HL7 EHR Technical Committee

PHR-System Functional Model, Release 1 DSTU November 2007

Chapter One: Overview

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Preface

i. Notes to Readers

The HL7 PHR-S Functional Model, through these and other documents, was released for public comment in August 2007. The PHR-S Functional Model has undergone extensive review and debate over the last year by the PHR Work Group (PHR WG), and the WG now invites your comments on it through an official ballot process. Your comments will be used to revise this Draft Standard for Trail Use (DSTU) version of the PHR Functional Model in preparation for a version that is intended to be balloted in the future as a fully accredited standard.

ii. Acknowledgements

The EHR Technical Committee is indebted to the following PHR WG facilitators for their contributions towards the material presented here. There have been a number of other work group members who have contributed greatly to the development of the PHR-S FM, but whose names cannot be listed here for brevity's sake.

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Gary Dickinson	WG Co-Facilitator	CentrifyHealth, Inc.
John Ritter	WG Co-Facilitator	Intel
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Donald T. Mon, PhD	Co-facilitator: Chapter 1 - Overview	AHIMA
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Lynne Rosenthal	Co-facilitator: Chapter 2 – Conformance Clause	National Institute of Standards and Technology
Jaime Ferguson	Co-facilitator: Chapter 3– Personal Health	Kaiser Permanente
Lenel James	Co-facilitators: Chapter 4– Supportive	Blue Cross Blue Shield Association
Pat Van Dyke	Co-facilitator: Chapter 4– Supportive	The ODS Companies, Delta Dental Plans Association
Tim McKay	Co-facilitator: Chapter 5 – Information Infrastructure	Kaiser Permanente

Name	Role	Organization
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Sue Mitchell	Co-Facilitator: Publications Working Group	Omnicare Information Solutions
John Ritter	Co-Facilitator: Publications Working Group	Intel Corporation

iii. Changes from Previous Release

This is the first balloted version of this document.

Chapter 1 Introduction and Overview

1 Background

1.1 Who is HL7?

Established in 1987, Health Level Seven (HL7) is an American National Standards Institute (ANSI) accredited, not-for-profit standards-development organization, whose mission is to provide standards for the exchange, integration, sharing, and retrieval of electronic health information; support clinical practice; and support the management, delivery and evaluation of health services. ANSI accreditation, coupled with HL7's own procedures, dictates that any standard published by HL7 and submitted to ANSI for approval, be developed and ratified by a process that adheres to ANSI's procedures for open consensus and meets a balance of interest requirement by attaining near equal participation in the voting process by the various constituencies that are materially affected by the standard (e.g., vendors, providers, government agencies, consultants, non-profit organizations). This balance of interest goal ensures that a particular constituency is neither refused participation nor is it allowed to dominate the development and ratification of a proposed standard. More information and background on ANSI is available on their website at: http://www.ANSI.org

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

The PHR-S WG makes a clear distinction between a PHR and a PHR System (PHR-S). The PHR is the underlying record that the software functionality of a PHR-System maintains. There has been much discussion surrounding the definition of a personal health record. The HL7 PHR-S Functional Model does not attempt to define the PHR, but rather identify the features and functions in a system necessary to create and manage an effective PHR.

The overarching theme of a PHR-S involves a patient centric tool that is controlled for the most part, by the individual. It should be immediately available electronically, and able to link to other systems, either in a “pull-push” or “push-pull” method. The PHR-S is intended to provide functionality to help an individual maintain a longitudinal view of his or her health history, and may be comprised of information from a plethora of sources—i.e., 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 a wealth of forms (advance directives) and advice (diet, exercise, disease management). A PHR-S would

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 could be connected to providers, laboratories, pharmacies, nursing homes, hospitals and other institutions and clinical resources.

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 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, graphing for 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 self-management, patient-provider communication and quality outcomes.

1.3 PHR WG Background and Charge

The HL7 Personal Health Record Work Group (PHR WG) was established in 2005 by the HL7-EHR Technical Committee. The WG consisted of a diverse set of stakeholders, including consumer advocates, clinicians, PHR system software suppliers, as well as IT and health information management professionals.

At that time, the EHR TC was focused on establishing the EHR-S Functional Model as a fully accredited ANSI standard. However, the EHR-TC anticipated that at some future point, an EHR-S would need to exchange health information with the emerging PHR-S. Thus, the PHR WG was initially charged with developing a Functional Model (FM) that identified the functions within a PHR that would be needed to exchange health information with an EHR. To that end, the PHR WG began its work by conducting an environmental scan on PHR requirements against which a system would then need to conform, as well as on PHR system functions already implemented in systems in the market. More recently, the WG investigated functionality of PHR-S developed outside of the United States and attempted to include such perspectives into the development of the FM.

The WG reviewed PHR definitions, functional descriptions, and other useful material from Connecting for Health, AHIMA, and the National Cancer Institute.

It also received a vast amount of information from the volunteers in the WG, who had direct knowledge of functionality of the systems in the market, expertise in protecting the confidentiality of health information and the privacy of the individual, and functionality of EHR systems (EHR-S).

The PHR WG developed its first PHR-S Functional Model based on the Connecting for Health Functional Description. As it was developing that early iteration, the healthcare industry was clearly moving forward on the need for and benefits of the personal health record. Consequently, after a little over a year's worth of effort, the WG concluded that it should develop a standard for a full PHR-S, rather than simply the exchange of health information between a PHR-S and an EHR-S as per its original charge. However, the original charge was not lost, as functions for the exchange of health information between a PHR-S and an EHR-S are simply a subset of PHR-S functions.

2 Purpose and Scope

2.1 PHR-S Functional Model Scope

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

2.2 This Functional Model Is Not:

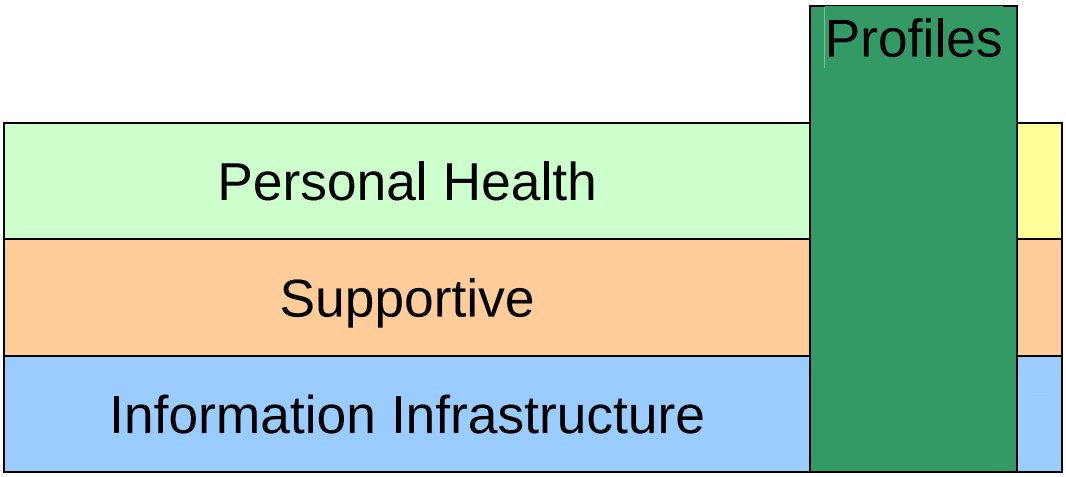
- A messaging specification
- An implementation specification
- A conformance specification
- A specification for the underlying PHR
- An exercise in creating a definition for a PHR
- A conformance or conformance testing metric

The information exchange enabled by the PHR-S supports the retrieval and population of clinical documents, event summaries, minimum data sets, claims attachments, and in the future will enable a longitudinal health record.

3 Overview and Definition of the Functional Model

The PHR-S Functional Model is divided into three sections: Personal Health, Supportive, and Information Infrastructure; yet to be developed functional profiles which overlay the outlined functions; and assigned priorities for the functions in the profile (see Figure 1). While the Functional Model should contain all reasonably anticipated PHR-S functions, it is not itself intended as a list of all functions to be found in a specific PHR-S. Functional profiles can be used to constrain the functions to an intended use. This document defines the Functional

Model and describes the general use of profiles and priorities (see the Appendix, PHR Sources, for examples of stakeholders that might create profiles).



(figure 1)

As previously mentioned, the PHR-S Functional Model is divided into three main sections: Personal Health, Supportive, and Information Infrastructure. Within the three 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 will eventually be the "normative" or ANSI accredited standard) as well as other associated information such as Description (reference information not 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 Functional Model is intended to include the superset of functions from which a subset can be generated by the account holder to illustrate what they need within their PHR-S. Only a subset of this inclusive set of functions will apply to any particular PHR-S.

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
Information Infrastructure	IN.1.0	Health Record Information Management/
	IN.2.0	Standards Based Interoperability
	IN.3.0	Security
	IN.4.0	Auditable Records

(figure 2)

3.1 PHR-S Functional Outline: The Functions and Their Use

PHR functions 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.

- Establish a standards-based method by which each realm (country) can apply these PHR functions to care settings, uses, and priorities.

- Inform those concerned with secondary use of PHR data and national infrastructure what functions can be expected in a PHR System.

3.1.1 Personal Health Functions

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

Example of PH function: The PH functions will ensure that the individual's demographic information is captured and maintained so that the individual is unambiguously identified.

Actors for Personal Health: The account holder is the principal user of these functions, because the data is descriptive of the user/owner of the PHR-S.

3.1.2 Supportive PHR Functions

Description: The Supportive functions are the subset of functions that assist with the administrative and financial requirements associated with the delivery of health care. Supportive PHR functions also provide input to systems that perform medical research, promote public health and seek to improve the quality of health care delivered.

Example of Supportive function: During the encounter, the Supportive functions could electronically query local immunization registries to ensure that the child is currently registered and determine the child's immunization status. After treatment, supportive PHR functions could report any immunization to an

immunization registry and will provide any encounter data required by financial and administrative systems.

Actors for Supportive functions: The account holder is the principal user of these functions, but under certain circumstances, health care providers might be expected to perform certain supportive functions.

3.1.3 Information Infrastructure Functions

Description: The information infrastructure functions consist of common functions that support Personal Health and Supportive functions. Information Infrastructure functions ensure that the PHR provides information privacy and security, promote interoperability between PHRs and potentially EHRs, and helps make PHR features accessible and easy to use.

Example of Information Infrastructure: The system must operate in a secure environment. Information Infrastructure functions ensure that PHR data, such as an immunization record, can only be viewed and updated after an individual or system authenticates identity with the PHR-S.

Actors for Information Infrastructure: These functions are expected to be performed transparently by PHR-S applications on behalf of PHR-S end users.

3.2 Components of PHR-S Functional Model

As previously stated, this package is released for public comment. However, please be aware that after the model has been refined through your comments, it is intended that the Functional Model will be released for ballot voting for approval as a fully accredited standard. Though the Functional Model contains many components, not all components are technically those that must be adhered to as part of the standard. Those components are provided in the model to offer more explanation, details, or guidance.

The components that are not technically the standard that must be adhered to are called “reference” components. Those that must be adhered to as part of the standard are called “normative” components.

Status	Description
Reference	Content of the PHR-S Functional Model Package that contains information that clarifies concepts or otherwise provides additional information to aid understanding and comprehension. Reference material is not balloted as part of the standard.
Normative	Content that is part of the PHR-S Functional Model which HL7 committee members and interested industry participants have formally reviewed and balloted following the HL7 procedures for Balloting Normative Documents. This HL7 developed Functional Model document has been successfully balloted as a normative standard by the HL7 organization.

(table 1)

Each function in the HL7 PHR-S Functional Model is identified and described using a set of elements or components as detailed below.

ID	Type	Name	Statement /Description	See Also in PRH-S FM	See Also in ERH-S FM	Conformance Criteria
		Intended as Normative	**Intended as Normative/ Reference**	**Intended as Reference**	**Intended as Reference**	**Intended as Normative**

(figure 3)

Function ID

This is the unique outline identification of a function in the outline. The Personal Health functions are identified by 'PH' followed by a number (Example PH.1.1.3.1; PH.1.1.3.2). Supportive functions are identified by an 'S' followed by a number (Example S.2.1; S.2.1.1). Information Infrastructure functions are identified by an 'IN' followed by a number (Example IN.1.1; IN.1.2). Numbering for all sections begins at n.1.

Function Type – Intended as Reference, Content in Chapters 3, 4 and 5

Indication of the line item as being a header (H) or function (F).

Function Name – Intended as Normative, Content in Chapters 3, 4 and 5

The name of the Function.
Example: Account Holder Profile

Function Statement – Intended as Normative, Content in Chapters 3, 4 and 5

Brief statement of the purpose of this function.
Example: Maintain PHR account holder demographics, preferences, advanced directives, consents and authorizations

Description – Intended as Reference, Content in Chapters 3, 4 and 5

Detailed description of the function, including examples if needed.
Example: The person that is the subject of the personal health record is referred to as the account holder to distinguish them as someone other than a patient or subject of the healthcare system. They create a record that begins with their relevant demographic information and includes other administrative statements necessary to provide care including advanced directives and consents for care

See Also in PHR-S FM – Intended as Reference, Content in Chapters 3, 4 and 5

This element is intended to identify relationships between functions within the PHR-S Functional Model. This can help the reader to quickly find all of the functions in the PHR-S FM related to a given concept.

See Also in EHR-S FM – Intended as Reference, Content in Chapters 3, 4 and 5

This element is intended to identify relationships of PHR-S functions to the EHR-S Functional Model. In the development of the PHR-S functions, it was noted that the EHR-S FM contained a similar or related concept. Since it is important not to lose the knowledge of that reference to the EHR-S FM, there are pointers to that EHR-S function in the PHR-S FM document.

Conformance Criteria – Intended as Normative, Content in Chapters 3, 4 and 5.

This element is intended to clarify how conformance to a given function may be viewed. Review Chapter Two: Conformance Clause, Sections 4 and 5, for further information on conformance criterion and their uses.

3.3 The 'Manage Hierarchy'
(what that means for wording consistency in conformance criteria)

Within the PHR working group, there was an intentional effort to create language consistency in the conformance criteria. The "Manage Hierarchy" diagram below was used to create semantic harmony within the conformance criteria, so that if the chapter on personal health has a conformance criteria using the term "nullify", that term had the same meaning if it was used in the Supportive section's conformance criteria.

The levels in the hierarchy are granular and have a parent-child relationship. For example, the diagram below (Figure 4) depicts that managing the "Capture" of information comes from an External Source or from an Internal Source. Similarly, under the 'Maintain' section of the diagram, the term "Store" could invoke all 4 verbs listed below (i.e. save, backup, compact, encrypt, archive). If the parent term was not used, then the respective verbs in the child would be cited individually in the criterion. If the term "Manage" is used, all of the applicable verbs included in the table are encompassed in that criterion.

MANAGE							
Capture		**Maintain**				**Output**	
Input (External)	Create (Internal)	Store	Update	Restrict Access	Remove Access	Read	Export
Receive Accept Download Import	Enter Compute Record	Save Backup Compact Encrypt Archive	Edit Correct Amend Augment Annotate Comment Associate Tag	Hide Mask Filter	Obsolete Inactivate Destroy Nullify Purge	View Report Display Access Present	Send Upload Synchronize

Figure 4

The hierarchical principle above was applied during the development of the PHR-S FM. Additional terms used in the model are found in the model's Glossary. It is important to be consistent in the terminology used in the PHR-S functional model conformance criteria so there is consistent interpretation of the conformance criteria's intent in defining the functionality.

4 Anticipated Uses

HL7 is an international community and supports the development of Functional Profiles, which are country specific (HL7 realm) specifications within a standard.

4.1 Anticipated Development Approach: Functional Profiles

A functional profile is a selected set of functions that are applicable for a particular purpose, group of users, degree of interoperability, custodian, etc. Functional profiles help to manage the master list of functions. It is not anticipated that the full Functional Model will apply to any single PHR-S implementation.

Similar to the EHR-S, a PHR-S does not conform directly to the Functional Model; rather, it conforms to a functional profile. For more information about creating, registering, and balloting functional profiles, see Chapter Two: Conformance Clause, Sections 2 and 6.

Functional profiles are the expression of usable subsets of functions from this PHR-S Functional Model. In this PHR-S Functional Model the reader will see a long list of Function Names and Function Statements, which serve as reasonable representations of functions that may be needed by an individual, or a provider in a clinical environment. The list of functions is not intended to be used in its entirety. For example, the functions outlined in this model apply differently to

different use scenarios. Many of the functions in the model apply to an individual, but some functions (e.g.,PH.1.2.5 Manage family history and genomics) might not be used by anyone. The list of functions is not considered to be in a usable form until a functional profile or constraint is generated.

The act of creating a functional profile is to support a business case for PHR-S use by selecting an applicable subset of functions from the PHR-S Functional Model. For example, a functional profile may be created by a vendor, to develop a unique product for a specific population; or by any person/entity wishing to stipulate a desired subset of functions for a particular purpose or specific realm (see the Appendix). Once an applicable subset of functions has been selected, the person/entity creating the profile gives each function a priority of essential now, essential future or optional. For more information about the steps to creating a functional profile, see the How-to Guide for Creating Functional Profiles.

A Conformance Clause defines the minimum requirements for profiles claiming conformance to the PHR System Functional Model. The Conformance Clause is a high level description of what is required of profiles and implementations. It, in turn, refers to other parts of the standard for details. The Conformance Clause describes concepts critical to the understanding and implementation of the Functional Model, such as: what is a profile, what are conformance criteria, and what is mandatory versus optional. A Conformance Clause can also provide a communication between the implementers (vendors) and users (buyers) as to what is required, and gives meaning to the phrases, “conforming profile” and “conforming PHR system”. Additionally, it serves as the basis for testing and certification activities that may be performed by organizations external to HL7.

APPENDIX: PHR Sources (Reference Section)

It is widely believed that health care costs are increasing at a rate that is not sustainable for the long term. Furthermore, there is a perception that the quality of care being delivered is not commensurate with the expense. There are many diverse and complicated reasons for these cost and quality trends, and as one means to address them, many health care industry stakeholders are beginning to engage consumers to address these issues through individual awareness and knowledge. On an ever increasing basis, Integrated Delivery Networks, Healthcare providers and Payers have been engaging their patients and members through innovative care management programs and wellness initiatives. The PHR has the potential to be an important component for the success of these programs, and there are tremendous opportunities surrounding their use and adoption.

As detailed in the Conformance Chapter, the PHR System Functional Model is a broad-based model. It is expected that profiles will be defined for both varied stakeholders and targeted uses of a PHR system. For example, a functional profile may be appropriate to reflect the specific requirements and expectations of one system from a particular stakeholder source e.g. Hospital, Medical Group, Payer, Health Record Bank. We provide examples below. (See diagram below and related description in Section 7 of Chapter 2, Conformance)

A. Provider-linked (tethered model)

The provider-linked PHR, sometimes called a tethered PHR, is distinguished from other PHR models primarily by its link to views of the medical record contained in the clinician-controlled electronic medical record (EHR). It is also distinguished by its ability to integrate transactional functions such as secure email exchange, e-prescribing, refill requests and clinical appointment scheduling into the PHR.

A provider linked PHR can accommodate self-entered data, data from medical devices and data from administrative sources as long as the data is tagged with the source of entry. The direct link to the provider's EHR enables consumers to flag any inaccuracies, reviewable by both the provider and account holder, thus improving the quality of the medical record and helping to increase patient safety. A benefit of the provider-linked PHR is the way that it naturally integrates the connection between providers and consumers for bidirectional information delivery.

Provider-linked PHRs can support interoperability with other PHRs, EHRs, and health information exchanges. Provider systems (and consumers) also can make choices about how they handle persistence (the amount of time their record is available for use) over time and the type and amount of access

for other providers (those who are not part of the group that "provides" the PHR to the individual).

B. Payer-based

One visible trend that has emerged in the health insurance industry over the past several years is a concept referred to as Care Management or Care Coordination. While originally focused on acute care situations, insurers have taken a very proactive role in supporting and encouraging consumer engagement in their health care to increase their understanding and involvement in during times of health as well as times of chronic or acute illnesses. This is all part of an over arching industry effort to engender overall member/patient wellbeing, in addition to controlling costs and improving outcomes. As part of this trend of greater payer participation in current disease management/care coordination activities, the payer-based PHR supports the role of the insurers as an "engaged actor" in the consumer engagement process.

The payer-based PHR can include aggregated system-populated clinical data (e.g., diagnoses, procedures, medications, lab results, etc.) from claims data as well as multiple providers, in addition to consumer entered data (e.g., allergies, history). The payer-based PHR could also include encounter information (i.e., a list of treating providers, dates and contact information) and patient messaging (reminders, appointment scheduling, research sources, etc.) Payer-based PHRs could include both patient-only access models and models supporting interoperability with health information exchanges and provider electronic medical record systems.

Many commercial health plans are moving in this direction, and will soon have data to demonstrate improvements in health outcomes. And recently, Medicare initiated a number of pilots to explore the use of PHRs with Medicare beneficiaries – CMS, as the largest payer in the United States, seeks to encourage Medicare beneficiaries to use PHRs to track their health care services and as a resource for better communication with their providers, with the hope that these tools will in fact improve health care and outcomes.

C. Health Record Bank

Health Record Banks, or Trusts, serve as a persistent secure health information repository for an individual. Information is aggregated from multiple sources for multiple uses with all access and use controlled by the individual concerned. It is likely that most health record banks will provide a comprehensive personal health record based upon the information, although this is not an explicit requirement.