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Zdravstvena informatika - Funkcionalni model HL7 za sistem elektronskih zdravstvenih zapisov, izdaja 2.1 (ERH FM) (ISO/DIS 10781:2023)

Health Informatics - HL7 Electronic Health Records-System Functional Model, Release 2.1 (EHR FM) (ISO/DIS 10781:2023)

Medizinische Informatik - HL 7 Funktionales Modell für ein elektronisches Gesundheitsaktensystem, Ausgabe 2.1 (EHRS FM) (ISO/DIS 10781:2023)

Informatique de santé - Modèle fonctionnel d'un système de dossier de santé informatisé, publication 2.1 (EHR FM) (ISO/DIS 10781:2023)

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Health Informatics — HL7 Electronic Health Record-System Functional Model, Release 2.1 (EHR FM)

*Informatique de santé — Modèle fonctionnel d'un système de dossier de santé informatisé, publication 2.1
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Foreword [from ISO template]

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 10781 was prepared by Technical Committee ISO/TC 215, *Health Informatics*, Working Group 1 on Models and Frameworks.

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0 Introduction

0.1 Notes to Readers

EHR System Functional Model Release 2.1 is based on a series of predecessors, starting in 2004 with the release of the first consensus Draft Standard, followed in 2007 by Release 1, followed in 2009 with Release 1.1 (jointly balloted with ISO TC215 and CEN TC251), followed in 2014 with Release 2.0 (jointly balloted with ISO TC215, CEN TC251, DICOM, SNOMED (IHTSDO), CDISC and GS1). HL7 also published Release 2.01 as an unballoted errata version in 2017.

0.2 Changes from Previous Release

The HL7 EHR-System Functional Model Release 2.1 had its first normative ballot in December 2019. Following are key changes from Release 2.0:

- Includes updates from HL7 errata Release 2.01;
- Record Infrastructure Section is updated to include three new Record Lifecycle Events: verify, encrypt and decrypt. There are now a total of 27 Record Lifecycle Events, describing how an Electronic Health Record System manages health record entries their lifespan, from first point of entry origination/retention to last point of entry deletion or destruction. The 27 Record Lifecycle Events match those specified in ISO 21089-2018, Health Informatics – Trusted end-to-end information flow and HL7 Fast Health Interoperable Resources (FHIR) Record Lifecycle Event Implementation Guide, published a part of FHIR Core STU-3 (March 2017) and now part of FHIR Core R4 (in ballot, September 2018).
- The 27 Record Lifecycle Event definitions/descriptions are updated according to agreements of the HL7 Vocabulary Alignment project (in joint collaboration of the HL7 EHR and Security Work Groups). The Glossary Section also includes those definitions/descriptions.
- The Conformance Clause is updated to include a definition/description of a new type of EHR-S FM Functional Profile (FP): Derived Companion FP.
- Trust Infrastructure is updated to include functions and conformance criteria to support ISO/HL7 Detailed Clinical Models (DCMs).

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0.3 Background

0.3.1 What are Electronic Health Record Systems?

The effective use of information technology is a key focal point for improving healthcare in terms of patient safety, quality outcomes, and economic efficiency. A series of reports from the U.S. Institute of Medicine (IOM) identifies a crisis of "system" failure and calls for "system" transformation enabled by the use of information technology. Such a change is possible by "an infrastructure that permits fully interconnected, universal, secure network of systems that can deliver information for patient care anytime, anywhere.

In developing this EHR-S Functional Model, HL7 relied on three well-accepted definitions: two provided by the U.S. Institute of Medicine and one developed by the European Committee for Standardization/ Comité Européen de Normalisation (CEN). This Functional Model leverages these existing EHR-S definitions and does not attempt to create a redundant definition of an EHR-S.

0.3.2 How were the Functions Identified and Developed?

To achieve healthcare community consensus at the outset, the functions are described at a conceptual level, providing a robust foundation for a more detailed work. Functions were included if considered essential in at least one care setting. Written in user-oriented language, the document is intended for a broad readership.

Functional Granularity is a term used to describe the level of abstraction at which a function is represented. Functions that are commonly grouped together in practice or by major systems have been consolidated where appropriate; functions requiring extra or separate language or involving different workflows have been kept separate where appropriate. For example, decision support is maintained as a separate section, but mapped to other key sections, to indicate the "smart" function behind an action. All of the functions could be expanded into more granular elements but a balance between a usable document and an unwieldy list of functions has been agreed upon. The goal of determining an appropriate level of functional granularity at this time is to present functions that can be easily selected and used by readers of this standard, but that are not so abstract that readers would need to create a large number of additional functions within each function.

Although the determination of functional granularity is a relatively subjective task, systematic evaluation of each function by diverse groups of industry professionals has resulted in a level of granularity appropriate for this EHR-S Functional Model. Every attempt has been made to provide supporting information in the functional descriptions to illustrate the more granular aspects of functions that may have been consolidated for usability purposes.

Keeping with the intent of this EHR-S Functional Model to be independent with regard to technology or implementation strategy, no specific technology has been included in the functions, but may be used in the examples to illustrate the functions. Inclusion of specific technologies in the examples does not endorse or support the use of those technologies as implementation strategies.

The EHR-S Functional Model and specific functions have been widely reviewed by healthcare providers, vendors, public health agencies, regulatory and accreditation bodies, professional societies, trade associations, researchers and other stakeholders. This Standard reflects input from all these reviewers.

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1 Scope

The HL7 EHR System Functional Model provides a reference list of functions that may be present in an Electronic Health Record System (EHR-S). The function list is described from a user perspective with the intent to enable consistent expression of system functionality. This EHR-S Functional Model, through the creation of Functional Profiles for care settings, realms, services and specialties, enables a standardized description and common understanding of functions sought or available in a given setting (e.g., intensive care, cardiology, office practice in one country or primary care in another country).

1.1 EHR-S Functional Model Scope

The HL7 EHR-S Functional Model defines a standardized model of the functions that may be present in EHR Systems. From the outset, a clear distinction between the EHR as a singular entity and systems that operate on the EHR – i.e., EHR Systems is critical. This Standard makes no distinction regarding implementation - the EHR-S described in a Functional Profile may be a single system or a system of systems. Within the normative sections of the Functional Model, the term “system” is used generically to cover the continuum of implementation options. This includes “core” healthcare functionality, typically provided by healthcare-specific applications that manage electronic healthcare information. It also includes associated generic application-level capabilities that are typically provided by middleware or other infrastructure components. The latter includes interoperability and integration capabilities such as location discovery and such areas as cross application workflow. Interoperability is considered both from semantic (clear, consistent and persistent communication of meaning) and technical (format, syntax and physical connectivity) viewpoints. Further, the functions make no statement about which technology is used, or about the content of the electronic health record. The specifics of 'how' EHR systems are developed or implemented is not considered to be within the scope of this model now or in the future. This EHR-S Functional Model does not address or endorse implementations or technology, nor does it include the data content of the electronic health record.

Finally, the EHR-S Functional Model supports research needs by ensuring that the data available to researchers follow the required protocols for privacy, confidentiality, and security. The diversity of research needs precludes the specific listing of functions that are potentially useful for research.

This Functional Model is not:

- a messaging specification
- an implementation specification
- a conformance specification
- an EHR specification
- a conformance or conformance testing metric
- an exercise in creating a definition for an EHR or EHR-S

It is important to note that the EHR-S Function Model does not include a discussion of clinical processes or the interaction of the healthcare actors. However, ISO 13940 Health Informatics – System of Concepts to Support Continuity of Care, is an international standard that does outline key principles and processes in the provision of healthcare. It is recommended that users of the EHR-S FM refer to this standard for clinical processes that EHR systems support.

This EHR-S Functional Model package includes both Reference and Normative sections.

Status	Description
Reference	Content of the EHR-S Functional Model Package that contains information which 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 EHR-S Functional Model which HL7 committee members and interested industry participants have formally reviewed and balloted following the HL7

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procedures for Balloting Normative Documents. This HL7 developed Functional Model document has been successfully balloted as a normative standard by the HL7 organization.
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Table 1: Normative Status Types

Each section within this document is clearly labeled "Normative" if it is normative. For example, in section 5 (Overview) section 5.3 is normative. In section 7, Conformance Clause; sections 7.1 through 7.6 are normative.

In the external Annex A, Function List, the Function ID, Function Name, Function Statement, and Conformance Criteria components are Normative in this Functional Model.

2 Normative References

The following referenced documents are indispensable for the application of this document.

ASTM E1769:1995, Standard guide for properties of electronic health records and record systems

HL7 Fast Health Interoperable Resources (FHIR), Release 4, January 2019

HL7 FHIR Record Lifecycle Event Implementation Guide, part of FHIR Core Release 4, January 2019

ISO 13606:2018, Health Informatics – Electronic health record communication, Parts 1-5

ISO 13940:2015, Health Informatics – System of concepts to support continuity of care

ISO 16527:2017, Health Informatics – HL7 personal health record system functional model, Release 1

ISO 20514:2005, Health Informatics – Electronic health record – definition, scope and context

ISO 21089:2018, Health Informatics – Trusted End-to-End Information Flows

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3 Terms and Definitions**3.1****access control**

a means of ensuring that the resources of a data processing system can be accessed only by authorized entities in authorized ways

3.2**base functional profile**

an existing domain or companion functional profile from which new functional profiles are created/derived

3.3**conformance**

the fulfillment of a product, process, or service of specified requirements

3.4**conformance criteria**

requirements indicating the behavior, action, capability that constitutes implementation of the function

3.5**conformance clause**

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

3.6**conformance statement**

a description of the function in an EHR system that have been implemented. It reflects the degree to which an EHR system has met the functionality has met the functional profile's requirements and may include optional functions and information

3.7**derived functional profile**

a functional domain or companion profile that is created from a base functional profile, (i.e., child functional domain profile to children's hospital domain profile)

3.8**extension**

the ability for an EHR-S to incorporate additional functionality beyond what is defined in the Functional Profile

3.9**functional profile**

a subset of the Functional Model, in which functions have been designated (sometimes in varying degrees) for certain EHR systems or healthcare delivery settings or narrow operation requirements

3.10**informative functional profile**

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

3.11**inherited criterion**

all the conformance criteria listed in a parent function will be inherited by all its children functions

3.12**registered functional profile**

a functional profile that has successfully completed HL7 EHR Work Group registration process and review

3.13**situational criterion**

criterion that is required if the circumstances given are applicable (IF/Then or Dependent SHALL)

4 Overview and Definition of the Functional Model (Normative)

The EHR-S Functional Model is composed of a list of functions, known as the Function List, which is divided into seven sections: Overarching, Care Provision, Care Provision Support, Population Health Support, Administrative Support, Record Infrastructure and Trust Infrastructure.

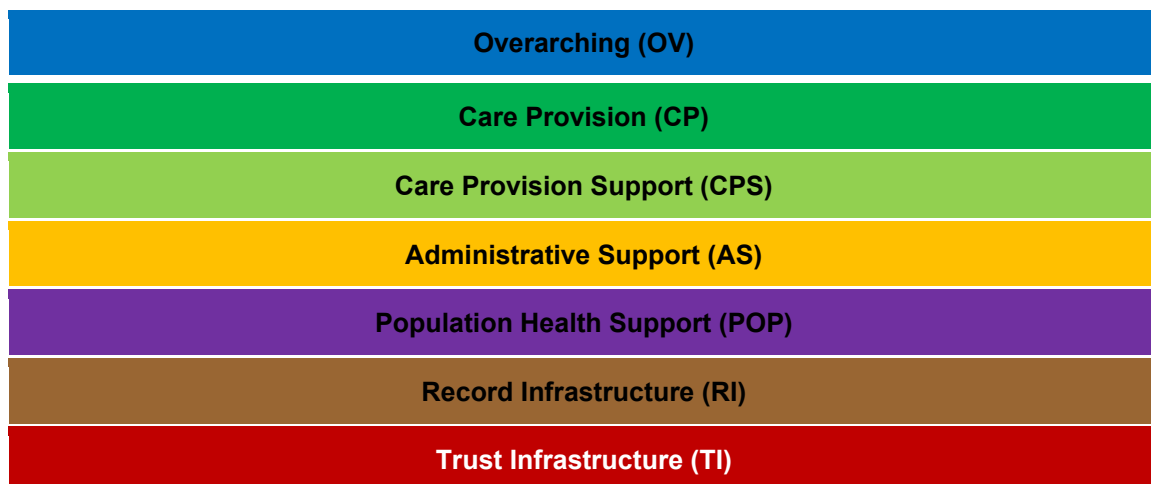


Figure 1: Function List Sections

Within the seven Sections of the Functional List the functions are grouped under header functions which each have one or more sub-functions in a hierarchical structure.

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4.1 Sections of the Function List

Below is a summary description of each of the seven sections:

- **Overarching:** The Overarching Section contains functions and conformance criteria that apply to complete EHR Systems and which are typically included in all EHR-S FM compliant profiles.
- **Care Provision:** The Care Provision Section contains those functions and conformance criteria that enable direct care to a specific patient and facilitate hands-on delivery of healthcare. The functions are general and are not limited to a specific care setting and may be applied as part of an Electronic Health Record supporting healthcare clinics, hospitals, services, specialties, acute, post-acute and long-term care settings.
- **Care Provision Support:** The Care Provision Support Section focuses on functions and conformance criteria supporting the provision of care. This section is organized generally in alignment with Care Provision Section. For example, CP.4 (Manage Orders) is supported directly by CPS.4 (Support Orders).
- **Population Health Support:** The Population Health Support Section focuses on functions and conformance criteria supporting the prevention and control of disease among a group of people (as opposed to the direct care of a single patient). This section includes functions to support input to systems that perform medical research, promote public health and improve the quality of care to a population.
- **Administrative Support:** The Administrative Support Section focuses on functions and conformance criteria enabling the management of clinical practice and facilitating administrative and financial operations. This includes management of resources, workflow and communication with patients and providers as well as the management of non-clinical administrative information on patients and providers.
- **Record Infrastructure:** The Record Infrastructure Section consists of functions and conformance criteria describing how an EHR system manages an EHR record, particularly those functions vital to managing the lifecycle of EHR record entries (such as origination/retention, attestation, amendment/update, access/use, translation/transformation, transmittal/disclosure, receipt, de-identification, archive...) and record entry lifespan (persistence, indelibility, continuity, audit, encryption). RI functions are core and foundational to all other functions of the EHR-S FM (CP, CPS, POP, AS).
- **Trust Infrastructure:** The Trust Infrastructure Section consists of functions and conformance criteria common to an EHR System infrastructure, particularly those functions foundational to system operations, security, efficiency and data integrity assurance, safeguards for privacy and confidentiality, and interoperability with other systems. TI functions are core and foundational to all other functions of the EHR-S FM (CP, CPS, POP, AS and RI).

4.2 Functional Profiles

While the Functional Model contains all reasonably anticipated EHR-S functions, it is not itself intended as a list of all functions to be found in a specific EHR-S or implementation thereof. Functional Profiles offer a method to constrain EHR-S FM functions and conformance criteria to an intended use.

In the aggregate, the EHR-S FM is intended to include the superset of functions from which a profile subset can be generated. This subset illustrates what is needed within an EHR-S. Only a subset of all EHR-S FM functions will apply to any particular EHR-S Functional Profile (FP).

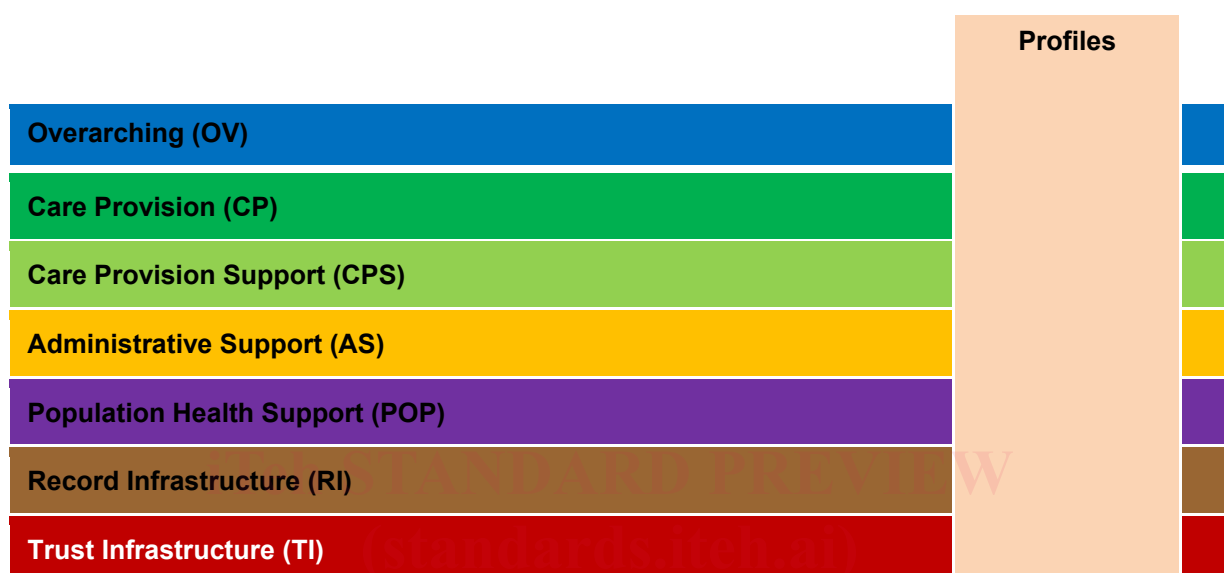


Figure 2. Profiling from the EHR-S FM.

Figure 2 shows that a profile would include all 7 sections of the Functional Model, however it may not be necessary to include all the functions and criteria within each section. A profile may include additional functions and criteria to meet the requirements of the particular profile domain or subject area.

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? Or how do you know what is mandatory versus optional?’* A Conformance Clause can also provide a communication between the implementers (producers) and users (buyers) as to what is required, and gives meaning to the phrases, “conforming profile” and “conforming EHR system”. Additionally, it serves as the basis for inspection, testing and/or certification activities which may be performed by organizations external to HL7.

Refer to the Conformance Clause, section 7, for additional information related to the rules for selecting and adding Conformance Criteria in the development of a Functional Profile.

4.3 EHR-S Function List Components

The EHR-S Function List is a list (superset) of functions organized into discrete sections. Functions describe the behavior of a system in user-oriented language so as to be recognizable to the key stakeholders of an EHR-S.

EHR-S functions can be used to:

- Describe end user defined benefits such as patient safety, quality outcomes and cost efficiencies in terms of standard EHR-S functions.
- Promote a common understanding of EHR system functions upon which developers, vendors, users and other interested parties can plan and evaluate EHR system designs and implementations.
- Provide the necessary framework to drive the requirements and applications of next level standards, such as EHR content, coding, information models, constructs and interoperability for information portability between sub-systems of an EHR system and across EHR systems.
- Establish a standards-based method by which each realm (country) can apply these EHR system functions to care settings, services, specialties, other uses and priorities.