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 RIM-and-FHIR Relationship with EHR-S FIM release-3

[2012 PSS #688]
**GOAL:** The goal of the Electronic Health Record (EHR) Work Group (WG) 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, including:

- Functional and Information Requirements-Specifications for Electronic Health Records (EHR) and systems (EHR-S),
- Functional and Information Requirements-Specifications for Personal Health Records (PHR) and systems (PHR-S),
- Definition of a high-level framework to support the interoperability requirements and life cycles, and
- Identification of existing and emerging information interoperability requirements and related HL7 artifacts.

An objective of the EHR Interoperability WG team, under the System Function-and-Information Model release-3 (EHR-S FIM r3) project #688 based-on UML-specified EHR/PHR Concept-of-Operations (CONOPS), Reference Model (RM), Function Use-Cases and Conformance-Criteria Scenarios; where, EHR-S FIM r3

- is create a clear, complete, concise, correct, consistent and easy-to-use
- 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.
- 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 EHR Usability Project is to translate existing, well established usability guidelines and health information management principles into functional conformance-criteria in the EHR-S FM standard.
SITUATION REPORT
EHR-S FIM Release-3 Preparation
The complete-and-latest version of the Summary-Report is available at:

EHR/PHR Concept-of-Operation was defined-and-refined into a System Reference-Model (RM); where,
1) System Function is defined-by a Use-Case lexicon-of system-operations bound-to Record-Entries; 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)
2) Conformance Criteria is defined-by a scenario-constrained use-case of
   a) business-context and
   b) subject-verb-object-terminology binding; where,
3) Scenario-Constrained Business-Context is defined-by
   a) pre-condition triggers,
   b) applicability of
      i) “SHOULD” or “SHALL” or “MAY” plus
      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
      i) scope-of-practice, organizational-policy,
      ii) 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), which is representative of US-Realm FHIR-profiles,
   c) IHE information-exchange behavioral-protocols, which may be refined-or-replaced by,
      i) Service-level-agreement workflow-protocols and
      ii) Key Performance Parameters (KPPs).
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 binding.
6) Interoperability-Specifications are generated with the EHR-S/PHR-S FIM r3 “Easy-Button (aka report-tool).”

CURRENT ACTIONS
1. HL7 Board to approve EHR-S FIM Release-3 open-IP; where, the EHR-S FIM home page is www.hl7.org/EHRS-FIM
2. Coordinate with FHIR WG to integrate EHR-S FIM & FHIR into a joint Sparx Enterprise Architect (EA) model; where,
   EA can generate integrated EHR-S FIM-FHIR interoperability requirements-specifications
3. Call for Participation in EHR-S/PHR-S FIM r3 based on a common EHR-S/PHR-S RM (Reference Model), where,
   an estimated 6 Full Time Equivalent (FTE) level of effort is estimated (2-FTEs per year for three-years)
WORKGROUP AND PROJECT LOGISTICS

- HL7 List Server Registration: http://www.hl7.org/myhl7/managelistservs.cfm
- HL7 Workgroup Call-Schedule: http://www.hl7.org/concalls/default.aspx

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- **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: EHRTeamCCD@lists.hl7.org
- **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; johnritter1@verizon.net
- **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: ehrwusability@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@verizon.net
- **Diabetes Data Strategy Project Wiki** 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
   c) LOINC for laboratory anatomical pathology, LOINC taxonomy for document types for inpatient notes
   d) RxNorm for pharmacy
   e) CVX and MVX for immunology
   f) HITSP C32, HL7 CCD and CCDCA-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 HPCPS for procedures
   j) PDA-F for scanned paper reports
   k) CDC value set race codes for demographics
   l) UCUM for units of lab measures
   m) NUCC Health provider taxonomy for provider types

2) **Common technical standards:**
   a) CTS or Common Terminology Service
   b) FHIR or Fast Healthcare Interoperability Resource with RESTful API
   c) CDS or Clinical Decision Support API
   d) CCD is Consolidated CDA
   e) CPR or Virtual Patient Record
   f) RDF or Resource Description Framework for semantic web applications
   g) RLUS or Retrieve Locate Update Service for heterogeneous database facades
   h) JSON or JavaScript 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
      ii) 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
   d) Administration Support
      i) AS.1 Manage Provider Information
      ii) AS.2 Manage Patient Demographics, Location and Synchronization
      iii) 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
   f) Record Infrastructure
      i) RI.1 Record Lifecycle and Lifespan
      ii) RI.2 Record Synchronization
      iii) 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/](http://www.hl7.org/implement/standards/fhir/)
   b) FHIR Administrative
      i) 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
      ii) Medications: Medication, MedicationPrescription, MedicationAdministration, MedicationDispense, MedicationStatement, Immunization, ImmunizationProfile
      iii) Diagnostic: Observation, DiagnosticReport, DiagnosticOrder, ImagingStudy, Specimen
      iv) Device Interaction: DeviceCapabilities, DeviceLog, DeviceObservation
   d) FHIR Infrastructure
      i) Support: List, Media, Other, DocumentReference, (Binary)
      ii) Audit: Provenance, SecurityEvent
      iii) Exchange: 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 Model
- **FY** Fiscal Year
- **IHE** [Integrating the Healthcare Enterprise](#)
- **IM** Information Model
- **MDHT** Model Driven Health Tools
- **MU** US Meaningful Use objectives-and-criteria
- **ONC** US Office of the National-Coodinator
- **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
MONTHLY SUMMARIES

(Reverse Chronological Order)

LEGEND

1) Capitalized and Underlined nouns and adjectives are concepts, which should be in the EHR-S FM data dictionary; and, they should also correspond to ISO 13940 Continuity-of-Care "CONTsys" concepts. See www.skmtglossary.org for standard healthcare data-dictionary / glossary.

2) Blue terms are recommended terms to be added to the conformance criteria.

3) Red terms are recommended terms to be removed from the conformance criteria.

4) Highlighted Yellow Sections are issues and/or new material for the main EHR WG to review and to comment on.
1 November 2013

For details see http://wiki.hl7.org/images/8/83/HL7_EHR-WG_Summary-Presentation_November_2013.pdf

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 RIM-and-FHIR Relationship with EHR-S FIM release-3 [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
EHR-S Concept-of-Operations (CONOPS) Use-Case A Clinician and Patient and/or their designated Agents have Encounters; where, they use a System GUI (Graphical-User-Interface) to manage Record-Entries and EMRs (Electronic Medical Records); where,

- The System, based-on Business Rules,
  - 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-Information and educational-Information
• enter EMR Records and associated Information: where,
  • Record Entries are Orders, Treatments, Observations and associated Information
  • Lists are Care-Plans, Care-Records, Findings, Problems-and-Concerns, Documents & Notes
• sign Encounter by the Clinician(s) and/or the Patient
• Conformance-Criteria are Scenario threads-of-execution through the Use-Case or Model.

The EHR Reference-Model (RM)\(^1\) (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

\(^1\) 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."
– defined-by system operation-and-data models; where,
  – EHR/PHR system RM is based-on a functional-use-case constrained hierarchical-lexicon of
    • nouns (Record-Entry data-types) and noun qualifiers,
    • verbs (manage operation-types) and verb qualifiers with
    • conditions (Business Rules based on laws, policies, preferences); where,
  – Conformance Criteria (CC) are use-case scenario-threads (context and subject-verb-object bindings).

4. Defines Conformance-Criteria syntax-and-semantics; where,
  – Function Conformance-Criteria and their profiles constrain the manage sub-types, Record-Entry sub-types
  – Functions can-be linked-to Information Exchanges (IEs),
  – IEs can-be linked-to implementation standards-technologies-paradigms-and-patterns (e.g., FHIR, FHIM, IHE).

5. Maintains post-conditions; where,

A System-Function (SF) Use-Case is a constrained-scope and refined-detail System Reference-Model; where,
SF Conformance-Criteria are System-Action scenario-threads through the SF Use-Case Model containing:

1) SF Invariant-condition (context)
   a) System Identifier (EHR or PHR)
   b) System Function (SF) Identifier
   c) Profile Identifier

2) SF CC Identifier (Number)

3) SF CC Pre-condition (trigger)
   a) Pre-condition is a verb-clause.
   b) After a Human-Action or System-Action; then,

4) SF CC Applicability
   a) The System SHALL, SHOULD or MAY
      i) “provide-the-ability-to”
      ii) “directly”

5) SF CC System-Action Bindings
   a) Operation linked-to Data-Type; where, conditionally,
   b) the System-Actions depends-on other-SF
   c) Data-Type are associated-with other Data-Types
   d) Information Exchange(s) are linked-to
      i) International Interoperability-Standards (e.g., FHIR)
      ii) Realm Interoperability-Specifications (e.g., FHIM)
      iii) Implementation Guides (e.g., Consolidated CDA)
      iv) Behavioral Interoperability-Specifications (e.g., IHE)
      v) Service Level Agreement (e.g., local workflow)

6) SF CC Post-Condition (expected-outcome)
   a) Post-condition is a subordinate-clause.
   b) “where, the System-Actions are ...”

7) SF CC See Also
   a) Supporting or related SFs (e.g., Infrastructure)
Business Rules constrain System-Actions "according to scope-of-practice, organizational policy, jurisdictional law, patient preference or consent."

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

Figure 5 EHR/PHR-RM Data-Types Model
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
   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 Administering-Provider, Patient, Medication, Dose, Route and Time.
         2) Immunization-History 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.
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.”

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**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