BS EN ISO 10781:2025

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

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# National foreword

This British Standard is the UK implementation of EN ISO 10781:2025. It is identical to ISO 10781:2023. It supersedes BS EN ISO 10781:2015, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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NORME EUROPÉENNE

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

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

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## European foreword

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This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2026, and conflicting national standards shall be withdrawn at the latest by February 2026.

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## Endorsement notice

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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).

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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;

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— 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.


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# 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).

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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 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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# Health informatics — HL7 Electronic Health Record-System Functional Model, Release 2 (EHR FM)

## 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. |

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| | |
|---|---|
| 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


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**3.6**
**conformance statement**
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**
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**
ability for an EHR-S to incorporate additional functionality beyond what is defined in the Functional Profile

**3.9**
**functional profile**
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**
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**
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 as show in Figure 1.

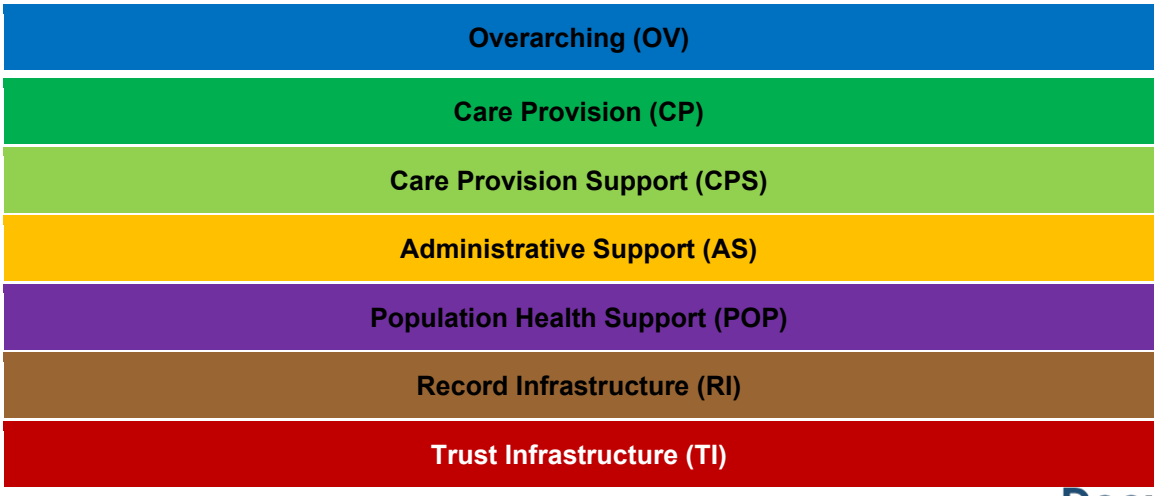


**Figure 1: Function List Sections**

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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.

## 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).

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## 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).

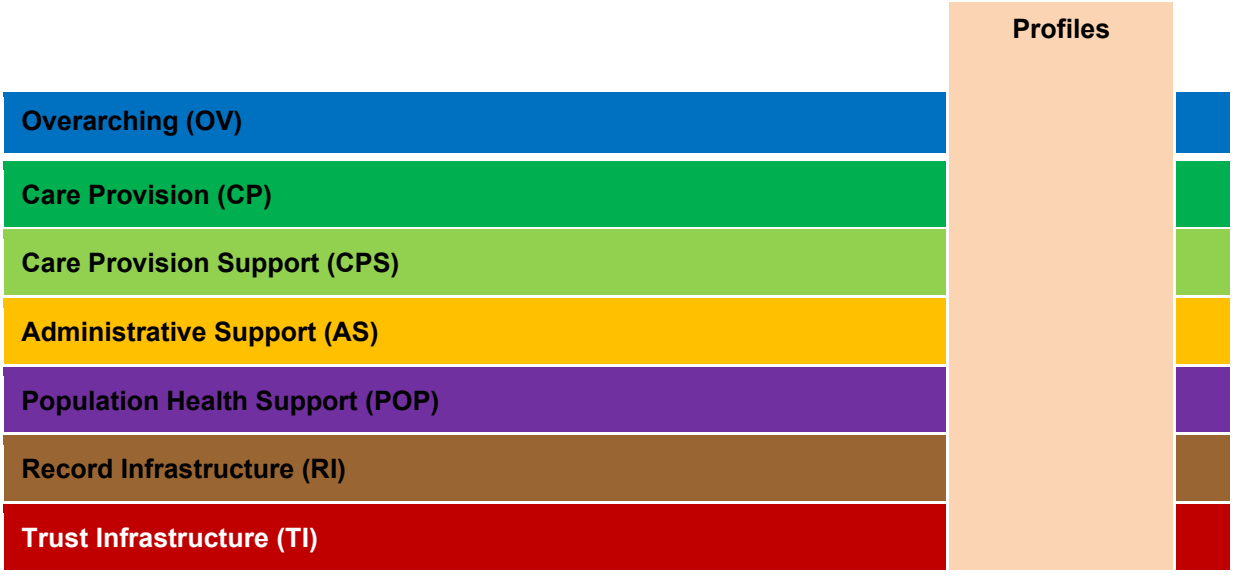


**Figure 2. Profiling from the EHR-S FM.**

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.

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- Inform those concerned with supporting subsequent use of data initially collected for the purpose of care (also known as “secondary use”) on what functions can be expected in an EHR system.
- Inform those concerned with supporting realm-specific health information infrastructure on what functions can be expected in an EHR Systems.

Each function in the HL7 EHR-S Functional Model is identified and described using a set of elements or components as detailed in Table 2.

| ID | Type | Name | Statement | Description | Conformance Criteria |
|---|---|---|---|---|---|
| CP.1 | H | Manage Clinical History | Manage the patient's clinical history lists used to present summary or detailed information on patient health history. | Patient Clinical History lists are used to present succinct “snapshots” of critical health information including patient history; allergy intolerance and adverse reactions; medications; problems; strengths; immunizations; medical equipment/ devices; and patient and family preferences. | |
| CP.1.4 | F | Manage Problem List | Create and maintain patient-specific problem lists. | A problem list may include, but is not limited to chronic conditions, diagnoses, or symptoms, injury/poisoning (both intentional and unintentional), adverse effects of medical care (e.g., drugs, surgical), functional limitations, visit or stay-specific conditions, diagnoses, or symptoms… | |
| CP.1.4 | C | | | | 1. The system SHALL provide the ability to manage, as discrete data, all active problems associated with a patient. |
| CP.1.4 | C | | | | 2. The system SHALL capture and render a history of all problems associated with a patient. |
| CP.1.4 | C | | | | 3. The system SHALL provide the ability to manage relevant dates including the onset date and resolution date of problem. |

**Table 2: Function List Example**

### 4.3.1 Function ID (Normative)

This is the unique identifier of a function in the Function List (e.g., CP.1.1) and uniquely identifies the function. The Function ID also serves to identify the section within which the function exists (CP = Care Provision Section) and the hierarchy or relationship between functions (CP.1.1 is at the same level as CP.1.2, CP.1.1 is also a parent of CP.1.1.1 and child of CP.1. In many cases the parent is fully expressed by the children. NOTE: For a detailed discussion and graphic of the parent and child relationship, see 6.6.1 Hierarchical Structure in Chapter 6, Conformance Clause.)

### 4.3.2 Function Type (Reference)

This is an indication of the line item as being a Header (H), Function (F) or Conformance Criteria (C). The Tag (T) is used to identify a new section in the spreadsheet and its related functions in the spreadsheet. A Tag has no directly associated Functions or Criteria.

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#### 4.3.3 Function Name (Normative)

This is the name of the Function and while expected to be unique within the Function List; it is not recommended to be used to identify the Function without being accompanied by the Function ID.

Example: Manage Medication List

#### 4.3.4 Function Statement (Normative)

This is a brief statement of the purpose of this function. While not restricted to the use of structured language that is used in the Conformance Criteria (see below); the Statement identifies the purpose and scope of the function.

Example: Create and maintain patient-specific medication lists.

#### 4.3.5 Description (Reference)

This is a more detailed description of the function, including examples if needed.

Sample Description: Medication lists are managed over time, whether over the course of a visit or stay, or the lifetime of a patient. All pertinent dates, including medication start, modification, and end dates are stored. The entire medication history for any medication, including alternative supplements and herbal medications, is viewable. Medication lists are not limited to medication orders recorded by providers, but may include, for example, pharmacy dispense/supply records, patient-reported medications and additional information such as age specific dosage.

#### 4.3.6 Conformance Criteria (Normative)

Each function in the Function List includes one or more Conformance Criteria. Conformance Criteria, which exist as normative language in this standard, define the requirements for conforming to the function. The language used to express a conformance criterion is highly structured with standardized components with set meanings. The structured language used to define Conformance Criteria in the Function List are further specified in the Conformance Section 7 and Glossary Section 8.

## 5 Anticipated Uses (Reference)

The HL7 International community supports development of Functional Profiles (FPs), which may be realm (country) specific specifications (i.e., tailored functional requirements) built off the base EHR-S FM Standard. There are a range of FPs developed and balloted by HL7 International or its national affiliates. These FPs designate a subset of functions from the base EHR-S FM for use in specific care settings (e.g., Ambulatory Care), services or specialties (e.g. Behavioral Health) or specify cross-cutting characteristics of EHR systems and/or records (e.g. the Records Management and Evidentiary Support). Balloted, approved and published FPs, based on the EHR-S FM, are available in the HL7 International library of Standards.

### 5.1 Development Approach: Functional Profiles

A “Functional Profile" is a selected set of functions applicable for a particular purpose, realm (country), domain, care setting, service or specialty.

It is not anticipated that any system or implementation will conform to all functions and conformance criteria set forth in the base EHR-S FM. Rather EHR systems or implementations may conform to one or more Functional Profiles.

For more information about creating, registering, and balloting Functional Profiles, see Conformance Section 7.

One may create a Functional Profile to support a business case for EHR-S use by selecting an applicable subset of functions from the based EHR-S FM list of functions, in effect constraining the model to meet specific requirements. For example, a Functional Profile may be created by a purchaser, to specify requirements; by a vendor, to specify capabilities of a system design; or by any person/entity wishing to stipulate a desired subset of functions for a particular purpose, for example, functions to support a care setting within a particular realm.

Readers may wish to focus on sections of the FM that are most relevant for their purpose of EHR-S use. For example, a clinician may read the Care Provision and Care Provision Support sections very closely, while technical specialists may focus especially on Record and Trust Infrastructure sections. Within an organization, it may be helpful to designate responsibility for reviewing different FM sections among staff with different responsibilities and expertise for use and support of the EHR system

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Three vignettes are included here to help readers in different positions or organizations envision how they would study, and ultimately utilize the EHR-S Functional Model.

### 5.1.1 Scenario 1 – Group Practice

Dr. Smith is part of a 50-person group practice. The practice currently has a clinical information system that provides billing, scheduling, and other administrative support. For several reasons, it will need to be upgraded or replaced within 2 years. It does not include electronic health records. Dr. Smith and interested colleagues review an Ambulatory Care registered profile to see how the use, setting and scenario illustrate the EHR functions related to their practice; they look at the Ambulatory Care prioritization of the individual functions that a group of experts working with HL7 have identified. With a good understanding of what the EHR functions would mean for their practice, Dr. Smith and several other providers then focus on the Care Provision and Care Provision Support sections, while clinic administration staff look at the Administrative Support section, while the technical support staff look at the Record and Trust Infrastructure sections. They all meet to discuss their conclusions. They plan to use the list of functions in discussions with vendors about their next EHR system, recognizing that some functions may not yet be available.

### 5.1.2 Scenario 2 - Hospital

Mr. Jones is the Chief Informatics Officer in a large hospital organization Their IT system was installed two years ago and includes patient tracking and ordering components; it was upgraded for compliance with United States HIPAA (Health Insurance Portability and Accountability Act). It does not include clinical decision support, performance monitoring, or public health reporting. Mr. Jones asks the Chief Medical Officer to organize a review of the HL7 EHR-S FM while his team also reviews it. They both begin by looking at an Acute Care Functional Profile to see how a group of experts working with HL7 have identified how an EHR-S can be used within a hospital. The scenario and prioritization of the individual functions is helpful. The CMO and several doctors and senior nurses review the Care Provision and Care Provision Support sections of the EHR-S Functional Model Acute Care profile; the CIO and his team focus on the Record and Trust Infrastructure sections but also look at the Care Provision and Care Provision Support sections. A small team of providers and IT staff meet to discuss their conclusions. They plan to use the list of functions in discussions with vendors about adding decision support, performance monitoring, and public health reporting to their existing system, recognizing that their budget will only allow very limited expansion in the near term.

### 5.1.3 Scenario 3 - IT Vendor

Ms. Green is the head of the clinical systems division of a large health IT company. Their product line includes both dedicated EHR systems and integrated systems that include an EHR. Their EHR and integrated systems have some decision support for medication ordering, but no performance monitoring/reporting functions. While most of their clients are larger provider organizations and hospitals, they are planning to expand into the small practice and home health markets with a simple, less expensive clinical system. In anticipation of HHS's implementation of the Merit-Based Incentive Payment System (MIPS), which provides financial incentives for providers who use IT to track patients, the company wants to add a range of functionality to its products that would meet or exceed these requirements. Ms. Green asks her staff to review the entire HL7 EHR-S FM package, and also review applicable care setting Functional Profiles. Based on these examples, they determine that they can add a relatively small number of functions to various products to be able to offer superior products for current and future clients. They see value in the EHR-S FM for their discussions with their clients about upgrades or new purchases.

## 5.2 Examples of Current Use

### 5.2.1 Functional Profile for Clinical Research based on the EHR-S FM

Below is the text of a November 2009 HL7 Press Release demonstrating industry use:

> Ann Arbor, Michigan, U.S.A.–November 5, 2009– Health Level Seven International® (HL7®), the global authority for interoperability and standards in healthcare information technology with members in 57 countries, today announced it has published the healthcare industry's first ANSI (American National Standards Institute)-approved standard that specifies the functional requirements for regulated clinical research in an electronic health record system (EHR-S). The HL7 EHR Clinical Research Functional Profile for EHR systems is based upon the HL7 EHR Work Group's EHR System Functional Model Release 1, which is also an ANSI-approved American National Standard.

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The EHR Clinical Research Functional Profile defines high-level requirements critical for using electronic health record data for regulated clinical research, and provides a roadmap for integrating the information environment that must support both the patient care and the downstream clinical research processes. According to Donald Mon, PhD, co-chair of the HL7 EHR Work Group and member of the HL7 Board of Directors, “This profile is an excellent demonstration of how important functional requirements for secondary data use, such as clinical research, can be integrated into the patient care work flow and documented in EHR systems.” Pharmaceutical, biotechnology, clinical research technology vendor, healthcare technology vendor, and federal regulatory stakeholders from the United States and the European Union collaborated for two years to identify and address a broad list of data protection, regulatory and ethical research requirements. The EHR Clinical Research Functional Profile is also a resource for the Certification Commission for Healthcare Information Technology (CCHIT) Clinical Research Work Group as they define new clinical research certification criteria for EHR systems. This functional profile will be complemented by the EHR-Clinical Research interoperability specification, currently being developed by the Health Information Technology Standards Panel (HITSP). Additionally, Dr. Rebecca Kush, President and CEO of the Clinical Data Interchange Standards Consortium (CDISC), commented that “CDISC is pleased to be a collaborator and to contribute clinical research standards and eSource Data Interchange concepts towards these initiatives. The ultimate goal is to accelerate the pace at which research informs healthcare for the benefit of patients and this functional profile contributes to the achievement of that goal.”

### 5.2.2 AHRQ adopts Health Level Seven International (HL7) Child Health Functional Profile Specification, Release 1 and incorporates key functionalities in the Children’s Electronic Health Record Format

Below is an excerpt from AHRQ’s Children's Electronic Health Record Format - https://healthit.ahrq.gov/health-it-tools-and-resources/pediatric-resources/childrens-electronic-health-record-ehr-format

“The Children’s Electronic Health Record (EHR) Format was developed to bridge the gap between the functionality present in most EHRs currently available and the functionality that would more optimally support the care of children. Specifically, the Format provides information to EHR system developers and others about critical functionality, data elements, and other requirements that need to be present in an EHR system to address health care needs specific to the care of children, especially those enrolled in Medicaid or the Children’s Health Insurance Program (CHIP). To address these needs, the Format includes a minimum set of data elements and applicable data standards that can be used as a starting point or checklist for EHR developers seeking to create a product that can capture the types of health care components most relevant for children….The Children’s EHR Format contains portions of the Health Level Seven International (HL7®) Child Health Functional Profile Specification, Release 1, and modifications thereof, developed by HL7, the copyright of which is owned by HL7. Portions of the Format that contain excerpts from the HL7 Child Health Functional Profile are identified in the Provenance Field…”

### 5.2.3 Linking clinical content descriptions to the EHR-S FM (Reference)

HL7 has ongoing initiatives to link clinical content descriptions to functions and criteria in the EHR-S FM. This clinical content linkage can be helpful input to developers of EHR-systems. Examples of these clinical content descriptions include the Domain Analysis Models (DAMs) and Detailed Clinical Models (DCMs). Each of these examples can be linked to applicable sections of the EHR-S FM. For example, a Care Plan DAM which can be linked to a care planning functions in the Care Provision and Care Provision Support sections in the EHR-S FM.

At a more detailed level, the DCMs can be linked to specific functions in the EHR-S FM or EHR-S Functional Profiles. For example, a DCM for the Apgar score can be linked to CP.3.1 Conduct Assessments and CPS 3.1 Support for Standard Assessments. Another example is using the DCM for blood pressure with CP.3.2 Manage Patient Clinical Measurements.

On the level of data elements, which can be specified in a DCM, or in a data table, the linkage to EHR-S FM is usually through an individual criterion. For example, CP.3.2 Manage Patient Clinical Measurements, for example criterion ‘The system SHALL provide the ability to capture patient vital signs including blood pressure, temperature, heart rate, and respiratory rate, as discrete elements of structured or unstructured data.’

Finally, similar to EHR-S FM Function TI.4 Standard Terminology and Terminology Services, a Function is created for Clinical Models and Clinical Models Services. The function name is 'TI.10 Standard or Preferred Clinical Models and Clinical Model Services'. There are three child functions:

- TI.10.1 Standard or Preferred Clinical Models. The statement is; Employ approved standard or Preferred Clinical Models to ensure structured data correctness and to enable semantic interoperability (both within an enterprise and externally). Support a standard or Preferred Clinical Model.

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- TI.10.2 Maintenance and Versioning of Standard or Preferred Clinical Models. The statement is; Enable version control according to scope of practice, organizational policy, and/or jurisdictional law to ensure maintenance of utilized standard or preferred clinical models. This includes the ability to accommodate changes to clinical models as the source clinical model undergoes its update process. Such changes need to be cascaded to clinical content embedded in templates, custom formularies, etc., as determined by existing policy.
- TI.10.3 Clinical Model Mapping; The statement is; Map or translate one clinical model to another as needed by local, regional, national, or international interoperability requirements.

# 6 Conformance Clause

## 6.1 Introduction (Reference)

Sections 6.2 through 6.7 are the HL7 EHR Work Group approved Conformance Clauses. As important background on conformance, please note the following:

1. This Conformance Clause defines what it means to conform to the EHR-S Functional Model.
2. Conformance to the Functional Model is defined for functional domain profiles, and for functional companion profiles. An EHR system does not directly conform to the Functional Model, rather it conforms to one or more Functional Profiles.
3. Conformance criteria are associated with functions in the EHR-S Functional Model.
4. This Conformance Clause does not specify inspection, testing or validation procedures to determine whether an EHR system conforms to an EHR-S Functional Profile or whether a Functional Profile conforms to the EHR-S Functional Model.

## 6.2 Scope and Field of Application (Normative)

This *Conformance Clause* defines the minimum requirements for *Functional Profiles* claiming conformance to the EHR System Functional Model. It also identifies how EHR systems achieve conformance to the Functional Model, which is via the system's conformance to a particular functional domain profile, multiple Functional Profiles, or combination of domain and companion profiles. This clause specifies:

1. The purpose, structure, and use of conformance criteria that are to be included in the Functional Model and conforming Functional Profiles,
2. The rules for defining conforming Functional Profiles of the Functional Model,
3. The relationship between Functional Profiles and EHR systems,
4. Sample Conformance Clauses and use case scenarios,
5. Guidance on the conformance requirements that a Functional Profile may levy on EHR systems,
6. Guidance on the purpose and use of an EHR system Conformance Statement.

While the conformance requirements for Functional Profiles can be found in this clause, they necessarily reference the Functional Model and other sources.

This Conformance Clause does not specify inspection, testing or validation procedures to assess a Functional Profile's conformance to the Functional Model. It also does not specify inspection, testing or validation procedures to determine whether an EHR system conforms to a Functional Profile or matches the EHR System Conformance Statement.

## 6.3 Concepts (Normative)

### 6.3.1 Functional Profiles

Creating a Functional Profile is a method for defining subsets of the Functional Model. A Functional Profile is a specification which uses the Functional Model to indicate which functions are required, desired, or implemented for certain EHR systems, healthcare delivery settings, or for other purposes (e.g., the functional profile for Records Management and Evidentiary Support).

Functional Profiles can be created by healthcare community stakeholders with interest in using and/or providing a Functional Profile for an EHR system. Functional Profiles can represent the functionality required and desired for a realm (country/region), domain, care setting or service/specialty, or reflect the functionality incorporated in a vendor's EHR system.

(NOTE: During the process of creating a Functional Profile, it may be important to discuss clinical processes, work flows and/or interaction(s) of the healthcare actors. The international standard 'ISO 13940 System of Concepts to Support Continuity of Care' provides an outline of key principles and processes in the provision of healthcare. We would highly recommend reviewing this standard as part of your work.)

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There are two types of Functional Profiles. The Functional Domain Profile is the common type of profile used to describe an EHR system for use in one or more care settings, or to describe an EHR system for use in a selected realm (country/region) to meet the rules, regulations and standards applicable for that realm, to describe an EHR system for use by a particular service or specialty, etc. The Functional Companion Profile is a type of profile that must be paired with one or more Domain Profiles. The purpose of a Companion Profile is to add unique features to an EHR System, such as for research or for evidentiary support. For example, many EHR systems in a clinic environment do not need to support clinical research. But for a clinic that was supporting advanced research, they may want an EHR system that was both capable of all of the expected functions for routine clinic patient care activities, but also had unique features to support the needs for research reporting and clinical trials.

Once a Functional Profile is defined its functions (complying with conformance criteria) can be implemented within EHR systems or it may trigger the creation of derived Functional Profiles. A *derived Functional Profile* is a Functional Profile that is created from an existing Functional Profile, inheriting FP functions and conformance criteria. There are two types of derived Functional Profiles: Derived Domain FP and Derived Companion FP.

There are two types of mandatory inheritance in the EHR-S FM. All Functional Domain Profiles will inherit the full set of functions in the EHR-S FM Overarching section and their related “SHALL” criteria. All criterion listed in a parent function will be applicable to all the children of that parent function.

A formal HL7 process exists for registering and balloting Functional Profiles. Functional Profiles that are submitted to the HL7 EHR WG with an attestation of conformance to Section 7: Conformance Clause of the HL7 EHR-S Standard and successfully complete review by the WG are designated as “*Registered Functional Profiles*”. Registered Functional Profiles that undergo formal public scrutiny via the HL7 consensus process as an Informative EHR TC ballot at the committee level will be designated as *HL7 functional domain or companion profiles*. HL7 Functional Profiles are eligible to undergo full membership ballot via the HL7 consensus process.

### 6.3.2 Conformance Model

Conformance to the Functional Model is defined for Functional Profiles. A functional domain profile conforms either (1) directly to the base EHR-S FM or (2) to another conforming functional domain profile. NOTE: All functional domain profiles must include all the functions and “SHALL” criteria of the Overarching Chapter. An EHR system does not conform directly to the Functional Model; rather, it conforms to a functional domain profile, or to a domain profile in combination with selected companion profile(s). Thus, Functional Profiles claim conformance to the Functional Model and EHR systems claim conformance to one or more conforming domain Functional Profiles. An EHR system can also claim conformance to a domain Functional Profile, in combination with one of more companion profiles. An EHR system cannot claim conformance to only a companion profile. Figure 3 (below) illustrates this relationship.

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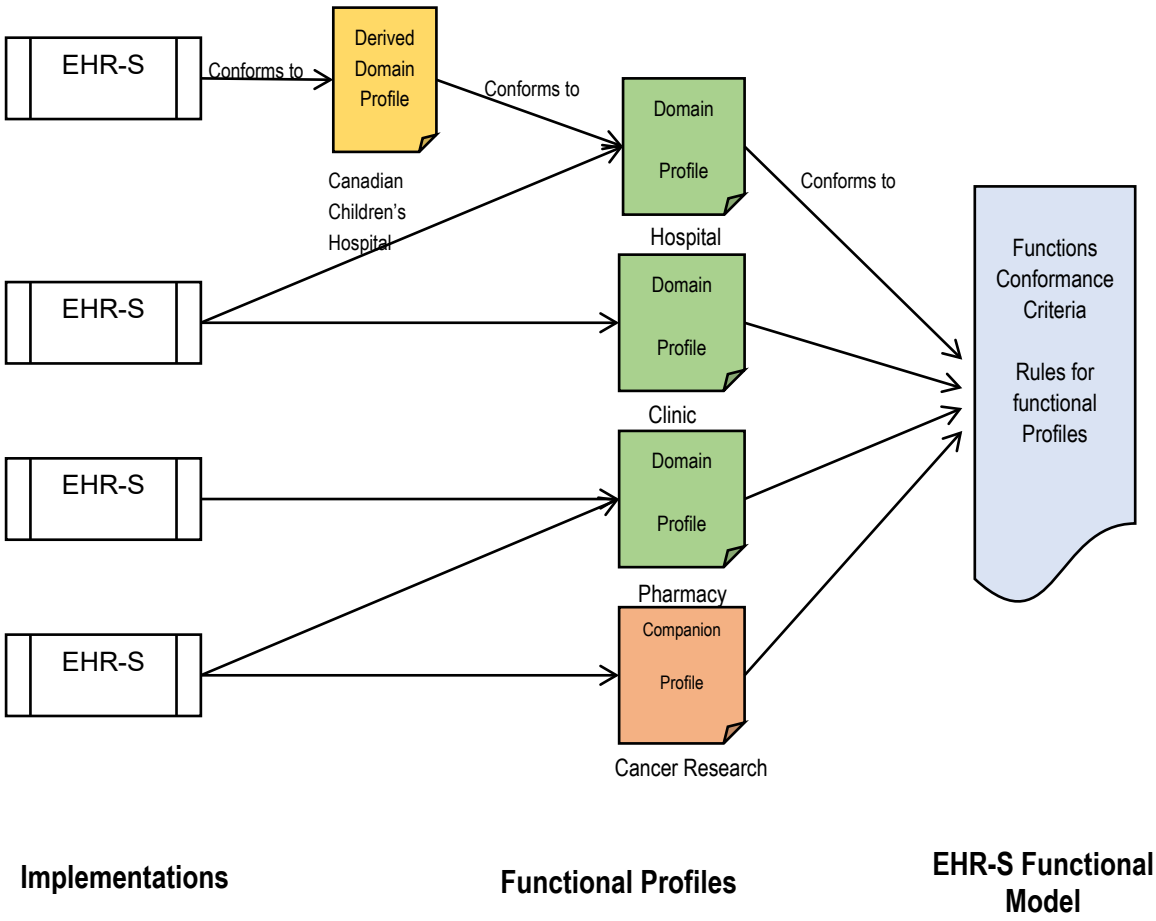


**Figure 3 Conformance Relationships**

### 6.3.3 Profile Traceability

Functional Profiles allow for added specificity and extensibility to the Functional Model with changes allowed to the base FM functions and criteria. However, Section 6.6 (following) defines rules for these changes. It is also required that any changes and additions be tracked. Two added columns in profiles accomplish this. One column will document the unique source FM row number for each item in the new profile (or source profile for a derived profile). The second column will provide codes for the type of changes from the source FM (or source profile). Together, these two traceability columns will keep track of the origins of the functions or criteria – and whether it is modified or unchanged from that within the FM or the source profile. This may be important when questions arise as to where did it come from, why was it chosen or modified, etc. It can also be helpful to have traceability back to the FM functions and criteria if and when revisions to a profile or for derived profile are needed to reflect care setting, regulatory, technology changes – or a future new release of the base EHR-S FM.

## 6.4 Normative Language (Normative)

The EHR-S Functional Model (i.e., all chapters) contains normative, informative, and reference sections. In this Conformance Clause section, the normative content defines how a Functional Profile achieves conformance to the Functional Model.

The following keywords (i.e., normative verbs) **SHALL** be used to convey conformance requirements:

- SHALL – to indicate a mandatory requirement to be followed (implemented) in order to conform. Synonymous with 'is required to'.
- SHALL NOT – to indicate a prohibited action. Synonymous with 'prohibited'.
- SHOULD – to indicate an optional recommended action, one that is particularly suitable, without mentioning or excluding others. Synonymous with 'is permitted and recommended'.
- MAY – to indicate an optional, permissible action. Synonymous with 'is permitted'.


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## 6.5 Conformance Criteria (Normative)

Every function in the Functional Model is associated with a set of conformance criteria. These *conformance criteria* form the basis for determining whether the function has been implemented.

### 6.5.1 Criteria in the Functional Profile

Functional Profiles also have conformance criteria associated with functions in the Functional Profile. The Functional Profile's criteria are either (1) adapted from the Functional Model conformance criteria with requirements or language specific to the purpose, care-setting, realm (country/region), domain, service or specialty focus of the Functional Profile; or otherwise (2) inherited directly from Functional Model. Functional domain and companion profiles **MAY** change Functional Model criteria to match the needs and priorities of the Functional Profile's constituency, e.g., by making it more specific, or changing it from 'may' or 'should' to 'shall'. Functional Profiles **MAY** change the criteria of a function to allow for alignment to realm specific nomenclature, including language distinctions and implication of non-english translations. In these cases, the International Organization for Standardization (ISO) country code (ISO 3166 Country Codes) **SHALL** be appended to the function ID in the Functional Profile.

The functional domain profile **SHALL NOT** be made less restrictive than the Functional Model by changing 'shall' criteria to 'may' or 'should' criteria (The functional companion profile **MAY** be less restrictive that the FM by ignoring 'shall' criterion). Functional domain and companion profiles **MAY** also add additional criteria.

### 6.5.2 'Dependent SHALL' Criteria

Conformance criteria that contain the keyword 'shall' **and** a dependency on situational conditions are called 'dependent shall' criteria. The 'dependent shall' **SHALL** contain the phrase "in accordance with scope of practice, organizational policy, or jurisdictional law" or other appropriate grammatical tie-in words (e.g., 'based on' rather than 'in accordance'). A 'dependent shall' criteria is used to highlight only these (i.e., scope of practice, organizational policy or jurisdictional law) conditions. A 'dependent shall' criterion is a mandatory criterion for Functional Profiles and situational for EHR systems. Specifically,

- All functional domain profiles SHALL inherit the criterion if the function appears in the Functional Profile.
- An EHR system is required to implement the Dependent SHALL criterion only if the criterion is applicable per the stated dependency in the Functional Model. (If the Dependent SHALL criterion is not applicable to the profile, the developer of the profile may still use the criterion if desired.)

### 6.5.3 Referencing Other Criteria or Functions

There is often a link between functions and their criteria with other functions and criteria. For example, a given function may depend on another function or on a specific criterion associated with another function.

A criterion in the Functional Profile that references another function in the Functional Profile **SHALL** reference that function by indicating its name and ID, as "X.n.n (Name)". If the referenced function is required to be implemented, then all the 'shall' criteria of this referenced function apply. If the referenced function is a parent with children, the reference must be explicit on whether the children are included in the reference, all or selected ones. See the examples below:

- The system SHALL/SHOULD/MAY conform to TI.1.1 (Entity Authorization).
- The system SHALL/SHOULD/MAY conform to TI.2 (Audit) and all child functions.
- The system SHALL conform to CPS.4 Support Orders, and separate function(s) The systems SHALL conform to CPS.4.3 Non-medication Orders. The systems SHALL conform to CPS.4.6 Support for Referrals and all children functions.

A criterion in the Functional Profile that references a specific criterion in another function **SHALL** reference that function by rewriting the referenced criterion as one of its own and indicating the function and criterion number from where it came (e.g. F#, CC3).

## 6.6 Functional Model Structure and Extensibility (Normative)

### 6.6.1 Hierarchical Structure

Functions **MAY** be contained (i.e., nested) within other functions. A nested function is a 'child' to its 'parent' (i.e., the function that contains it). A child **SHALL** always have a parent. A function that is not a parent to another function is considered a 'leaf'. Figure 4 illustrates this hierarchical structure.

The Functional Model is represented as a hierarchical list of functions, consisting of functional header parents, functional header children and functional leaf functions. Headers include an ID, Name and "H" in the column labeled "Type". Parent and Child Headers **MAY** contain conformance criteria only if the criteria apply to all its

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descendent functions (i.e., children, grandchildren, and leafs). Parent, Child and Leaf functions contain at a minimum the following: ID, Name, Statement, Description, and Conformance Criteria and have a “F” in the “Type” column. Conformance criteria listed in a parent function **SHALL** be inherited by all its child functions. Conformance Criteria have a “C” in the “Type” column.

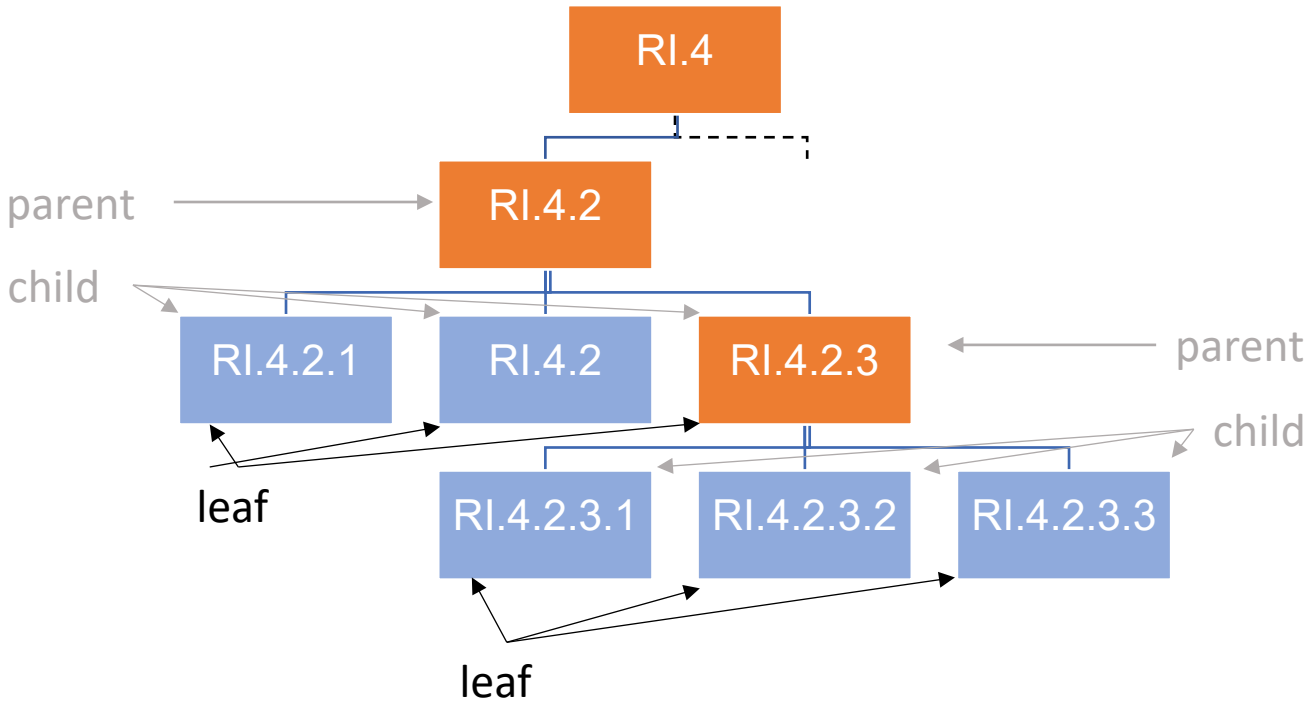


**Figure 4 Portion of the Functional Model hierarchical structure**

(Note: The numbering schema above reflects functions in the Record Infrastructure (RI) chapter.)

Functional Profiles either:

- Select functions from the Functional Model for inclusion in the Functional Profile,
- Deem a function in the Functional Model as not applicable, thus do not select it for inclusion in the Functional Profile, or,
- Add a new child function when it has been determined that there is no applicable function in the Functional Model to represent a functional need in the Functional Profile.

### 6.6.2 Naming Convention

Functional Profiles **SHALL NOT** change the name or statement of a function except to allow for alignment to realm specific nomenclature, including language distinctions and implication of non-english translations. In these cases, the International Organization for Standardization (ISO) country code (ISO 3166 Country Codes) **SHALL** be appended to the function ID in the Functional Profile. It is recommended that the HL7 Affiliate for the respective realm coordinate with the profile development process to maintain a mapping of the Functional Model function name and/or statement and the realm-adjusted name and/or statement.

### 6.6.3 Priorities

Functional Profiles indicate the importance and/or immediacy of a Functional Profile by associating a priority with a function. Three priorities have been defined, Essential Now, Essential Future, and Optional:

- Essential Now indicates that the implementation of the function is mandatory, as of the profile issuance date.
- Essential Future indicates that the implementation of the function is currently optional but will be mandatory at some future time, which is specified by the Functional Profile
- Optional indicates that the implementation of the function is optional.

Any or all of these priorities **SHALL** be used in a Functional Profile. If the Essential Future priority is used, then Functional Profiles are required to define the timeframe associated with implementing functions. A timeframe **MAY** be a date, time allotment (e.g., year 2014 or 4 months after Functional Profile publication), or event (e.g., republication of this Functional Profile). A Functional Profile **MAY** define multiple timeframes for the same


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