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Health informatics — HL7 Personal Health Record System Functional Model, Release 1 (PHRS FM)

Informatique de santé — Modèle fonctionnel d'un système de dossier de santé personnel, version 1 (PHRS 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.

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 documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215, *Health informatics*.

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Introduction

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. In September 2013, the standand was updated, re-balloted, and the comments reconciled – resulting in the current version.

Information about HL7 is given in Annex F.

Changes from Previous Release

Not Applicable for Release 1.

Background

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.

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1 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 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 Annex D, Anticipated Uses).

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, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 and context*

3 Terms and definitions

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

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

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