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Health Informatics — HL7 Electronic Health Records-System Functional Model, Release 2 (EHR FM) (ISO 10781:2015)

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National foreword

This British Standard is the UK implementation of EN ISO 10781:2015. It supersedes BS EN ISO 10781:2009 which is withdrawn.

BSI, as a member of CEN, is obliged to publish EN ISO 10781 as a British Standard. However, attention is drawn to the fact that during the development of this European Standard, the UK committee voted against its approval as a European Standard.

The UK committee vote was not a comment on the quality of the specification, nor on its value in those situations where it is being used. Rather, the vote reflects the dual concerns that both the method and the content are too specific, based primarily on requirements from the US.

The UK proposal was that this document should have been brought forward within ISO/CEN as a Technical Specification, and not an International Standard, for the following reasons:

a) While this is one reasonable way to specify Electronic Health Record (EHR) systems, it is not the only way or the best way in all situations.

b) The roles and functions of EHR systems are evolving fast and so while it is useful to collaborate internationally on Technical Specifications, it is not yet an area where international regulation or International Standards are helpful or appropriate.

c) The boundary between EHR systems and Personal Health Records (PHR) systems is not clear cut, nor is the boundary between EHR systems and Social Care. This is particularly important for the UK, where the direction is for integration across health and social care.

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 secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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NORME EUROPÉENNE

EUROPÄISCHE NORM

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Supersedes EN ISO 10781:2009

English Version

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Informatique de santé - Modèle fonctionnel d'un système de dossier de santé électronique, publication 2 (EHR FM) (ISO 10781:2015)

Funktionales Modell für ein elektronisches Gesundheitsaktensystem (EHRS FM), Ausgabe 2 (ISO 10781:2015)

This European Standard was approved by CEN on 30 April 2015.

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European foreword

This document (EN ISO 10781:2015) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by DIN.

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 2016, and conflicting national standards shall be withdrawn at the latest by February 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 10781:2009.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 10781:2015 has been approved by CEN as EN ISO 10781:2015 without any modification.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/HL7 10781 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO/HL7 10781:2009), which has been technically revised.

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Introduction

Information for readers

EHR System Functional Model Release 2.0 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, then in 2009 with Release 1.1, jointly balloted with ISO/TC 215 and CEN/TC 251. Release 2.0 reflects many changes, including ballot comments that had been made on past ballots and where the HL7 EHR Work Group had committed to bringing consideration of requested changes forward. It also includes comments that were considered for future use from the ISO ballot of 2009 as well as considerations of the Comment Only ballot that was circulated in May 2011.

Other inclusions were made as a result of the multiple EHR System Functional Profiles that have been written on Functional Model Releases 1 and 1.1. There was great learning in those various domain as well as companion profiles. The EHR-S FM also incorporated two other Draft Standards for Trial Use: HL7 EHR Lifecycle Model and HL7 EHR Interoperability Model.

Changes from previous Release

The HL7 EHR-System Functional Model Release 2 had its first normative ballot in May 2012. The key changes as a result of the first normative ballot included the following.

- Moved the normative parts of the Glossary into the Conformance clause section as use of glossary consistently is key to ease in reading and understanding the model.
- Improved consistency in representation of Headers, Functions and Conformance Criteria throughout the model.
- Updated the conformance clause for ease of reading especially as it related to the different types of profiles: domain profiles and companion profiles.
- Provided clarity for functional description and related conformance criteria.
- Updated the content to be more current.

To see all of the comments and reconciliation of the Normative 1 ballot, please see the HL7 Ballot Website for the ballot cycle of May 2012.

Background

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 US 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.”(HHS Goals in “Pursuing HL7 EHR Functional Standard” in Memorandum to HIMSS from C. Clancy and W. Raub co-chairs of HHS Council on the Application of Health Information Technology, dated November 12, 2003.) A critical foundational component for resolving these system and infrastructure issues is the Electronic Health Record System (EHR-S).

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

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Existing EHR System Definitions

The IOM's 1991 report, The Computer-Based Patient Record: An Essential Technology, and updated in 1997 (Dick, R.S, Steen, E.B., and Detmer, D.E. (Editors), National Academy Press: Washington, DC) defined an EHR System as follows.

- The set of components that form the mechanism by which patient records are created, used, stored, and retrieved.
- A patient record system is usually located within a health care provider setting. It includes people, data, rules and procedures, processing and storage devices (e.g. paper and pen, hardware and software), and communication and support facilities.
- The 2003 IOM Letter Report, Key Capabilities of an Electronic Health Record System, defined the EHR System as including:
- Longitudinal collection of electronic health information for and about persons, where health information is defined as information pertaining to the health of an individual or health care provided to an individual.
- Immediate electronic access to person- and population-level information by authorized, and only authorized, users.
- Provision of knowledge and decision-support that enhance the quality, safety, and efficiency of patient care.
- Support of efficient processes for health care delivery.

The 2003 ISO/TS 18308 references the IOM 1991 definition above as well as ISO 13606:

- A system for recording, retrieving and manipulating information in electronic health records.

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.

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Drafts of the EHR-S Functional Model and of specific functions have been widely reviewed by healthcare providers, vendors, and other stakeholders. This proposed standard reflects input from all these reviewers.

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Health Informatics — HL7 Electronic Health Records-System Functional Model, Release 2 (EHR FM)

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 and realms, 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. Section 1.1.3 describes the basis and foundation for the HL7 definition of an EHR System. Notably, the EHR-S Functional Model does not address whether the EHR-S is a system-of-systems or a single system providing the functions required by the users. This International 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.

The EHR-S Functional Model is not sufficient to provide a longitudinal health record; however, it will contribute to its development. The information exchange enabled by the EHR-S supports the population of clinical documents, event summaries, minimum data sets, claims attachments, and in the future will enable a longitudinal health record.

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Additionally, 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 is an international standard that does outline key principles and processes in the provision of healthcare. Users of the EHR-S FM can refer to ISO 13940 for clinical processes that EHR systems support.

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

Table 1 — Normative Status Types

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.

Each section within this document is clearly labelled "Normative" if it is normative. For example, in Clause 7, Conformance Clause, subclauses 7.2 and 7.4 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, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TR 12773-1:2009, *Business requirements for health summary records — Part 1: Requirements*

ISO/TS 13606-4:2009, *Health informatics — Electronic health record communication — Part 4: Security*

ISO/TS 17090-1:2002, *Health informatics — Public key infrastructure — Part 1: Framework and overview*

ISO 18308:2011, *Health informatics — Requirements for an electronic health record architecture*

ISO/IEC 2382-8:1998, *Information technology — Vocabulary — Part 8: Security*

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

3 Terms and definitions

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 and/or derived

3.3
conformance
fulfilment of a product, process or service of specified requirements

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3.4
conformance criteria
requirements indicating the behaviour, action and/or 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

3.6
conformance statement
description of the functions in an EHR system that have been implemented, reflecting the degree to which an EHR system has met the functional profile's requirements and which 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
capability of 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
one of a set of conformance criteria listed in a parent function that is 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

EXAMPLE 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.

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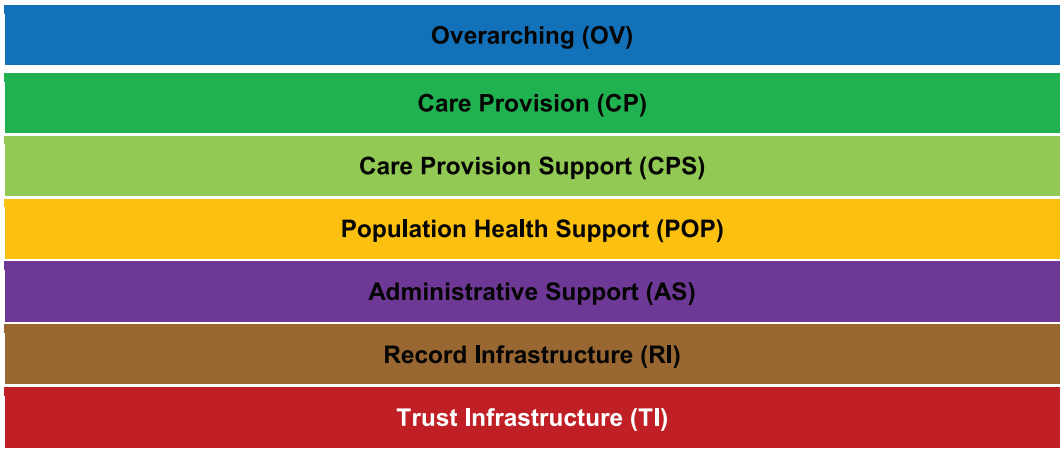

Figure 1 — Function List Sections

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.

4.1 Sections of the Function List

The seven sections of the function list reflect content of the Interoperability Model, now integrated in the Functional Model, and input from several profiles if the R.1.1 version of the Functional Model. Below is a summary description of each of the seven sections:

- Overarching: The Overarching Section contains Conformance Criteria that apply to all EHR Systems and consequently must be included in all EHR-S FM compliant profiles.
- Care Provision: The Care Provision Section contains those functions and supporting Conformance Criteria that are required to provide direct care to a specific patient and enable 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 offices, clinics, hospitals and speciality care centres.
- Care Provision Support: The Care Provision Support Section focuses on functions needed to enable 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 those functions required of the EHR to support 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 at a multi-patient level.
- Administrative Support: The Administrative Support Section focuses on functions required in the EHR-S to enable the management of the clinical practice and to assist with the 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 Chapter consists of functions common to EHR System record management, particularly those functions foundational to managing record lifecycle (origination, attestation, amendment, access/use, translation, transmittal/disclosure, receipt, de-identification, archive…) and record lifespan (persistence, indelibility, continuity, audit, encryption). RI functions are core and foundational to all other functions of the Model (CP, CPS, POP, AS).

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- Trust Infrastructure: The Trust Infrastructure Chapter consists of functions 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 Model (CP, CPS, POP, AS and RI).

4.2 Functional Profiles

While the Functional Model should contain 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. Functional Profiles should be used to constrain the functions to an intended use. This document defines the Functional Model and describes the general use of profiles and priorities (See 1.4 Anticipated Uses).

In the aggregate, the Functional Model is intended to include the superset of functions from which a subset can be generated by the user. This subset created by the user illustrates what is needed within an EHR-S. Only a subset of the superset of functions will apply to any particular EHR-S Profile.

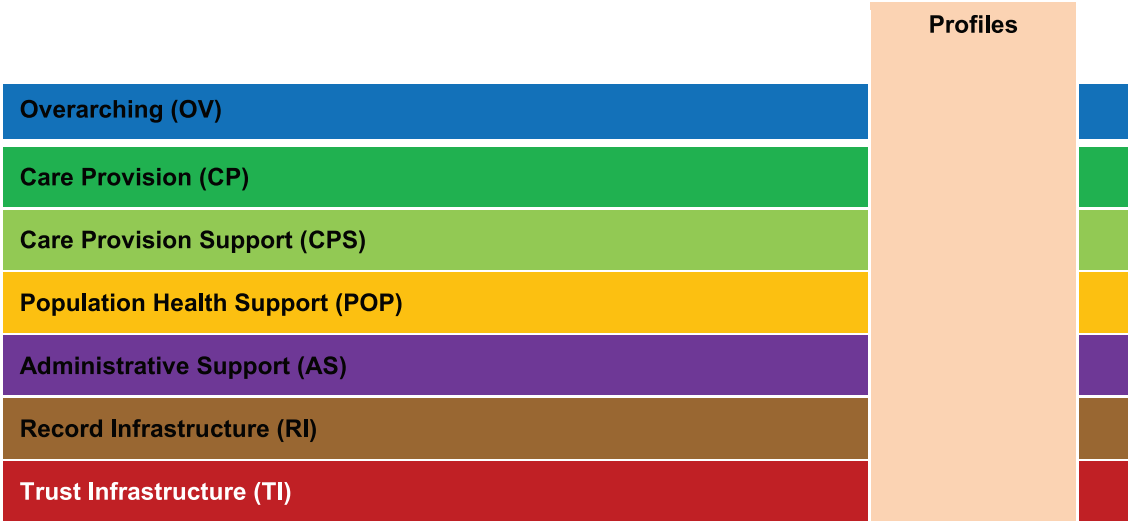

Figure 2 — Profiling from the EHR-S FM

Figure 2 shows that a profile would include all seven 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 profile.

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 (vendors) 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 testing and certification activities which may be performed by organizations external to HL7.

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

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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 behaviour 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:

- Facilitate describing 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 functions upon which developers, vendors, users and other interested parties can plan and evaluate EHR-S functions.
- 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-S and across EHR-S'.
- Establish a standards-based method by which each realm (country) can apply these EHR functions to care settings, uses, and priorities.
- 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 below.

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Table 2 — Function List Example

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.

4.3.1 Function ID (Normative)

This is the unique identifier of a function in the Function List (e.g. CP.1.1) and should be used to uniquely identify the function when referencing functions. 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. 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.

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.

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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 should clearly identify 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.

Example 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 is defined in the Conformance Chapter: Sections 2.4 Conformance Criteria and Section 2.9 Glossary Action Verb Hierarchy and Use.

5 Anticipated Uses (Reference)

HL7 is an international community and supports the development of Functional Profiles, which may be country specific (HL7 realm) specifications within a standard. It is anticipated that there will be profiles registered with HL7 that designate a subset of functions from the model for use in specific care settings (e.g. Behavioural Health) or functional areas (e.g. the Records Management and Evidentiary Support EHR). Examples of functional profiles will be included as reference documents in the HL7 How-to Guide for Creating Functional Profiles

5.1 Anticipated Development Approach: Functional Profiles

A “Functional Profile” is a selected set of functions that are applicable for a particular purpose, user, care setting, domain, et cetera. Functional profiles help to manage the master list of functions. The full Functional Model is not intended to apply to any single EHR-S implementation.

As such, an EHR system does not conform directly to the Functional Model; rather, it conforms to one or more Functional Profiles. For more information about creating, registering, and balloting Functional Profiles, see Chapter Two: Conformance Clause, Sections 2 and 6.

Functional profiles are the expression of usable subsets of functions from this EHR-S Functional Model. In this EHR-S Functional Model the reader will see a long list of Function Names and Function Statements, which serve as reasonable representations of functions that may be needed for a clinical environment. The list of functions is not intended to be used in its entirety. For example, the functions outlined in this model apply differently to different care settings. Many of the functions in the model apply to a nursing home setting, but some like CP.1.7.2.3 (Manage Orders for Blood Products and Other Biologics) would not apply. The list of functions is not considered to be in a usable form until a Functional Profile or constraint is generated.

The act of creating a Functional Profile is to support a business case for EHR-S use by selecting an applicable subset of functions from the EHR-S Functional Model list of functions, in effect constraining the model to meet specific requirements. For example, a Functional Profile may be created by a

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purchaser, to indicate requirements; by a vendor, to indicate the capability of specific products; or by any person/entity wishing to stipulate a desired subset of functions for a particular purpose, including a care setting within a specific realm. Once an applicable subset of functions has been selected, the person/entity creating the profile gives each function a priority of essential now, essential future or optional. For more information about the steps to creating a Functional Profile, see the HL7 *How-to Guide for Creating Functional Profiles and Related Tooling*.

Readers may wish to focus on the specific section of the EHR-S Functional Model that is more relevant for their everyday work. For example, a clinician might read the Care Provision and Care Provision Support sections very closely, while technical specialists might focus especially on the Trust Infrastructure section. Within an organization, it might be helpful to delegate responsibility for scrutinizing the different sections among staff with different responsibilities and expertise.

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 Trust Infrastructure section. They all meet to discuss their conclusions. They plan to use the list of functions in discussions with vendors about their next IT 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 the 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 Functional Model while his team also reviews it. They both begin by looking at an Acute Care balloted profile to see how a group of experts working with HL7 have identified how an EHR-S could 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 Trust Infrastructure section 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 Medicare Reform law, 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 the Medicare requirements.

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Ms. Green asks her staff to review the entire HL7 EHR-S Functional Model package, and also review the care setting profile examples included as exhibits in theHL7 How-to Guide for Creating Functional Profiles and Related Tooling. Based on the examples of care setting Functional Profiles, they determine that they could 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 Functional Model 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, USA–November 5, 2009– Health Level Seven® (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.

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 Announces Children's Electronic Health Record Format

Below is an excerpt from a February, 2013 Press Release demonstrating industry use of the HL7 Child Health Functional Profile: http://www.ahrq.gov/news/newsroom/press-releases/2013/childehrpr.html

The benefits of electronic health records (EHRs) may become more widely available to children through an EHR format for children's health care announced today by the US. Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ) and Centres for Medicare and Medicaid Services (CMS).... Use of EHRs continues to improve the quality and safety of health care in the United States, but many existing EHR systems are not tailored to capture or process health information about children. The EHR format for children's health care announced today includes recommendations for child-specific data elements such as vaccines and functionality that will enable EHR developers to broaden their products to include modules tailored to children's health of Paediatrics (AAP) and the American Academy of Family Physicians. The format is built on specifications from sources that include the Health Level Seven International (HL7®) EHR-S Functional Model, the HL7 Child Health Work Group's Child Health Functional Profile, and the HHS Health Resources and Services Administration's Health IT for Children Toolbox.

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See the link below to access a copy of the "Children's EHR Format" http://healthit.ahrq.gov/childehrFormat

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 function T4 Standard Terminology and Terminology Services, a function could be created for DCM and DCM services. The work on this function could be considered for inclusion in the next version of the EHR-S FM.

6 Conformance Clause

6.1 Introduction (Reference)

The following is the EHR Work Group approved Conformance Clause. 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 testing or validation procedures to determine whether an EHR system conforms to a 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:

5. The purpose, structure, and use of conformance criteria that are to be included in the Functional Model and conforming Functional Profiles,
6. The rules for defining conforming Functional Profiles of the Functional Model,

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7. The relationship between Functional Profiles and EHR systems,
8. Sample Conformance Clauses and use case scenarios,
9. Guidance on the conformance requirements that a Functional Profile might levy on EHR systems,
10. 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 testing or validation procedures to assess a Functional Profile's conformance to the Functional Model. It also does not specify testing or validation procedures to determine whether an EHR system conforms to a Functional Profile or matches its 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. profile for Records Management and Evidentiary Support EHR).

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 care setting or application, or reflect the functionality incorporated in a vendor's EHR system.

(NOTE: During the process of creating a profile, it may be important to discuss clinical processes and/or the interaction 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.)

Once a Functional Profile is defined it can be implemented by 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 functions from the base (existing) Functional Profile.

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 to meet the rules, regulations and standards applicable for that realm. 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 might 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.

There are two types of mandatory inheritance in the EHR-S FM. All Functional Domain Profiles will inherit all functions in the Overarching section of the Function List Chapter 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 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 6: 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 WG ballot at the committee level will be designated as *HL7 Informative functional domain or companion profiles*. HL7 Informative Functional Profiles are eligible to undergo full membership ballot via the HL7 consensus process. *For additional information on registering*

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and/or balloting Functional Profiles, see the reference information in the How To Guide for Profiles (under development).

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 Functional Model or (2) to another conforming functional domain profile. NOTE: All 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 a selected companion profile. 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 illustrates this relationship.

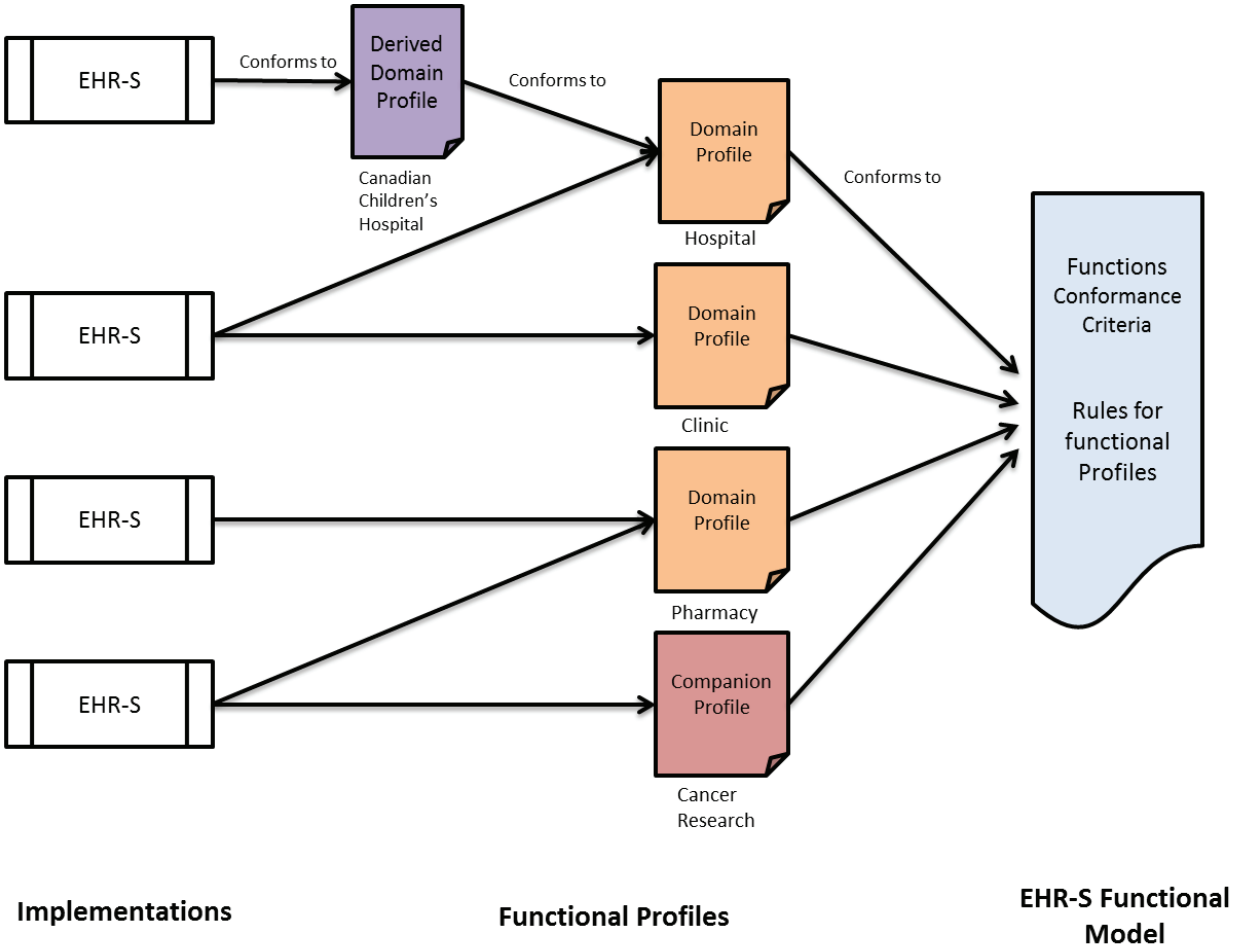

Figure 3 — Conformance Relationships

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 six of this chapter 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

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that within the FM or the source profile. This may be important when questions arise as to where did it come from, why did you choose or modify it, 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 FM.

6.4 Normative Language (Normative)

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'.

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

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 criteria with care-setting and application specific information or (2) if no care-setting or application specific criteria are present, 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.

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- 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 2 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 labelled "Type". Parent and Child Headers **MAY** contain conformance criteria only if the criteria apply to all its 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 an "F" in the "Type" column. Conformance criteria listed in a parent function **SHALL** be inherited by all its children functions. Conformance Criteria have a "C" in the "Type" column.

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