HL7 EHR System Functional Model and Standard

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Delta Dental Plans Association
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Ambassador Webinar
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The Drivers

- Concerns about cost, quality and efficiency
- By all stakeholders
  - Employers
  - Healthcare providers
  - Consumers
  - Government

The Need

- Complete patient health information
- At the point of care
- With clinical decision support

Successful Projects

- Reduced costs through chronic care management programs
- Improved healthcare through clinical decision making
- Improved patient participation and compliance through computer based reminders
- Improving safety, quality and efficiency of healthcare

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
- Development of Release 2
- 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
  - Institutes of Medicine (IOM) for guidance on care delivery functions
  - IOM & HL7 to coordinate development of a functional model for an EHR *system*, not a transaction
  - Need: 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/CEN 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
- Release 2.0 balloted as a normative model in April 2012. Five international standards organizations involved.

EHR-S FM's position within HL7

- Health Level Seven (HL7) is an international Standards Development Organization (SDO)
- The term "HL7" is often used synonymously for the HL7 organization and the HL7 messaging standard
- HL7 standards are divided into multiple camps:
  1. Healthcare-related data/information/routing Standards:
     - Messaging Standards (V2.x and V3)
     - Document Standards (CDA)
  2. Healthcare-related Functional Standards (EHR-S FM)
  3. Other Standards (CCOW, Vocabulary, Security, Healthcare Devices, etc.)

Sample of an “HL7 message”

- **Sample v2 message (is difficult to read):**

MSH|^~\&|ADT1|MCM|LABADT|MCM|199912311100|SECURITY|ADT^A01|MSG00001|P|2.3|<cr>

EVN|A01|199912311058||<cr>

PID|||PATID4321^5^M11||DOE^JOHN^A^II||19500227|M||C|123 MAIN STREET^^ANYTOWN^NY^12345-1234|GL|(123)555-1212|(123)555-2121 ||S||PATID4321001^2^M10|123456789|123456^NY|<cr>

NK1|SMITH^SALLY^J|WIFE||||||NK^NEXT OF KIN<cr>

PV1|1|I|1000^215^01||||001234^SMITH^CHRIS^M.|||SUR||||ADM|A0|<cr>

- **Translation:**

Patient John A. Doe, II was admitted on December 31, 1999 at 10:58 a.m. by doctor Chris M. Smith (#001234) for surgery (SUR). He has been assigned to nursing unit 1000, room 215, bed 01.

Background and Context (con't)

- **Sample v3 (CDA) document (raw):**

```
<?xml version="1.0" encoding="UTF-8" ?>  <!-- ?xml-stylesheet type="text/xsl"
    href="IMPL_CDAR2.xsl"?   -->
-- <ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
 <typeId root="2.16.840.1.113883.1.3" extension="a" />
 <id root="1.3.6.4.1.4.1.2835.2.999021" />
 <code />
 <effectiveTime value="20060131185806+0500" />
 <confidentialityCode />
 <languageCode code="en-US" />
  - <recordTarget>
    - <patientRole>
 <id extension="54321" root="2.16.840.1.113883.3.933" />
      - <addr use="H">
        <streetAddressLine>23 Main Street</streetAddressLine>
        <city>Anytown</city>
        <state>NY</state>
        <postalCode>12345</postalCode>
        <country>USA</country>
      </addr>
```

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        <postalCode>12345</postalCode>
        <country>USA</country>
      </addr>
```

Background and Context (con't)

- **Sample v3 (CDA) document (is easy to read when rendered):**

Patient ID:

54321

Home address:

23 Main St., Anytown, NY. 12345

The EHR-S Functional Model

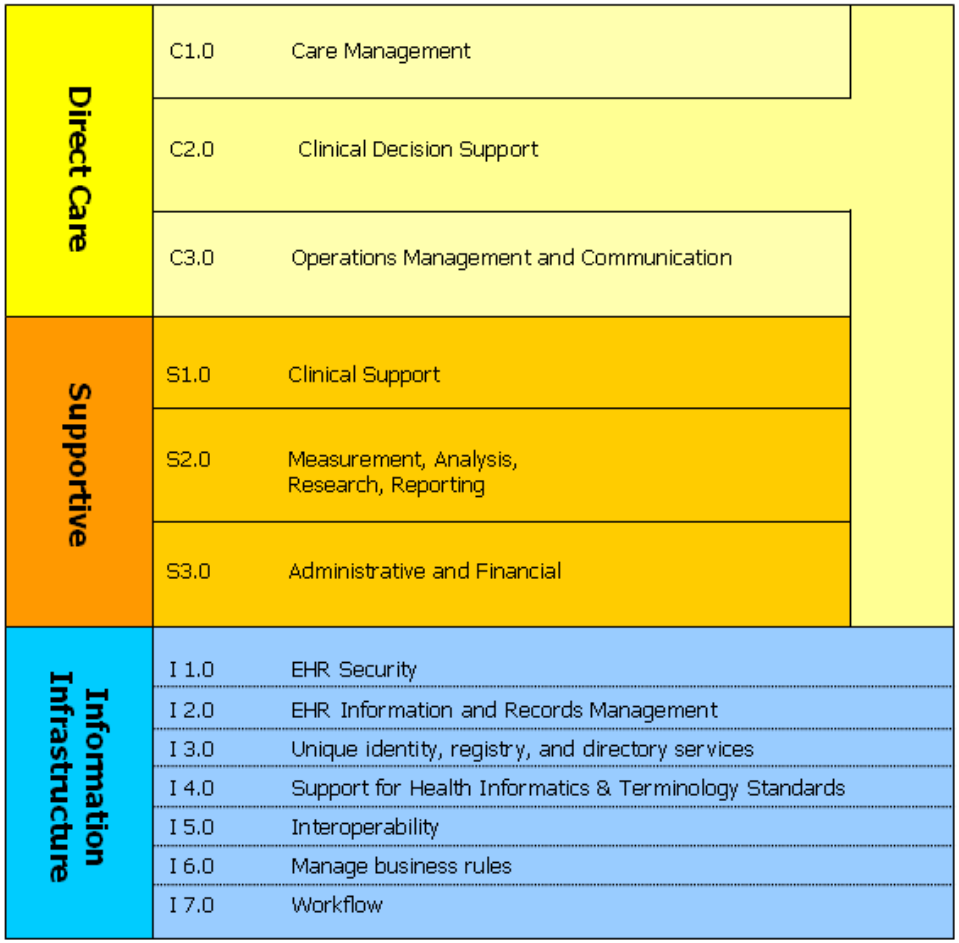
Is Not…

- 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



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

This represents the R.1.1 Structure

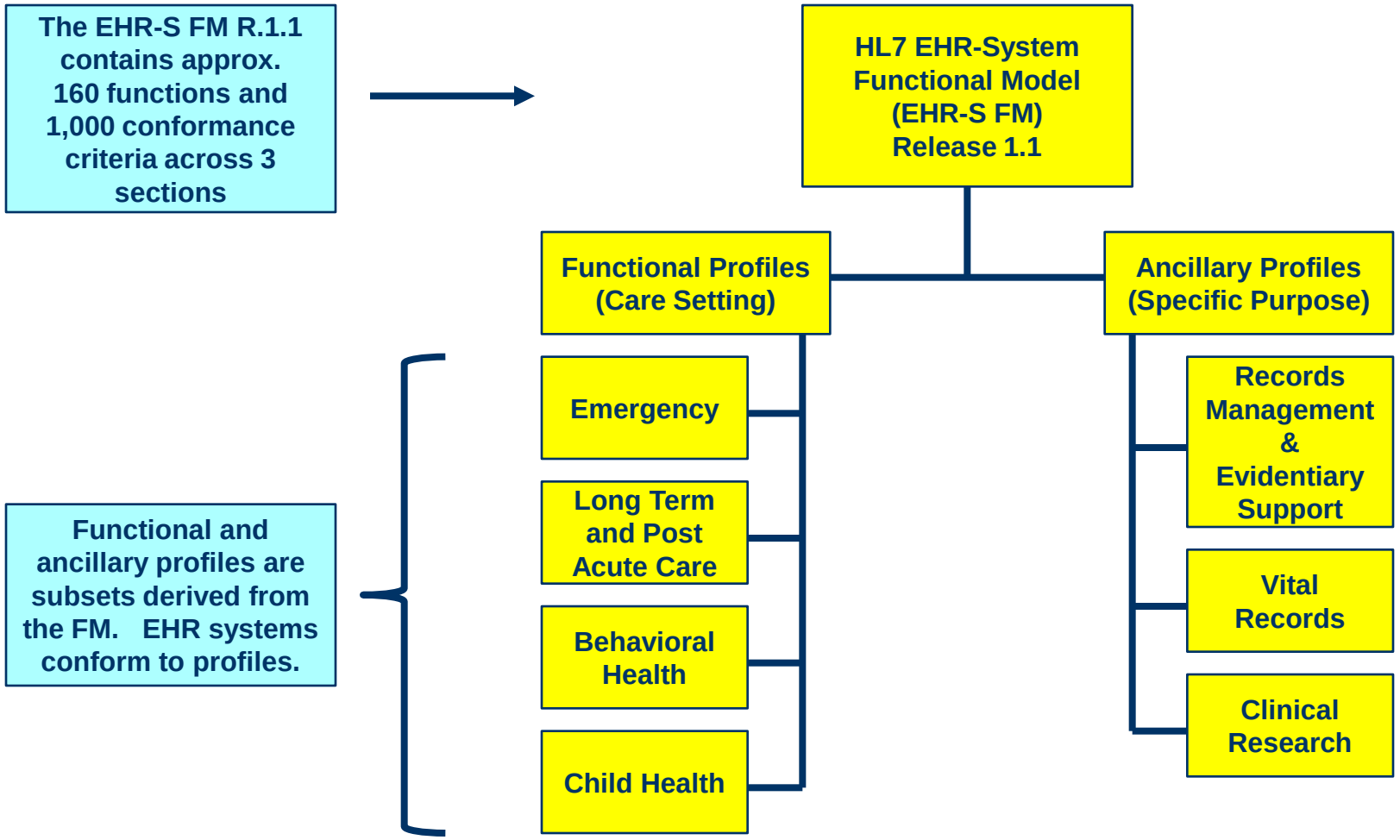
EHR-S Functional Model & Standard

- 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

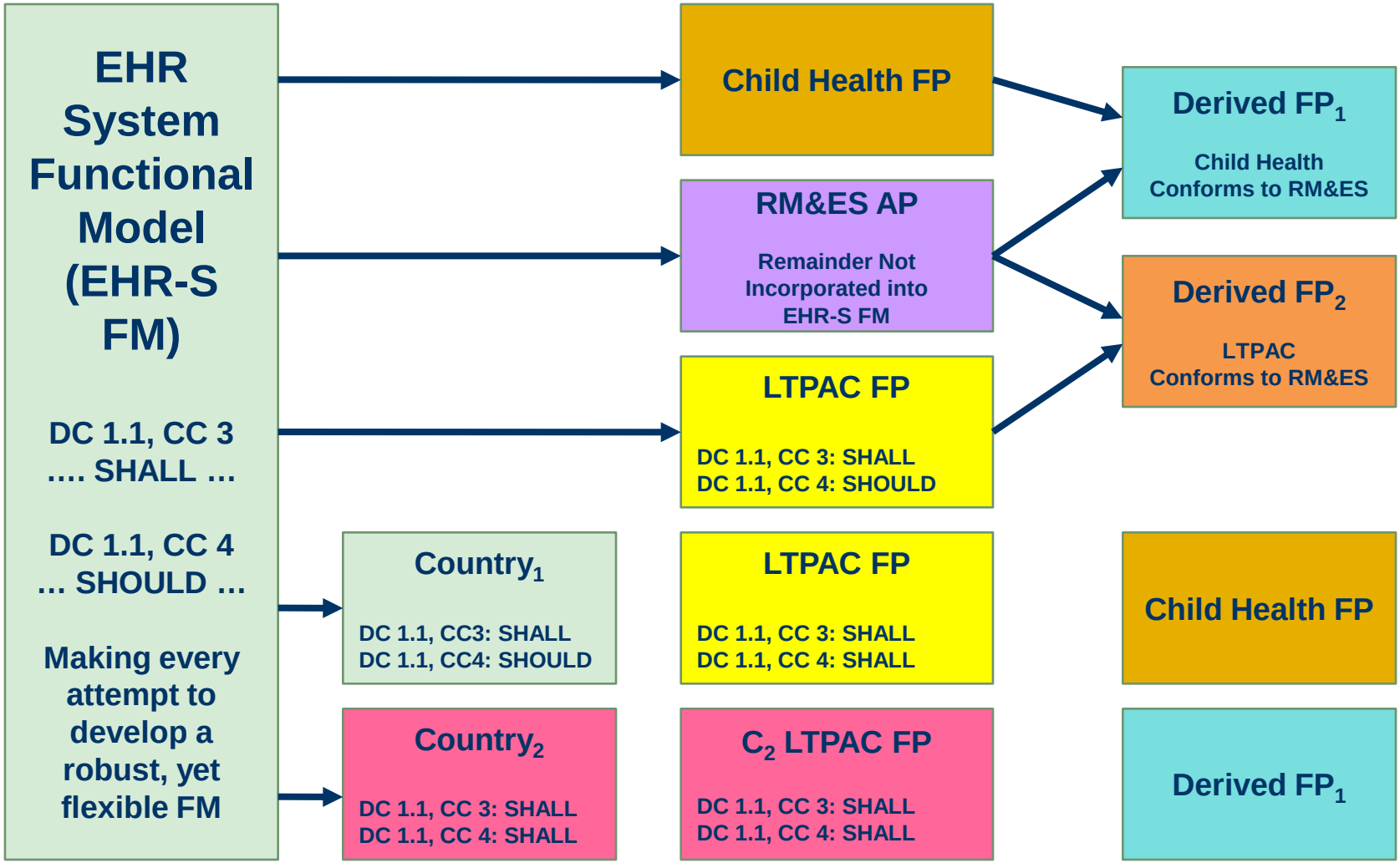
The Structure of the Functional Model

ID#	Type	Name	Statement/Description	See Also	
DC.1.1.1	F	Identify and Maintain a Patient Record	**Statement**: Identify and maintain a single patient record for each patient. **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.	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



Conformance to the Functional Model



Other Functional Profiles Available

- Dietetics/Food & Nutrition
- Public Health
- E-Prescribing (jointly with NCPDP)
- Pharmacist/Pharmacy (jointly with NCPDP)

Standards vs Certification

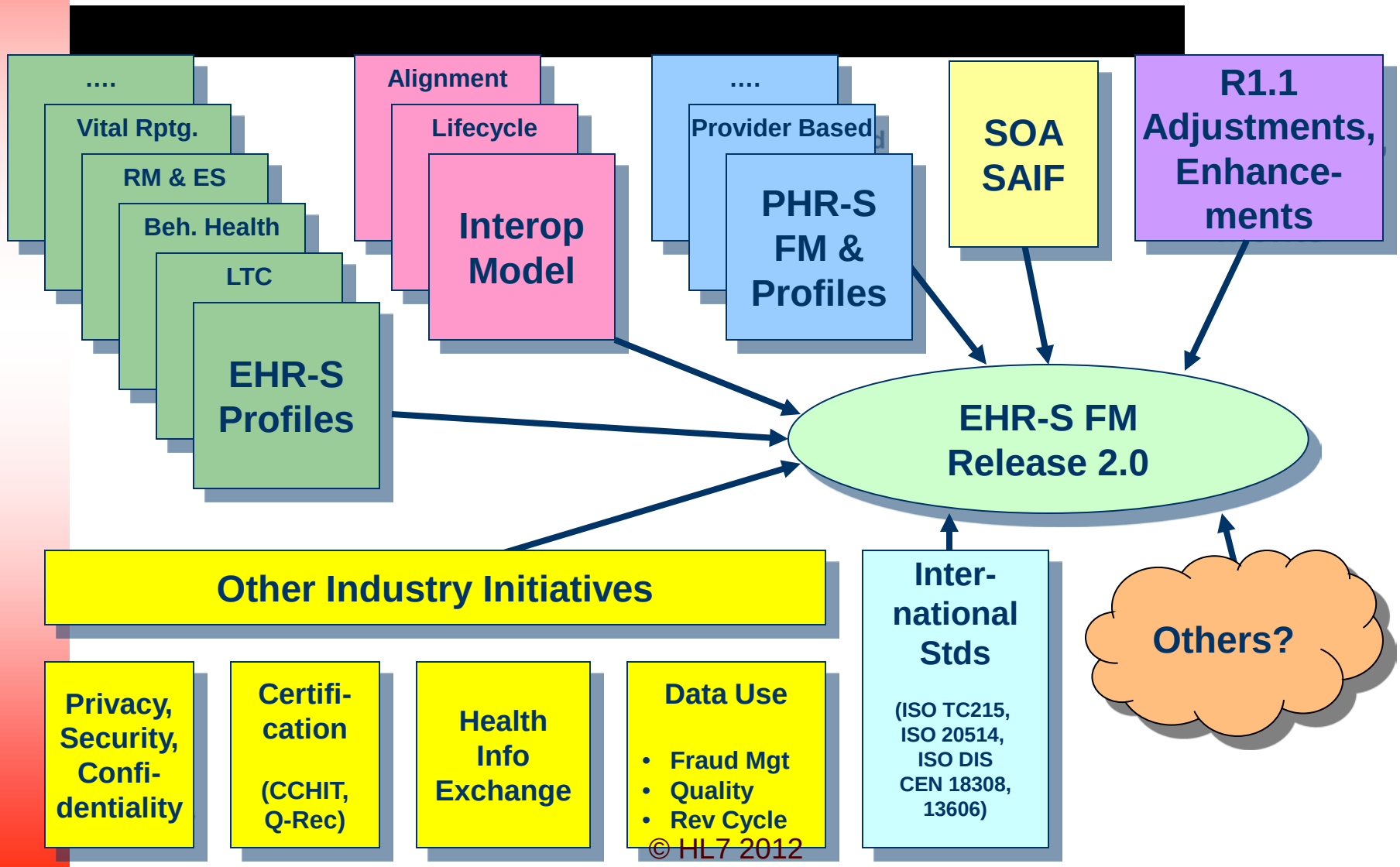
- Gold standard vs. specific purpose incentives
  - Wide spread EHR adoption
  - Pay for performance
- Standards development organization (SDO) vs. public/private collaborative
- Avoid perceived conflict of interest (where a single organization both develops the standard and certifies against it)
- Product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

Functional Model & Certification

HL7 EHR-S Standard				Product Certification			
Function ID	Function	Conformance Criteria		Certification Criteria	Certification Year		
		No.	Clause		2008	2009	2010
1.0							
1.1	ABC	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**

Inputs to Release 2.0 (R2)

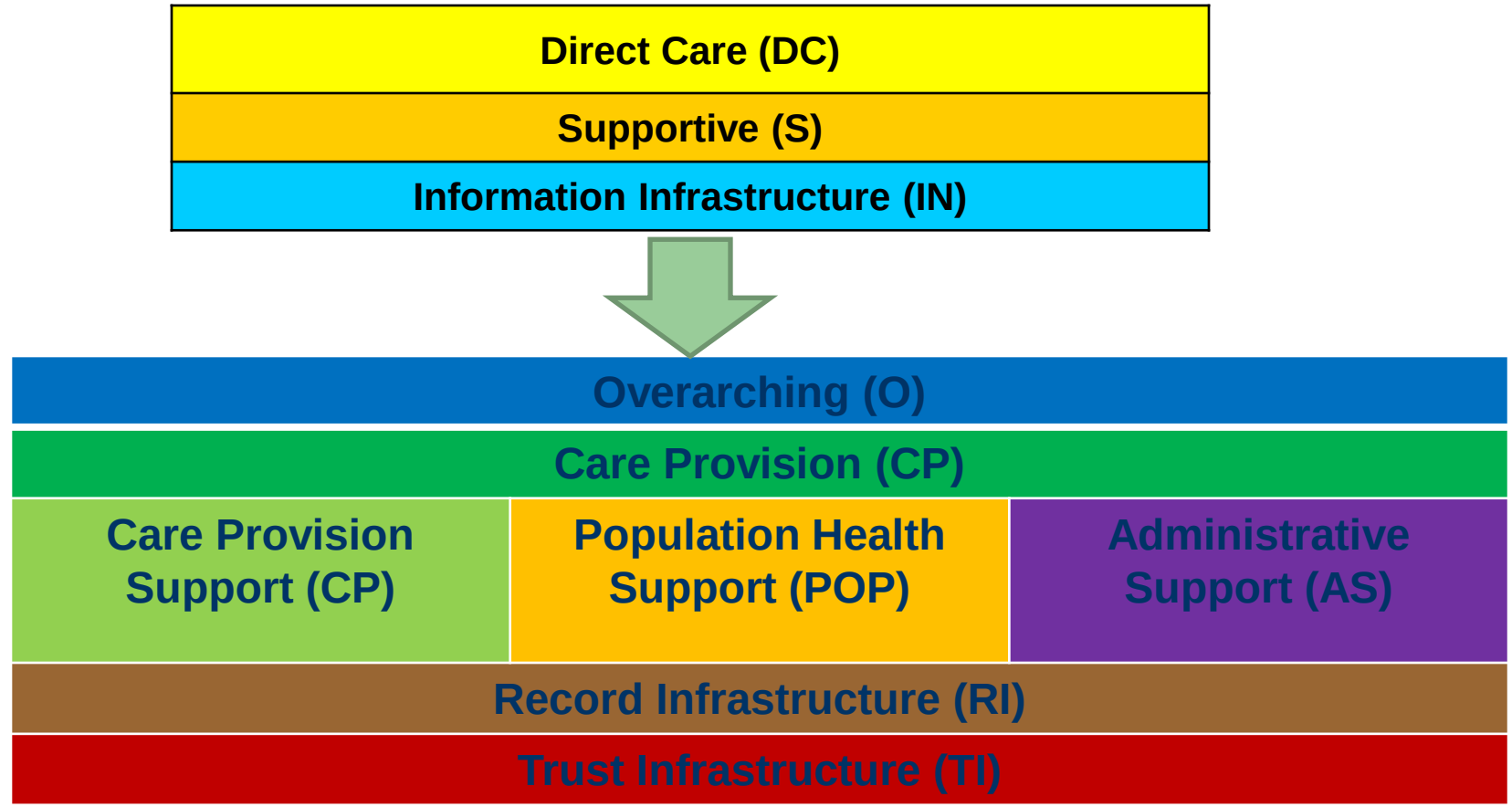


Extension of Function List

- **The number of conformance criteria increased from 972 in R1.0, 983 in R1.1 and 2,310 in R2.0**

HL7 EHR-S Functional Model, Release 2					
Summary Breakdown of Functions and Conformance Criteria				Release 1	Release 1.1
Chapter		Functions	Conformance Criteria	Conformance Criteria	Conformance Criteria
OV	Overarching Criteria	2	33		
CP	Care Provision	41	494		
CPS	Care Provision Support	76	559		
POP	Population Health Support	18	108		
AS	Administration Support	55	249		
RI	Records Infrastructure	37	186		
TI	Trust Infrastructure	93	681		
	TOTALS:	**322**	**2,310**	**972**	**983**

Chapter Reorganization



Overarching Criteria Chapter

- **Criteria that apply to all EHR Systems and consequently must be included in all EHR-S FM compliant profiles**
- **Examples:**

Overarching	OV.1	The system SHALL conform to function TI.1.1 (Entity Authentication).
		The system SHALL conform to function TI.1.2 (Entity Authorization).
		The system SHALL conform to function TI.1.3 (Entity Access Control).
		IF the system receives or transmits data for which jurisdictionally established interchange standards exist, THEN the system SHALL conform to function IN.5.1 (Interchange Standards) to support interoperability.
		The system SHOULD conform to function IN.6 (Business Rules Management).
		The system SHOULD conform to function IN.7 (Workflow Management).
	OV.2	Manage User Help

Care Provision

- **Focus on functions required to provide care to a specific patient and enable hands-on delivery of healthcare**
- **Organized in general order of an encounter**

Care Provision	**CP.1**	Manage Clinical History
	CP.2	Render Externally-sourced Information
	CP.3	Manage Clinical Documentation
	CP.4	Manage Orders
	CP.5	Manage Results
	CP.6	Manage Treatment Administration
	CP.7	Manage Future Care
	CP.8	Manage Patient Education & Commun
	CP.9	Manage Care Coordination & Reportin

Example child functions:

CP.1	**Manage Clinical History**
CP.1.1	Manage Patient History
CP.1.2	Manage Allergy, Intolerance and Adverse Reaction List
CP.1.3	Manage Medication List
CP.1.4	Manage Problem List
CP.1.5	Manage Strengths List
CP.1.6	Manage Immunization List
CP.1.7	Manage Medical Equipment, Prosthetic/Orthotic, Device List
CP.1.8	Manage Patient and Family Preferences

Care Provision Support

- **Focus on functions required to support the provision of care to a specific patient to enable hands-on delivery of healthcare**
- **Organized in alignment with Care Provision chapter**

Example child functions:

Care Provision Support		
	CPS.1	Record Management
	CPS.2	Support Externally-sourc
	CPS.3	Support Clinical Docume
	CPS.4	Support Orders
	CPS.5	Support Results
	CPS.6	Support Treatment Adm
	CPS.7	Support Future Care
	CPS.8	Support Patient Educatic
	CPS.9	Support Care Coordinati

CPS.4	**Support Orders**
CPS.4.1	Manage Order Set Templates
CPS.4.2	Support Medication & Immunization Orders
CPS.4.2.1	Support for Medication Interaction & Allergy Checking
CPS.4.2.2	Support for Patient Specific Dosing and Warnings
CPS.4.2.3	Support for Medication Ordering Efficiencies
CPS.4.2.4	Support for Medication Recommendations
CPS.4.3	Support for Non-Medication Ordering
CPS.4.4	Support Orders for Diagnostic Tests
CPS.4.5	Support Orders for Blood Products and Other Biologics

Population Health Support

Population Health Support	POP.1	Support for Health Maintenance, Preventive Care and Wellness
	POP.2	Support for Epidemiological Investigations of Clinical Health Within a Population
	POP.3	Support for Notification and Response
	POP.4	Support for Monitoring Response Notifications Regarding a Specific Patient's Health
	POP.5	Donor Management Support
	POP.6	Measurement, Analysis, Research and Reports
	POP.7	Public Health Related Updates
	POP.8	De-Identified Data Request Management
	POP.9	Support Consistent Healthcare Management of Patient Groups or Populations
	POP.10	Manage Population Health Study-Related Identifiers

Example child functions:

POP.6	**Measurement, Analysis, Research and Reports**
POP.6.1	Outcome Measures and Analysis
POP.6.2	Performance and Accountability Measures
POP.6.3	Support for Process Improvement
POP.6.4	Support for Care System Performance Indicators (Dashboards)

Administration Support

[redacted]inistrative and

Administration support		
	AS.1	Manage Provider Information
	AS.2	Manage Patient Demographics, Location and Synchronization
	AS.3	Manage Personal Health Record Interaction
	AS.4	Manage Communication
	AS.5	Manage Clinical Workflow Tasking
	AS.6	Manage Resource Availability
	AS.7	Manage Encounter/Episode of Care Management
	AS.8	Manage Information Access for Supplem[redacted]
	AS.9	Manage Administrative Transaction Proc[redacted]

Example child functions:

AS.1	**Manage Provider Information**
AS.1.1	Manage Provider Registry or Directory
AS.1.2	Manage Provider's Location Within Facility
AS.1.3	Provider's On Call Location
AS.1.4	Manage Provider's Location(s) or Office(s)
AS.1.5	Team/Group of Providers Registry or Directory
AS.1.6	Provider Caseload/Panel
AS.1.7	Manage Practitioner/Patient Relationships

Record Infrastructure

- **Focus on records, record entries and record management, including R1.1 functions/criteria and key provisions of the RM-ES Functional Profile, EHR Interoperability and Lifecycle Model DSTUs.**
- **Consists of Release1.1's :**
  - **IN.2 (Record Management, except Audit),**
  - **IN.8 (Record Archive/Restore) and**
  - **IN.10 (Record Lifecycle -previously EHR Lifecycle Model DSTU).**

Record Infrastructure	RI.1	Record Lifecycle and Lifespan
	RI.2	Record Synchronization
	RI.3	Record Archive and Restore

Example child functions:

RI.1.1	Record Lifecycle
RI.1.1.1	Originate and Retain Record Entry
RI.1.1.2	Amend Record Entry Content
RI.1.1.3	Translate Record Entry Content
RI.1.1.4	Attest Record Entry Content
RI.1.1.5	View/Access Record Entry Content
RI.1.1.6	Transmit and/or Disclose Record Entries
RI.1.1.7	Receive and Retain Record Entries
RI.1.1.8	De-identify Record Entries
RI.1.1.9	Pseudomynize Record Entries
RI.1.1.10	Re-identify Record Entries
RI.1.1.11	Extract Record Entry Content

Trust Infrastructure

- **Contains the remaining Release 1.1 Infrastructure functions, including Audit.**

Trust Infrastructure		
	TI.1	Security
	TI.2	Audit
	TI.3	Registry and Directory Services
	TI.4	Standard Terminology and Terminology Services
	TI.5	Standards-Based Interoperability
	TI.6	Business Rules Management
	TI.7	Workflow Management
	TI.8	Database Backup and Recovery
	TI.9	System Management Operations and I

TI.1	**Security**
TI.1.1	Entity Authentication
TI.1.2	Entity Authorization
TI.1.3	Entity Access Control
TI.1.4	Patient Access Management
TI.1.5	Non-Repudiation
TI.1.6	Secure Data Exchange
TI.1.7	Secure Data Routing
TI.1.8	Information Attestation
TI.1.9	Patient Privacy and Confidentiality

Example child functions

Layout of EHR-S FM R2

- Function Name
- Function Statement
- Function Description
- Examples
- Conformance Criteria
- See Also

Next Steps

- Redevelopment of current profiles based on R2
- Realm (country)-based profiles
- Map Functional Model to HL7 messages, documents, data
- Development of a corresponding Information Model

Want to Know More?

- Join HL7
- Review the HL7 web site
- Subscribe to HL7 EHR WG list serve
- Join our Tuesday Work Group calls
  - 3:00- 4:30 PM Eastern

www.hl7.org/ehr

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Q & A