HL7 EHR Work Group &
Meaningful Use Functional Profile Project Team

# Meaningful Use Functional Profile

## Based on HL7 EHR System Functional Model and Standard, Release 2.0, US Realm Functional Profile

# Overview Chapter

## May 2014


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# Preface

## *Notes to Readers: Introduction*

1. This document is a precursor to the full HL7 Meaningful Use Functional Profile (MU FP), anticipated for ballot in August 2014. The Ballot Overview document is accompanied by a Ballot Worksheet, both of which are to be considered part of this ballot.

2. The MU FP Ballot Overview and Worksheet are published at this time for HL7 "Comment Only" ballot. The original objective was to prepare these documents for Informative ballot and for the first Functional Profile (FP), based on ISO/HL7 10781 Electronic Health Record System Functional Model Release 2, to be published with the Enterprise Architect-based FP development tool. While the FP Tool is almost ready, it was not in time to meet current HL7 ballot timeframes (to open 28 March 2014).

3. Without publication facilities of the FP Tool, this ballot was refocused to the MU FP Project Team's analysis worksheet. (Contributing team members include: Gora Datta, Gary Dickinson, Stephen Hufnagel, Hetty Kahn, Thomas Lukasik, Riki Merrick, Julie Richards, Eve Rubillos, Rob Savage, Serafina Versaggi and Diana Warner. CMS agreed to be an external project collaborator.)

4. The MU FP Project Team did a reverse analysis, starting with the published ONC/NIST Test Procedures for Meaningful Use Stages 1&2 and mapping back to corresponding functions and conformance criteria of the EHRS FM. See:
   http://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method

5. The intent of the MU FP is to build the EHRS FM to a common end point with US Meaningful Use EHR System Functional Requirements (as specified by US regulations, ONC Meaningful Use Certification Criteria and NIST Test Procedures).

6. Per #5 and with the HL7 MU FP, EHR Systems can be simultaneously cross-certified for US Meaningful Use and ultimately ISO/HL7 10781 EHRS FM R2.1 compliance (without extra work).

7. The MU FP Ballot Worksheet comprises two TABs:

   Test Procedure to Function/Criteria TAB with four columns
   A. ONC/NIST Test Procedure – Key Functions
   B. ONC/NIST Test Procedure – Test Steps
   C. EHRS FM – Primary Related Function – ID and Function Name
   D. EHRS FM – Primary Related Conformance Criteria – by number

   Regulation/Test Procedure Reference TAB
   A. Regulatory Reference
   B. Description
   C. ONC/NIST Test Procedure – w/link

8. Primary related functions and criteria from the EHRS FM (Columns C-D) are those that clearly correspond to what the Tester does in each Test Step of the Test Procedure (Column B). (An extensive list of secondary functions and criteria were also compiled but not included in the MU FP Ballot Worksheet.)

9. The MU FP Ballot Worksheet is keyed (and ordered row-wise) by Regulatory Reference and corresponding ONC/NIST Test Procedure. The full HL7 Meaningful Use Functional Profile will be keyed (and ordered) as per the Sections, Sub-Sections and Functions in the EHRS FM, i.e.:

    Care Provision (CP)
    Care Provision Support (CPS)
    Administrative Support (AS)
    Population Heath Support (POP)
    Record Infrastructure (RI)
    Trust Infrastructure (TI)

10. GAPS identified in Column C of the MU FP Ballot Worksheet have been "filled" with proposed new criteria in Column D.

11. Updates to existing criteria are noted in red.

12. The voter is requested to review the MU FP Ballot Worksheet and:
    A) Regarding what the Tester does in each Test Step (Column B), note any additional primary EHRS FM R2 functions and conformance criteria not already identified.
    B) If additional GAPS are identified, suggest appropriate conformance criteria language to "fill" the gap.

13. All comments will be considered as the full MU FP ballot documents are prepared for August 2014 ballot.

Thank you for your review and input.

## *Acknowledgements*

This effort was sponsored by the Health Level Seven International, Incorporated. A project team focused on this Meaningful Use Functional Profile was formed in Summer 2013 under the HL7 Electronic Health Record Work Group (EHR WG).

## *Changes from Previous Release*

[First Release = Not Applicable]

# BACKGROUND

## *Project Scope Statement*

The scope of this project is to develop an EHR System Meaningful Use Functional Profile, referred hereafter as MU FP, by identifying functions/criteria from HL7/ISO 10781, EHR System Functional Model Release 2, pertinent to U.S. Meaningful Use (MU) Stages 1, 2 (and 3, as it develops) and aligning the same with ONC 2014 Certification Criteria.

The HL7 Meaningful Use Functional Profile (MU FP) conforms to the HL7 EHR-S FM Release 2.0 and identifies functional requirements and conformance criteria corresponding to US Meaningful Use Stage 1 and 2 certification criteria.

The Project may use the Enterprise Architect-EA (© Sparx Systems) based HL7 EHR-Tooling Product to develop the FP (when available).

## *Project Need*

Interest has been expressed by the US Office of National Coordinator (ONC), CMS, CDC and many others (including international organizations) regarding the correspondence of US Meaningful Use certification criteria with related EHR System functions and conformance criteria of HL7/ISO 10781, EHR System Functional Model Release 2.

This also opens the potential for EHR Systems to be certified against MU Stage 1 & 2 criteria (US realm) and related HL7/ISO 10781 criteria (international) simultaneously – without extra work by the certifier or certified entity.

## *Target Realm*

The MU FP is targeted toward the U.S. realm.

## *Target End-Date*

The MU FP's target end-date is October 2014.

## *Sponsors*

### HL7 International and HL7 EHR Work Group

Founded in 1987, Health Level Seven International (HL7, http://www.HL7.org ) is a not-for-profit healthcare standards development organization (SDO) accredited by the American National Standards Institute (ANSI). While traditionally involved in the development of messaging standards used by healthcare systems to exchange data, HL7 has begun to develop structured document standards related to healthcare information systems. In 2002, a newly formed HL7

EHR Special Interest Group began development of a functional model for EHR systems. Shortly thereafter, a number of organizations approached HL7 to develop a consensus standard to define the necessary functions for an EHR system. The EHR Special Interest Group was promoted to a full technical committee (EHR-TC, later renamed to the EHR Work Group, EHR WG), and in 2004 published the *EHR-S Functional Model (EHR-S FM)* as a Draft Standard for Trial Use (DSTU). The Functional Model underwent membership level ballot in September 2006 and January 2007, and it was approved as a standard in February 2007. In 2009, EHR-S Functional Model Release 1.1 was jointly balloted and published by ISO TC215 and CEN TC251.

In March 2014, EHR-S FM Release 2 completed balloting and was approved for publication by HL7. Balloting continues at ISO TC215 and CEN TC251 and will conclude with approval and publication of EHR-S FM Release 2.1, anticipated for late Spring 2014.

The HL7 EHR Work Group intends that unique functional profiles be developed by subject matter experts in various care settings to inform developers, purchasers, and other stakeholders of the functional requirements of systems developed for specific domains.

## *What is a Functional Profile?*

The EHR-S FM is a list of all functions that COULD be present in EHR systems and criteria for achieving that function. Any given EHR-S will perform one or more functions (i.e., a subset) from the FM list (i.e., the superset), depending on the purpose of the system. The select subset of functions and the criteria for conforming to these functions characterize the EHR-S capabilities and are referred to as a "functional profile". The functions and conformance criteria will vary across functional profiles, depending on the operational needs of the system, i.e., what the system is in place to accomplish.

## *EHR-S Definitions and Standards*

The HL7-S EHR-S FM is based on the International Standards Organization (ISO) *ISO/TR-20514 Health Informatics – Electronic health record – Definition, scope and context*[1] and states:

> *"The primary purpose of the EHR is to provide a documented record of care that supports present and future care by the same or other clinicians…. Any other purpose for which the health record is used may be considered secondary."*
>
> *"The Core EHR contains principally clinical information; it is therefore chiefly focused on the primary purpose. The Core EHR is a subset of the Extended EHR. The Extended EHR includes the whole health information landscape; its focus therefore is not only on the primary purpose, but also on all of the secondary purposes as well. The Extended EHR is a superset of the Core EHR."*

In this respect, the MU FP may be regarded as a set of Extended (i.e., not Core) EHR functions.

[1] ISO/TR 20514: Health informatics -- Electronic health record -- Definition, scope and context. 2005-10-17 (Available at: http://www.iso.org)

## *The term "Jurisdiction"*

For the purposes of this document, the term "jurisdiction" is used as follows:

> A *jurisdiction* is an area, generally geo-political, in which a governmental agency or corporation has public health oversight and/or management responsibilities; a territorial range of authority or control. The jurisdiction could be a state, a metropolitan area (New York City, Chicago, etc.), a county within a state, or some other subdivision of a larger jurisdiction. A jurisdiction might encompass the entire country, as is the case with nationwide jurisdictions such as the jurisdictions of the Department of Veterans Affairs and the Federal Bureau of Investigation. A *subordinate jurisdiction* is a jurisdiction that is a subset of another jurisdiction.

## *Systems, Components, and Applications*

An EHR system consists of a collection of systems, applications, modules, or components, developed on different architectures. For example, a provider might pair one vendor's clinical documentation system with another's tracking, discharge, or prescribing system. An EHR system may be provided by a single vendor, multiple vendors, or by one or more development teams.

## *Organization of the HL7 EHR-S Functional Model*

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.

| |
|---|
| **Overarching (OV)** |
| **Care Provision (CP)** |
| **Care Provision Support (CPS)** |
| **Population Health Support (POP)** |
| **Administrative Support (AS)** |
| **Record Infrastructure (RI)** |
| **Trust Infrastructure (TI)** |

**Table 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.

## *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 of the earlier versions 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 specialty care centers.
- 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, & 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).
- 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).

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 | F | 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: Example of Functional Model Elements**

### Function ID

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

**Function Type**
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.

**Function Name**
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*

**Function Statement**
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*

**Description**
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.*

**Conformance Criteria**
Each function in the Function List includes one or more Conformance Criteria. A Conformance Criteria, which exists as normative language in this standard, defines the requirements for conforming to the function. The language used to express a conformance criterion is highly structured with standardized components with set meanings.

Example: *1. The system SHALL provide the ability to manage, as discrete data, all active problems associated with a patient.*

## *Conformance Clause*

These profiles are based on the HL7 EHR-S Functional Model, Release 2, January 2014.

Key to the Functional Model and derived profiles is the concept of *conformance,* which is defined as *"verification that an implementation faithfully meets the requirements of a standard or*

*specification"*. In the Functional Model and in derived profiles, the general concept of conformance may be expressed in a number of forms. For instance, a profile can be said to conform to the Functional Model if it adheres to the defined rules specified by the Functional Model specification. Similarly, an EHR system may claim conformance to one of these profiles if it meets all the requirements outlined in the profile.

## *Conformance Criteria*

Each function defined in the Functional Model or profiles is associated with specific *conformance criteria,* which are statements used to determine if a particular function is met (i.e., "the system SHALL capture, display and report all hearing tests associated with a patient"). Conformance criteria have been developed in accordance with the standards set forth by the EHR Work Group. In order to ensure consistent, unambiguous understanding and application of the Functional Profile, a consistent set of keywords (normative verbs) has been employed to describe conformance requirements.

The key words SHALL, SHALL NOT, SHOULD, and MAY in this document are to be interpreted as described in HL7 EHR-S Functional Model, Release 2, May 2013 Conformance Clause:

| | |
|---|---|
| **SHALL** | Indicates a mandatory requirement to be followed (implemented) in order to conform. Synonymous with 'is required to' and 'must'. |
| **SHOULD** | Indicates an optional recommended action, one that is particularly suitable, without mentioning or excluding others. Synonymous with 'is permitted and recommended'. |
| **MAY** | Indicates an optional, permissible action. Synonymous with 'is permitted'. |

**Table 3: Optionality key words**

## *Functional Profiles*

A "Functional Profile" is a selected set of functions that are applicable for a particular purpose, user, care setting, domain, etc. Functional profiles help to manage the master list of functions. It is not anticipated that the full Functional Model will 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.

Functional profiles are the expression of usable subsets of functions from the EHR-S Functional Model. 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 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.

## *Conformance of Derived Functional Profiles*

Derived profiles may prove valuable for:

*1.* specifying certain subsets of EHR systems used to care for specific groups of population, e.g., children, adults, women, or geriatrics; and/or specific care settings, e.g., acute care, ambulatory care, specialty care, pharmacy, laboratory, or radiology.
2. supporting information exchanges between clinical care and public health information systems.

In order for a derived functional profile to claim conformance with one or more domain's listed in the MU FP, the derived profile **SHALL** adhere to the principles and methods detailed in the Conformance Clause of the EHR-S FM.

## *Normative Language*

Additional clarification is necessary to understand the standardized nomenclature used to describe the actions performed by a system. The following excerpt from the EHR-S FM R2 Glossary, illustrates the hierarchical nature of the nomenclature. For example, the term "Capture" is used to describe a function that includes both direct data entry ("Enter") and indirect data entry (e.g., "Import" from another system. Similarly, "Maintain" is used to describe a function that entails storing, updating, and/or removing data.

| **Manage (Data)** | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Capture** | **Maintain** | | | **Render** | | | **Exchange** | **Determine** | | **Manage-Data-Visibility** |
| Auto-Populate<br>Enter<br>Import<br>Receive | Store<br>Archive<br>Backup<br>Decrypt<br>Encrypt<br>Recover<br>Restore<br>Save | Update<br>Annotate<br>Attest<br>Edit<br>Harmonize<br>Integrate<br>Link<br>Tag | Remove<br>Delete<br>Purge | Extract | Present | Transmit | Export<br>Import<br>Receive<br>Transmit | Analyze | Decide | De-Identify<br>Hide<br>Mask<br>Re-Identify<br>Unhide<br>Unmask |

**Table 4: "Manage Data" Action-Verbs**

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