

HL7 EHR System Functional Model and Standard



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Agenda

- **Current Status**
- **Overview of EHR System (EHR-S) Functional Model**
- **Walk through of EHR-S FM**
- **Conformance Clause and Profiles**
- **Distinction between Standards and Product Certification**
- **Next Steps**

EHR vs. EHR-S

- **EHR**

- The underlying single, logical patient record
- The data elements comprising the record
- Needs to serve as the record of care for legal, business, and disclosure purposes

- **EHR-S**

- Software that provides functionality to:
 - Manage and maintain the record
 - Accomplish the various clinical, research, and business purposes of the record
- Monolithic system or a system of systems

How It Started - Request from US Govt

- April, 2003: CMS asked
 - IOM for guidance on care delivery functions
 - IOM & HL7 to coordinate development of a functional model for an EHR *system*, not a transaction
 - Needed for pay for performance
- April, 2003: HL7 EHR WG began work on EHR-S FM
- July 31, 2003: IOM Committee on Data Standards for Pt. Safety releases Letter Report

From DSTU to ANSI & ISO Accreditation

- **July, 2004: Approved as a draft standard for trial use (DSTU)**
- **February, 2007: Release 1.0 approved as a fully American National Standards Institute (ANSI) accredited standard**
- **November, 2009: Release 1.1 approved as a International Organization for Standardization (ISO) standard**
- **Working on Release 2.0 now, anticipate a late 2010 ballot for industry voting**

The EHR-S Functional Model

Is Not...

- A messaging specification
- An EHR specification
- An implementation specification (not the “how”)
 - Does not prescribe technology
 - Does not dictate how functions must be implemented (e.g., via the user interface, database design)

Is...

- A system specification
- An EHR system specification
- A reference list of functions that may be present in an EHR-S (the “what”)
 - Enables consistent expression of functionality
 - Provides flexibility for innovation and product differentiation
 - Gold standard, sensitive to what can practically be done by a system, future system development

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

EHR-S Functional Model & Standard

- **Function names & statements 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
- **Conformance criteria**
 - Required criteria: Mandatory
 - Optional criteria: Two levels

The Structure of the Functional Model

ID#	Type	Name	Statement/Description	See Also	
DC.1.1.1	F	Identify and Maintain a Patient Record	<p>Statement: Identify and maintain a single patient record for each patient.</p> <p>Description: A single record is needed for legal purposes, as well as to organize it unambiguously for the provider. Health information is captured and linked to the patient record. Static data elements as well as data elements that will change over time are maintained. The patient is uniquely identified, after which the record is tied to that patient. Combining information on the same patient, or separating information where it was inadvertently captured for the wrong patient, helps maintain health information for a single patient. In the process of creating a patient record, it is at times advantageous to replicate identical information across multiple records, so that such data does not have to be re-entered. For example, when a parent registers children as new patients, the address, guarantor, and insurance data may be propagated in the children's records without having to re-enter them.</p>	S.1.4.1 S.2.2.1 S.3.1.2 S.3.1.5 IN.2.1 IN.2.3	1. The system SHALL create a single logical record for each patient.
					2. The system SHALL provide the ability to create a record for a patient when the identity of the patient is unknown.
					3. The system SHALL provide the ability to store more than one identifier for each patient record.
					4. The system SHALL associate key identifier information (e.g., system ID, medical record number) with each patient record.
					5. The system SHALL provide the ability to uniquely identify a patient and tie the record to a single patient.
					6. The system SHALL provide the ability, through a controlled method, to merge or link dispersed information for an individual patient upon recognizing the identity of the patient.
					7. IF health information has been mistakenly associated with a patient, THEN the system SHALL provide the ability to mark the information as erroneous in the record of the patient in which it was mistakenly associated and represent that information as erroneous in all outputs containing that information.
					8. IF health information has been mistakenly associated with a patient, THEN the system SHALL provide the ability to associate it with the correct patient.
					9. The system SHALL provide the ability to retrieve parts of a patient record using a primary identifier, secondary identifiers, or other information which are not identifiers, but could be used to help identify the patient.

Existing Profiles

The EHR-S FM contains approx. 160 functions and 1,000 conformance criteria across 3 sections



HL7 EHR-System Functional Model (EHR-S FM) Release 1.1

Functional Profiles (Care Setting)

Ancillary Profiles (Specific Purpose)

Emergency

Long Term and Post Acute Care

Behavioral Health

Child Health

Records Management & Evidentiary Support

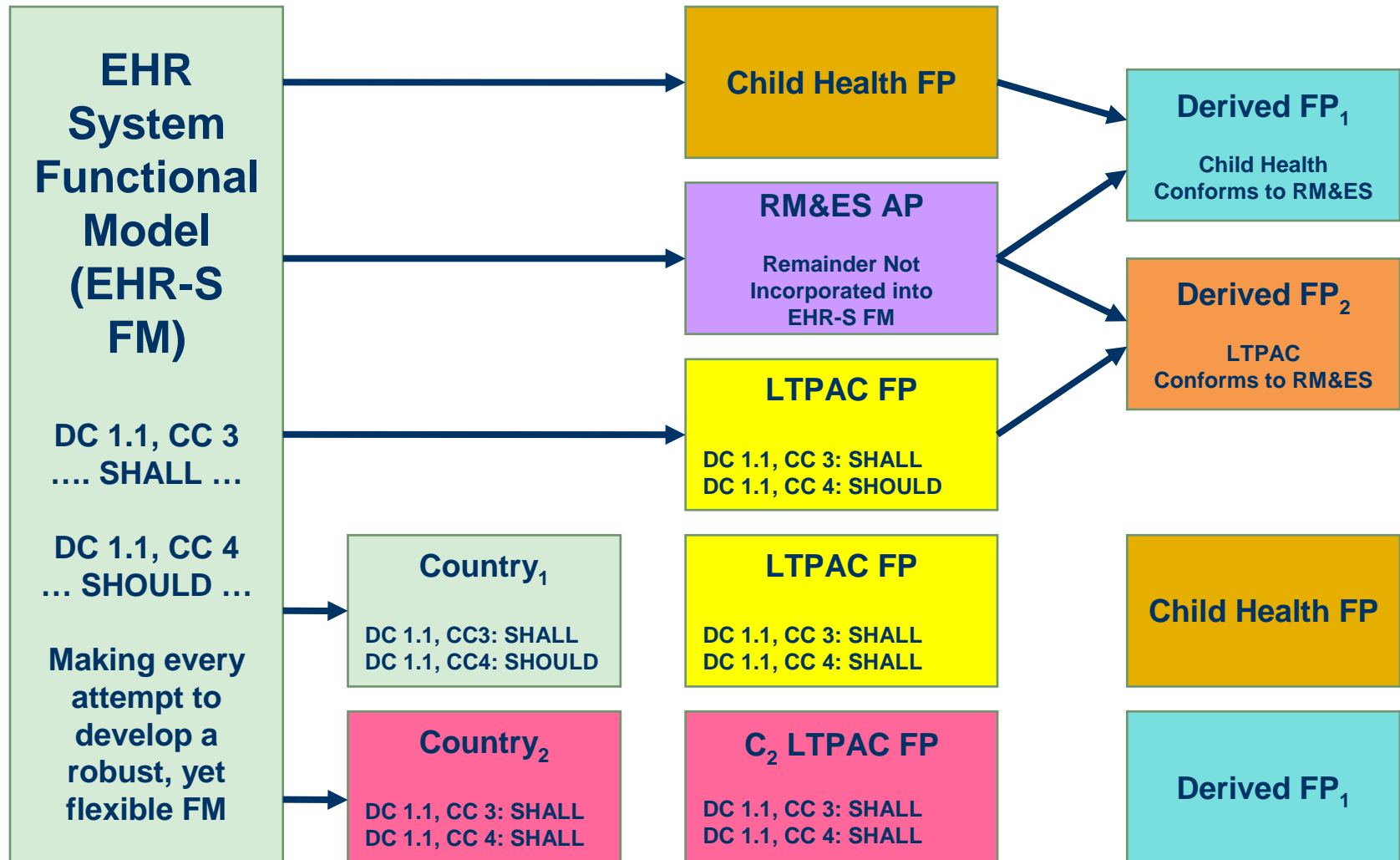
Vital Records

Clinical Research

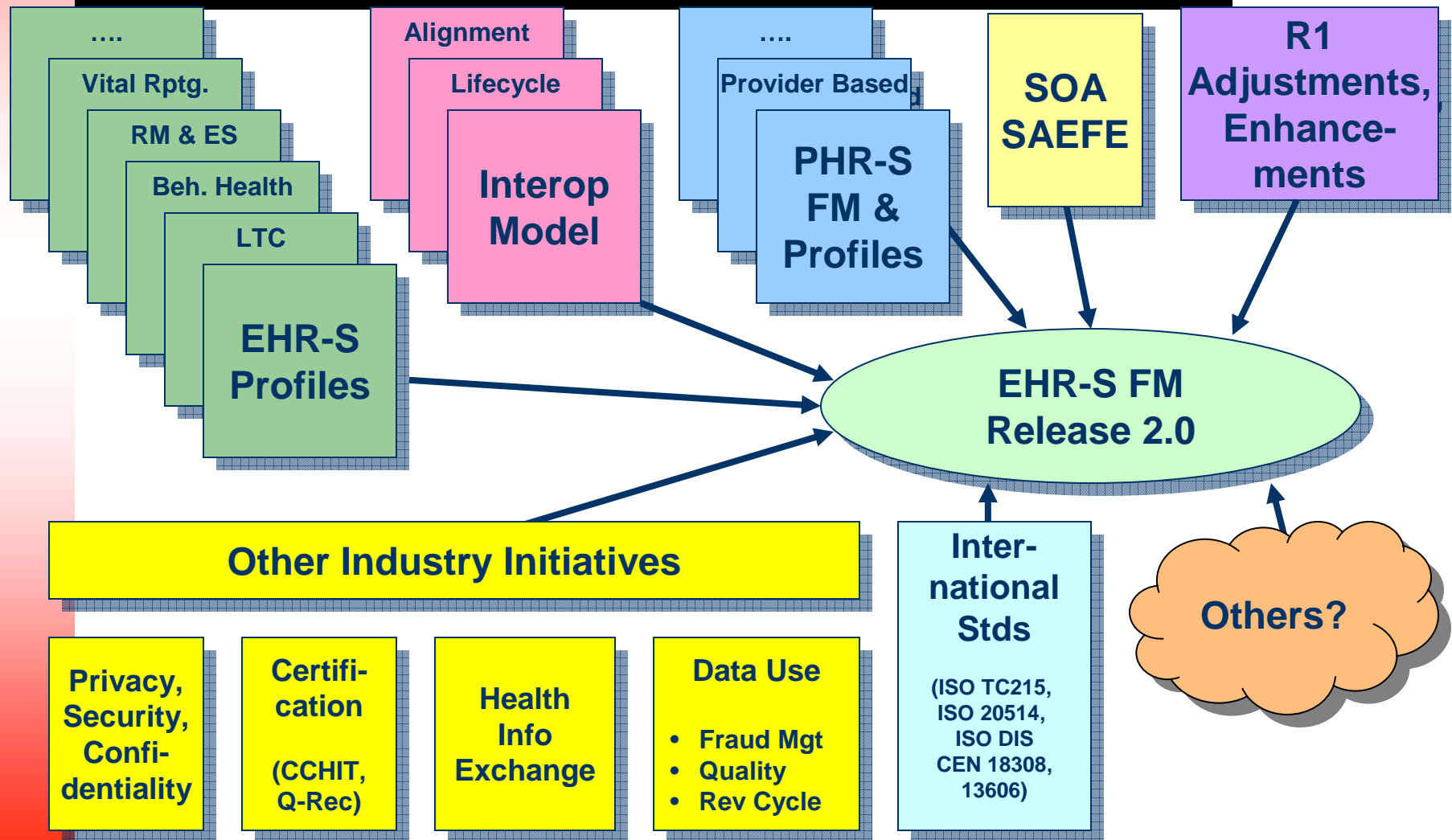
Functional and ancillary profiles are subsets derived from the FM. EHR systems conform to profiles.



Conformance to the Functional Model



Inputs to Release 2.0 (R2)



Functional Profiles Under Development

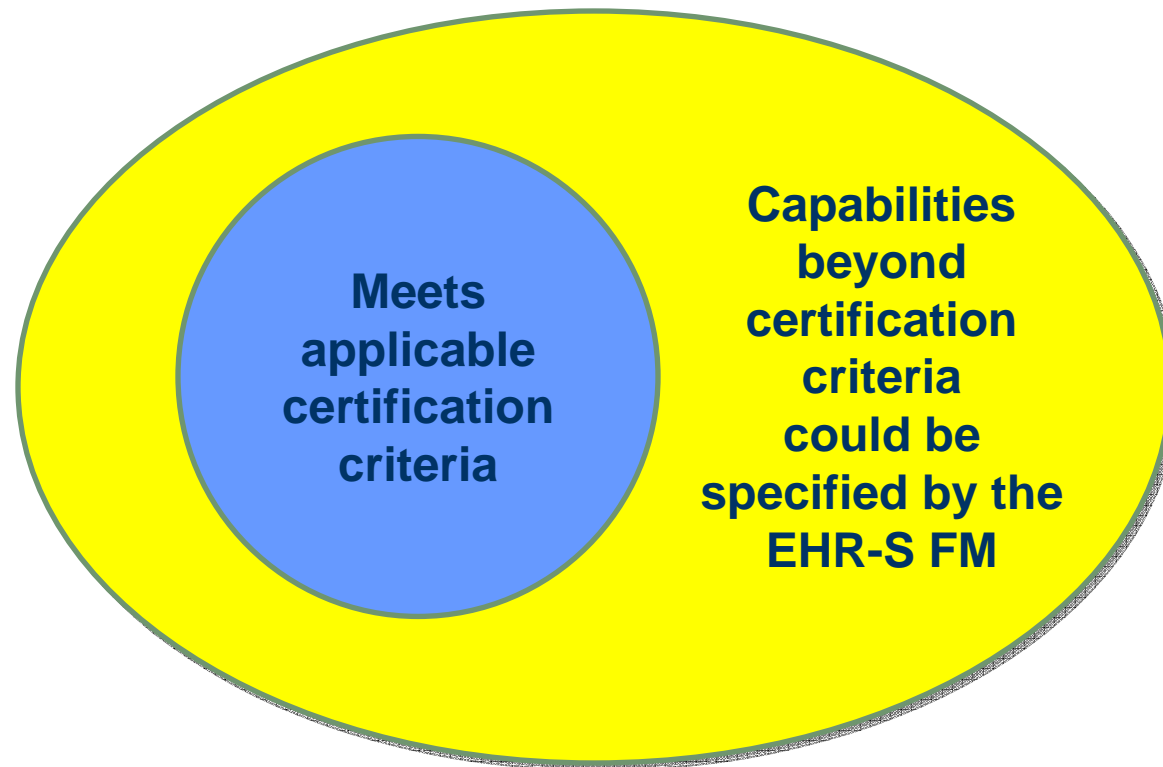
- Ambulatory Oncology
- Dental
- Stand Alone e-Prescribing
- Pharmacist/Pharmacy Provider
- Dietetics/Food & Nutrition
- Emergency (Updating first release)

Definition: Complete EHR

“...EHR technology that has been developed to meet all applicable certification criteria adopted by the Secretary. We believe this definition helps to create a clear distinction between a Complete EHR, an EHR Module, and Certified EHR Technology. The term Complete EHR is not meant to limit the capabilities that a Complete EHR can include. Rather, it is meant to encompass EHR technology that can perform all of the applicable capabilities required by certification criteria adopted by the Secretary and distinguish it from EHR technology that cannot perform those capabilities. **We fully expect some Complete EHRs to have capabilities beyond those addressed by certification criteria adopted by the Secretary.**”

- Standards & Certification Interim Final Rule

A Way to Specify the Complete EHR



Diffs between Standards & Certification

- **Gold standard vs. specific purpose incentives**
 - Wide spread EHR adoption
 - Pay for performance
- **Standards development organization (SDO) vs. public/private collaborative**
- **Avoid perceived conflict of interest (where a single organization both develops the standard and certifies against it)**
- **Product certification references standards**

HL7 & CCHIT Working Together

HL7 EHR-S Standard				CCHIT Product Certification			
Function ID	Function	Conformance Criteria		Certification Criteria	Certification Year		
		No.	Clause		2008	2009	2010
1.0	ABC						
1.1		1	...SHALL.....	...SHALL.....	X		
		2	...SHOULD.....	...SHALL.....		X	
		3	...SHALL.....	...SHALL.....	X		
		4	...MAY.....	...(Did not adopt)			
		5	...SHOULD.....	...SHALL.....		X	
		6	...SHALL.....	...SHALL.....			X

- **Granularity:** Individual conformance criterion may be certified in a year different from other criteria in the same function
- **Dependent on essential now vs. future, market availability, & priority for improving quality of care**



Next Steps

- Looking for other profiles to be developed
- Realm (country)-based profiles
- Map Functional Model to HL7 messages, documents, data

Want to Know More?

- Join HL7, review the HL7 web site
- Subscribe to HL7 EHR WG list server
- Attend open public sessions (no HL7 membership required)

www.hl7.org/ehr

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Q & A