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

*Informatique de santé — Modèle fonctionnel d'un système de
dossier de santé personnel, version 2 (PHR-S FM)*



This document is a preview generated by ELS



COPYRIGHT PROTECTED DOCUMENT

© ISO 2023

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	vi
Introduction.....	viii
0.1 Notes to Readers	viii
0.2 Changes from Previous Release	viii
0.3 Background.....	viii
0.3.1 Personal Health Record (PHR) Versus a Personal Health Record System (PHR-S)	viii
0.3.2 Designation of Sections.....	ix
1 Scope.....	1
1.1 PHR-S Functional Model Scope.....	1
2 Normative References.....	1
3 Terms and Definitions.....	1
4 The Functional Model.....	2
4.1 Overview and Definition	2
4.2 PHR-S Functional Outline.....	6
4.2.1 The Functions and Their Use	6
4.2.2 Personal Health Section Functions	6
4.2.3 Personal Health Support Section Functions	6
4.2.4 Record Infrastructure Section and Trust Infrastructure Section Functions	6
4.3 Common Major Concepts Across the Model.....	7
4.3.1 Consistency in the Conformance Criteria.....	7
4.3.2 PHR Account Holder Privacy	7
4.3.3 Functionality versus Implementation.....	7
4.3.4 Relevant Standards	7
4.3.5 Consents, Authorizations, and Preferences.....	7
4.3.6 Scope of Downstream Uses of PHR data.....	8
4.4 Type of Profiles.....	8
5 Conformance Clause.....	8
5.1 Introduction (Reference).....	8
5.2 Scope and Field of Application (Normative).....	9
5.3 Concepts (Normative)	9
5.3.1 Functional Profiles	9
5.3.2 Conformance Model (Normative).....	10
5.3.3 Profile Traceability (Normative).....	11
5.4 Normative Language (Normative).....	12
5.5 Conformance Criteria (Normative).....	12
5.5.1 Introduction.....	12
5.5.2 Criteria in the Functional Profile.....	12
5.5.3 'Dependent SHALL' Criteria	12
5.5.4 Referencing Other Criteria or Functions.....	12
5.6 PHR-S FM Structure and Extensibility (Normative)	13
5.6.1 Hierarchical Structure.....	13
5.6.2 Naming Convention.....	14
5.6.3 Priorities	14
5.6.4 Extensibility	14
5.7 Functional Profile Conformance (Normative).....	14
5.7.1 Introduction.....	14
5.7.2 Rules for Domain Functional Profiles	14
5.7.3 Rules for Creating New Functions in Functional Profiles.....	16
5.7.4 Rules for Derived Functional Profiles	17
5.7.5 Conformance Statement.....	18
5.7.6 Rules for Companion Functional Profiles.....	18
5.8 Use Cases and Samples (Reference)	19
5.8.1 Functional Profile Use Cases	19
5.8.2 Sample Domain Functional Profile Conformance Clauses.....	20
5.9 Interpreting and Applying Conditional 'SHALL' (Reference).....	21

5.9.1 Construction of Conformance Criteria Using the Conditional 'SHALL' Overview.....21

5.9.2 General Concepts21

5.9.3 Rationale for 'Dependent SHALL'22

5.9.4 How to Apply the 'Dependent SHALL'22

6 Glossary.....24

6.1 Preface (Reference)24

6.2 Introduction (Normative).....24

6.3 Overview (Reference)24

6.4 The Action-Verb Structure (Normative).....24

6.4.1 Secure (System) Hierarchy24

6.4.2 Data Management Hierarchy25

6.4.3 How Action-Verbs are defined.....26

6.4.4 Deprecated Action-Verbs.....32

6.5 Guidelines for Use (Reference)35

6.5.1 General Guidance35

6.5.2 Constructing Rigorous Conformance Criteria.....36

7 PHR System Conformance Claim via Self-Attestation.....37

8 Glossary Supplement: Record Lifecycle Events and Descriptions (Normative)37

8.1 Record Lifecycle Events (See RI.1.1.1).....37

Annex A (Normative) Function List.....40

Annex B (Informative) Glossary of Terms for the EHR-S FM.....41

Annex C (Informative) Background71

C.1 What is HL7?71

C.2 The HL7 Electronic Health Records Work Group.....71

C.3 PHR WG Background and Charge71

Annex D Bibliography73

Annex E (Normative) Function List.....74

Annex F (Informative) PHR Sources75

F.1 Provider-linked.....75

F.2 Payer-linked.....75

F.3 Health Record Bank.....76

F.4 Hybrid Payer & Provider Linked.....76

F.5 Web-based, Consumer-centric Model76

Annex G (Informative) Anticipated Uses77

G.1 International Community and Realm Specifications.....77

G.2 Anticipated Development Approach: Functional Profiles.....77

Annex H (Informative) Mobile Device Impact on – and Issues related to – PHRs78

H.1 Introduction78

H.2 PHR Relationship to Mobile Devices78

H.3 Trustworthiness of Mobile Device Information Sources78

H.4 Possibility of Consumer Alteration of Professionally-sourced Data78

H.5 Possibility of Other Alterations of Professionally-sourced Data.....78

H.6 Possibility of Insufficient/Unexpected Governance or Management of Professionally-sourced Data79

H.7 Interoperability Standardization within Health Information Exchange Environments79

H.8 Various Types of Mobile Devices.....79

H.9 Functionality (or capability) –Nuances of Various Information Exchange Systems79

H.10 Labeling of Mobile Devices (and corresponding software) as “Regulated” by the FDA79

H.11 Amount or Type of Data80

H.12 Future Vision.....80

H.13 Location of Data-At-Rest.....80

H.14 Management of lost, stolen, or misplaced mobile devices81

H.15 Consents, Authorizations, and other Governance issues81

H.16 Location Awareness Services81

H.17 Use of multiple mobile devices81

H.18 Usage heuristics81

H.19	Difference Between “Patient-entered” and “Patient-sourced” Data.....	82
H.20	Difference Between “Author-of-the-data” and “Source-of-the data”.....	82
H.21	Relationships between PHR, EHR, and Mobile Devices.....	82
H.22	Responses to Rules-engine Requests	83
H.23	Security and Privacy Obligations Vary Between Providers and Consumers	83

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 document should be noted (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

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

This document was prepared by HL7 (as ANSI/HL7 PHRSFM, R2-2021) and drafted in accordance with its editorial rules. It was assigned to Technical Committee ISO/TC 215, *Health informatics* and adopted under the "fast-track procedure".

This first edition of ISO 16527 cancels and replaces the ISO/HL7 16527:2015, which has been technically revised.

The main changes are as follows:

- updates to many functional requirements, including those relevant to:
 - patient advance directives, consents and authorizations;
 - PHR account management, activation, deactivation and account transfers;
 - allergies, intolerances and adverse reactions;
 - problem list management and integration from multiple sources;
 - care plans, treatment guidelines and protocols;
 - clinical decision support;
 - nutrition and dietary information;

- health calendar;
- annotation of externally sourced information;
- record corrections and amendments;
- reduction of data duplication – same data from multiple sources;
- customized data views and reports;
- Record Infrastructure including:
 - record entry management,
 - lifespan and lifecycle events – fully compatible with ISO/HL7 10781 – Electronic Health Record System Functional Model, Release 2.1;
- Trust Infrastructure including:
 - authorization,
 - authentication,
 - access control and audit – fully compatible with ISO/HL7 10781 – Electronic Health Record System Functional Model, Release 2.1.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 Notes to Readers

The HL7 Personal Health Record System Functional Model (PHR-S FM) was approved as a Draft Standard for Trial Use (DSTU) in July 2008. In September 2010 the PHR-S FM was presented to ISO TC215 as a New Work Item Proposal (NWIP) ballot and received comments from the international community. The comments from that ballot were used to update and improve the draft standard. The standard was updated, re-balloted, and the comments reconciled in September 2013 resulting in Release 1, and again in 2019 resulting in Release 2.

0.2 Changes from Previous Release

This personal health –focused standard (PHR-S FM) was developed in harmony with the clinically-focused HL7 EHR System Functional Model (EHR-S FM). When the EHR-S FM's layout was enhanced from Release 1 format to Release 2 format, the HL7 Personal Health Record Work Group determined to update and harmonize the PHR-S FM from Release 1 format to Release 2 format as well. The PHR-S FM will follow the format of the EHR-S FM with respect to the replacement of the Information Infrastructure Section with two individual sections: the Record Infrastructure section and the Trust Infrastructure section.

0.3 Background

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

The PHR WG makes a clear distinction between a PHR and a PHR System (PHR-S). The PHR is the underlying record (e.g., data, information, pictures, sounds, graphs, or videos) that the software functionality of a PHR-S maintains. There has been much discussion surrounding the definition of a personal health record. The PHR-S FM does not attempt to define the PHR, but rather to identify system features and functions necessary to create and effectively manage PHRs. The PHR-S FM offers examples of data elements, but is not intended to provide details necessary to specify a data model.

The overarching theme of a PHR-S involves a patient-centric tool that is controlled, for the most part, by the individual PHR Account Holder. A PHR-S should be immediately available electronically and able to link to other systems. The PHR-S provides functionality to help an individual maintain a longitudinal view of his or her health history, and may be comprised of information from a number of sources – e.g., from providers and health plans, as well as from the individual. Data collected by the system is administrative and/or clinical, and the tool may provide access to health-related forms (e.g., Advance Directives) and advice (e.g., diet, exercise, or disease management). A PHR-S might also help the individual collect behavioral health, public health, patient-entered and patient-accessed data (including medical monitoring devices), medication information, care management plans and the like, and might be connected to providers, laboratories, pharmacies, nursing homes, hospitals and other institutions and clinical resources. This PHR-S-FM is universal and therefore generic by design. There may be additional constraints in certain realms or regions. For example, in the US Realm, the management of laboratory results is subject to the Clinical Laboratory Improvement Amendments (CLIA) federal regulation.

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

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

0.3.2 Designation of Sections

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

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

1 Scope

1.1 PHR-S Functional Model Scope

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

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

This Functional Model Is Not:

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

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

2 Normative References

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

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

3 Terms and Definitions

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

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

base functional profile

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