7 EHR-S/PHR-S Functional Model Chapter 2: Conformance Clause

Term	Definition	Reference
Conformance Criteria	statements of requirement indicating the behavior, action, capability that constitutes implementation of the function	HL7 EHR-S/PHR-S Functional Model Chapter 2: Conformance Clause
Conformance clause	section of a specification that defines the requirements, criteria, or conditions to be satisfied in order to claim conformance	HL7 EHR-S/PHR-S Functional Model Chapter 2: Conformance Clause
Conformance statement	statement associated with a specific implementation of a profile of the EHR-S or PHR-S Functional Model.	HL7 EHR-S/PHR-S Functional Model Chapter 2: Conformance Clause
Consent, Informed Consent	1) agreement, approval, or permission as to some act or purpose given voluntarily by a competent person 2) communication process between the caregiver and the (subject of care), and which may refer to consent for treatment, special procedures, release of information and advance directives [which give instructions regarding the (subject of care's) wishes in special medical situations] 3) voluntary agreement with what is being done or proposed (express or implied)	ISO 18308:2011 (1) CPRI (2) Canadian Institute for Health Information (CIHI) (3)
Consumer (in relation to healthcare services)	1) individual who may become a subject of care 2) person who is the receiver of health-related services and who is an actor in a health information system 3) person requiring, scheduled to receive, receiving or having received a healthcare service	ISO 12773-1:2009 (1)
Continuity of Care	component of patient care quality consisting of the degree to which the care needed by a patient is coordinated among practitioners and across organizations and time	ISO 21089:2018
Credentials	1) (identity) data that are transferred to establish the claimed identity of an entity 2) (healthcare practice) documented evidence of (a healthcare professional's) licensure, education, training, experience, or other qualifications	ISO/IEC 2382:2015 (1) JCAHO (2)
Criteria	expected level(s) of achievement, or specifications against which performance can be assessed	JCAHO
Critical Value, Panic Value	diagnostic result (e.g., from laboratory, radiology, pathology) on a patient that must be reported immediately to the care provider and which may require urgent therapeutic action or intervention	
Current medication	1) medication that a patient is actively using, either on a regular basis or on an ad hoc basis (e.g., "two pills as needed for pain") 2) medication that has been dispensed to a patient and whose administration has not yet been completed according to the medication's intended duration, dose, frequency, and quantity	
Dashboard	user interface based on predetermined reports, indicators and data fields, upon which the end user can apply filters and graphical display methods to answer pre-determined business questions, which is often intuitive and suited to regular use with minimal training	
Data	(healthcare) information elements which are input, stored, processed or output by the automated information system which support the clinical and business functions of a healthcare organization	

Term	Definition	Reference
Data aggregation	process by which data is collected, manipulated and expressed in summary form to provide information. Data aggregation is primarily performed for reporting purposes, policy development, health service management, research, statistical analysis, and population health studies.	ISO TS 18308:2011
Data Attribute, Data Element, Data Item	single unit of data that in a certain context is considered indivisible	ISO 21089:2018
Data Consistency	for the uses intended, subject (data) elements that are clear and well defined enough to yield similar results in similar analyses	ISO 21089:2018
Data Enterer	A person who transfers content, written or dictated by someone else, into a clinical document. The guiding rule of thumb is that an author provides the content found within the header or body of the document, subject to their own interpretation, and the Data Enterer adds that information to the electronic system. In other words, a Data Enterer transfers information from one source to another (e.g. transcription from paper form to electronic system).	
Data Integrity	1) (non-alteration) property that data has not been altered or destroyed in an unauthorized manner 2) (wholeness) accuracy, consistency and completeness of data/record content	ISO 7498-2:1998 (1) JCAHO, modified (2)
Data Quality	1) degree to which a given data set satisfies the requirements of its intended use 2) aggregate construct composed of conformance with end-use requirements including specifications for accurate, timely, relevant, complete, understood, and trusted 3) fitness for use for a particular task 4) conformance with a specification for a defined end-use	Olsen, Jack E., Data Quality: The Accuracy Dimension, Morgan Kaufmann Publishers, San Francisco, CA, 2003 (1,2) Kahn, MG, Raebel, MA, Glanz, JM, Riedlinger, K and Steiner, JF. A Pragmatic Framework for Single-site and Multisite Data Quality Assessment in Electronic Health Record-based Clinical Research. Med Care. 2012 (3)
Data Reliability	for the uses intended, subject (data) elements that demonstrate accuracy, completeness, integrity, stability, repeatability and precision	JCAHO, modified
Data Transmission	sending of data or information from one location to another location; exchange of data between person and program, or program and program, when the sender and receiver are remote from each other	CPRI JCAHO
Data Validity, Data Validation	1) process used to determine if data are accurate, complete, or meet specified criteria. Note: Data validation may include format checks, completeness checks, check key tests, reasonableness checks, and limit checks 2) verification of correctness (reflecting the true situation)	ISO/IEC 2382-8:1998 (1) JCAHO (2)
Decision support system	See "Clinical Decision Support"	

Term	Definition	Reference
Decrypt, Decryption	1) process of making encrypted data reappear in its original unencrypted form; reversal of a corresponding reversible encipherment 2) decode or render information readable by algorithmically transforming ciphertext into plaintext	ISO 7498-2:1989 (1) HL7 v3 ObligationPolicy value set, modified (2)
De-identification	process of removing the association between a set of identifying data and the data subject	ISO 25237:2008
Delegate	give authority, function, or responsibility to another	ISO/IEC 15414:2015, modified
Demographic Data	data related to identifying an individual (such as name, date of birth, age, gender, etc.). May also include emergency and other types of contact information for the individual and administrative data (such as health insurance eligibility)	
Deprecate	(data/record content) designate data/record content as obsolete, erroneous or untrustworthy, as indication against its future use	ISO 21089:2018
Derived profile	profile created from an existing profile	HL7 EHR-S Functional Model Chapter 2: Conformance Clause
Destroy	(data/record content) purge or expunge data/record content stored in electronic or magnetic media, typically based on explicit criteria, so that it is completely unreadable and cannot be accessed or used	ISO 21089:2018
Digital Signature	1) electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified 2) data appended to, or a cryptographic transformation of a data unit that allows a recipient of the data unit to prove the source, signer and integrity of the data unit and protect against forgery; this term is usually reserved for digital values or checksums calculated using asymmetric techniques, where only the originator of the message can generate the digital signature but many people can verify it	HIPAA (1) ISO 7498-2:1998, modified (2)
Directive	instruction how to proceed or act	
Directory	index or catalog of entities (e.g., individuals or organizations)	
Disable-Access		
Disclose	release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information	HIPAA
Disclosure	(health information) release of information to third parties within or outside the healthcare provider organization from an individual's (health) record with or without the consent of the individual to whom the record pertains	CPRI
Disease management	system of coordinated healthcare interventions and communications for persons and populations with particular sickness, illness or ailment	
Discrete capture	(data) input of an individual item of data	
Discrete data	data that contains distinct or separate values	
Dispense (a medication)	[See "Fill (a prescription or a medication order)"]	
Document	See "Clinical Document"	
Documentation	process of recording information in the (health) record	JCAHO

Term	Definition	Reference
Download	to copy or move programs or information into a computer's memory, especially from a large datastore or the internet	
Effectiveness	(of care) degree to which the care is provided in the correct manner, given the current state of knowledge, to achieve the desired or projected outcome for the subject of care (patient)	JCAHO
e.g.	for example ("exempli fratia" in Latin)	
EHR	electronic health record See "Electronic Health Record"	
EHR-S FM	HL7 Electronic Health Record System Functional Model	
Electronic Health Record	1) comprehensive, structured set of clinical, demographic, environmental, social, and financial data and information in electronic form, documenting the health care given to a single individual 2) Information relevant to the wellness, health and health care of an individual, in computer-processable form and represented according to a standardized information model 3) repository of (organized sets of) information regarding the health of a subject of care, in computer processable form 4) a virtual compilation of non-redundant health data about a person across a lifetime, including facts, observations, interpretations, plans, actions, and outcomes. Health data include information on allergies, history of illness and injury, functional status, diagnostic studies, assessments, orders, consultation reports, treatment records, etc. Health data also include wellness data such as immunization history, behavioural data, environmental information, demographics, health insurance, administrative data for care delivery processes, and legal data such as consents	ASTM E1769:1995 (1) ISO 18308:2011 (2) ISO 20514:2015, modified (3) CPRI:1995 (4)
Electronic Health Record Architecture	generic structural components from which all EHRs are built, defined in terms of an information model	ISO 18308:2011
Electronic Health Record System	system for recording, retrieving and handling information in electronic health records	ISO 18308:2011 ISO 13606-1:2019
Electronic Consult (e-Consult), Teleconsultation	healthcare consultation carried out remotely using audiovisual telecommunications between doctor and subject of care (patient)	
Electronic Referral (e-Referral), Tele-referral	an act of referring someone (typically to a specialist) for consultation, review, or further action via an electronic service	
Electronic Signature (e-Signature)	electronic sound, symbol, or process, attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the contract or record	

Term	Definition	Reference
Employer	in occupational health, the company, organization, or individual that provides compensation (either direct or indirect) for a job, as reported by the person.	HL7 Occupational Data for Health Project
Employment Status	in occupational health, a person's self-reported, coded economic relationship to work (e.g. having one or more jobs) for a specified time period. Generally, employment status refers to whether or not a person has at least one job (i.e., is working for compensation), unemployed (i.e., searching for work for compensation), or not in the labor force (e.g., disabled, chooses not to work, etc.).	HL7 Occupational Data for Health Project
Encounter	interaction between a subject of care (patient) and care provider(s) for the purpose of obtaining and/or providing healthcare-related service(s)	
Encrypt	encode or render information unreadable by algorithmically transforming plaintext into ciphertext where data are temporarily re-arranged into an unreadable or unintelligible form for confidentiality, transmission, or other security purposes	HL7 Version 3 Standard: Security and Privacy Ontology, Release 1, modified
Encryption	process of encoding a message so that its meaning is not obvious	US Office of Technology Assessment
Enterprise	commercial or industrial activity or organization or business that has specific social objectives that serve its primary purpose	
Entity	1) physical, digital, conceptual, or other kind of thing with some fixed aspects, such as a person, body, or object 2) something or someone that has a separate, distinct and identifiable existence; something or someone that has a unique identity (e.g., a person, an organization)	W3C, modified (1)
Entry	[See "Record Entry"]	
Event	1) noteworthy occurrence that has a location in time and space 2) (patient) anything that takes place or happens to the patient or is related to the patient, especially something important such as an incident (e.g. adverse event), procedure or diagnosis 3) (trigger) stimulus that causes a noteworthy change in the state of an object, or a signal that invokes the behaviour of an object	HL7 Reference Information Model (3)
Evidence	1) (demonstrate truth) everything that is used to determine or demonstrate the truth of an assertion 2) (fulfill burden of proof) currency by which one fulfills the burden of proof	ISO 21089:2018
Exchange	(information) act of people and organizations passing information from one to another, especially electronically	
Explicit Consent	permission that is freely and directly given, expressed either viva voice or in writing.	ISO 18308:2011
Externally-Sourced	(information) Refers to an information object captured from outside the immediate system (e.g., EHR system), e.g., faxes, referral authorizations, consultant reports, laboratory results, encounter notes from another healthcare organization	
Extract	1) select, copy out or cite a set of health data/record content, typically based on explicit criteria 2) remove for separate consideration or publication.	ISO 21089:2018
Family History	record of health information about a subject of care's (patient's) close relatives; including e.g., disorders, environment, lifestyle, age at and cause of death	

Term	Definition	Reference
Fast Track	route, course, or method that provides for more rapid results than usual	
Fetal Death	Death prior to the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy and which is not an induced termination of pregnancy. The death is indicated by the fact that after such expulsion or extraction, the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.	
Fill (a prescription or a medication order)	assign, count, label, and disburse/transport dose(s) of a medication in preparation for administration to a subject of care (patient). Note: In the FM the term "fill" represents the combined notions of medication filling and prescription.	
Filter	ability to programmatically separate and constrain data into specific value sets	
Flow Sheet	tabular summary of information that is arranged to display the values of variables as they change over time	CEN TC251
FM	functional model, (i.e., HL7 Electronic Health Record System Functional Model, HL7 Personal Health Record Functional Model)	
Formulary	preferred list of drug products that typically limits the number of medications available within a therapeutic class for purposes of purchasing, ordering, dispensing, administration and reimbursement. A government body, third-party insurer or health plan, or a provider organization may compile a formulary and its constraints may be mandatory.	
Function	1) computation which takes some arguments or inputs and yields an output; any particular input yields the same output every time. 2) subroutine (software process) which returns a value	
Generic Orders	general diagnostic or treatment orders	
Genotype	1) genetic makeup, as distinguished from the physical appearance, of an organism or a group of organisms 2) combination of alleles located on homologous chromosomes that determines a specific characteristic or trait	American Heritage Science Dictionary:2005
Genetic Disorder (also Genetic Illness, Inherited Disorder)	disease or condition caused by an absent or defective gene or by a chromosomal aberration (e.g., Down Syndrome)	American Heritage Science Dictionary:2005
Guidelines	1) indication or outline of recommendations (e.g., for use/guidance in clinical practice) 2) systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances	

Term	Definition	Reference
Health Care, Healthcare	activities, services, or supplies related to the health of an individual, including: a) preventative, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, counselling, service, or procedure with respect to the physical or mental condition, or functional status, of a patient or affecting the structure or function of the body; b) sale or dispensing of a drug, device, equipment, or other item pursuant to a prescription; or c) procurement or banking of blood, sperm, organs, or any other tissue for administration to patients	HIPAA ISO 18308:2011 ISO 21089:2018
Health Care Activity, Healthcare Activity	undertakings (such as assessments, interventions) that comprise a healthcare service	ISO 12773-1:2009
Health Care Agent, Healthcare Agent	See "Agent"	
Health Care Informatics, Healthcare Informatics	scientific discipline that is concerned with the cognitive, information processing and communication tasks of healthcare practice, education and research, including the information science and technology to support these tasks	Directory of the European Standardization Requirements for Healthcare Informatics and Telematics v2.1
Health Care Organization, Healthcare Organization	See "Health Care Provider"	
Health Care Party, Healthcare Party	Individual or organization involved in the process of health care	ISO 18308:2011
Health Care Professional, Healthcare Professional	1) (care provision) individual who is entrusted with the direct or indirect provision of defined healthcare services to an individual subject of care or to populations 2) (qualification) person that is authorized by a nationally recognized body to be qualified to perform certain health services. Note: The types of registering or accrediting bodies differ in different countries and for different professions. Nationally recognized bodies include local or regional governmental agencies, independent professional associations and other formally and nationally recognized organizations. They may be exclusive or non-exclusive in their territory. Examples of health professionals are physicians, registered nurses and pharmacists.	ISO 21089:2018, modified (1,2) CEN 1613:1994, modified (1,2)
Health Care Provider, Healthcare Provider	1) individual or organization licensed, certified or otherwise authorized or permitted to, directly or indirectly, administer or provide health care services, to individuals (patients) or populations, in the ordinary course of business or practice of a profession, including a health care facility 2) generic term used to describe many types of organizations that provide healthcare services	ISO 13606-4:2019, modified (1) ISO 18307:2001, modified (2) JCAHO, modified (2)

Term	Definition	Reference
Health Care Service, Healthcare Service	service provided (by a health care provider) with the intention of directly or indirectly improving the health of the person or populations to whom it is provided	ISO 12773-1:2009
Health Condition	aspect of a person or group's health that may require some form of intervention. Note: These interventions could be anticipatory or prospective, such as enhancing wellness, wellness promotion or illness prevention (e.g., immunization), also symptoms, health problems (not yet diagnosed), diagnoses (known or provisional), e.g., a) diabetes, or physiological changes that affect the body as a whole or one or more of its parts, b) benign positional vertigo, and/or affect the person's well-being, c) psychosis, and/or affect the person's usual physiological state, d) pregnancy, lactation.	ISO 12773-1:2009
Health Information	1) information about a person relevant to his or her health 2) any information, whether oral or recorded in any form or medium, that a) is created or received by a healthcare provider, health plan, public health authority, employer, life insurer, school or university, or healthcare clearing-house; and b) relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual	ISO 18308:2011 (1) HIPAA (2)
Health Insurance Carrier, Health Plan, Payer	individual or group plan that provides, or pays the cost of, medical care; may be public or private entity	HIPAA, modified
Health Issue	concern or situation related to the health of a subject of care, as identified or stated by a specific health care party	ISO 18308:2011, modified
Health Record	account compiled by healthcare providers of a variety of subject of care (patient) health information, such as assessment findings, treatment details and progress notes	JCAHO, modified
Health Record Entry	See "Record Entry"	
Health-related Factors, Social Determinants of Health	1) circumstances, influences, causes or issues that affect or describe a patient's ability to receive or respond to treatment, or maintain wellness (including physical, mental, social, spiritual, community, and/or economic dimensions). A patient's strengths (positive factors) or weaknesses (negative factors) may impact a patient's care or recovery and may be recorded as part of the EHR to support the development of care plans and treatment options (e.g. coverage by insurance (typically a positive factor) versus unemployment (typically a negative factor). Examples of factors include: family support, financial support, health insurance levels, good overall health, employment status/type, access to care, and education level. Heath-related factors may be included in a patient's problem list (e.g. ambulatory status, or addictions). 2) conditions in the places where people live, learn, work, and play affect a wide range of health risks and outcomes	CDC:2018 (2)

Term	Definition	Reference
Identifier	1) (claimed) piece of information used to claim an identity, before a potential corroboration by a corresponding authenticator 2) (unique) identity information that unambiguously distinguishes one entity from another one in a given identity domain	ISO 13606-1:2019, modified (1) ISO 21089:2018
i.e.	that is to say or in other words ("id est" in Latin)	
Immunization History	history of immunization (vaccination) events for a subject of care (patient)	
Implied Consent	consent inferred from signs, actions, or facts, or by inaction or silence	ISO 18308:2011
Including	indicates a minimum set of values or options which must be instantiated	
Indelible	impossible to remove or erase	ISO 21089:2018
Individually Identifiable Health Information	information, including demographic information collected from an individual, that a) is created or received by a healthcare provider, health plan employer, or healthcare clearing-house; and b) relates to the past, present or future physical or mental health or condition of an individual, the provision of healthcare to an individual, or the past, present, or future payment for the provision of healthcare to an individual, and i) identifies the individual, or ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual	HIPAA
Industry	in occupational health, self-reported title (with associated code) that identifies the kind of business (i.e., primary business activity), conducted by a person's employer	HL7 Occupational Data for Health Project
Information	interpreted set(s) of data that can assist in decision making; data to which meaning is assigned, according to context and assumed conventions	JCAHO, modified US National Security Council, modified
Integrity	(message) proof that message content has not altered, deliberately or accidentally in any way, during transmission See also "Data Integrity"	ISO/IEC 7498-2:1998
Interchange standards	standards specifying the form(s), method(s) and mechanisms by which information, typically electronic data, are exchanged	
Internet Engineering Task Force (IETF)	large open international community of network designers, operators, vendors, and researchers concerned with the evolution of the Internet architecture and the smooth operation of the Internet	
Interoperability	1) (semantic) ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged 2) (standards-based) ability for data to be shared across clinicians, laboratory, hospital, pharmacy and patient, facilitated by data exchange schema and standards, regardless of the application or application vendor; also, ability of health information systems to work together within and across organizational boundaries in order to advance the health status of, and the effective delivery of healthcare for, individuals and communities.	IEEE:1990, modified (1) ISO 21089:2018 (1,2)

Term	Definition	Reference
Interoperate, Interoperation	coordinate information, services, and/or functionality among systems	
Interpretation	conclusion that a health care provider (or possibly machine - in the form of clinical decision support) comes to based upon knowledge and scrutiny/analysis of information available (e.g., in the course of diagnosis/treatment of a subject's (patient's) condition	
Intervention	1) action(s) whose purpose is to improve health or to alter the course of a disease 3) action(s) taken to maximize the prospects of achieving goals of care, including the removal of barriers to success	
Input mechanism	approach, typically utilizing a user interaction device, for data input, (e.g., keyboard and mouse)	
Intolerance	non-immunological adverse physiological sensitivity to a substance; may be manifest by an inability to endure, withstand, absorb, or metabolize a substance (e.g. lactose)	
Jurisdictional Law	statute and/or legal requirement of a domain or realm	
Legal Hold, Litigation Hold	operation that tags or otherwise cues special access management and destruction suspension for Record Entries deemed relevant, consistent with organization policy under the legal doctrine of "duty to preserve", also notifying records owners and other designated parties of the special data controls on access, retention, and destruction processes	ISO 21089:2018
Legal Hold Release, Litigation Hold Release	operation that untags or otherwise removes cues for special access management and destruction suspension for record entries as organization policy had required under the legal doctrine of "duty to preserve", also notifying records owners and other designated parties of the release of special data controls and that the organization will resume normal data retention and destruction processes; provide notification to the records owners of the release of data and that the organization will resume normal data retention and destruction processes	ISO 21089:2018
Lifecycle	(record entry) stages during the lifespan of a health record entry instance	ISO 21089:2018
Lifecycle Event	(record entry) operation occurring during the course of record entry instance lifespan such as: originate, retain, amend (update), attest, exchange (transmit, receipt), access/view	ISO 21089:2018
Lifespan	(record entry) period of time from the point of record entry instance origination to the point of record entry instance loss, destruction or deletion	ISO 21089:2018
Link	(record entries) perform an operation that connects (establish a relationship between) two or more separate but related health records so that access or use of one necessarily means equal access to ability to use of all the connected records	ISO 21089:2018
Logical Record	reference to a data record that is independent of its physical location; may be physically stored in two or more locations	
Longitudinal Personal Health Record, Lifetime Personal Health Record	permanent, coordinated record of significant information, in chronological sequence; may include all historical data collected or be retrieved as a user designated synopsis of significant demographic, genetic, clinical and environmental facts and events maintained within an automated system	ASTM E1384:2013

Term	Definition	Reference
Maintain	keep, preserve and support	
Manage	take charge of; master	
Management	conducting, administering, supervising	
Mask. Masking	1) conceal from view, disguise or hide 2) process of obscuring (masking) specific data elements within data stores. It ensures that sensitive data is replaced with realistic but not real data. The goal is that sensitive customer information is not available outside of the authorized environment. Effective data masking requires data to be altered in a way that the actual values cannot be determined or reengineered, functional appearance is maintained, so effective testing is possible.	
Master File	dataset containing definitional entries in common across system, business units and, in some cases, organizational boundaries (e.g., master files may include data group and attribute definitions, security policy and domain definitions, security classification and clearance definitions, healthcare service definitions, care protocol definitions)	ISO 21089:2018
Master Patient Index	catalog within a given healthcare organization which serves as a directory to patients (subjects of care)	CPRI, modified
MAY	indicates an optional, permissible action	
Measure	collect quantifiable data about a function or process	JCAHO
Medical	relating to the study or practice of medicine	
Medication reconciliation	comprehensive evaluation of a patient's medication regimen any time there is a change in therapy in an effort to avoid medication errors (e.g., omissions, duplications, dosing errors, or drug interactions), and to observe the patient's medication compliance and adherence patterns. The medication reconciliation process should include a comparison of the existing and previous medication regimens and should occur at every transition of care in which new medications are ordered, existing orders are rewritten, existing orders are adjusted, or if the patient has added nonprescription medications to [his or her] self-care.	American Pharmacists Association
Merge	(record entries) perform an operation that combines or joins the content of two or more health records, resulting in a single logical record entry (e.g., includes health records found to be registered as separate patients but are really one)	ISO 21089:2018
Message	logically ordered dataset designed to communicate essential information between systems	ISO 21089:2018
Messaging Standard	in the context of Health IT, specifies the structure and format of electronic data exchange, enabling disparate healthcare applications to exchange key sets of clinical and administrative data	HL7
Metadata	data that define and describes other data	ISO/IEC 11179-3:2003 ISO 1087-1:2000
Need-to-Know	requirement for access to, knowledge, or possession of the classified information in order to perform tasks, functions or services	ISO/IEC 2382:2015, modified
Network	electronic data transmission facility which can comprise just a point-to-point wire link between two devices, or a complex arrangement of transmission lines	ISO 21089:2018

Term	Definition	Reference
Non-repudiation	(of origination, of submission, of receipt) service that provides proof of the integrity and source of data (both in an unforgeable relationship) and that only the signer could have created the associated signature, which can be verified by any party	ASTM E1762:2013, modified
Notes	brief record of facts, topics, or thoughts, often captured as an aid to memory; clinical documents are forms of clinical notes	
Notice, Notification	information presented or transmitted to an interested party; may not require recipient's action or response	
Obfuscation	action of making something obscure, unclear, or unintelligible	
Occupation	in occupational health, self-reported title (with an associated code) that identifies a person's type of work, i.e., the set of activities or tasks that a person is paid to perform or, if unpaid, the person's contribution to a household/family business/community	HL7 Occupational Data for Health Project
On-Demand	as soon as or whenever required	
Order	prescription of a qualified health care professional regarding diagnostic testing and/or treatment of a subject of care (patient)	
Order sets	1) pre-defined template that provides support in making clinical decisions for a specific condition or medical procedure 2) a grouping of orders that standardizes and expedites the ordering process for a common clinical scenario	
Originate	(record entry) create or initiate an entry in a persistent datastore, such as an electronic or personal health record (EHR/PHR)	ISO 21089:2018
Organization	unique framework of authority within which a person or persons act, or are designated to act towards the same purpose	ISO 6523:1998
Organizational Policy	generally adopted by a governance body within an organization: 1) deliberate system of principles to guide decisions and achieve rational outcomes 2) statement of intent, typically implemented as a procedure or protocol	
Outcome	1) result of the performance (or non-performance) of a function or process(es) 2) condition or occurrence traceable to a cause	JCAHO, modified
Output	produce and deliver health record content in the form and manner expected by a viewer or recipient (e.g., printout, visual rendering, tagged or delimited data stream)	ISO 21089:2018
Party	natural person or any other entity considered to have the same rights, powers and duties of a natural person	ISO/IEC 15414:2015
Patient	1) subject of care 2) individual who is receiving or registered as eligible to receive healthcare services or having received healthcare services	ISO 21089:2018, modified (2)
Patient and Family Preferences	health care treatment choices influenced by but not limited to language, religious, or cultural preferences selected by the subject of care (patient) and his/her family	

Term	Definition	Reference
Patient Identifier	set of data that is used for uniquely distinguishing one patient from another patient	
Patient Record	See "Health Record"	
Patient Representative	designated to bearing the character or power of the patient; acting for the patient's benefit, e.g. guardian, legal representative, surrogate, or advocate	UK CancerWeb
Patient Safety	See "Safety"	
Patient-Level Data	within the context of the Population Health arena, refers to data that is collected (and analyzed) regarding a single patient (e.g., "Person123 is left-handed"). Note: patient-level data may be de-identified.	
Patient-Originated Data	Data provided and/or entered by the subject of care (patient), e.g., an individual (or their representative) may provide or enter health information from personal memory and/or by using information that was recorded on a piece of paper	American Academy of Pediatrics:2011
Performance	way in which an individual, group or organization carries out, accomplishes and fulfils its important functions and processes, usually with regard to effectiveness	JCAHO, modified
Performance Indicator, Performance Measure	standard or criteria used to assess the capabilities of functions, processes and outcomes within an organization; quantification of processes and outcomes using one or more dimensions of performance, such as timeliness or availability.	JCAHO, modified
Permission (Parental)	affirmation or agreement, provided by the parent or guardian of a patient, to undertake a clinical action; in most cases, clinicians have an ethical (and legal) obligation to obtain parental permission to undertake recommended medical interventions See also "Consent, Informed Consent"	American Academy of Pediatrics:2011
Persistent	1) data in a final form intended as a permanent record, such that any subsequent modification is recorded together with the original data 2) existing or remaining in the same state for an indefinitely long time	ISO 21089:2018 (2)
Pesonal Health Information (PHI)	1) information about an identifiable person which relates to the physical or mental health of the individual, or to provision of health services to the individual, and which may include: a) information about the registration of the individual for the provision of health services; b) information about payments or eligibility for healthcare with respect to the individual; c) a number, symbol or particular assigned to an individual to uniquely identify the individual for health purposes; d) any information about the individual collected in the course of the provision of health services to the individual; e) information derived from the testing or examination of a body part or bodily substance; f) identification of a person (e.g. a health professional) as provider of healthcare to the individual 2) information that concerns a person's health, medical history, medical treatment or genetic characteristics in a form that enables the person to be identified	ISO 27799:2008 (1) MEDSEC (2)
Personal Health Record (PHR)	health record, or part of a health record, for which the subject of care or a legal representative of the subject of care is the data controller	ISO 18308:2011

Term	Definition	Reference
Phenotype	physical appearance of an organism as distinguished from its genetic makeup; the phenotype of an organism depends on which genes are dominant and on the interaction between genes and environment	American Heritage Science Dictionary:2005
PHR	personal health record See "Personal Health Record"	
PHR-S FM	HL7 Personal Health Record System Functional Model	
PHR Account	1) provides the PHR Account Holder with: a) access to his or her personal health data and b) access to the functions of a PHR system 2) conceptually similar to a bank account (e.g., health record bank), which provides controlled access to data and to the functions of the system in which the data are stored; may be hosted on a stand-alone personal computer, within an EHR system (i.e., as a portal), a web-based system, or other portable electronic device	
PHR Account Holder	1) subject of the PHR Account, controls access to and permissions of the PHR Account, and controls the movement of data in and out of the PHR Account 2) synonymous with the terms "patient" or "consumer." Note: In certain PHR Account matters related to decision making, the term PHR Account Holder is also meant to include the PHR Account Holder Proxy, as he or she may be the PHR Account Holder's substitute decision maker.	
PHR Account Holder Proxy	person who is appropriately authorized to act on behalf of the PHR Account Holder within the PHR Account; could be a family member, friend or substitute decision maker	
PHR Application	set of software that offers PHR functionality and related services to PHR Account Holders through individual PHR Accounts	
PHR Authorization	permission granted by a PHR Account Holder to an Authorized PHR User to use function(s) of the PHR System for intended and permitted purposes. PHR Authorizations may be to specific individuals or to specific remote computer systems. PHR Authorizations also may be role-based, i.e., granted to a class of individuals or a class of remote computer systems. PHR Authorizations may include varying levels of access, e.g., "read-only," "write-only," "read/write," etc. The exact permissions and levels of PHR Authorizations may vary based on different PHR Sponsors and PHR Service Providers.	
PHR Service Provider	organization that delivers PHR Application(s) to PHR Account Holders. A PHR Service Provider may offer PHR Applications directly to PHR Account Holders or indirectly via contracted PHR Sponsors. PHR Service Providers are often PHR system vendors, enabling the distinction between direct PHR Application providers and third-party sponsors (such as physician offices or hospitals). See "PHR Sponsor".	

Term	Definition	Reference
PHR Sponsor	entity that provides PHR Account Holders access to a given PHR Application (e.g., a physician office, a health system, an employer, a pharmacy, a health plan). A PHR Sponsor may not necessarily be the same entity as the PHR Service Provider.	
Policy	1) set of rules related to a particular purpose. A rule can be expressed as an obligation, an authorization, a permission or a prohibition. 2) formal, approved description of how a governance, management of clinical care process is defined, organized and carried out	ISO/IEC 15414:2015 (1) JCAHO (2)
Population Health	1) art, process, science and a product of enhancing the health condition of a specific number of people within a given geographical area 2) health outcomes of a group of individuals, including the distribution of such outcomes within the group	
Practice Guideline	See "Guideline"	
Prevention	actions taken to: 1) reduce susceptibility or exposure to health problems (primary prevention) 2) detect and treat disease in early stages (secondary prevention) 3) alleviate the effects of disease and injury (tertiary prevention)	
Primary Record	records captured and maintained for the chief purpose of: a) supporting individual health and providing healthcare; b) clinical use including care, interventions and decision making	ISO 21089:2018
Principal	highest in rank, authority, character, importance, or degree; most considerable or important; chief; main (e.g., principal diagnosis)	
Principal provider	healthcare provider who is the most responsible and accountable for managing or coordinating the members of a care team(s) that deliver health care to an individual	
Principle	an accepted or professed rule of action or conduct, an adopted rule or method for application in action	
Privacy	1) quality or state of being hidden from, or undisturbed by, the observation or activities of other persons 2) freedom from intrusion into the private life or affairs of an individual when that intrusion results from undue or illegal gathering and use of data about that individual and the ability of an individual or group to seclude themselves, or information about themselves, and thereby express themselves selectively 3) right of individuals to keep information about themselves from being disclosed to anyone 4) (information practices) security principle that protects individuals from the collection, storage and dissemination of information about themselves and the possible compromises resulting from unauthorized release of that information	AHIMA, modified (1,2,3) ISO/IEC 2382-8:2015, modified (2,3) HL7 Security Work Group (4)
Problem	(clinicial) issue for which an assessment is made and a plan or intervention is initiated	ISO 12773-1:2009, modified

Term	Definition	Reference
Problem List	1) list that includes the most important health problems facing a subject of care (patient) such as nontransitive illnesses or diseases and injuries suffered; may include signs and symptoms 2) list of a patient's problems that serves as an index to his or her record 3) list of current and active diagnoses as well as past diagnoses relevant to the current care of the patient	US Centers for Medicare and Medicaid Services (CMS) (3)
Process	sequence of goal-directed, interrelated series of actions, events, mechanisms, or steps taking place in a prescribed manner and leading to the accomplishment of some result	ISO/IEC 15414:2015, modified
Profile	(EHR or PHR System) Functional Model subset, in which functions have been designated for particular purposes, domains, services, specialties or care settings. A Functional Profile (FP) allows selection of functions and conformance criteria from the base FM, as well and revisions and extensions to those functions and criteria.	HL7 EHR/PHR System Functional Model Chapter 2: Conformance Clause
Protocol	1) (care) written plan specifying the procedures to be followed in giving a particular examination, conducting research, or providing care for a particular condition (2) set of instructions that describe the procedure to be followed when investigating a particular set of findings for a subject of care (patient), or the method to be followed in the management of a given disease	ISO 21089:2018 (1)
Provide the ability to ...	phrase that conveys the notion that the corresponding FM-specified system functionality will enable a user to perform a given task, rather than having the system perform the task itself (i.e., without user intervention)	
Provider	See "Health Care Provider"	
Pseudonymize, Pseudonymization	1) removal of individually identifiable data/record content by replacing with identity-bearing content for another entity 2) sub-class of de-identification which can be performed with or without the possibility of re-identifying the subject of the data/record content	ISO 25237:2017, modified ISO 21089:2018, modified
Public Health	1) area of health care that deals with the health of populations in geo-political areas, such as States and counties 2) field of medicine concerned with safeguarding and improving the health of the community as a whole	Dorland's Medical Dictionary
Purpose	1) (of use) context and conditions of data/record use at a specific point in time, and within a specific setting 2) (of a system) practical advantage or intended effect of the system	ASTM 1986:2013, modified (1) ISO/IEC 15414:2015 (2)
Quality	1) character, characteristic or property of anything that makes it good or bad, commendable or reprehensible, thus the degree of excellence that a thing possesses 2) totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs or fitness for use.	JCAHO, modified CEN TC251, modified
Quality Improvement	approach to the continuous study and improvement of the processes of providing healthcare services to meet the needs of patients and others	JCAHO

Term	Definition	Reference
Reactivate	(record entry) recreate or restore full status to health records and their content from a previous state of deletion or deprecation	ISO 21089:2018
Real-time	actual time during which something takes place; the system may partly analyze the data in real time (as it comes in)	
Receive	capture an exchange artifact (e.g., message, document, API resource) from an external system or entity (e.g., acquire data objects that exist elsewhere for potential inclusion in an EHR or PHR record)	ISO 21089:2018
Recommendation	a suggestion or proposal as to the best course of action, especially one put forward by an authoritative body See "Guidance"	
Record	See "Health Record"	
Record Entry	1) (evidentiary) persistent documentation, recording or evidence of facts, context, findings and observations, with associated supporting system data or metadata, regarding an action taken to support individual health or provide healthcare 2) (indivisible notation) semantically indivisible clinical statement which may be structurally large or small, but which loses meaning if broken up 3) (instance) discrete notation, recording instance or dataset in (EHR/PHR/other) system datastore, suitably attributed, which forms part of, or a whole, contribution to a health(care) record at one place and time	ISO 21089:2018 (1,2) ISO 18308:2011, modified (3) ISO 13606-2:2019, modified (3)
Registry	1) directory-like system that focuses solely on managing data pertaining to one conceptual entity 2) server capable of holding data for the systematic and continuous follow up of information objects maintained in accordance with specific rules	Canada Health Infoway (1) ISO 21089:2018
Re-identify	restore information to data that would allow the identification of the source of the information or the information subject	HL7 Version 3 Standard: Security and Privacy Ontology, Release 1
Release of Information	disclosure of documents containing (subject of care-) identifiable information to a third party requestor	CPRI
Reminder	type of notification that is specifically to prompt the recipient with information they may have previously received (e.g. an appointment reminder); distinct from an alert, where immediate action is required	
Report	1) make or present an official or formal account or summary of 2) formal rendering (e.g., document) that gives information about a particular subject	ISO 21089:2018
Repudiate, Repudiation	denial by a user or a system that it was the source of certain information or the sender or receiver of a message or the agent of an action requested from the system	ASTM E1762:2013, modified
Resource	entity which is essential to some behaviour and which requires allocation or may become unavailable because it is in use or used up	ISO/IEC 15414:2015
Resource Utilization	1) process of making the best use of available resources in order to achieve a particular objective 2) total amount of resources consumed, compared against the amount of resources planned for a specific process	