From HITSP to HL7 EHR System Function and Information Model (EHR-S FIM) Release 3.0 Interoperability Specifications... a Ten Year Journey

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Welcome to www.HITSP.org

The Healthcare Information Technology Standards Panel (HITSP) is a cooperative partnership between the public and private sectors. The Panel was formed for the purpose of harmonizing and integrating standards that will meet clinical and business needs for sharing information among organizations and systems.

UPDATE:
HITSP’s contract with HHS concluded on April 30, 2010. Dr. David Blumenthal, the National Coordinator for Healthcare Information Technology, thanked the Panel for their contributions. To read his letter, click here.

PROGRAM OF WORK

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<tr>
<td>IS 01</td>
<td>Electronic Health Record (EHR) Laboratory Results Reporting</td>
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<tr>
<td>Specification defines specific standards to support the interoperability between electronic health records and laboratory systems and secure access to laboratory results and interpretations in a patient-centric manner.</td>
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# EHR-S Functional Model at a Glance

## Direct Care

<table>
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<tr>
<th>C1.0</th>
<th>Care Management</th>
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<tr>
<td>C2.0</td>
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## Supportive

<table>
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<tr>
<th>S1.0</th>
<th>Clinical Support</th>
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<tr>
<td>S2.0</td>
<td>Measurement, Analysis, Research, Reporting</td>
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<td>S3.0</td>
<td>Administrative and Financial</td>
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## Information Infrastructure

<table>
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<th>I 1.0</th>
<th>EHR Security</th>
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<tr>
<td>I 2.0</td>
<td>EHR Information and Records Management</td>
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<tr>
<td>I 3.0</td>
<td>Unique identity, registry, and directory services</td>
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<tr>
<td>I 4.0</td>
<td>Support for Health Informatics &amp; Terminology Standards</td>
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<tr>
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<td>Manage business rules</td>
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<tr>
<td>I 7.0</td>
<td>Workflow</td>
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Functions describe the behavior of a system in user-oriented language so as to be recognizable to the key stakeholders of an EHR System.
The HL7 International EHR System Functional Model (EHR-S FM) outlines important features and functions that should be contained in an EHR system.

Through the creation of functional profiles, this model provides a standard description and common understanding of functions for healthcare settings.

To date, HL7 has developed or is developing profiles for areas such as child health, emergency care, long term care, behavioral health and vital statistic reporting.

US National Institute of Standards and Technology (NIST) along with its accredited certification bodies (ACB) use EHR functional profiles such as the CRFP as a basis for certifying EHR systems.

The EHR-S FM is the original product of the HL7 EHR Work Group that was created in 2000 at the request of the National Health Information Infrastructure (NHII) (now known as the office of the National Coordinator (ONC)).
Executive-Summary

- HITSP Stared Doing Interoperability Specifications in ‘2005
- The release of the EHR System Functional Model (EHR-S FM) Release 3 is targeted for ‘2015; where,
  - it will become EHR-S Function-and-Information Reference-Architecture Release 3.0 (EHR-S FIM RA-3.0),
  - which builds upon and incorporates lessons learned from the EHR-S FM ‘2008 Release 1.1 and ‘2013 Release 2.0; and where,
  - the EHR-S FIM RA-3.0 is intended to facilitate pragmatic domain-specific tool-based,
    - acquisition, development, implementation, test-and-certification requirements-specification
    - for EHR capabilities-and-systems.
- A ‘2015 US-domain Meaningful Use (MU) Profile will be developed to demonstrate the EHR-S FIM RA-3.0’s utility.
HL7 EHR WG Tooling Vision
Using Sparx Enterprise Architect

• Proposed methodology and tools to support the development of EHR Interoperability Specifications.

• End-to-End lifecycle Scope
  – Use Case, mapped to
  – EHR System Functions, mapped to
  – Information Exchanges (IEs), mapped to
  – Information Model mapped it
  – Interoperability Specifications, mapped to
  – Standard IE content and transport
EHR-S FIM Tool Components

Use Case

- S&I Framework’s Use Case Simplification
  - Reusable Actors, Systems, Roles
  - Reusable Scenario Event Steps
  - Reusable Actions
  - Reusable Requirements
  - Reusable Data Objects and Data Elements
  - Context Constraints
EHR-FIM Tool Components
EHR-S Functional Model R 2.0

- The 2006 EHR-S FM had approximately
  - 130 functions with
  - 1000 conformance criteria.

- The 2013 EHR-S FM R2 has over
  - 320 functions with
  - 2300 conformance criteria.
EHR-FM Tool Components
HL7 Fast Healthcare Information Resources (FHIR)

• HITSP “C32” Continuity of Care Document (CCD) had 16 Data Modules
• FHIR will have approximately 150 data modules
• FHIR defines a set of granular clinical concepts.
  – The resources can be managed in isolation, or aggregated into complex documents.
  – Technically, FHIR is designed for the web; the resources are based on simple XML, with an http-based RESTful protocol where each resource has predictable URL.
NIST’s EHR Tooling Strategy

Use Cases
- healthcare use case development
- create requirements to guide the standards development

Standards
- implementation guide development
- ensure use case requirements are satisfied
- create testable assertions criteria

Implementation
- application implements the standard

Test Cases
- specification of test cases
- tests cases should test all requirements specified in the implementation guide

Test Data
- development of test messages
- messages support test cases valid and invalid

Implementation Guide Authoring and Management Tool (IGAMT)

Vendors

Test Case Authoring and Management Tool (TCAMT)

Test Scripts
- processable test cases
- methods and tools to transform test cases into machines processable instructions

Test Execution
- execution of the test scripts
- test engine interprets test scripts
- validate message against test material

Results
- juror document or test report
- create inspection document
- provide validation test report

Analysis
- automated or human analysis
- test or certification managers determine pass/fail based on results

Test Material
- artifacts to support testing
- XML message profiles
- vocabulary
- validation context files

IGAMT and TCAMT

Test Case Authoring and Management Tool (TCAMT)

Testing Infrastructure (Test Engine)

Testing Infrastructure (Validation) and TCAMT

Testing Organizations
Statement: Provide the ability to manage clinical orders and results including medication, non-medication, diagnostic tests, blood products, other biologics and referrals, using order sets as appropriate.

Description: The provision of clinical care includes the need to order from a variety of treatments using order sets as appropriate as well as reviewing the results of treatment. Orders for treatments may include medications, non-medication therapies (e.g. physical therapy, special diet, immunizations, non-allopathic regimens); diagnostic care (e.g., laboratory, radiology); blood products and other biologics (e.g., blood transfusions, human growth hormones). Patients are often referred to other health care providers for more specialized diagnostic workup and/or treatment. An effective EHR-S must include support and management of these processes and associated documentation.

Example: (notional scenario based on conformance criteria) During an encounter, patient problems, previous treatments, care plans and results are reviewed; then, orders or order-sets, based-on accepted clinical practices and/or order set templates, may be created by the clinician. If an order or order-set is created, discrete data elements associated with the order(s) are recorded and any appropriate order related or patient-related information is noted. Patient orders and/or order-sets are reported-to or coordinated with appropriate sources, appropriate clinicians and organizations (e.g., PHRs, schools, registries, public health), according to scope of practice, organizational policy and/or jurisdictional law.
EXAMPLE: CP.4 Manage Orders
EHR-S Components Dependent-on Clinician-Activities

NOTE: EHR-S FIM is NOT intended to imply a specific architecture or workflow!

act CP.4 Manage Orders

CP.4 Manage Orders

Manage Records
Manage Trusts
Manage Business Rules

Start

End

Encounter

Clinician Activities

Manage Schedules
Manage Events
Manage Terminology
Manage Lists
Manage Documents & Notes

EHR-S Components

Schedule
Event
Patient Information
Terminology
List
Document or Note

Orders Schedule
Administrative Information
Clinical Information

Orders
Schedule

Order Set

Order

is-a

Clinical Document or Note

6/13/2013

RED: Recommend deletion, Blue: Recommended Insertion
EXAMPLE: CP.4 Manage Orders
Conceptual Information Model (CIM)

ISSUE: data associated with CDS
EXAMPLE: CP.4. Manage Orders
Conformance Criteria (CC) Applicable to this CDM

class CP.4 Manage Orders (attributes)

Order-Execution-Time Enumeration
- admission
- discharge
- post-operative
- conditional
- standing

Order Lifecycle Stage Enumeration
- new
- cancellation
- modification
- renewal
- discontinuation
- conditional
- other

Order
- annotation
- comments & instructions (free text)
- demographic information
- indication/justification
- order activation date & time
- order set tag
- oral verification :boolean
- ordering clinician
- Order Execution Time
- Order Lifecycle Stage
- Order Type
- problem/diagnosis
- patient name
- patient identification number
- patient DOB or age
- patient instructions
- problem/diagnosis code link
- problem/diagnosis code or description
- Signature
- status
- supporting documentation
- urgency status
- user-created instructions or system prompts

Order Type Enumeration
- diagnostic test
- non-medication
- medication
- blood product & biologics
- referral

CPS.8.4 Support for Communications Between Provider and Patient and/or the Patient Representative

SHALL CCs have bolded borders.
EXAMPLE: CP.4 Manage Orders
Conformance Criteria (CC) Applicable to this CDM

1. CP.4#01 The system **SHALL** provide the ability to manage role-based, context-based and/or user-based order entry. *(add reference TI role based function or remove here)*

2. CP.4#02 The system **SHALL** provide the ability to manage the order lifecycle creation, renewal, modification and discontinuation, **etc.** of orders.

3. CP.4#03 The system **SHALL** provide the ability to render relevant, relevant patient-specific laboratory test results when entering an order.

4. CP.4#04 The system **SHALL** provide the ability to manage the status of an order (e.g. open, completed, in process). *(harmonize with CP.4.2)*

5. CP.4#05 The system **MAY** provide the ability to capture, maintain and render order entry with an appropriate registration process when the identity of the patient is **unknown** or in an **urgent** situation.

6. CP.4#06 The system **SHOULD** provide the ability to manage standing orders or orders that may be submitted by providers other than licensed providers according to scope of practice, organizational policy and/or jurisdictional law. *(standing order = pre-established conditional set of order = CPS 4.1, CPS.4.1 CC#4, CC#11) Verbal orders?*

7. CP.4#07 The system **SHALL** provide the ability to capture and render problem/diagnosis as a required element of an order.

8. CP.4#08 The system **MAY** provide the ability to capture, maintain and render, as discrete data, a diagnosis/problem code and/or description associated with an order of any type (including prescriptions and medications ordered for administration).

**NOTE:** EHR-S FIM is **NOT** intended to imply a specific architecture or workflow!
EXAMPLE: CP.4 Manage Orders
Conformance Criteria (CC) Applicable to this CDM

9. CP.4#09 The system MAY provide the ability to link an order of any type (including medication order) with a related clinical problem(s) and/or diagnosis code(s) and description.

10. CP.4#10 The system SHALL provide the ability to annotate and render comments and instructions with an order. (same as CC11?)

11. CP.4#11 The system SHOULD provide the ability to annotate and render free text comments and instructions with an order. (same as CC10?)

12. CP.4#12 The system SHOULD provide the ability to tag frequently used and institutionally-approved order sets as “favorites” or “preferences” to facilitate retrieval and ordering.

13. CP.4#13 The system MAY provide the ability to manage orders submitted to or received from external organizations and/or facilities such as Health Information Exchanges (HIE) or regional Electronic Health Record Systems (EHR-S).

14. CP.4#14 The system SHALL render the patient name, identification number, and age or date of birth on all order screens.

15. CP.4#15 The system SHALL provide the ability to capture, maintain and render an indicator of oral verification ("read-back") of the complete order by the person receiving the telephone or verbal order.

16. CP.4#16 The system SHALL provide the ability to capture and render the urgency status (e.g., As-Soon-As-Possible or STAT) associated with an order.

17. CP.4#17 The system SHOULD provide the ability to render order history for any order, including the ordering clinician, order details, date, and time.

18. CP.4#18 The system SHOULD provide the ability to tag and render a field as required for a complete order by order type.

NOTE: EHR-S FIM is NOT intended to imply a specific architecture or workflow!
19. CP.4#19 The system SHOULD provide the ability to tag orders to be activated at a future date and time including admission orders, discharge orders, and post-operative orders.

20. CP.4#20 The system SHOULD provide the ability to render orders for all order types.

21. CP.4#21 The system MAY provide the ability to manage conditional orders that can be activated when certain criteria and conditions are met.

22. CP.4#22 The system SHOULD provide the ability to capture, store and render the identity of all providers who signed an order.

23. CP.4#23 The system SHOULD provide the ability to render a list of active orders for a patient.

24. CP.4#24 The system SHOULD provide the ability to render a list of orders by similar or comparable type (e.g., all radiology or all laboratory orders).

25. CP.4#25 The system SHOULD provide the ability to render a list of outstanding orders for multiple patients (as opposed to outstanding orders for a single patient).

26. CP.4#26 The system SHOULD provide the ability to capture the provider's order-cancellation request.

27. CP.4#27 The system SHOULD provide the ability to transmit an order-cancellation request.

28. CP.4#28 The system SHALL conform to function CPS.8.4 (Support for Communication between Provider and Patient and/or the Patient Representative) to manage information regarding orders.

NOTE: EHR-S FIM is NOT intended to imply a specific architecture or workflow!
HL7 EHR System Functional Model and Standard

Q & A