

## DIN EN ISO 10781



ICS 35.240.80

**Entwurf**

Einsprüche bis 2023-06-14  
Vorgesehen als Ersatz für  
DIN EN ISO 10781:2015-12

**Medizinische Informatik –  
HL 7 Funktionales Modell für ein elektronisches  
Gesundheitsaktensystem, Ausgabe 2.1 (EHRS FM) (ISO/DIS 10781:2023);  
Englische Fassung prEN ISO 10781:2023**

Health Informatics –  
HL7 Electronic Health Record-System Functional Model, Release 2.1 (EHR FM)  
(ISO/DIS 10781:2023);  
English version prEN ISO 10781:2023

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

**Anwendungswarnvermerk**

Dieser Norm-Entwurf mit Erscheinungsdatum 2023-04-14 wird der Öffentlichkeit zur Prüfung und Stellungnahme vorgelegt.

Weil die beabsichtigte Norm von der vorliegenden Fassung abweichen kann, ist die Anwendung dieses Entwurfs besonders zu vereinbaren.

Stellungnahmen werden erbeten

- vorzugsweise online im Norm-Entwurfs-Portal von DIN unter [www.din.de/go/entwuerfe](http://www.din.de/go/entwuerfe) bzw. für Norm-Entwürfe der DKE auch im Norm-Entwurfs-Portal der DKE unter [www.entwuerfe.normenbibliothek.de](http://www.entwuerfe.normenbibliothek.de), sofern dort wiedergegeben;
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- oder in Papierform an den DIN-Normenausschuss Medizin (NAMed), 10772 Berlin oder Am DIN-Platz, Burggrafenstr. 6, 10787 Berlin.

Die Empfänger dieses Norm-Entwurfs werden gebeten, mit ihren Kommentaren jegliche relevanten Patentrechte, die sie kennen, mitzuteilen und unterstützende Dokumentationen zur Verfügung zu stellen.

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DIN-Normenausschuss Medizin (NAMed)

## Nationales Vorwort

Dieses Dokument (prEN ISO 10781:2023) wurde vom Technischen Komitee ISO/TC 215 „Health Informatics“ in Zusammenarbeit mit dem Technischen Komitee CEN/TC 251 „Medizinische Informatik“ erarbeitet, dessen Sekretariat von NEN gehalten wird.

Das zuständige deutsche Normungsgremium ist der Arbeitsausschuss NA 063-07-02 AA „Interoperabilität“ im DIN-Normenausschuss Medizin (NAMed).

Dieses Dokument enthält unter Berücksichtigung des DIN-Präsidialbeschlusses 1/2004 nur die Englische Originalfassung von prEN ISO 10781:2023.

Der Bedarf für eine Deutsche Fassung wird derzeit beraten.

Für die in diesem Dokument zitierten Dokumente wird im Folgenden auf die entsprechenden deutschen Dokumente hingewiesen:

|                  |       |                            |
|------------------|-------|----------------------------|
| ISO 13606-1:2019 | siehe | DIN EN ISO 13606-1:2019-11 |
| ISO 13606-2:2019 | siehe | DIN EN ISO 13606-2:2019-11 |
| ISO 13606-3:2019 | siehe | DIN EN ISO 13606-3:2019-11 |
| ISO 13606-4:2019 | siehe | DIN EN ISO 13606-4:2019-11 |
| ISO 13606-5:2019 | siehe | DIN EN ISO 13606-5:2019-11 |
| ISO 13940:2015   | siehe | DIN EN ISO 13940:2016-07   |

Aktuelle Informationen zu diesem Dokument können über die Internetseiten von DIN ([www.din.de](http://www.din.de)) durch eine Suche nach der Dokumentennummer aufgerufen werden.

## Änderungen

Gegenüber DIN EN ISO 10781:2015-12 wurden folgende Änderungen vorgenommen:

- a) Anpassungen an die Aktualisierungen des HL7 Errata Release 2.01.
- b) Der Abschnitt über die Datensatzinfrastruktur (en: Record Infrastructure) wurde aktualisiert und enthält nun drei neue Datensatz-Lebenszyklus-Ereignisse (en: Record Lifecycle Events): Verifizieren, Verschlüsseln und Entschlüsseln. Es gibt jetzt insgesamt 27 Datensatz-Lebenszyklus-Ereignisse, die beschreiben, wie ein elektronisches Gesundheitsaktensystem (EGA-S, en: EHR-S) Einträge in Gesundheitsakten während ihrer Lebensdauer verwaltet, von der Erstellung/Aufbewahrung des ersten Eintrags bis zur Löschung oder Vernichtung des letzten Eintrags. Die 27 Datensatz-Lebenszyklus-Ereignisse entsprechen denen, die in ISO/TS 21089:2018, Health Informatics - Trusted end-to-end information flow und HL7 Fast Health Interoperable Resources (FHIR) Record Lifecycle Event Implementation Guide, veröffentlicht als Teil von FHIR Core STU-3 (März 2017) und jetzt Teil von FHIR Core R4 (in der Abstimmung, September 2018), festgelegt sind.
- c) Die Definitionen/Beschreibungen der 27 Datensatz-Lebenszyklus-Ereignisse werden entsprechend den Vereinbarungen des Projektes HL7 Vocabulary Alignment (in gemeinsamer Zusammenarbeit von HL7 EHR und Security Work Groups) aktualisiert. Der Glossarabschnitt enthält ebenfalls diese Definitionen/Beschreibungen.
- d) Der Konformitätsabschnitt wird aktualisiert, um eine Definition/Beschreibung eines neuen Typs von EGA-S-FM-Funktionsprofil (FP) aufzunehmen: Derived Companion FP.

- e) Die Vertrauensinfrastruktur wurde aktualisiert, um Funktionen und Konformitätskriterien zur Unterstützung des ISO/HL7 detaillierten klinischen Models (en: Detailed Clinical Models; DCMs) aufzunehmen.

## **Nationaler Anhang NA** (informativ)

### **Einleitung**

#### **NA.1 Was sind elektronische Gesundheitsaktensysteme?**

Der effektive Einsatz von Informationstechnologie ist ein zentraler Punkt für die Verbesserung des Gesundheitswesens im Hinblick auf die Sicherheit der Patienten, die Qualität der Ergebnisse und die wirtschaftliche Effizienz. Eine Reihe von Berichten des U.S. Institute of Medicine (IOM) stellt eine Krise aufgrund eines „Systemversagens“ fest und fordert einen „Systemwandel“, der durch den Einsatz von Informationstechnologie ermöglicht wird. Eine solche Veränderung ist möglich durch „eine Infrastruktur, die ein vollständig verbundenes, universelles, sicheres Netzwerk von Systemen ermöglicht, das jederzeit und überall Informationen für die Versorgung von Patienten liefern kann“.

Bei der Entwicklung dieses EGA-S-Funktionsmodells hat sich HL7 auf drei anerkannte Definitionen gestützt: zwei vom U.S. Institute of Medicine bereitgestellte und eine vom Europäischen Komitee für Normung/Comité Européen de Normalisation (CEN) entwickelte. Dieses Funktionsmodell nutzt diese bestehenden EGA-S-Definitionen und beabsichtigt nicht, eine redundante Definition eines EGA-S zu erstellen.

#### **NA.2 Wie wurden die Funktionen ermittelt und entwickelt?**

Um von Anfang an einen Konsens in der Gesundheitsversorgung zu erzielen, werden die Funktionen auf einer konzeptionellen Ebene beschrieben, um eine robuste Grundlage für eine detailliertere Arbeit zu schaffen. Funktionen wurden aufgenommen, wenn sie in mindestens einer Pflegesituation als wesentlich angesehen wurden. Das Dokument ist in einer anwenderorientierten Sprache verfasst und richtet sich an eine breite Leserschaft.

Funktionale Granularität ist ein Begriff, der die Abstraktionsebene beschreibt, auf der eine Funktion dargestellt wird. Funktionen, die in der Praxis oder bei größeren Systemen häufig zusammengefasst werden, wurden gegebenenfalls zusammengelegt; Funktionen, die eine zusätzliche oder separate Sprache erfordern oder unterschiedliche Arbeitsabläufe beinhalten, wurden gegebenenfalls getrennt gehalten. So wird beispielsweise die Entscheidungshilfe als separater Abschnitt beibehalten, aber anderen wesentlichen Abschnitten zugeordnet, um die "intelligente" Funktion hinter einer Handlung zu verdeutlichen. Alle Funktionen könnten noch weiter verfeinert werden, doch es wurde sich auf ein ausgewogenes Verhältnis zwischen einem nutzbaren Dokument und einer umfangreichen Liste von Funktionen geeinigt. Das Ziel bei der Festlegung einer angemessenen funktionalen Granularität ist zum jetzigen Zeitpunkt, Funktionen bereitzustellen, die von den Lesern dieser Norm einfach ausgewählt und verwendet werden können, die aber nicht so abstrakt sind, dass die Leser eine große Anzahl von zusätzlichen Funktionen innerhalb jeder Funktion erstellen müssten.

Obwohl die Bestimmung der funktionalen Granularität eine vergleichsweise subjektive Aufgabe ist, hat die systematische Bewertung jeder Funktion durch verschiedene Gruppen von Fachleuten aus der Branche zu einer Granularität geführt, die für dieses EGA-S-Funktionsmodell angemessen ist. Es wurde versucht, in den Funktionsbeschreibungen unterstützende Informationen bereitzustellen, um die detaillierteren Aspekte von Funktionen zu veranschaulichen, die aus Gründen der Benutzerfreundlichkeit möglicherweise zusammengefasst wurden.

Entsprechend der Absicht dieses EGA-S-Funktionsmodells, in Bezug auf Technologie oder Implementierungsstrategie unabhängig zu sein, wurde keine spezifische Technologie in die Funktionen aufgenommen, darf aber in den Beispielen zur Illustration der Funktionen verwendet werden. Die Aufnahme bestimmter Technologien in die Beispiele stellt keine Befürwortung oder Unterstützung der Verwendung dieser Technologien als Implementierungsstrategien dar.

Das EGA-S-Funktionsmodell und die spezifischen Funktionen wurden von Gesundheitsdienstleistern, -anbietern, Gesundheitsbehörden, Regulierungs- und Akkreditierungsbehörden, Berufsverbänden, Han-

delsvereinigungen, Forschern und anderen Interessengruppen eingehend geprüft. Diese Norm spiegelt den Beitrag all dieser Prüfer wider.

## Nationaler Anhang NB (informativ)

### Anwendungsbereich

Das HL7 EHR System Functional Model bietet eine Referenzliste von Funktionen, die in einem elektronischen Gesundheitsaktensystem (EGA-S) vorhanden sein können. Die Funktionsliste wird aus der Perspektive des Anwenders beschrieben, um eine einheitliche Darstellung der Systemfunktionen zu ermöglichen. Dieses EGA-S-Funktionsmodell ermöglicht durch die Erstellung von Funktionsprofilen für Pflegesituationen, -bereiche, -dienste und -fachgebiete eine genormte Beschreibung und ein gemeinsames Verständnis der Funktionen, die in einer bestimmten Umgebung (z. B. Intensivpflege, Kardiologie, Arztpraxis in einem Land oder Primärversorgung in einem anderen Land) angestrebt werden oder verfügbar sind.

#### NB.1.1 Anwendungsbereich des EGA-S-Funktionsmodells

Das HL7 EHR-S Functional Model definiert ein genormtes Modell der Funktionen, die in EGA-Systemen vorhanden sein können. Von Beginn an ist eine klare Unterscheidung zwischen der EGA als einzelne Entität und Systemen, die innerhalb der EGA ausgeführt werden – d. h. EGA-Systeme – von entscheidender Bedeutung. Diese Norm macht keinen Unterschied hinsichtlich der Implementierung – das in einem Funktionsprofil beschriebene EGA-S kann ein einzelnes System oder ein System von Systemen sein. In den normativen Abschnitten des Funktionsmodells wird der Begriff „System“ generisch verwendet, um das gesamte Spektrum der Implementierungsmöglichkeiten abzudecken. Dazu gehören „Kernfunktionen“ des Gesundheitswesens, die üblicherweise von gesundheitsspezifischen Anwendungen bereitgestellt werden, mit denen elektronische Gesundheitsinformationen verwaltet werden. Außerdem gehören dazu auch die entsprechenden generischen Fähigkeiten auf Anwendungsebene, die in der Regel von Middleware oder anderen Infrastrukturkomponenten bereitgestellt werden. Letztere umfassen Interoperabilitäts- und Integrationsfunktionen wie die Standortermittlung und Bereiche wie den anwendungsübergreifenden Arbeitsablauf. Interoperabilität wird sowohl aus semantischer Sicht (klare, konsistente und dauerhafte Kommunikation der Bedeutung) als auch aus technischer Sicht (Format, Syntax und physische Verbindung) betrachtet. Darüber hinaus geben die Funktionen keinen Aufschluss darüber, welche Technologie verwendet wird, oder über den Inhalt der elektronischen Gesundheitsakte. Die Einzelheiten, „wie“ EGA-Systeme entwickelt oder implementiert werden, werden weder jetzt noch in Zukunft als Teil des Anwendungsbereichs dieses Modells angesehen. Dieses EGA-S-Funktionsmodell berücksichtigt oder befürwortet weder Implementierungen oder Technologien, noch umfasst es den Dateninhalt der elektronischen Gesundheitsakte.

Zu guter Letzt unterstützt das EGA-S-Funktionsmodell die Anforderungen der Forschung, indem es sicherstellt, dass die den Forschern zur Verfügung stehenden Daten den erforderlichen Protokollen für Datenschutz, Vertraulichkeit und Sicherheit entsprechen. Die Vielfalt der Forschungsanforderungen schließt die spezifische Auflistung von Funktionen aus, die für die Forschung potenziell nützlich sind.

Dieses Funktionsmodell ist keine:

- Meldungsspezifikation
- Implementierungsspezifikation
- Konformitätsspezifikation
- EGA-Spezifikation
- Konformitätsmetrik oder Konformitätsprüfungsmetrik
- Anleitung zur Erstellung einer Definition für ein EGA oder EGA-S

Es ist zu beachten, dass das EGA-S-Funktionsmodell keine Diskussion über klinische Prozesse oder die Interaktion der Akteure im Gesundheitswesen beinhaltet. ISO 13940 Health Informatics – System of Concepts to Support Continuity of Care ist jedoch eine internationale Norm, die die wichtigsten Grundsätze und Prozesse in der Gesundheitsversorgung beschreibt. Es wird empfohlen, dass sich die Anwender des EGA-S-FM bei klinischen Prozessen, die EGA-Systeme unterstützen, auf diese Norm beziehen.

Dieses EGA-S-Funktionsmodell-Paket enthält sowohl Referenz- als auch normative Abschnitte.

**Tabelle NB.1 — Normative Statustypen**

| Status   | Beschreibung                                                                                                                                                                                                                                                                                                                                             |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Referenz | Inhalt des EGA-S-Funktionsmodell-Pakets, der Informationen enthält, die Konzepte verdeutlichen oder anderweitig zusätzliche Informationen bereitstellen, um Verständnis und Verständlichkeit zu erleichtern. Das Referenzmaterial wird nicht als Teil der Norm festgelegt.                                                                               |
| Normativ | Inhalte, die Teil des EGA-S-Funktionsmodells sind, das von HL7-Komiteemitgliedern und betroffenen Branchenteilnehmern formell geprüft und entsprechend den HL7-Verfahren für die Abstimmung normativer Dokumente festgelegt wurden. Dieses von HL7 entwickelte Funktionsmodell wurde von der HL7-Organisation erfolgreich als normative Norm festgelegt. |

Jeder Abschnitt in diesem Dokument ist deutlich mit „Normativ“ gekennzeichnet, wenn er normativ ist. Beispielsweise ist in Abschnitt 5 (Overview) der Unterabschnitt 5.3 normativ. In Abschnitt 7, Conformance Clause, sind die Unterabschnitte 7.1 bis 7.6 normativ.

Im externen Anhang A, Function List, sind die Komponenten Function ID, Function Name, Function Statement und Conformance Criteria in diesem Funktionsmodell normativ.

## Nationaler Anhang NC (informativ)

### Begriffe

Reihenfolge und Inhalt der folgenden Begriffe sind identisch mit denen im Abschnitt Begriffe der Englischen Fassung.

Für die Anwendung dieses Dokuments gelten die folgenden Begriffe.

ISO und IEC stellen terminologische Datenbanken für die Verwendung in der Normung unter den folgenden Adressen bereit:

- ISO Online Browsing Platform: verfügbar unter <https://www.iso.org/obp>
- IEC Electropedia: verfügbar unter <https://www.electropedia.org/>

#### 3.1

##### **Zugriffskontrolle**

Mittel zur Sicherstellung, dass auf die Ressourcen eines Datenverarbeitungssystems nur von dazu berechtigten Entitäten und in autorisierter Art und Weise zugegriffen werden kann

#### 3.2

##### **Basisfunktionsprofil**

bestehendes Domänen- oder begleitendes Funktionsprofil, aus dem neue Funktionsprofile erstellt/abgeleitet werden

#### 3.3

##### **Konformität**

Erfüllung eines Produkts, eines Prozesses oder einer Dienstleistung von festgelegten Anforderungen

#### 3.4

##### **Konformitätskriterien**

Angaben zur Anforderung, die das Verhalten, die Aktion oder die Fähigkeit anzeigen, das bzw. die die Verwirklichung der betreffenden Funktion darstellt

#### 3.5

##### **Konformitätsabschnitt**

Abschnitt einer Spezifikation, der die Anforderungen, Kriterien oder Bedingungen festlegt, die erfüllt werden müssen, um Anspruch auf Konformität erheben zu können

#### 3.6

##### **Konformitätserklärung**

Beschreibung der Funktionen in einem EGA-System, die umgesetzt wurden. Sie entspricht dem Grad, in dem ein EGA-System die Anforderungen des Funktionsprofils erfüllt hat und kann optionale Funktionen und Informationen enthalten

#### 3.7

##### **abgeleitetes Funktionsprofil**

Domänenfunktions- oder begleitendes Funktionsprofil, das aus einem Basisfunktionsprofil abgeleitet wird (d. h. Kind Domänenfunktionsprofil aus dem Kinderklinik-Domänenprofil)

### 3.8

#### **Erweiterung**

Fähigkeit eines elektronischen Gesundheitsaktensystems, das zusätzliche Funktionalitäten integriert, die über die hinausgehen, die in den Funktionsprofilen festgelegt wurden

### 3.9

#### **Funktionsprofil**

Teilmenge des Funktionsmodells, bei dem Funktionen (manchmal in unterschiedlichem Maße) bestimmt wurden für bestimmte elektronische Gesundheitsaktensysteme oder Einstellungen für die Gesundheitsversorgung oder enge Betriebsanforderungen

### 3.10

#### **informatives Funktionsprofil**

registriertes Funktionsprofil, das erfolgreich die genaue formelle öffentliche Prüfung durch den HL7-Konsensprozess bestanden hat

### 3.11

#### **vererbtes Kriterium**

alle Konformitätskriterien, die in einer übergeordneten Funktion aufgelistet sind und die allen ihren untergeordneten Funktionen vererbt werden

### 3.12

#### **zugelassenes Funktionsprofil**

Funktionsprofil, das erfolgreich die Registrierung und Überprüfung durch die HL7-Arbeitsgruppe „Elektronische Gesundheitsaktensysteme“ (EHR WG) abgeschlossen hat

### 3.13

#### **Situationskriterium**

Kriterium, das erforderlich ist, wenn die entsprechenden Umstände eingetreten sind (WENN/Dann oder abhängiges MUSS)

## Nationaler Anhang ND (informativ)

### Literaturhinweise

DIN EN ISO 13606-1:2019-11, *Medizinische Informatik — Kommunikation von Patientendaten in elektronischer Form — Teil 1: Referenzmodell (ISO 13606-1:2019); Englische Fassung EN ISO 13606-1:2019*

DIN EN ISO 13606-2:2019-11, *Medizinische Informatik — Kommunikation von Patientendaten in elektronischer Form — Teil 2: Spezifikation für den Austausch von Archetypen (ISO 13606-2:2019); Englische Fassung EN ISO 13606-2:2019*

DIN EN ISO 13606-3:2019-11, *Medizinische Informatik — Kommunikation von Patientendaten in elektronischer Form — Teil 3: Referenzarchetypen und Begriffslisten (ISO 13606-3:2019); Englische Fassung EN ISO 13606-3:2019*

DIN EN ISO 13606-4:2019-11, *Medizinische Informatik — Kommunikation von Patientendaten in elektronischer Form — Teil 4: Sicherheit (ISO 13606-4:2019); Englische Fassung EN ISO 13606-4:2019*

DIN EN ISO 13606-5:2019-11, *Medizinische Informatik — Kommunikation von Patientendaten in elektronischer Form — Teil 5: Interface-Spezifikation (ISO 13606-5:2019); Englische Fassung EN ISO 13606-5:2019*

DIN EN ISO 13940:2016-07, *Medizinische Informatik — Begriffssystem zur Unterstützung der Kontinuität der Versorgung (ISO 13940:2015); Englische Fassung EN ISO 13940:2016*

## Contents

Page

|       |                                                                                                                                                                                                               |     |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|
| 0     | Introduction.....                                                                                                                                                                                             | vi  |
| 0.1   | Notes to Readers .....                                                                                                                                                                                        | vi  |
| 0.2   | Changes from Previous Release .....                                                                                                                                                                           | vi  |
| 0.3   | Background.....                                                                                                                                                                                               | vii |
| 0.3.1 | What are Electronic Health Record Systems? .....                                                                                                                                                              | vii |
| 0.3.2 | How were the Functions Identified and Developed? .....                                                                                                                                                        | vii |
| 1     | Scope.....                                                                                                                                                                                                    | 1   |
| 1.1   | EHR-S Functional Model Scope.....                                                                                                                                                                             | 1   |
| 2     | Normative References.....                                                                                                                                                                                     | 2   |
| 3     | Terms and Definitions.....                                                                                                                                                                                    | 2   |
| 4     | Overview and Definition of the Functional Model (Normative).....                                                                                                                                              | 3   |
| 4.1   | Sections of the Function List .....                                                                                                                                                                           | 4   |
| 4.2   | Functional Profiles .....                                                                                                                                                                                     | 5   |
| 4.3   | EHR-S Function List Components.....                                                                                                                                                                           | 5   |
| 4.3.1 | Function ID (Normative).....                                                                                                                                                                                  | 6   |
| 4.3.2 | Function Type (Reference) .....                                                                                                                                                                               | 6   |
| 4.3.3 | Function Name (Normative) .....                                                                                                                                                                               | 7   |
| 4.3.4 | Function Statement (Normative).....                                                                                                                                                                           | 7   |
| 4.3.5 | Description (Reference).....                                                                                                                                                                                  | 7   |
| 4.3.6 | Conformance Criteria (Normative).....                                                                                                                                                                         | 7   |
| 5     | Anticipated Uses (Reference) .....                                                                                                                                                                            | 7   |
| 5.1   | Development Approach: Functional Profiles .....                                                                                                                                                               | 7   |
| 5.1.1 | Scenario 1 – Group Practice .....                                                                                                                                                                             | 8   |
| 5.1.2 | Scenario 2 - Hospital.....                                                                                                                                                                                    | 8   |
| 5.1.3 | Scenario 3 - IT Vendor.....                                                                                                                                                                                   | 8   |
| 5.2   | Examples of Current Use.....                                                                                                                                                                                  | 8   |
| 5.2.1 | Functional Profile for Clinical Research based on the EHR-S FM .....                                                                                                                                          | 8   |
| 5.2.2 | AHRQ adopts Health Level Seven International (HL7) Child Health Functional Profile<br>Specification, Release 1 and incorporates key functionalities in the Children’s Electronic<br>Health Record Format..... | 9   |
| 5.2.3 | Linking clinical content descriptions to the EHR-S FM (Reference).....                                                                                                                                        | 9   |
| 6     | Conformance Clause.....                                                                                                                                                                                       | 10  |
| 6.1   | Introduction (Reference).....                                                                                                                                                                                 | 10  |
| 6.2   | Scope and Field of Application (Normative).....                                                                                                                                                               | 10  |
| 6.3   | Concepts (Normative) .....                                                                                                                                                                                    | 10  |
| 6.3.1 | Functional Profiles .....                                                                                                                                                                                     | 10  |
| 6.3.2 | Conformance Model .....                                                                                                                                                                                       | 11  |
| 6.3.3 | Profile Traceability .....                                                                                                                                                                                    | 12  |
| 6.4   | Normative Language (Normative).....                                                                                                                                                                           | 12  |
| 6.5   | Conformance Criteria (Normative).....                                                                                                                                                                         | 13  |
| 6.5.1 | Criteria in the Functional Profile .....                                                                                                                                                                      | 13  |
| 6.5.2 | ‘Dependent SHALL’ Criteria .....                                                                                                                                                                              | 13  |
| 6.5.3 | Referencing Other Criteria or Functions.....                                                                                                                                                                  | 13  |
| 6.6   | Functional Model Structure and Extensibility (Normative) .....                                                                                                                                                | 13  |
| 6.6.1 | Hierarchical Structure .....                                                                                                                                                                                  | 13  |
| 6.6.2 | Naming Convention.....                                                                                                                                                                                        | 14  |
| 6.6.3 | Priorities .....                                                                                                                                                                                              | 14  |
| 6.6.4 | Extensibility .....                                                                                                                                                                                           | 15  |
| 6.7   | Functional Profile Conformance (Normative).....                                                                                                                                                               | 15  |
| 6.7.1 | Rules for Functional Domain Profiles .....                                                                                                                                                                    | 15  |
| 6.7.2 | Rules for Creating New Functions in Functional Profiles.....                                                                                                                                                  | 16  |
| 6.7.3 | Rules for Derived Functional Profiles .....                                                                                                                                                                   | 18  |
| 6.7.4 | Conformance Statement.....                                                                                                                                                                                    | 18  |
| 6.7.5 | Rules for Functional Companion Profiles.....                                                                                                                                                                  | 18  |

|                       |                                                                                             |    |
|-----------------------|---------------------------------------------------------------------------------------------|----|
| 6.8                   | Use Cases and Samples (Reference) .....                                                     | 19 |
| 6.8.1                 | Functional Profile Use Cases .....                                                          | 19 |
| 6.8.2                 | Sample Functional Domain Profile Conformance Clauses .....                                  | 20 |
| 6.8.3                 | Interpreting and Applying a Conditional ‘SHALL’ (Reference) .....                           | 20 |
| 6.8.4                 | General Concepts .....                                                                      | 21 |
| 6.8.5                 | Rationale for ‘Dependent SHALL’ .....                                                       | 21 |
| 6.8.6                 | How to Apply the ‘Dependent SHALL’ .....                                                    | 22 |
| 7                     | EHR System Conformance Claim via Self-Attestation.....                                      | 23 |
| 7.1                   | The Name and Version of the standard that the software product is compliant with .....      | 23 |
| 7.2                   | A full listing of the conformance criteria that the software product is compliant with..... | 23 |
| 8                     | Glossary.....                                                                               | 24 |
| 8.1                   | Preface (Reference) .....                                                                   | 24 |
| 8.2                   | Introduction (Normative) .....                                                              | 24 |
| 8.3                   | Overview (Reference) .....                                                                  | 24 |
| 8.4                   | The Action-Verb Structure (Normative) .....                                                 | 24 |
| 8.4.1                 | Secure (System) Category .....                                                              | 24 |
| 8.4.2                 | Data Management Category .....                                                              | 25 |
| 8.4.3                 | How Action-Verbs are defined.....                                                           | 26 |
| 8.4.4                 | Deprecated Verbs .....                                                                      | 31 |
| 8.5                   | Guidelines for Use (Reference) .....                                                        | 34 |
| 8.5.1                 | General Guidance .....                                                                      | 34 |
| 8.5.2                 | Constructing Rigorous Conformance Criteria.....                                             | 35 |
| 9                     | Glossary Supplement: Record Lifecycle Events and Descriptions (Normative) .....             | 24 |
| 9.1                   | Record Lifecycle Events (See RI.1.1.1).....                                                 | 36 |
| Annex A (normative)   | Function List .....                                                                         | 38 |
| Annex B (informative) | Glossary of Terms for EHR-S FM .....                                                        | 39 |
| Annex C (informative) | Background .....                                                                            | 67 |
| C.1                   | What is HL7? .....                                                                          | 67 |
| C.2                   | The HL7 Electronic Health Records Work Group.....                                           | 67 |
| Annex D               | Bibliography .....                                                                          | 68 |

## Foreword [from ISO template]

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

## 0 Introduction

### 0.1 Notes to Readers

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

### 0.2 Changes from Previous Release

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

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

## 0.3 Background

### 0.3.1 What are Electronic Health Record Systems?

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

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

### 0.3.2 How were the Functions Identified and Developed?

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

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

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

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

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

– *Entwurf* –

# Health Informatics — HL7 Electronic Health Record-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, realms, services and specialties, enables a standardized description and common understanding of functions sought or available in a given setting (e.g., intensive care, cardiology, office practice in one country or primary care in another country).

### 1.1 EHR-S Functional Model Scope

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

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

This Functional Model is not:

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

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

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

| Status    | Description                                                                                                                                                                                                                                       |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Reference | Content of the EHR-S Functional Model Package that contains information which clarifies concepts or otherwise provides additional information to aid understanding and comprehension. Reference material is not balloted as part of the standard. |
| Normative | Content that is part of the EHR-S Functional Model which HL7 committee members and interested industry participants have formally reviewed and balloted following the HL7                                                                         |

|                                                                                                                                                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 referenced documents are indispensable for the application of this document.

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

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

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

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

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

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

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

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

## 3 Terms and Definitions

### 3.1

#### access control

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

### 3.2

#### base functional profile

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

### 3.3

#### conformance

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

### 3.4

#### conformance criteria

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

### 3.5

#### conformance clause

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

### 3.6

#### conformance statement

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

### 3.7

#### **derived functional profile**

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

### 3.8

#### **extension**

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

### 3.9

#### **functional profile**

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

### 3.10

#### **informative functional profile**

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

### 3.11

#### **inherited criterion**

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

### 3.12

#### **registered functional profile**

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

### 3.13

#### **situational criterion**

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

## 4 Overview and Definition of the Functional Model (Normative)

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

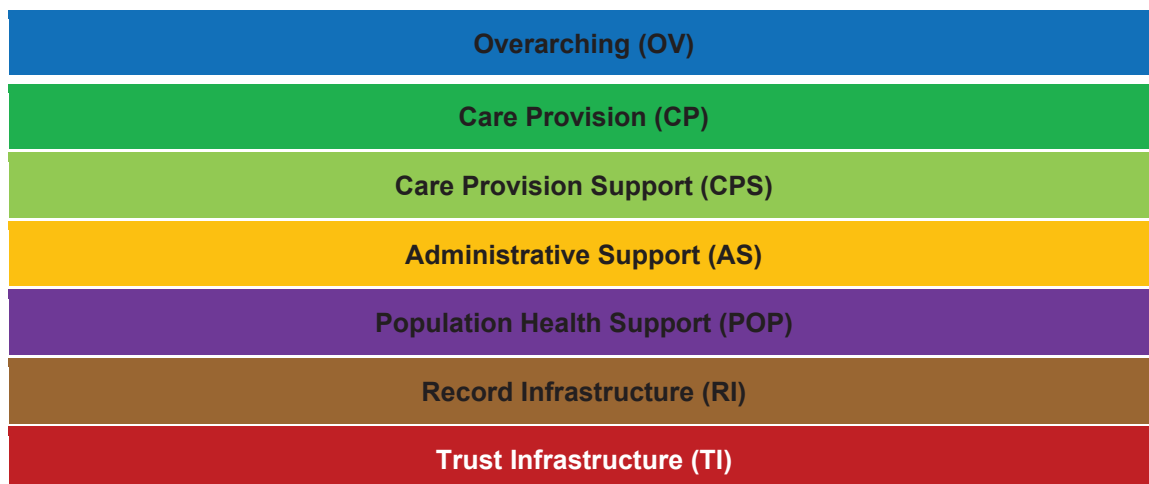


**Figure 1: Function List Sections**

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

## 4.1 Sections of the Function List

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

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

## 4.2 Functional Profiles

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

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

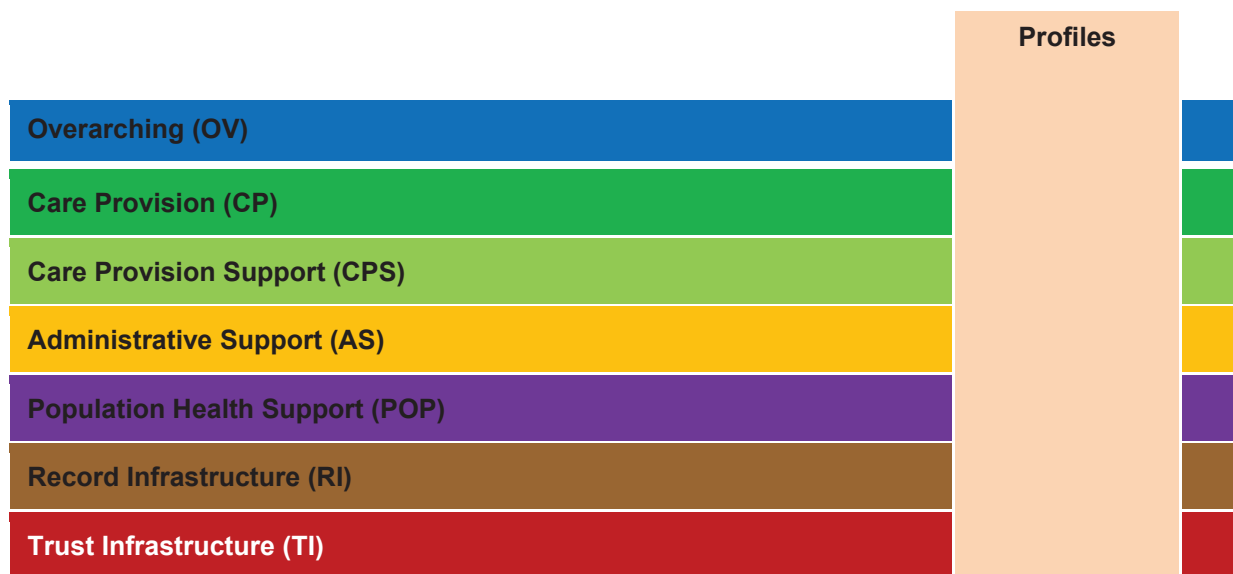


**Figure 2. Profiling from the EHR-S FM.**

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

The Conformance Clause is a high-level description of what is required of profiles and implementations. It, in turn, refers to other parts of the standard for details. The Conformance Clause describes concepts critical to the understanding and implementation of the Functional Model, such as: *‘What is a profile? What are Conformance Criteria? Or how do you know what is mandatory versus optional?’* A Conformance Clause can also provide a communication between the implementers (producers) and users (buyers) as to what is required, and gives meaning to the phrases, “conforming profile” and “conforming EHR system”. Additionally, it serves as the basis for inspection, testing and/or certification activities which may be performed by organizations external to HL7.

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

## 4.3 EHR-S Function List Components

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

EHR-S functions can be used to:

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

- 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.

| 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.

#### 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 might 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 might read the Care Provision and Care Provision Support sections very closely, while technical specialists might focus especially on Record and Trust Infrastructure sections. Within an organization, it might 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

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 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 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 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 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.

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.

- 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 a 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:

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,
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 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.)