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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 (EHR 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 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.

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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 HL7, reference HL7 EHR system functional model 2.1) 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 10781 cancels and replaces the ISO/HL7 10781:2015, which has been technically revised.

The main changes are as follows:

— changes to the Record Infrastructure Section to accommodate three additional record lifecycle events (verify, encrypt, decrypt) and ensure compatibility with FHIR Core R4 Record Lifecycle Event Implementation Guide (2019) and recent updates to ISO 21089:2018, Trusted End-to-End Information Flows;

— changes to the Glossary Section to support the full set of record lifecycle events (now 27 in total) and corresponding descriptions;

— previously identified updates included in the EHR-S FM R2.01 errata version;

— changes to the Conformance Chapter to align with characteristics and requirements of recent EHR-S FM R2 based Functional Profiles, including FPs developed for the US Meaningful Use (EHR Incentive) Program, 2011/2014 and 2015 Editions;

— domain analysis (models and artifacts) companion to EHR system development and implementation.

— adding a header in the TI section on clinical model services (DCMs, CIMI models, FHIR, HL7 template) comparable to TI.4 Standard Terminology and Terminology Services.

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.

0 Introduction

0.1 Notes to Readers

Electronic Health Record (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 spart of FHIR Core STU-3 (March 2017) and now part of FHIR Core R4 (in ballot, September 2018).
- The 27 Record Lifeycle 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).

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 can 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

1.1 EHR-S Functional Model 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).

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. Table 1 explains the differences between 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 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: 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 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.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 20514:2005, Health Informatics – Electronic health record – definition, scope and context

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

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

3.3
conformance
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
section of a specification that defines the requirements, criteria, or conditions to be satisfied in order to claim conformance