
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

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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).

	Profiles	
Personal Health		
Supportive		
Record Infrastructure and Trust Infrastructure		

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.

Personal Health	PH.1.0 Account Holder Profile
	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 research, records management and evidentiary support, usability, or preventative care.

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.

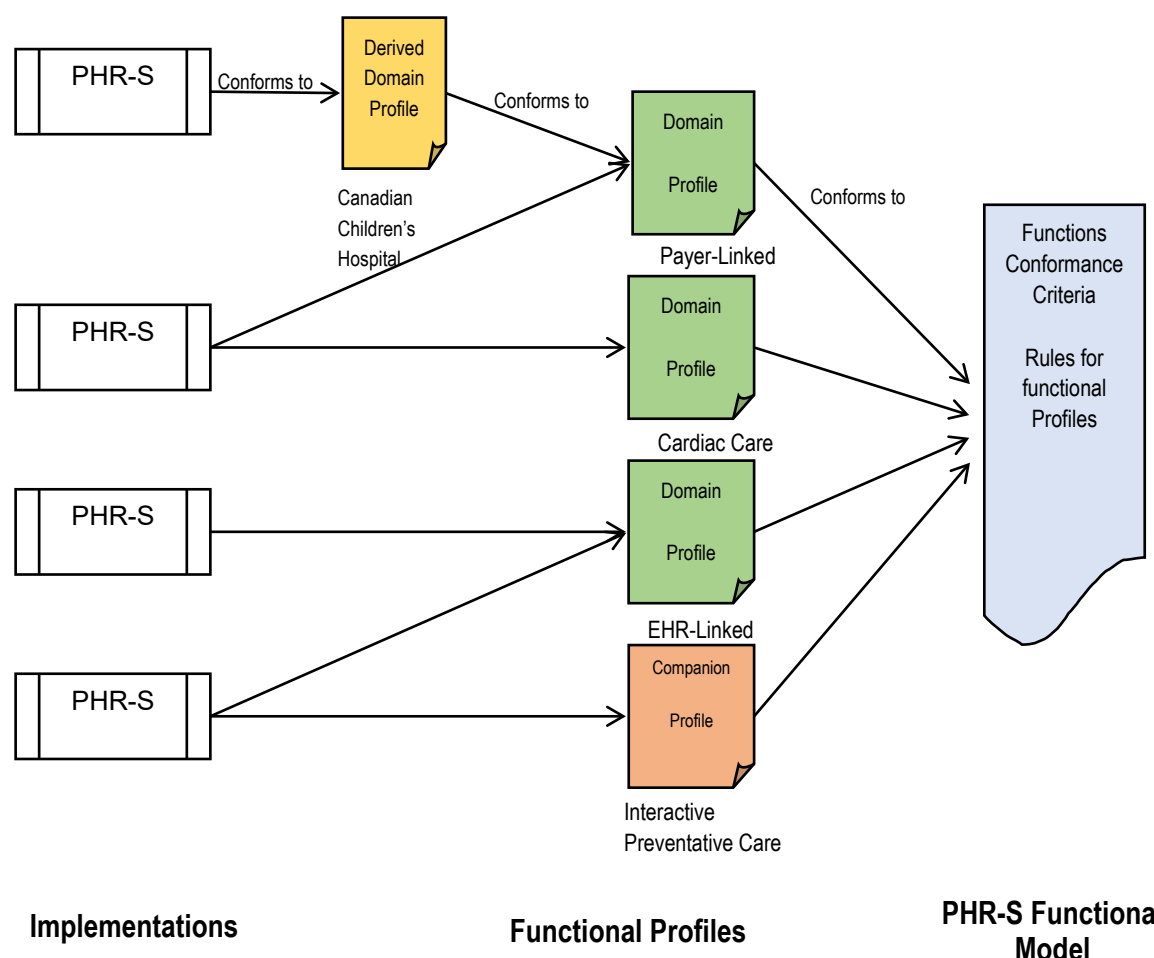


Figure 3: Conformance Relationships

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 than 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.

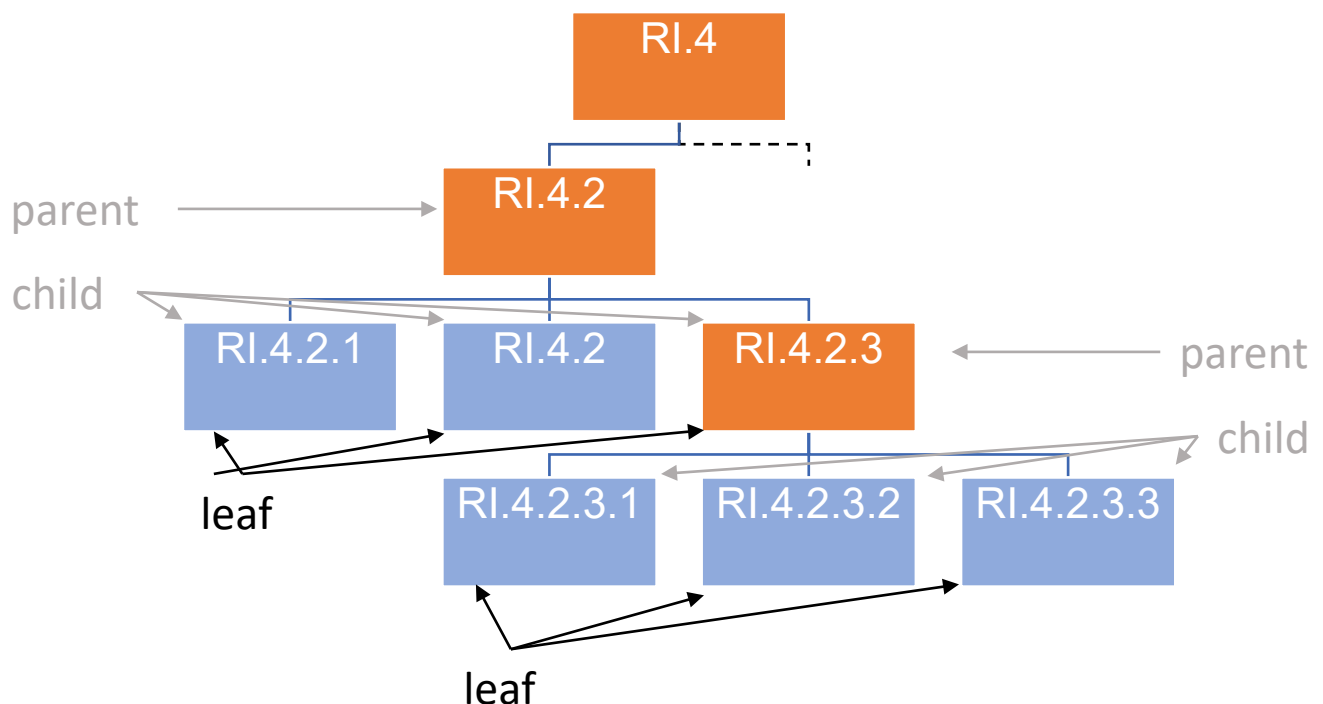


Figure 4: Portion of the PHR-S FM hierarchical structure

(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.

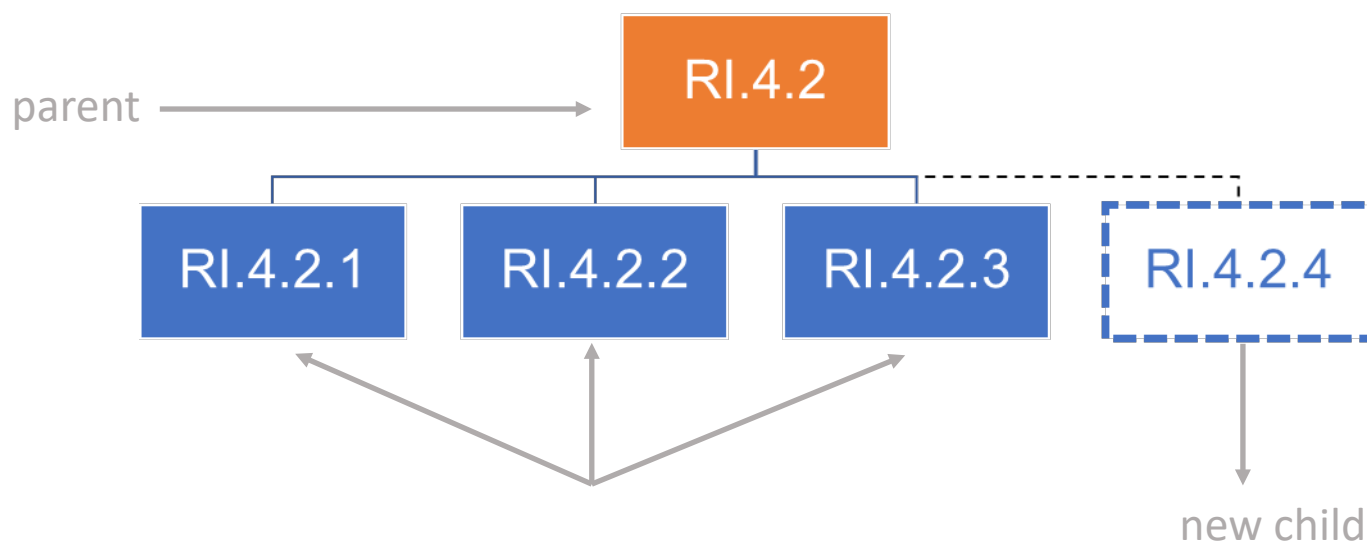


Figure 5: Creating a new function

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 FM's 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

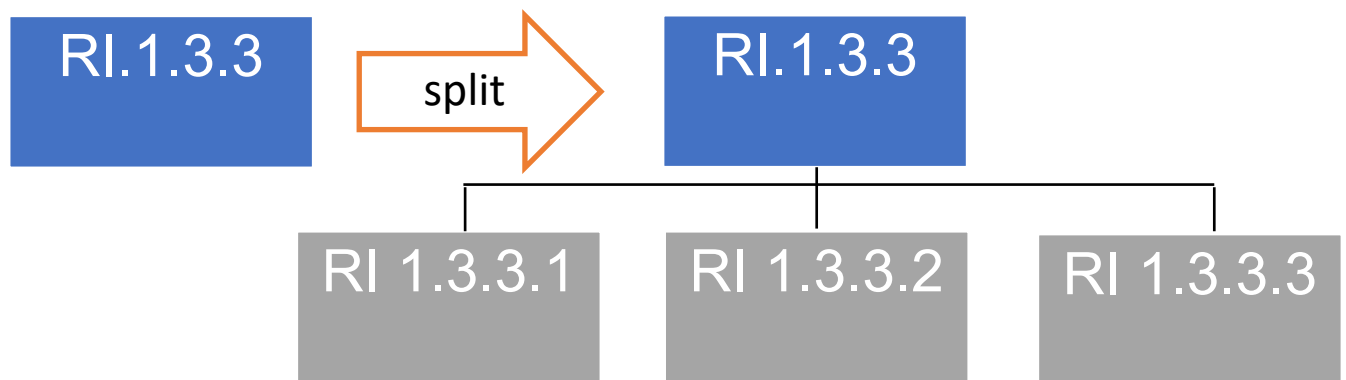


Figure 6: Splitting a function

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.

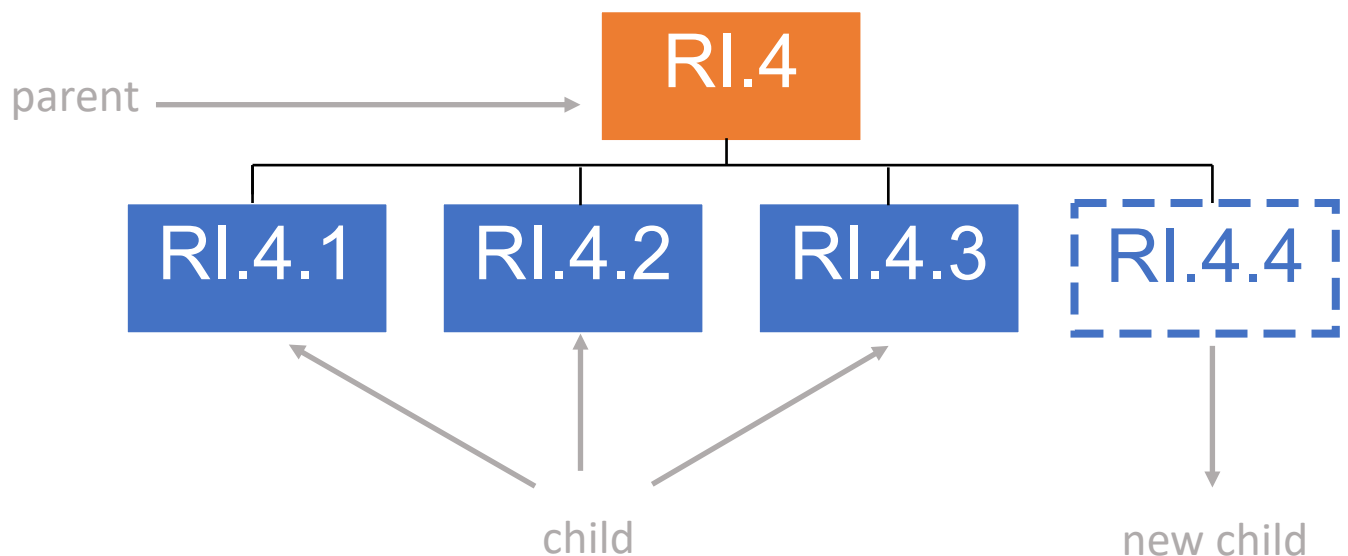


Figure 7: Adding a New Child Function

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.