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Health informatics — HL7 Personal Health Record System Functional Model, Release 2 (PHRS FM)

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

PROOF/ÉPREUVE

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted (see www.iso.org/directives).

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

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

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

0.3.2 Designation of Sections

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

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

1 Scope

1.1 PHR-S Functional Model Scope

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

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

This Functional Model Is Not:

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

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

2 Normative References

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

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

3 Terms and Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 The Functional Model

4.1 Overview and Definition

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

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

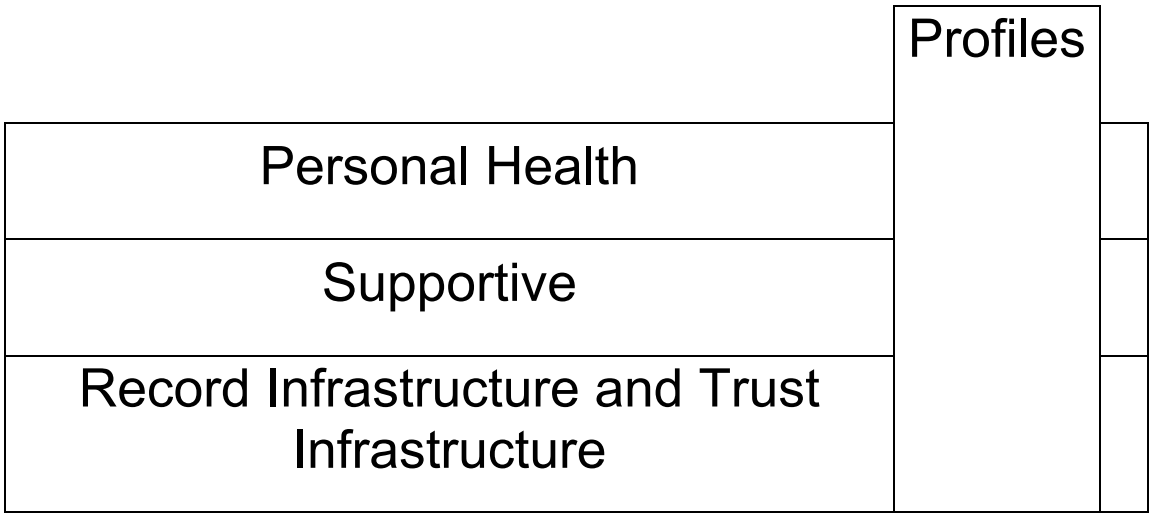

Figure 1: PHR-S Function List Sections

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

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