

## **December 2013**

# EHR Work-Group (EHR WG) Cumulative FY14 Summary-Report

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Edmond Scientific subcontractor to Veterans Health Administration/
Health Informatics/ Office of Informatics & Analytics/ Knowledge Based Systems
The complete-and-latest version of the Summary-Report is available at:
<a href="http://wiki.hl7.org/images/0/0a/Hufnagel">http://wiki.hl7.org/images/0/0a/Hufnagel</a> - FY2014 HL7-EHR-WG Summary-Reportpdf

## **EXECUTIVE SUMMARY**

This executive-summary and report specifically address potential EHR impacts and/or EHR trends, which are important for the VA, IPO and DOD to-be aware-of.

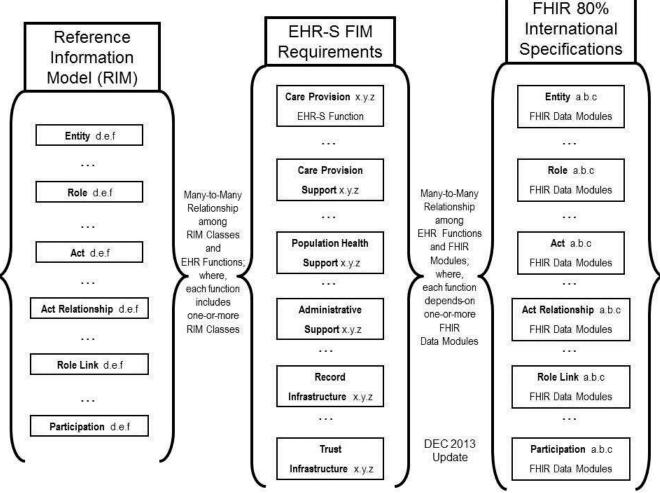


Figure 1 HL7 EHR-S FIM release-3 Relationship with HL7 RIM-and-FHIR [Jan 2012 PSS #688]

**INTRODUCTION:** the *purpose* of this report is to document the EHR and PHR System release-3 Function—and-Information-Model (FIM) development and related projects impacting the release-3 FIM. An agile approach is being followed, where monthly report-content is refined; until ultimately, the report can be generated by the Sparx Enterprise Architect tool as a demonstration of the release-3 FIM "Easy-Button" Interoperability-Specification (IS) report-generation capability. All EHR WG release-3 FIM documentation published at <a href="http://wiki.hl7.org/index.php?title=EHR Interoperability WG">http://wiki.hl7.org/index.php?title=EHR Interoperability WG</a> are working-drafts.

**GOAL:** The *goal* of the <u>Electronic Health Record (EHR) Work Group (WG)</u> is to support the HL7 mission of developing standards for EHR data, information, functionality, and interoperability. The Work Group creates and promotes appropriate and necessary standards. *Objectives* include:

- 1) Functional and Information Requirements-Specifications for Electronic Health Records (EHR) and systems (EHR-S),
- 2) Functional and Information Requirements-Specifications for Personal Health Records (PHR) and systems (PHR-S),
- 3) Definition of a high-level framework to support the interoperability requirements-specifications and life cycles, and
- 4) Identification of existing and emerging information interoperability-requirements and related HL7 artifacts.
- A Jan 2012 Project #688 System Function-and-Information Model release-3 (EHR-S FIM r3) objective of the EHR Interoperability WG is an UML-specified EHR/PHR Concept-of-Operations (CONOPS), Reference Model (RM), set-of Function Use-Cases with Conformance-Criteria Scenarios; where, EHR-S FIM r3 is to-be
  - o create a clear, complete, concise, correct, consistent and easy-to-use; because,
  - HL7 ballot-publishable from the Sparx Systems Enterprise-Architect tool
  - targeted for 3-to-5 years from now; because,
    - joint ISO-HL7 ballots are very challenging to manage and
    - sufficient-time is needed to address the structural issues identified by the EHR-S FM r2 ballot; where, VA voted negative, due to inconsistency, non-intuitiveness and unnecessary-complexity/non-usability.
- A second-objective of the EHR Interoperability WG is to produce a Meaningful Use profile for EHR-S FM r2 and r3.
- The objective of the Resource Management Evidentiary Support (RM-ES) project team is to provide expertise to the EHR work group, other standards groups and the healthcare industry on records management, compliance, and data/record integrity for, EHR systems and related to EHR governance to support the use of medical records for clinical care and decision-making, business, legal and disclosure purposes.
- The *objective* of the <u>EHR Usability Project</u> is to translate existing, well established usability guidelines and health information management principles into functional conformance-criteria in the EHR-S FM standard.

## SITUATION

EHR/PHR Concept-of-Operation was defined-and-refined into a System Reference-Model (RM); where,

- 1) **System Functions** are defined-by **Use-Case** lexicons-of system-operations bound-to System-entities; where,
  - a) System-operations are verbs refined into a "manage" operation-type-model (aka verb-hierarchy) and
  - b) System-entities are subject-and-object nouns refined into a Record-Entry data-type-model (aka information model)
  - c) Terminology value-sets are bound-to Record-Entry discrete-data-elements.
- 2) Conformance Criteria are defined-by a scenario-constrained use-case of
  - a) business-context and
  - b) subject-verb-object-terminology bindings; where,
- 3) Scenario-Constrained Business-Context is defined-by
  - a) pre-condition triggers,
  - b) applicability of
    - i) "The System SHOULD or SHALL or MAY"
    - ii) "provide-the-ability-to-manage Record-Entries" or "directly-manage Record-Entries," where,
      - (1) a use-case constrained verb-hierarchy applies and
      - (2) a use-case constrained data-model applies; where,
  - c) post-condition Business-Rules are "according-to
    - scope-of-practice, organizational-policy, jurisdictional-law, and patient-preferences."
- 4) Information-Exchange is defined-by a scenario subject-verb-object-terminology binding mapped to
  - a) **FHIR** (Fast Healthcare Interoperability Resource), which is representative of the International-Realm,
  - b) **FHIM** (Federal Health Information Model) US-Realm FHIR-profile or alternative-realm FHIR-profile,
  - c) **Terminology** value-sets, appropriate to the selected-realm,
  - d) **IHE information-exchange behavioral-protocols**, which may-be refined-or-replaced by,
    - SLA-DURSA (Service-level-agreement Data-Use-and-Reciprocal-Support-Agreement ) and
    - **KPPs** (Key Performance Parameters).
    - Cost estimation facets
- 5) **EHR-S/PHR-S Profile** is defined-by a set-of System-Function Use-Cases, with further constrained scenario'
  - a) applicability
  - b) business-context
  - c) subject-verb-object-terminology bindings.
- 6) Interoperability-Specifications are generated with the FIM r3 "Easy-Button" aka reporting-tool.

## **ACTIONS**

- 1. **HL7 Board approval** of EHR-S FIM Release-3 open-IP; where, the EHR-S FIM home page is www.hl7.org/EHRSFIM
- 2. **FHIR WG Coordination** to integrate EHR-S FIM-FHIR into a joint Sparx Enterprise Architect (EA) model; where, EA can generate integrated EHR-S FIM-FHIR International-Realm interoperability requirements-specifications
- 3. FHIM Team Coordination to integrate EHR-S FIM-FHIR-FHIM into a joint Sparx Enterprise Architect (EA) model; where EA can generate integrated EHR-S FIM-FHIR-FHIM US-Realm interoperability requirements-specifications
- 4. **Call-for-Participation** in EHR-S/PHR-S FIM r3 based on a common EHR-S/PHR-S RM (Reference Model), where, 6 Full Time Equivalent (FTE) level-of-effort is estimated (2-FTEs per-year for three-years)

  Calls every-Tuesday, 1PM ET, + 1-770-657-9270, PC 510269# and please joint EHR Interoperability ListServer

## **Plan-of-Actions & Milestones Dashboard**

| POA&M Task  | Start   | Done    | POC   | Comment                                  |
|---|---------|---------|-------|--|
| CONOPS  | 12-2013 | 12-2013 | SPH   |  |
| Reference Model   | 06-2013 | 12-2013 | SPH   |  |
| Conformance Criteria  |         |         | GD    | RM Based on Gary D. Jul 2013 spreadsheet |
| manage operation-ty pe                                      |         | 05-2013 | EHRWG | Verb-Hierarchy was part of r2 ballot     |
| Record-Entry data-types                                     | 01-2012 |         | SPH   | To-be refined for each function          |
| Care Provision  |         |         |       |  |
| CP.1 Manage Clinical History                                |         |         |       |  |
| CP.2 Render Externally Sourced Information                  |         |         |       |  |
| CP.3 Manage Clinical Documentation                          |         |         |       |  |
| CP.4 Manage Orders  | 01-2012 |         | SPH   | √ 2012 prototy pe → Todo wrt RM          |
| CP.5 Manage Results   | 01-2012 |         | SPH   | √ 2012 prototy pe → Todo wrt RM          |
| CP.6 Manage Treatment Administration                        |         |         | SPH   | √ 2012 prototy pe → Todo w rt RM         |
| CP.6.1 Medication Management                                | 01-2012 |         |       | √ Use case done, CCs in progress         |
| CP.6.2 Immunization Management                              | 01-2012 |         |       |  |
| CP.7 Manage Future Care                                     |         |         |       |  |
| CP.8 Manage Patient Education &                             |         |         |       |  |
| Communication   |         |         |       |  |
| CP.9 Manage Care Coordination & Reporting                   |         |         |       |  |
| Care Provision Support                                      |         |         |       |  |
| CPS.1 Record Management                                     |         |         |       |  |
| CPS.2 Support Externally Sourced Information                |         |         |       |  |
| CPS.3 Support Clinical Documentation                        |         |         |       |  |
| CPS.4 Support Orders  |         |         |       |  |
| CPS.5 Support for Results                                   |         |         |       |  |
| CPS.6 Support Treatment Administration                      |         |         |       |  |
| CPS.7 Support Future Care CPS.8 Support Patient Education & |         |         |       |  |
| CPS.8 Support Patient Education & Communication             |         |         |       |  |
| CPS.9 Support Care Coordination & Reporting                 |         |         |       |  |
| Population Health Support                                   |         |         |       |  |
| POP.1 Support for Health Maintenance,                       |         |         |       |  |
| Prev entive 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   |         |         |       |  |
| 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                                   |         |         |       |  |
| 710.7 Manage Communication                                  |         |         |       |  |

| POA&M Task                                | Start   | Done  | POC | Comment                          |
|---|---------|-------|-----|----------------------------------|
| AS.5 Manage Clinical Workflow Tasking     | Start   | Dolle | POC | Comment                          |
| AS.6 Manage Resource Availability         |         |       |     |                                  |
| AS.7 Support Encounter/Episode of Care    |         |       |     |                                  |
| Management                                |         |       |     |                                  |
| AS.8 Manage Information Access for        |         |       |     |                                  |
| Supplemental Use                          |         |       |     |                                  |
| AS.9 Manage Administrative Transaction    |         |       |     |                                  |
| Processing                                |         |       |     |                                  |
| Trust Infrastructure                      |         |       |     |                                  |
| TI.1 Security                             | 12-2012 |       |     | √ 2012 prototy pe → Todo w rt RM |
| TI.2 Audit                                | 12-2012 |       |     | √ 2012 prototy pe → Todo wrt RM  |
| TI.3 Registry and Directory Services      |         |       |     |                                  |
| TI.4 Standard Terminology and Terminology |         |       |     |                                  |
| Serv ices                                 |         |       |     |                                  |
| 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     |         |       |     |                                  |
| Performance                               |         |       |     |                                  |
| Record Infrastructure                     |         |       |     |                                  |
| RI.1 Record Lifecy cle and Lifespan       |         |       | SPH |                                  |
| RI.1.1.2 Record Entry Create              | 12-2012 |       |     | √ 2012 prototy pe → Todo wrt RM  |
| RI.2 Record Synchronization               |         |       |     |                                  |
| RI.3 Record Archive and Restore           |         |       |     |                                  |
|   |         |       |     |                                  |

## **WORKGROUP AND PROJECT LOGISTICS**

HL7 List Server Registration: <a href="http://www.hl7.org/myhl7/managelistservs.cfm">http://www.hl7.org/myhl7/managelistservs.cfm</a>

HI7 Workgroup Call-Schedule: <a href="http://www.hl7.org/concalls/default.aspx">http://www.hl7.org/concalls/default.aspx</a>
 EHR WG Wiki: <a href="http://wiki.hl7.org/index.php?title=EHR">http://wiki.hl7.org/index.php?title=EHR</a>

Health Level Seven - Electronic Health Record Work Group Weekly Teleconference Schedule Revised: 20 November 2013 List Server Time Screen Activity Lead(s) Dial-In (for agendas, Day **US ET** Sharing announcements) 1-877-668-4493 Records Management/ Mon 1200 Warner, Gelzer <u>Link</u> EHR Legal Code 927 002 088# Evidentiary Support EHRS FM Release 3 Hufnagel, 1-770-657-9270, 1300 Link EHR Interop Dickinson Passcode 510269# Planning Meaningful Use Functional 1-770-657-9270, Tues 1400 Datta, Dickinson Link EHR Interop Passcode 510269# Profile 1-770-657-9270. 1500 FULL EHR WG Co-Chairs Link EHR WG Passcode 510269# Ritter, Dickinson, 1-770-657-9270. 1200 Personal Health Record WG TRA EHR PHR Passcode 510269# Doo Wed Mon, Ritter, Rocca, 1-770-657-9270. 1300 EHR System Usability WG Link EHR Usability Passcode 510269# Gartner Thur Open 1-770-657-9270. Fri 0930 EHR WG Co-Chairs Co-Chairs TRA N/A Passcode 510269#

• EHR CCD to Blue Button Tool Project Wiki - This project defined the conversion of an HL7 Continuity of Care Document (CCD) to the Blue Button format via an XSLT style sheet tool.

Project contact: Lenel James and Keith Boone. List Service: <a href="mailto:EHRTeamCCD@lists.hl7.org">EHRTeamCCD@lists.hl7.org</a>

- EHR-S FM Profile Tool Project Wiki This project, sponsored by the HL7 Tooling Workgroup, will produce a (web-based and/or desktop) tool to create EHR-S FM profiles (starting with the EHR-S FM R2), with enforced profiling rules, and exports as documents, support for and XML interchange format for reuse across profile tool instances or for use in other tools. Project contact: John Ritter; <a href="mailto:johnritter1@verizon.net">johnritter1@verizon.net</a>
- EHR Usability Project Wiki This project has been launched to translate existing, well established usability guidelines and health information management principles into functional criteria in the EHR System Functional Model (EHR -S FM) standard. Project contact: John Ritter, Don Mon, Mitra Rocca and Walter Suarez List Service: ehrwgusability@lists.hl7.org
- PHR Project Wiki The HL7 Personal Health Record System Functional Model provides a reference list of functions that may be present in a Personal Health Record System (PHRS).
   Project contact: John Ritter; johnritter1@v erizon.net
  - <u>Diabetes Data Strategy Project Wiki</u> The scope for this project is to focus on the minimum data set and data standards in EHR systems for diabetes assessment in children in outpatient clinic settings, based on clinical and business requirements. Project contact: Don Mon;

donmon@rti.org

## REFERENCE INFORMATION

#### 1) Common Clinical informatics standards:

- a) SNOMED CT for problems, smoking status
- b) **DICOM** for radiology
- LOINC for laboratory anatomical pathology, LOINC tax onomy for document types for inpatient notes
- d) RxNorm for pharmacy
- e) CVX and MVX for immunology
- f) HITSP C32, HL7 CCD and CCDA-CCD for VLER Health data
- g) ICD9 CPT4/HCPCS ICD9PCS for TRICARE billing data.
- h) ICD-10 and SNOMED CT for outpatient visits, ICD-10 and LOINC for admissions encounter data
- i) CPT4 and HCPCS for procedures
- i) PDA-F for scanned paper reports
- k) CDC value set race codes for demographics
- I) UCUM for units of lab measures
- m) NUCC Health provider tax onomy for provider types

#### 2) Common technical standards:

- a) CTS or Common Terminology Service
- b) FHIR or Fast Healthcare Interoperability Resource with RESTrill API
- c) CDS or Clinical Decision Support API
- d) CCDA is Consolidated CDA
- e) VPR or Virtual Patient Record
- f) RDF or Resource Description Framework for semantic web applications
- g) RLUS or Retriev e Locate Update Service for heterogeneous database facades
- h) JSON or Jav a Script Object Notation
- i) WS\* or Web Service Standards

## 3) EHR-S FM r2.0 Perspectives

## a) Care Provision

- i) CP.1 Manage Clinical History
- ii) CP.2 Render Externally Sourced Information
- iii) CP.3 Manage Clinical Documentation
- iv) CP.4 Manage Orders
- v) CP.5 Manage Results
- vi) CP.6 Manage Treatment Administration
- vii) CP.7 Manage Future Care
- viii) CP.8 Manage Patient Education & Communication
- ix) CP.9 Manage Care Coordination & Reporting

#### b) Care Provision Support

- i) CPS.1 Record Management
- ii) CPS.2 Support Externally Sourced Information
- iii) CPS.3 Support Clinical Documentation
- iv) CPS.4 Support Orders
- v) CPS.5 Support for Results
- vi) CPS.6 Support Treatment Administration
- vii) CPS.7 Support Future Care
- viii) CPS.8 Support Patient Education & Communication
- ix) CPS.9 Support Care Coordination & Reporting

## c) Population Health Support

- i) POP.1 Support for Health Maintenance, Preventive Care and Wellness
- POP.2 Support for Epidemiological Investigations of Clinical Health Within a Population
- iii) POP.3 Support for Notification and Response
- iv) POP.4 Support for Monitoring Response Notifications Regarding a Specific Patient's Health
- v) POP.5 Donor Management Support
- vi) POP.6 Measurement, Analysis, Research and Reports

- vii) POP.7 Public Health Related Updates
- viii) POP.8 De-Identified Data Request Management
- ix) POP.9 Support Consistent Healthcare Management of Patient Groups or Populations
- x) POP.10 Manage Population Health Study-Related Identifiers

#### d) Administration Support

- i) AS.1 Manage Provider Information
- ii) AS.2 Manage Patient Demographics, Location and Synchronization
- i) AS.3 Manage Personal Health Record Interaction
- iv) AS.4 Manage Communication
- v) AS.5 Manage Clinical Workflow Tasking
- vi) AS.6 Manage Resource Availability
- vii) AS.7 Support Encounter/Episode of Care Management
- viii) AS.8 Manage Information Access for Supplemental Use
- ix) AS.9 Manage Administrative Transaction Processing

#### e) Trust Infrastructure

- i) TI.1 Security
- ii) TI.2 Audit
- iii) TI.3 Registry and Directory Services
- iv) TI.4 Standard Terminology and Terminology Services
- v) TI.5 Standards-Based Interoperability
- vi) TI.6 Business Rules Management
- vii) TI.7 Workflow Management
- viii) TI.8 Database Backup and Recovery
- ix) TI.9 System Management Operations and Performance

#### Record Infrastructure

- i) RI.1 Record Lifecy cle and Lifespan
- ii) RI.2 Record Synchronization
- ii) RI.3 Record Archive and Restore

#### 4) FHIR (Fast Healthcare Interoperability Resources)

a) FHIR Data Dictionary is at:

http://www.hl7.org/implement/standards/fhir/

## ) FHIR Administrative

- Attribution: Patient, RelatedPerson, Practitioner, Organization
- ii) Resources: Device, Location, Substance, Group
- iii) Workflow Management: Encounter, Alert, Supply, Order, OrderResponse
- iv) Financial: Coverage

#### c) FHIR Clinical

- i) General: AdverseReaction, Allergy Intolerance, CarePlan, Family History, Condition, Procedure, Questionnaire
- Medications: Medication, MedicationPrescription, MedicationAdministration, MedicationDispense, MedicationStatement. Immunization. ImmunizationProfile
- iii) Diagnostic: Observation, DiagnosticReport, DiagnosticOrder, ImagingStudy, Specimen
- iv) Device Interaction: DeviceCapabilities, DeviceLog,
  DeviceObservation

#### d) FHIR Infrastructure

- Support: List, Media, Other, DocumentReference, (Binary)
- ii) Audit: Provenance, Security Event
- iii) Ex change: Document, Message, OperationOutcome, Query
- iv) Conformance: Conformance, ValueSet, Profile

#### e) Acronyms

• aka also known as

CC EHR-S FIM Conformance Criteria
 CDA Clinical Document Architecture

• **DD** Data Dictionary

CIM Conceptual Information Model

• **CP** Care Provision

CPS Care Provisioning Support
 EA Enterprise Architect
 EHR-S EHR System

EHR-S FIM EHR-S Function-and-Information Model

FHA US Federal Health Architecture
 FHIM US Federal Health Information Model
 FHIR Fast Healthcare Interoperability Resources
 FIM EHR-S Function and Information Model
 FIM(MU) EHR-S FIM Meaningful Use profile

FM Function ModelFY Fiscal Year

IHE <u>Integrating the Healthcare Enterprise</u>

• IM Information Model

MDHT Model Driv en Health Tools

MU US Meaningful Use objectives-and-criteria
 ONC US Office of the National-Coordinator

OHT Open Health Tools

• POA&M Plan of Actions and Milestones

• R 2/3 Release 2 or 3

RI Resource Infrastructure

• RIM HL7 Reference Information Model

S&I ONC Standards & Interoperability Framework

WBS Work Breakdown Structure

WG Work Group

| 2  | 1  | November 201310  |
|----|----|--|
| 3  |    |  |
| 4  |    | MONTHLY SUMMARIES  |
| 5  |    | (Reverse Chronological Order)  |
| 6  | LE | GEND   |
| 7  | 1) | Capitalized and Underlined nouns and adjectives are concepts, which should be in the EHR-S FM data dictionary; and, they should also correspond                      |
| 8  |    | to ISO 13940 Continuity -of-Care "CONTsys" concepts. See <a href="www.skmtglossary.org">www.skmtglossary.org</a> for standard healthcare data-dictionary / glossary. |
| 9  | 2) | Blue terms are recommended terms to be added to the conformance criteria.  |
| 10 | 3) | Red terms are recommended terms to be removed from the conformance criteria.   |
| 11 | 4) | Highlighted Yellow Sections are issues and/or new material for the main EHR WG to-review and to-comment-on.  |
| 12 |    |  |
| 13 |    |  |

## 1 November 2013

For details see http://wiki.hl7.org/images/8/83/HL7\_EHR-WG\_Summary-Presentation\_November\_2013.pdf

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- 1) **EHR WG** is waiting on the EHR-S FM Release-2 ISO ballot comments; where, the HL7 release-2 ballot-comments have already been reconciled. The ISO ballot closes on 3-Dec-2013; and then, the ISO-ballot-comments can be reconciled during December-and-January and EHR-S FM release-2 can be finalized in January 2014. The EHR WG has also been updating the EHR-S FM release-2 add-on to the Sparx EA-tool to support the creation of profiles.
- 2) **PHR WG** is waiting on the PHR FM Release-2 ISO ballot-comments, which close 3-Dec-2013 and will be reconciled during December-and-January; where, the HL7 release-2 ballot-comments have already been reconciled.
- 3) EHR RMES WG is discussing release authorization within the S&I Framework esMd group; where, esMD is analyzing the situation where healthcare-payers frequently request that providers submit additional medical-documentation for a specific claim, to support claims processing and other administrative functions, such as the identification of improper payments. Currently, Medicare Review Contractors request approximately 2 million medical documents per year by mailing a paper request letter via US Postal Service to healthcare providers. Until recently, providers had only two options for submitting the requested records: 1) mail paper or 2) send a fax. The manual paper process is costly, time consuming and can delay proper claims processing on both the senders' and receivers' end.
- 4) **EHR Usability WG** is collecting issues and mitigations into a reference library, which can be the basis of integrating usability into the release-3 EHR-S FIM.
- 5) **EHR Interoperability WG** focused on the May-2014 Meaningful-Use Profile for the EHR-S FM release-2 and preparation for release-3:2016; where, the November release-3 focus was to define Reference-Models for Concept-of-Operations, Function Information-and-Conformance-Criteria:
  - Figure 1 HL7 EHR-S FIM release-3 Relationship with HL7 RIM-and-FHIR [Jan 2012 PSS#688]
  - Figure 2 EHR/PHR Concept-of-Operations (CONOPS)
  - Figure 3 EHR-S/PHR-S RM
    - Figure 4 EHR/PHR-RM Operation-Types Model (Verb-Hierarchy
  - Figure 5 EHR/PHR-RM Data-Types Model
  - Figure 6 CP.6.2 Immunization-Management Use-Case
  - Figure 7 CP.6.2#01 Immunization-Management Conformance-Criteria
  - Figure 8 EHR-S FIM-FHIR-FHIM Requirements-Specification Relationship
- Figure 9 Example EHR-S FIM-FHIR Requirements-Specifications
  - Figure 10 Example EHR-S FIM-FHIR-FHIM Requirements-Specification

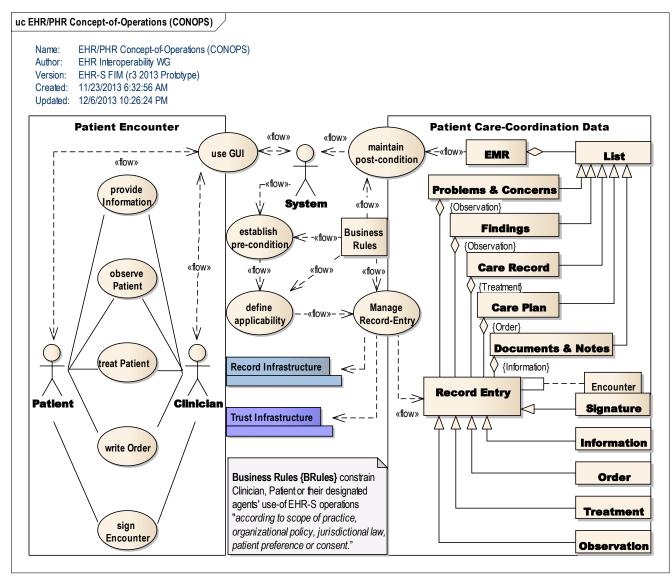


Figure 2 EHR/PHR Concept-of-Operations (CONOPS)

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EHR-S Concept-of-Operations (CONOPS) Use-Case A <u>Clinician</u> and <u>Patient</u> and/or their designated <u>Agents</u> have <u>Encounters</u>; where, they *use* a System <u>GUI</u> (Graphical-User-Interface) to <u>manage Record-Entries</u> and <u>EMRs</u> (Electronic Medical Records); where,

- The <u>System</u>, based-on <u>Business Rules</u>,
  - establishes pre-conditions to trigger information flow
  - determines (SHALL/SHOULD/MAY) applicability for the System to-provide-the ability-to-manage or directly-manage
  - maintains post-conditions in accordance with
    - scope-of-practice, organizational-policy,
    - jurisdictional-law, and patient-preferences.
- The Clinician, Patient (or their designated agent) can
  - review the Patient EMR (Electronic Medical Record) and associated Information
  - observe and treat the Patient, write Orders, document the Encounter, provide Information

- provide patient-<u>Information</u> and educational-<u>Information</u>
- enter EMR Records and associated Information; where,
  - Record Entries are Orders, Treatments, Observations and associated Information
  - <u>Lists</u> are <u>Care-Plans</u>, <u>Care-Records</u>, <u>Findings</u>, <u>Problems-and-Concerns</u>, <u>Documents & Notes</u>
- sign <u>Encounter</u> by the Clinician(s) and/or the Patient
- Conformance-Criteria are Scenario threads-of-execution through the Use-Case or Model.

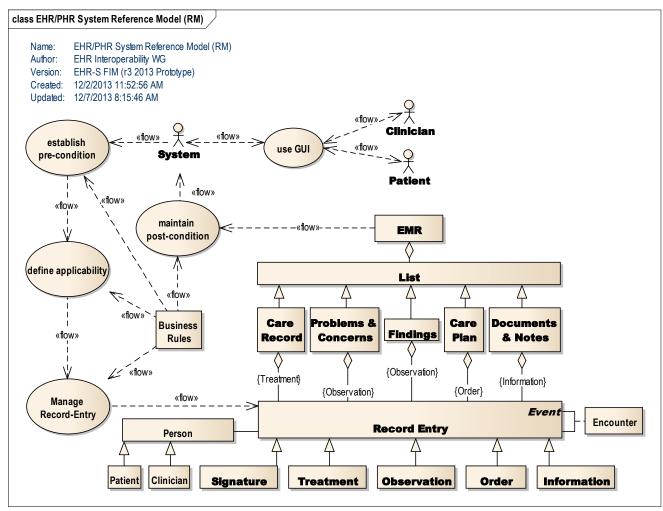


Figure 3 EHR-S/PHR-S RM

## The EHR Reference-Model (RM)<sup>1</sup> [based-on OASIS RM definition]

- 1. Establishes pre-conditions
- 2. Defines applicability (The System SHALL/SHOULD/MAY "provide-the-ability to manage" or "directly-manage")
- 3. Structures **Record-Entry** relationships

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HL7 EHR-WG Summary

According to the Organization for the Advancement of Structured Information Standards (**OASIS**) a reference model is "an abstract framework for understanding significant relationships among the entities of some environment, and for the development of consistent standards or specifications supporting that environment. A reference model is based on a small number of unifying concepts and may be used as a basis for education and explaining standards to a non-specialist. A reference model is not directly tied to any standards, technologies or other concrete implementation details, but it does seek to provide a common semantics that can be used unambiguously across and between different implementations."

- 79 defined-by system operation-and-data models; where, 80 EHR/PHR system RM is based-on a functional-use-case constrained hierarchical-lexicon of nouns (Record-Entry data-types) and noun qualifiers. 81 82 verbs (manage operation-types) and verb qualifiers with conditions {Business Rules based on laws, policies, preferences}; where, 83 Conformance Criteria (CC) are use-case scenario-threads (context and subject-verb-object bindings). 84 4. Defines Conformance-Criteria syntax-and-semantics; where, 85 86 Function Conformance-Criteria and their profiles constrain the manage sub-types, Record-Entry sub-types 87 Functions can-be linked-to Information Exchanges (IEs), IEs can-be linked-to implementation standards-technologies-paradigms-and-patterns (e.g., FHIR, FHIM, IHE). 88 89 5. Maintains post-conditions; where, 90 91 A System-Function (SF) Use-Case is a constrained-scope and refined-detail System Reference-Model; where, 92 SF Conformance-Criteria are System-Action scenario-threads through the SF Use-Case Model containing: 93 1) SF Invariant-condition (context) a) System Identifier (EHR or PHR) 94 95 b) System Function (SF) Identifier 96 c) Profile Identifier 97 2) SF CC Identifier (Number) 98 3) **SF CC Pre-condition** (trigger) 99 a) Pre-condition is a verb-clause. b) After a Human-Action or System-Action; then, 100 101 4) SF CC Applicability 102 a) The System SHALL, SHOULD or MAY "provide-the-ability-to" 103 "directly" 104 105 5) SF CC System-Action Bindings a) Operation linked-to Data-Type; where, conditionally, 106 b) the System-Actions depends-on other-SF 107 c) Data-Type are associated-with other Data-Types 108 109 d) Information Exchange(s) are *linked-to* International Interoperability-Standards (e.g., FHIR) 110 ii) Realm Interoperability-Specifications (e.g., FHIM) 111 iii) Implementation Guides (e.g., Consolidated CDA) 112 113 iv) Behavioral Interoperability-Specifications (e.g., IHE) v) Service Level Agreement (e.g., local workflow) 114 6) SF CC Post-Condition (expected-outcome)
- b) "where, the System-Actions are ..." 117 7) SF CC See Also
- a) Supporting or related SFs (e.g., Infrastructure) 119

a) Post-condition is a subordinate-clause.

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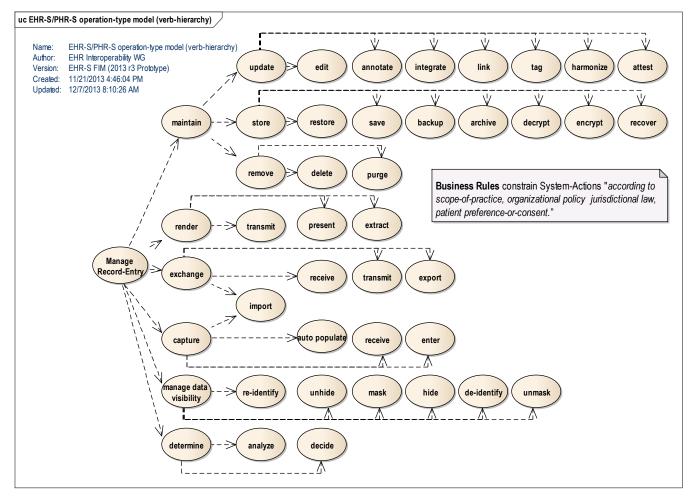


Figure 4 EHR/PHR-RM Operation-Types Model (Verb-Hierarchy)

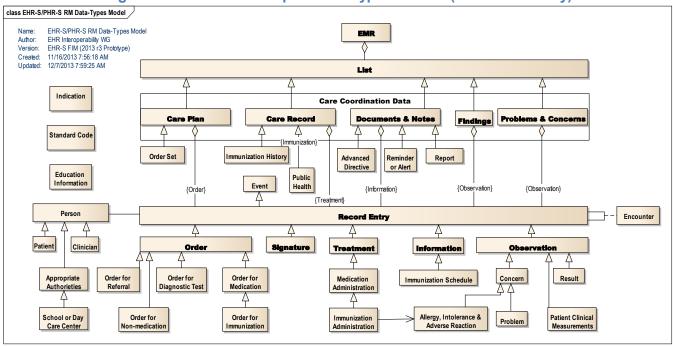


Figure 5 EHR/PHR-RM Data-Types Model

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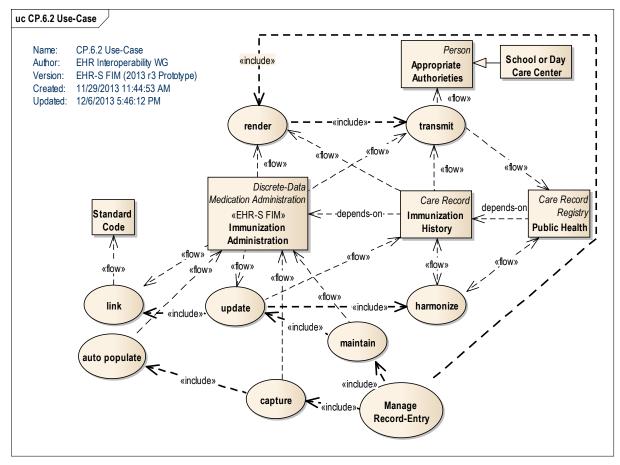


Figure 6 CP.6.2 Immunization-Management Use-Case

The Release-3 EHR System Immunization-Management Function Use-Case includes

- 1) A Clinician uses the EHR-S, during an Encounter, to
  - a) review EMR, Alerts-and-Notifications
  - b) enter Observations, Treatments, Orders and associated Documents and Notes
  - c) sign the Encounter

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- d) Immunization Management involves the following:
  - i) **System-Actions:** auto-populate, capture, determine, exchange, harmonize, link, maintain, manage, render, transmit, update; where,
    - (1) Immunization-Administration is
      - (a) linked with Standard-Codes
      - (b) transmitted to Population Health Registries
      - (c) *auto-populated as* a by-product of verification of <u>Administering-Provider</u>, <u>Patient</u>, <u>Medication</u>, <u>Dose</u>, <u>Route</u> and <u>Time</u>.
    - (2) <u>Immunization-History</u> is
      - (a) Updated-with the Immunization-Administration Record-Entries
      - (b) harmonized with Public-Health Registries
      - (c) rendered and transmitted; where,
        - (i) transmitted to Appropriate Authorities (e.g., Schools and Day Care Centers);
  - ii) Data: Immunization-Administration, Immunization-History, Public-Health Registry

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- iii) Associated Data: Alerts-and-Notification, Allergy-Intolerance-or-Adverse-Event, Patient-Clinical-Measurement, Patient-Directive, Immunization-Schedule, Patient-Educational-Information, Signature.
- e) Where all System-Actions are "according to scope-of-practice, organizational-policy, jurisdictional-law, patient preference-or-consent."

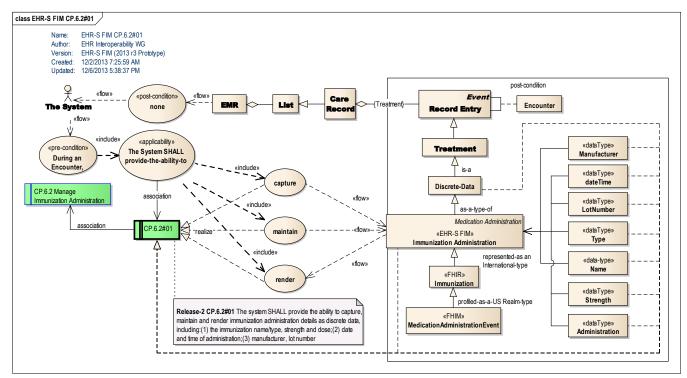


Figure 7 CP.6.2#01 Immunization-Management Conformance-Criteria

CP.6.2#01 During an Encounter, the system SHALL provide-the-ability-to capture, maintain and render Immunization Administration; where,

- Treatment Record-Entry details are as discrete-data, including
  - immunization name/type, strength and dose; date-and-time of administration;
  - manufacturer, lot number
- Immunization Administration can be realized-by FHIR; where,
  - Immunization-Administration is then associated with the following resources:
    - AdverseReaction and other Observations,
    - Patient, Practitioner, Organization, Location;
- Immunization-Administration can be realized-by FHIR-profiles based-on the US Realm FHIM Immunization and related Domains.

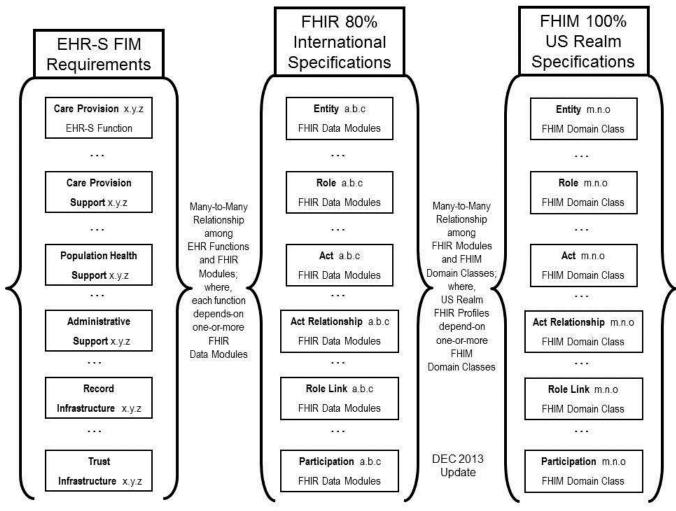


Figure 8 EHR-S FIM-FHIR-FHIM Requirements-Specification Relationship

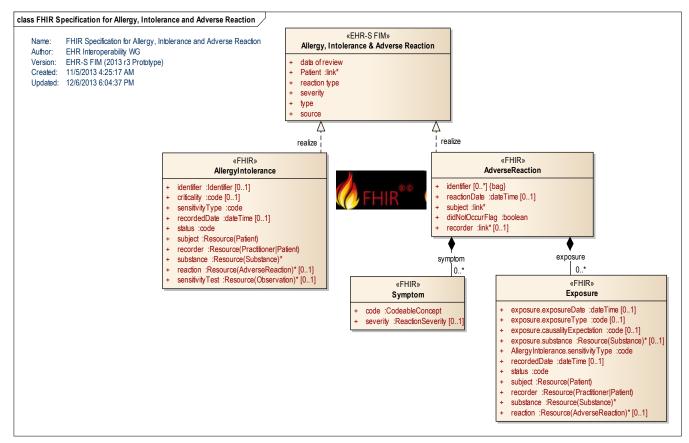


Figure 9 Example EHR-S FIM-FHIR Requirements-Specifications

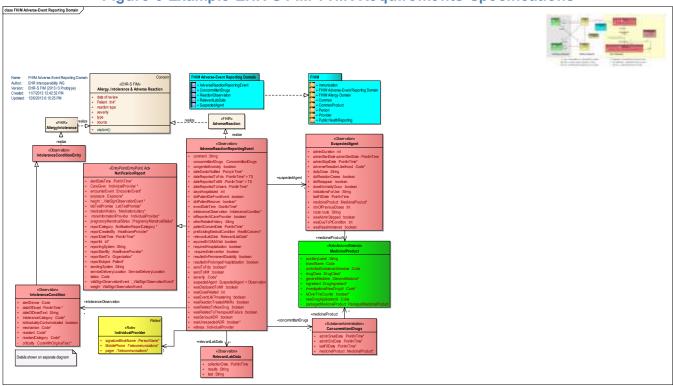


Figure 10 Example EHR-S FIM-FHIR-FHIM Requirements-Specification

|   | CURRENT ISSUES-ACTIONS   |
|---|--|
| 5 | 5. <b>HL7 Board approval</b> of EHR-S FIM Release-3 open-IP; where, the EHR-S FIM home page is www.hl7.org/EHRSFIM   |
| 6 | 6. FHIR WG Coordination to integrate EHR-S FIM-FHIR into a joint Sparx Enterprise Architect (EA) model; where,       |
|   | EA can generate integrated EHR-S FIM-FHIR International-Realm interoperability requirements-specifications           |
| 7 | 7. FHIM Team Coordination to integrate EHR-S FIM-FHIR-FHIM into a joint Sparx Enterprise Architect (EA) model; where |
|   | EA can generate integrated EHR-S FIM-FHIR-FHIM US-Realm interoperability requirements-specifications                 |
| 8 | B. Call-for-Participation in EHR-S/PHR-S FIM r3 based on a common EHR-S/PHR-S RM (Reference Model), where,           |