

# **HL7 EHR Work Group**

## **Personal Health Record System Functional Model, Release 1 Draft Standard for Trial Use July 2008**

### **Chapter Two: Conformance Clause**

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Chapter 2: Introduction ( <i>Reference</i> ).....	2
Conformance Clause .....	2
1. Scope and Field of Application (Normative) .....	2
2. Concepts (Normative) .....	3
2.1 <i>Functional Profiles</i> .....	3
2.2 <i>Conformance Model</i> .....	3
3. Normative Language (Normative) .....	4
4. Conformance Criteria (Normative).....	4
4.1 <i>Criteria in the Functional Profile</i> .....	4
4.2 <i>'Dependent SHALL' Criteria</i> .....	5
4.3 <i>Referencing Other Criteria or Functions</i> .....	5
5. Functional Model Structure and Extensibility (Normative) .....	6
5.1 <i>Hierarchical Structure</i> .....	6
5.2 <i>Naming Convention</i> .....	7
5.3 <i>Priorities</i> .....	7
5.4 <i>Extensibility</i> .....	7
6. Functional Profile Conformance (Normative).....	7
6.1 <i>Rules for Functional Profiles</i> .....	8
6.2. <i>Rules for Creating New Functions in Functional Profiles</i> .....	9
6.3. <i>Rules for Derived Functional Profiles</i> .....	10
6.4 <i>Conformance Statement</i> .....	10
7. Use Cases and Samples ( <i>Reference</i> ) .....	11
7. 1 <i>Functional Profile Use Cases</i> .....	11
7.2 <i>Sample Functional Profile Conformance Clauses</i> .....	12
8. Interpreting and Applying 'Dependent SHALL' ( <i>Reference</i> ) .....	13
8.1 <i>General Concepts</i> .....	13
8.2 <i>Rationale for 'Dependent SHALL'</i> .....	14
8.3 <i>How to Apply the 'Dependent SHALL'</i> .....	14
9. Definitions ( <i>Reference</i> ).....	16

## Chapter 2: 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:

1. This conformance clause defines what it means to conform to the PHR-S FM.
2. 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.
3. Conformance criteria are associated with every function in the PHR-S FFM.
4. 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 FFM.

The technical and management staff of the U.S. National Institute of Standards and Technology, Information Technology Laboratory (NIST) provided orientation and education to the PHR Work Group (PHR WG) of the EHR WG on conformance. With significant input and support from NIST, we have developed this conformance clause. The existing profile development “How To” guide for the EHR-S FM is referenced and applicable for PHR-S profile development.

## Conformance Clause

### 1. *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 PHR-S FM, which is via the system’s conformance to a particular functional profile. 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.

## 2. Concepts (Normative)

### 2.1 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 PHR-S FM 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 7 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, Employer or Payer). 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.

A formal process exists for registering and balloting functional profiles. Functional profiles that are submitted to the HL7 EHR WG with an attestation of conformance to Chapter 2: Conformance Clause of the HL7 PHR-S FM Standard and successfully complete review by the WG are designated as "*Registered functional profiles*". Registered functional profiles that undergo formal public scrutiny via the HL7 consensus process as an Informative EHR WG ballot at the Work Group level will be designated as *HL7 Informative functional profiles*. HL7 Informative functional profiles are eligible to undergo full membership ballot via the HL7 consensus process. *For additional information on registering and/or balloting functional profiles, see the reference information in the EHR-S How To Guide for Profiles.*

### 2.2 Conformance Model (Normative)

Conformance to the PHR-S FM is defined for functional profiles. A functional profile conforms either (1) directly to the PHR-S FM or (2) to another conforming functional profile. A PHR system does not conform directly to the PHR-S FM; rather, it conforms to a functional profile. Thus, functional profiles claim conformance to the PHR-S FM and PHR systems claim conformance to one or more conforming functional profiles. Figure 1 illustrates this relationship.

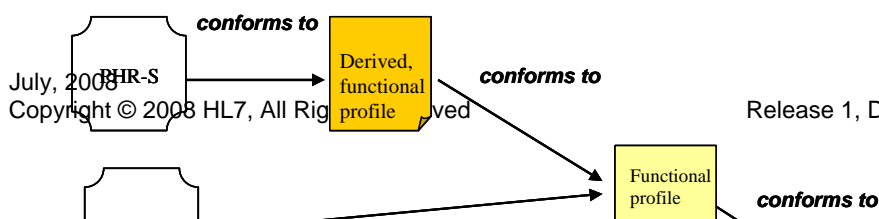


Figure 1 Conformance Relationships

### 3. 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'.

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

### 4. Conformance Criteria (Normative)

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.

#### 4.1 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. Functional profiles **MAY** also add additional criteria.

#### *4.2 '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 "in accordance with user role, organizational policy, 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 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 criterion only if the criterion is applicable per the stated dependency in the PHR-S FM

#### *4.3 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.

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 from where it came.

## 5. PHR-S FM Structure and Extensibility (Normative)

### 5.1 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 2 illustrates this hierarchical structure.

The PHR-S FM is represented as a hierarchical list of functions, consisting of functional headers and 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 a "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.

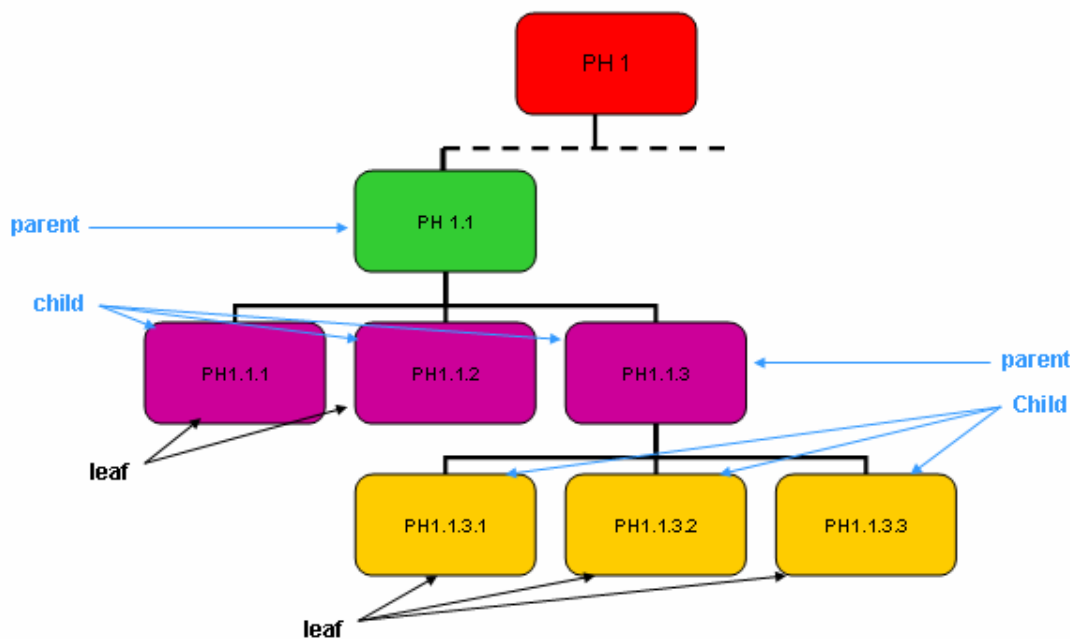


Figure 2 Portion of the PHR-S FM hierarchical structure

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.

## 5.2 Naming Convention

Functional profiles **SHALL NOT** change the name or statement of a function except to allow for alignment to realm specific nomenclature. 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. The specific ISO Country Code designation is left up to the profile developers. It is recommended that the profile contain the mapping of the PHR-S FM function name and/or statement and the realm-adjusted name and/or statement. It is further recommended that the HL7 Affiliate for a specific realm would coordinate the use of ISO Country Codes for all profiles under the specific realm.

## 5.3 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 2008, 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-2008, EF-2009).

## 5.4 Extensibility

To accommodate changes in technology as well as functional profiles' needs, the PHR-S FM is designed for extensibility. 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 6.2.

# 6. Functional Profile Conformance (Normative)

A functional profile claiming conformance to the PHR-S FM **SHALL** meet all requirements specified in the Rules for Functional profiles.

### 6.1 Rules for Functional Profiles

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.

#### 6.1.1 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 4.3.
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 6.2.
8. Be structured in accordance with the structural requirements defined for the PHR-S FM in Section 5.

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

1. Create additional functions according to the rules specified in Section 6.2.
2. Contain conformance criteria more specific and limited in scope than those of the PHR-S FM.

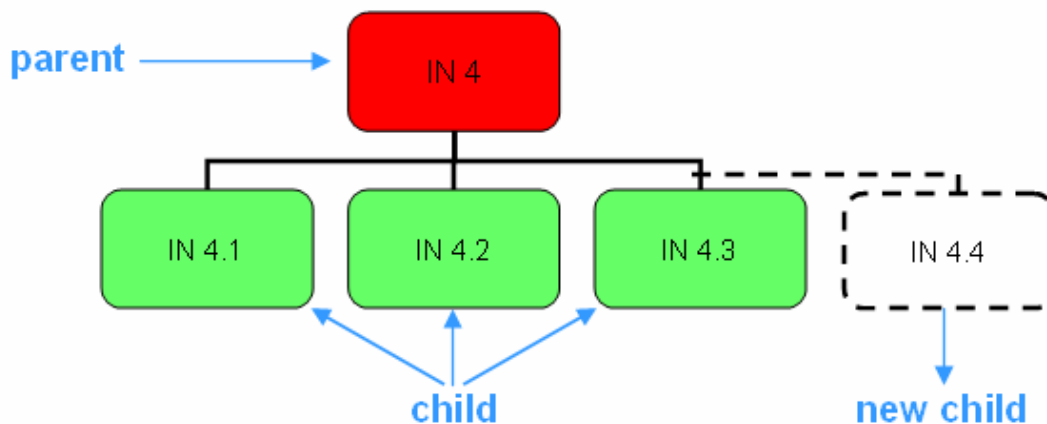
3. Replace the text 'standard(s)-based' found in some criteria with specific standards and/or specifications named at the most discrete level of designation.
4. Change a 'should' criterion to a 'shall' or a 'may' criterion.
5. Change a 'may' criterion to a 'shall' or a 'should' criterion.
6. Ignore a '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.

#### 6.1.3 Functional 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 5.2.
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).

### 6.2. 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 . Figure 3 illustrates the addition of a new child function.



**Figure 3 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.
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).
  4. When a child function is created, its parent function **SHALL** be labeled a header ("H") function.
  5. 'Non-leaf' functions **SHALL NOT** be split. This preserves the structure of the underlying PHR-S FM in the functional profiles.

If new children functions are created by a functional profile, then these new functions **SHOULD** be forwarded to the HL7 EHR WG for review. The EHR WG **MAY** use this as input for changes to the PHR-S FM (e.g., inclusion, relaxation of conformance criteria).

### 6.3. 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 6.1.
2. Adhere to the rules for creating new functions as specified in Section 6.2, 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.

### 6.4 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.

## **7. Use Cases and Samples (Reference)**

### **7.1 Functional Profile Use Cases**

#### **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 4 on the next page. 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 Work Group for registration review, comment and ballot.

#### **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 4 on the next page.

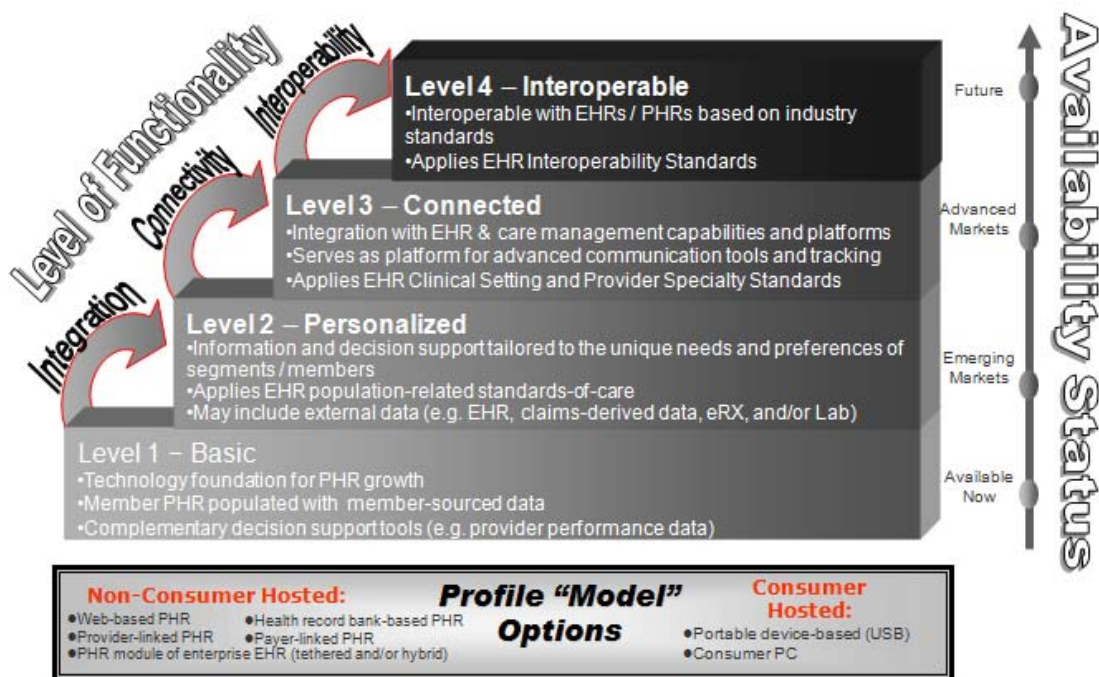
The Community of Interest or stakeholder does not want to create a new functional profile from scratch. After looking at the list of HL7 Registered PHR Functional Profiles, they find an existing functional profile that is very close to what they want. Using this functional profile as the base, they accept 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.

#### **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 7.2). 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 6.1 and 6.2 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 4: Examples of Profile Options by "Model" and/or Level of Functionality**

## 7.2 Sample Functional Profile Conformance Clauses

To aid functional profile developers in developing a conformance clause for their functional profile, as required by Section 6.1 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.

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

This 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 with 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.

**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.

**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.

## **8. Interpreting and Applying 'Dependent SHALL' (Reference)**

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 system **SHALL** enable PHR-S security administrators to grant authorizations to principals according to user role, organizational policy, or jurisdictional laws.*

### **8.1 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:

- User role which applies to the various PHR Account Holder's possible or alternative roles – which may be care setting specific or not, or may be related to whether the PHR is about them or is for their dependent.
- Organizational policy 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.
- Jurisdictional law 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 "in accordance with user role, organizational policy or jurisdictional law" or other appropriate grammatical tie-in words (e.g., "based on" rather than "in accordance"). 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 system **SHALL** enable 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 Table 1 below.

	'SHALL' Criterion	'Dependent SHALL' Criterion
<b>Must be present in the functional profile?</b>	Yes, either verbatim or modified (e.g., constrained or refined)	Yes, verbatim. If a dependency exists, add additional criteria reflecting the dependency.
<b>Must be implemented by PHR systems?</b>	Yes.	Situational - only implement if 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'**

## 8.2 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).

## 8.3 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 system **SHALL** enable PHR-S security administrators to grant authorizations to principles in accordance with HIPAA\*.

2. The system **SHALL** enable 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**

- 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 3) in these new criteria.

Examples:

1. The system **SHOULD** enable PHR-S security administrators to grant authorizations to principals.

2. The system **MAY** enable PHR-S security administrators to grant authorizations for roles.
3. The system **SHOULD** enable PHR-S security administrators to grant authorizations within contexts.
4. The system **SHALL** enable PHR-S security administrators to grant authorizations for roles for organizations with ten employees or more.

## 9. Definitions (Reference)

Additional terms are listed in the HL7 PHR-S FM Glossary.

Base functional profile:	An existing functional profile from which new (child) functional profiles are created/derived.
Conformance:	The fulfillment of a product, process, or service of specified requirements.
Conformance criteria:	Requirements indicating the behavior, action, or capability that constitutes implementation of the function.
Conformance clause:	A section of a specification that defines the requirements, criteria, or conditions to be satisfied in order to claim conformance.
Conformance Statement:	A 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.
Derived functional profile:	A functional profile that is created from a base functional profile. Also known as a child functional profile.
Extension:	The ability for a PHR-S to incorporate additional functionality beyond what is defined in a functional profile.
Functional profile:	A 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.
Informative functional profile:	A registered functional profile that has successfully completed formal public scrutiny via the HL7 consensus process.
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.
Registered functional profile:	A functional profile that has successfully completed HL7 EHR Work Group registration process and review.
Situational criterion:	Criterion that is required if the circumstances given are applicable.

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., lab 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 physical record may be operated by a number of parties, including 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 access to 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.

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