

# **Advanced EHR-S Functional Model and Standard: Profiles Against the EHR & PHR System Functional Models**

Presented by:

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# Agenda

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- **Recap of the EHR-S Model and Intro to PHR-S FM**
- Review of key conformance-related concepts
- Review of EHR-S Conformance Chapter & How To Process
- Summary of current and in-process Profiles

# EHR-S Functional Model & Standard

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- **Normative (ANSI standard):** Function names, statements & **conformance criteria** provide a reference list of functions that:
  - May be present in an EHR-S
  - Understandable from a user's perspective
  - Enables consistent expression of functionality
- **Reference (not balloted):** Profiles (provide use cases for further explanation or understanding), How-To Guide, Glossary, Function Descriptions

# EHR-S Functional Model at a Glance

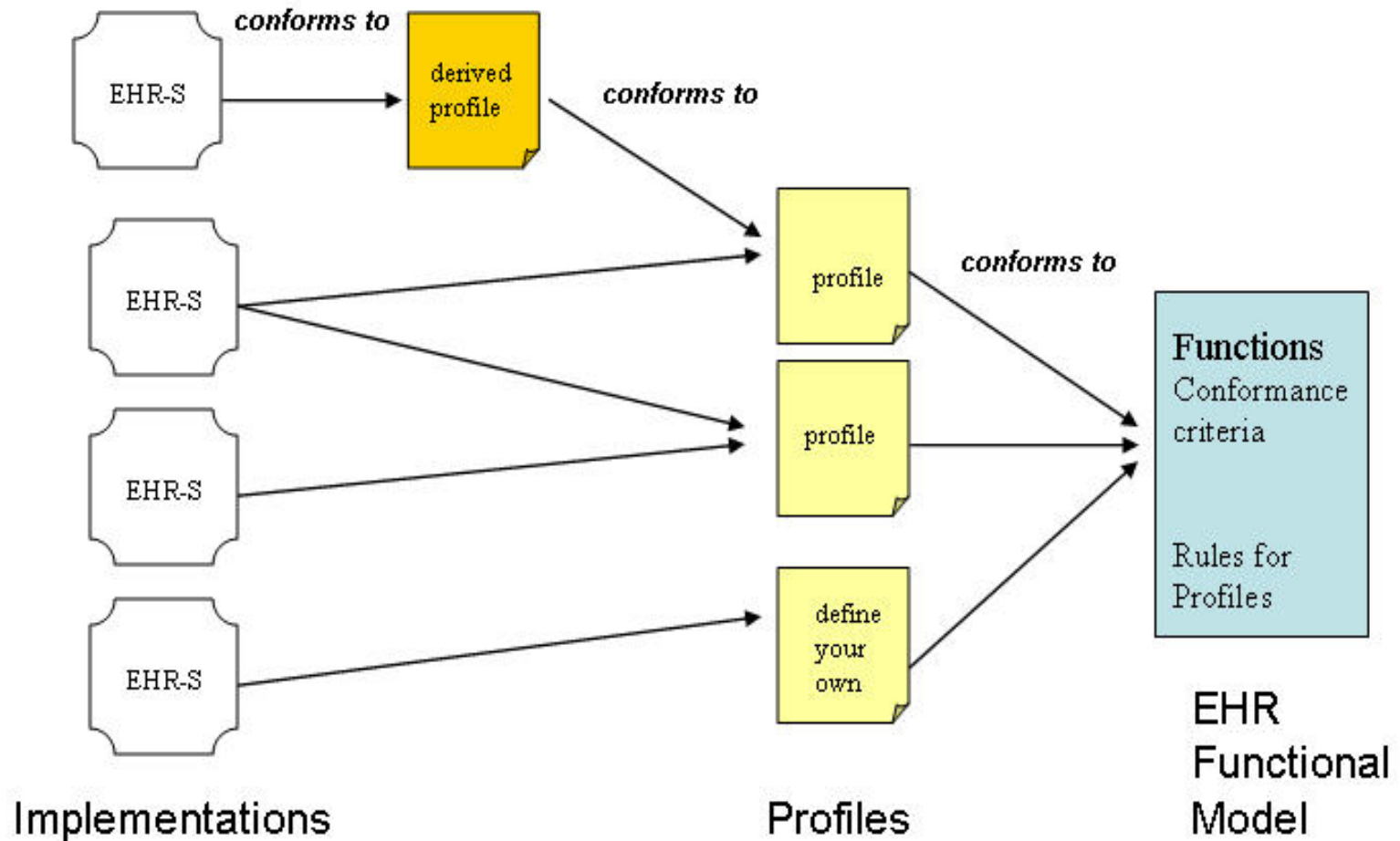
Direct Care	C1.0	Care Management
	C2.0	Clinical Decision Support
	C3.0	Operations Management and Communication
Supportive	S1.0	Clinical Support
	S2.0	Measurement, Analysis, Research, Reporting
	S3.0	Administrative and Financial
Information Infrastructure	I 1.0	EHR Security
	I 2.0	EHR Information and Records Management
	I 3.0	Unique identity, registry, and directory services
	I 4.0	Support for Health Informatics & Terminology Standards
	I 5.0	Interoperability
	I 6.0	Manage business rules
	I 7.0	Workflow

**Functions describe the behavior of a system in user-oriented language so as to be recognizable to the key stakeholders of an EHR System**

# Care Setting Profiles-Variable Functions

	Inpatient	Outpatient	Home
			Medication Admin Record
	Medication Administration Record		Lifestyle
	Bed management	Wellness Reminders	Wellness Reminders
	Drug-Drug Interactions	Drug-Drug Interactions	Drug-Drug Interactions
	Notes	Notes	Notes
	Results Reporting	Results Reporting	Results Reporting
	Order Management	Order Management	Order Management
	Event Capture	Event Capture	Event Capture
	Security	Security	Security
	Demographic Management	Demographic Management	
	Record Management	Record Management	Record Management

# Conformance to Profiles



# PHR-S Functional Model at a Glance

<b>Personal Health</b>	PH.1.0 Account Holder Profile
	PH.2.0 Manage Historical Clinical Data And Current State Data
	PH.3.0 Wellness, Preventive Medicine, and Self Care
	PH.4.0 Manage Health Education
	PH.5.0 Account Holder Decision Support
	PH.6.0 Manage Encounters with Providers
<b>Supportive</b>	S.1.0 Provider Management
	S.2.0 Financial Management
	S.3.0 Administrative Management
	S.4.0 Other Resource Management
<b>Information Infrastructure</b>	IN.1.0 Health Record Information Management
	IN.2.0 Standards Based Interoperability
	IN.3.0 Security
	IN.4.0 Auditable Records

**Draft Standard of functions to describe the behavior of a system in plain language so as to be recognizable to the key stakeholders of a PHR System**

## PH.2.5 Manage Current State Data Set

### PH.2.5.3 Manage Test Results

**Statement/Description:** Capture, maintain and present the results of diagnostic tests including inpatient, ambulatory and home-monitoring tests.

**Example:** The results reporting list will display when the most recent EKG was done or ....

1. The system **SHALL** provide the ability to filter results by factors that supports results management, such as type of test and date range.
2. The system **SHOULD** indicate normal and abnormal results depending on the data source.
3. The system **SHOULD** provide the ability to filter lab results by range ...
4. The system **SHOULD** display numerical results in graphical form and allow ....
5. The system **SHALL** provide the ability to group tests done on the same day.
6. The system **SHOULD** trigger decision support algorithms from the results
7. **IF** the system contains the electronic order, **THEN** the results **SHOULD** be linked to a specific order.
8. The system **SHALL** provide the ability for account holders to annotate a result.
9. The system **MAY** display a link to an image associated with results.

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# Review of Conformance Concepts

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## The basics:

- **Motivation – why care about conformance**
- **Definitions**
- **EHR-S FM Conformance Clause**

# Motivation

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- **What does it mean to “claim conformance”?**
  - Profiles, EHR system?
- **What do they actually conform to?**
- **What criteria (requirements) are met?**
  - ➔ **Conformance Clause.**
- **How can a conformance claim be verified?**
  - ➔ **Test suites, test tools, testing and certification**

# Definitions: Fitting it all together

## Certification

qualified bodies to do the testing and certification  
control board - advisory and arbiter

## Validation

Process - policy and procedures for testing

## Conformance Testing

Test suite, Test tool  
(test software, test scripts, test criteria)

## Profile

## Standard

Conformance clause, conformance criteria

We are  
concerned  
with

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# EHR-S FM Chapter 2: Conformance Clause

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- **Normative chapter**
- **Defines conformance to the Functional Model**
- **Contents:**
  - Concepts – conformance, profiles, derived profiles
  - Structure of the FM
  - **Normative language**
  - **Priorities**
  - Conformance Criteria
  - **Rules for profiles**
  - Reference materials:
    - Example use cases, sample conformance clauses
    - Interpreting and understanding ‘dependent shall’ criteria
    - Definitions

# EHR-S FM Conformance Clause

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- **Normative Language – keywords**
  - **SHALL:** Mandatory requirement ('is required to')
  - **SHOULD:** Optional, recommendation ('is encouraged')
  - **MAY:** Optional, permissible action ('is permitted')
  - **Some profiles have added:**
    - **SHALL NOT** – indicates a prohibited action ('prohibited')
- **Priorities –**
  - **Assigned by profile to each function**
  - **Timing of when a function gets implemented by the system**
  - **3 priorities**
    - **Essential Now (EN)** – implementation of function is mandatory
    - **Essential Future (EF)** – optional now, mandatory at some time in future
      - Profile defines the time frame (date, time allotment, event)
      - Multiple time frames (e.g., EF-2008, EF-2009)
    - **Optional (O)**

# Overview of Profile Rules

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- **Highlights of Chapter 2's profile rules**
  - **Section 4 Conformance criteria**
  - **Section 5 Structure**
  - **Section 6 Functional profile conformance**
    - **Section 6.1.1 SHALL rules**
    - **Section 6.2.1 MAY rules**
    - **Section 6.2.3 SHALL NOT rules**
    - **Section 6.2 rules for creating new functions**
    - **Section 6.3 rules for derived profiles**

# Overview of Profile Rules (continued)

## Profiles claiming conformance **SHALL** for each function: (6.1.1#4, #5, #6)

- Indicate its priority: Essential Now (EN), Essential Future (EF), Optional (O)
- Include criteria
  - Inherit any ‘SHALL’ criteria from FM’s function
  - NOT change a FM ‘SHALL’ criterion to ‘SHOULD’ or ‘MAY’
  - Make at least 1 criterion mandatory (‘SHALL’)
  - Copy any ‘Dependent SHALL’ criteria and adhere to rules (*more on this later*)
    - (a special type of criteria, with its own set of rules)

## Profiles claiming conformance **MAY** for each function:

- Adapt applicable FM criteria to match needs of profile (6.1.2)
  - Make it more specific or constrained
  - Change ‘SHOULD’ or ‘MAY’
  - Add new criteria

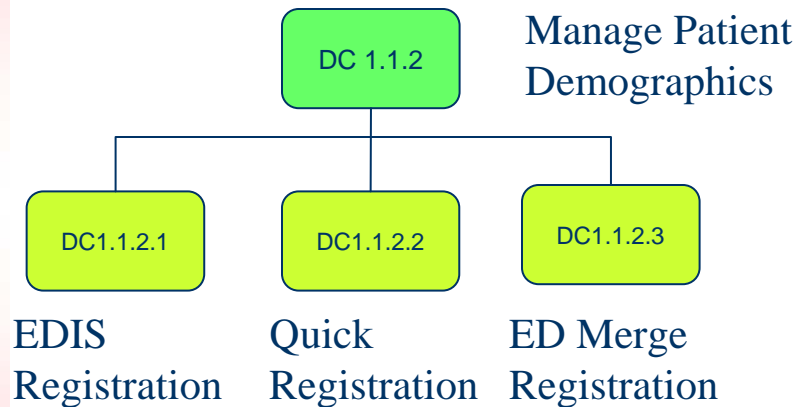
- FM **SHALL** always remains as a **SHALL** in the profile
- FM **SHOULD** can
  - remain as a **SHOULD** in the profile
  - be changed to a **SHALL** or **MAY** in the profile
  - be omitted from the profile
- FM **MAY** can
  - remain as a **MAY** in the profile
  - be changed to a **SHALL** or **SHOULD** in the profile
  - Be omitted from the profile

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# Examples

## ● Emergency Dept IS Profile

Added new children functions



## ● Child Health Profile

Added new criteria



### New Criteria

- If required by the scope of practice, THEN the system SHALL capture time of birth, down to the minute, and date of birth.
- The system SHALL provide the ability to indicate that a patient's gender is unknown.
- The system MAY provide the ability to compute post-conceptual age for the purposes of decision support.

# Example

## DC1.8.4 Manage Patient Clinical Measurements

1. IF required by the scope practice, THEN the system SHALL capture patient vital signs such as blood pressure, temperature, heart rate, respiratory rate, and severity of pain as discrete elements of structured or unstructured data.
2. IF required by the scope of practice, THEN the system SHALL capture psychiatric symptoms and daily functioning as structured or unstructured data
3. The system SHOULD capture other clinical measures such as peak expiratory flow rate, size of lesions, oxygen saturation, height, weight, and body mass index as discrete elements of structured or unstructured data.
4. The system SHOULD compute and display percentile values when data with normative distributions are entered.
5. The system MAY provide normal ranges for data based on age and other parameters such as height, weight, ethnic background, gestational age.

## DC1.8.4 Manage Patient Clinical Measurements

1. The system SHALL capture patient vital signs **including** blood pressure, temperature, heart rate, respiratory rate, and severity of pain as discrete elements of structured or unstructured data.
2. *(deleted)*
3. The system SHOULD capture other clinical measures such as peak expiratory flow rate, size of lesions, oxygen saturation, height, weight, and body mass index as discrete elements of structured or unstructured data.
4. The system SHOULD compute and display percentile values when data with normative distributions are entered.
5. The system MAY provide normal ranges for data based on age and other parameters such as height, weight, ethnic background, gestational age.
6. The system SHALL document both the time the vital sign was record as well as the time the vital sign was entered into the system
7. The system SHOULD display trends of vital signs
8. The system SHOULD provide a means for automated capture and recording of vital signs via external devices

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## Summary of current & in-progress Profiles (Mar 2009)

Profile Name	Sponsor	Status	Type	Realm
Emergency Department Information Systems (EDIS)	American College of Emergency Physicians	Registered	Care setting Specialty (emergency medicine, emergency nursing)	US
Records Management and Evidentiary Support	ASPE, AHIMA, NCPDP	Balloted	Specialty (legal) Ancillary	Universal
Child Health	HL7 Pediatric Data Standards SIG	Standard	Specialty (child health)	US
Behavioral Health	US Health and Human Services (HHS) Substance Abuse & Mental Health Services Admin (SAMHSA)	Standard	Care setting	US
Electronic Health Records/Clinical Research	EClinicalForum	Approval In-Process	Ancillary	Universal
Health Authority-linked PHR	Trilogy Integrated Resources	Registered	Specialty, sponsor	Universal

# Questions?

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