



HL7 EHR-S FIM r-3 Easy-Button Report on '2013 CP.6.2 Immunization Management-Prototype

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100% generated by the HL7 EHR-S FIM r3 "Easy-Button" Tool on January 2, 2014
The complete-and-latest versions of EHR Interoperability WG documents are available at:
http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG

Executive Summary

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; where, the Work Group and its projects create-and-promote appropriate-and-necessary standards. **HL7 Project Scope Statement (PSS) #688** is for ISO/HL7 10781 r3:2017 EHR-S FIM; where, EHR-S Function-and-Information Model Release-3 is planned for '2017 ballot. This report demonstrates 1-function of 150-functions remaining to-be done over the next three-years.

Our **vision** is to restructure the '2014 EHR-S FM Release-2 into clear, complete, concise, correct, consistent and easy-to-use functions and conformance criteria within the '2017 UML-modeled EHR-S FIM Release-3 Easy-Button tool; where, the EHR-S FIM Enterprise Architect (**EA**) platform is capable-of managing specific-profiles (e.g., personal health record, behavioral health, long-term care, emergency department, inpatient, outpatient or individual-system); where, profile reports or web-sites can be automatically-generated, which include:

1. Constraints according-to patient-preference, situation, scope-of practice, organizational-policy and jurisdictional-law
2. Functional use-case entities, system-actions information-exchanges, conformance-criteria scenarios
3. Interoperability-specifications, including selectable implementation paradigms
4. Requirements lifecycle-traceability and configuration-baselines.
5. Implementation-paradigm profile-additions; such as, those for messages, CDA documents, web-services, interface behavioral-specifications and realm-specific data-models with terminology-bindings can be added to produce a fully-qualified exchange-architecture, of system Information-Exchanges (**IEs**) and implementable-and-testable Interoperability-Specifications (**ISs**); where, this document contains a small HL7-International Fast Healthcare Interoperability Resource (**FHIR**) and US-realm Federal Healthcare Information Model (**FHIM**) example of profile-additions.

Our **Linguistic-kiss Methodology** hierarchically-constrains the UML-modeled EHR-S lexicon-of entities, actions and information-flows into function document-sections and sub-sections modeled-as use-case paragraphs of user-story scenario-sentences; where, these scenario-sentences are also known as conformance-criteria (**CCs**). As an example, the Immunization-Management function's use-case has 23 CC user-story scenarios, which can-be further constrained according-to patient-preference, situation, scope-of practice, organizational-policy and jurisdictional-law.

Our "**Easy-Button tool**" is an EHR-informatics knowledge-repository and force-multiplier, which institutionalizes informatics-wisdom; where, it empowers users to efficiently-and-effectively reuse informatics-knowledge in EHR-related areas such as

- Business requirements, use-cases, user-story scenarios;
- Platform-independent (logical) architectural design-specifications
- Platform-specific (implementable) development, test and certification ISs, profiles, and guides.

The **benefit** of our recommended methodology-and-technology is that high-quality and low-cost EHR-S FIM profiled web-sites and reports can be generated in hours-or-days by one-person; where formerly, weeks-or-months were required by an integrated product team. Initial results may still require subject-matter-expert verification-and-validation (V&V) to identify special-needs and gaps; where, a capability approach proposal can be developed as-the-basis-of both strategic gap-mitigation and tactical investment-and-execution planning.

The **benefit** of using Sparx Enterprise Architect (**EA**) as the underlying EHR-S FIM "Easy-Button" platform is the built-in support for enterprise-wide, full-lifecycle, model-driven, architecture-and-design solutions for visualizing, analyzing, simulating, testing and maintaining EHR-related systems, software, processes and architectures; where, EA is a collaborative team-based modeling, design, management-and-documentation tool based on UML 2.4.1. EA's Standard XML Metadata Interchange (XMI) export capability supports the use of other tools, such as IBM's Rational Software/System Architect

The estimated **cost** to bring the EHR-S FIM "Easy-Button" vision to fruition is 3-FTEs allocated for 2-years; where, 6-total FTEs = 2-weeks per-function * 150 functions = 5-hours per conformance criteria (CC) * 2500 CC. And, adding specific implementation-paradigm capabilities requires additional resources.



**** Call-for-Participation ****

EHR Workgroups-AND-Projects Logistics

- HL7 List Server Registration: <http://www.hl7.org/myhl7/managelistservs.cfm>
- HL7 Workgroup Call-Schedule: <http://www.hl7.org/concalls/default.aspx>
- EHR WG Wiki: <http://wiki.hl7.org/index.php?title=EHR>

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

- **EHR CCD to Blue Button Tool 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** is sponsored by the HL7 Tooling Workgroup and is producing 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** was 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 WG** provides a reference list of functions that may be present in a Personal Health Record System (PHR-S).
Project contact: John Ritter; johnritter1@verizon.net
- **Diabetes Data Strategy Project** focus is 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
- **EHR Interoperability WG** has two active projects
 - **EHR-S FM Meaningful Use profile**
 - **EHR-S FIM Release-3** preparation is restructuring release-2; where, the benefit of this formally-specified EA tool-based Concept-of-Operation and Reference Model is a clear, complete, concise, correct and consistent EHR-S and PHR-S Function-and-Information Model, profiles and resultant Interoperability-Specifications (ISs); where, ISs include appropriate implementation-paradigm specifications (V2 or V3 messaging, CDA, FHIR profiles, web-services, RLUS Data Services).

Plan-of-Actions & Milestones Dashboard

POA&M Task	#	Start	Done	POC	Status-Risks-Mitigations
CONOPS		12-2013	12-2013	SH, GD	Potential for minor changes in the future
Reference Model		06-2013	12-2013	SH, GD	Potential for minor changes in the future
<i>manage operation-type</i>			05-2013	EHRWG	Verb-Hierarchy was part of r2 ballot
Record-Entry data-types		01-2012	active	SH, GD	Data-Model to-be refined for each function
HL7 IP for EHR-S FIM		01-2014	active	EHRWG	ISSUE: Board approval needed
www.HL7.org/EHR		12-2013	active	EHRWG	ISSUE: PSS approval needed
Implementation Paradigm Integration		01-2014	1-2017	EHRWG	ISSUE: Integrated or linked models?
V2 and V3 messaging, CCDA, RLUS API		01-2014	1-2017	EHRWG	RECOMMENDATION: linked
FHIR		01-2014	1-2017	EHRWG	ISSUE: shared governance (CCB & CM)?
FHIM		01-2014	1-2017	EHRWG	ISSUE: shared governance (CCB & CM)?
EHR-S FIM r3 Resources	6	01-2014	1-2017	EHRWG	ISSUE: 6 FTEs for EHR-S & PHR-S FIM r3
EHR-S and PHR-S FM Modelling	143	1-2014	1-2017	Interop	3 FTEs = 1 week-per-function (143)
Other work (Pub., FHIR, FHIM, V2/3 msg.)		pending	1-2017	EHRWG	1 FTE
EHR-S specific work		pending	1-2017	EHRWG	1 FTE
PHR-S specific work		pending	1-2017	EHRWG	1 FTE
Care Provision	37				
CP.1 Manage Clinical History	9	pending			
CP.2 Render Externally Sourced Information	2	pending			
CP.3 Manage Clinical Documentation	6	pending			
CP.4 Manage Orders	7	01-2012	inactive	SH, GD	√ 2012 prototype → Todo wrt RM

POA&M Task	#	Start	Done	POC	Status-Risks-Mitigations
CP.5 Manage Results	2	01-2012	inactive	SH, GD	√ 2012 prototype → Todo wrt RM
CP.6 Manage Treatment Administration	3	01-2012	inactive	SH, GD	√ 2012 prototype → Todo wrt RM
CP.6.1 Medication Management		01-2013	inactive		
CP.6.2 Immunization Management		10-2013	active		√ Use case done, CCs in progress
CP.7 Manage Future Care	3	pending			
CP.8 Manage Patient Education & Communication	2	pending			
CP.9 Manage Care Coordination & Reporting	3	pending			
Care Provision Support	67				
CPS.1 Record Management	14	pending			
CPS.2 Support Externally Sourced Information	9	pending			
CPS.3 Support Clinical Documentation	13	pending			
CPS.4 Support Orders	10	pending			
CPS.5 Support for Results	1	pending			
CPS.6 Support Treatment Administration	5	pending			
CPS.7 Support Future Care	2	pending			
CPS.8 Support Patient Education & Communication	7	pending			
CPS.9 Support Care Coordination & Reporting	6	pending			
Population Health Support	17				
POP.1 Support for Health Maintenance, Preventive Care and Wellness	3	pending			
POP.2 Support for Epidemiological Investigations of Clinical Health Within a	1	pending			

POA&M Task	#	Start	Done	POC	Status-Risks-Mitigations
Population					
POP.3 Support for Notification and Response	1	pending			
POP.4 Support for Monitoring Response Notifications Regarding a Specific Patient's Health	1	pending			
POP.5 Donor Management Support	1	pending			
POP.6 Measurement, Analysis, Research and Reports	6	pending			
POP.7 Public Health Related Updates	1	pending			
POP.8 De-Identified Data Request Management	1	pending			
POP.9 Support Consistent Healthcare Management of Patient Groups or Populations	1	pending			
POP.10 Manage Population Health Study-Related Identifiers	1	pending			
Administration Support	22				
AS.1 Manage Provider Information	8	pending			
AS.2 Manage Patient Demographics, Location and Synchronization	1	pending			
AS.3 Manage Personal Health Record Interaction	3	pending			
AS.4 Manage Communication	5	pending			
AS.5 Manage Clinical Workflow Tasking	5	pending			
AS.6 Manage Resource Availability	7	pending			
AS.7 Support Encounter/Episode of Care Management	6	pending			
AS.8 Manage Information Access for Supplemental Use	6	pending			

POA&M Task	#	Start	Done	POC	Status-Risks-Mitigations
AS.9 Manage Administrative Transaction Processing	6	pending			
Trust Infrastructure					
Tl.1 Security	25	01-2012	inactive	GD, SH	√ 2012 prototype → Todo wrt RM
Tl.2 Audit	1	01-2012	inactive	GD, SH	√ 2012 prototype → Todo wrt RM
Tl.3 Registry and Directory Services	1	pending			
Tl.4 Standard Terminology and Terminology Services	1	pending			
Tl.5 Standards-Based Interoperability	6	pending			
Tl.6 Business Rules Management	1	pending			
Tl.7 Workflow Management	1	pending			
Tl.8 Database Backup and Recovery	1	pending			
Tl.9 System Management Operations and Performance	1	pending			
Record Infrastructure					
RI.1 Record Lifecycle and Lifespan RI.1.1.2 Record Entry Create	25	12-2012	inactive	GD, SH	√ 2012 prototype → Todo wrt RM
RI.2 Record Synchronization	1	pending			
RI.3 Record Archive and Restore	1	pending			

Legend

- 1) Capitalized and Underlined nouns-and-adjectives are Record-Entry data-types aka data-model, which should be in the EHR-S FIM data dictionary; and, *italicized* verbs are *manage* sub-types aka verb-hierarchy. See www.skmtglossary.org for standard healthcare data-dictionary / glossary.
- 2) **Blue-Bold words** are recommended -additions to original text.
- 3) **Red-Bold words** are recommended-deletions from the original text.
- 4) **Highlighted Yellow words** are issues-Actions and/or important new material for the main EHR WG to-review.

Acknowledgements

This work is based-on and is intended to institutionalize ideas developed within

- American Health Information Community (**AHIC**) Use cases
- ANSI Healthcare Information Technology Standards Panel (**HITSP**) Interoperability Specifications
- ONC's Standards and Interoperability (**S&I**) framework Use-Case Simplification initiative
- DOD and VA Integrated and now Interoperable EHR (**iEHR**) initiative
- DOD and VA respective EHR Modernization initiatives.
- Open Source EHR Custodial Agent (**OSEHRA**)
- Clinical Information Modeling Initiative (**CIMI**)
- Joint HL7-and-OMG Healthcare Service Specification Project (**HSSP**)
- HL7 International EHR Workgroup (**EHR WG**) and Architecture Review Board (**ArB**)

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EHR-S FIM r3 CP.6.2 Immunization Management Report

Type: **Package**
Package: 2013 Prototype
Detail: Created on 11/4/2013, Last modified on 1/1/2014

Introduction: This report summarizes the '2013 EHR-S FIM Release-3 prototype work done in anticipation of EHR-S FM Release-2 ballot reconciliation; where, once release-2 is finalized and a configuration baseline has been established, then, release-3 work can truly commence.

January '2012 Project Scope Statement #688 EHR-S FIM Release 3.0 purpose:

- add core information models for each EHR-S FM function
 - 1) make the EHR-S FM easier to use for analysts and engineers
 - 2) verify and validate EHR-S FM Release 2.0
- Service Aware Interoperability Framework (SAIF) DSTU demonstration
- Add Conceptual Information Model & Logical Data Model to EHR-S Functions
- Incorporate S&I Framework simplification methodology
- EHR-S function correspond to a set-of Use Cases (UC) & scenarios.
- New Use Cases and scenarios composed from reusable use-case and scenario elements
- EHR-S FM should associate information models to functions
- Maintain domain profile traceability

Reference: '2003 Institute of Medicine (IOM) Key Capabilities of an Electronic Health Record System

- Decision Support,
- Results Management,
- Order Entry/Mgmt./CPOE,
- Administrative Processes,
- Patient Support/Education
- Health Information and Data,
- Reporting & PopHealth Mgmt. ,
- Communication and Connectivity

Issues:

1. HL7 IP license vs. need for convenient access to EHR-S FIM versions-and-profiles.
2. www.hl7.org/EHR home-page for EHR-S FIM versions-and-profiles.
3. FHIR WG Coordination to integrate EHR-S FIM-FHIR into a joint Sparx Enterprise Architect (EA) model
4. FHIM Team Coordination to integrate EHR-S FIM-FHIR-FHIM into a joint Sparx Enterprise Architect (EA) model
5. Concurrently maintaining release-2 baseline traceability to release-2 profiles and release-3.
6. Maintaining consistency across profiles and releases.
7. Maintaining traceability and consistency with FHIR, FHIM, IHE and implementation paradigms.

Introduction

Type: **Package**
 Package: EHR-S FIM r3 CP.6.2 Immunization Management Report
 Detail: Created on 12/23/2013, Last modified on 1/1/2014

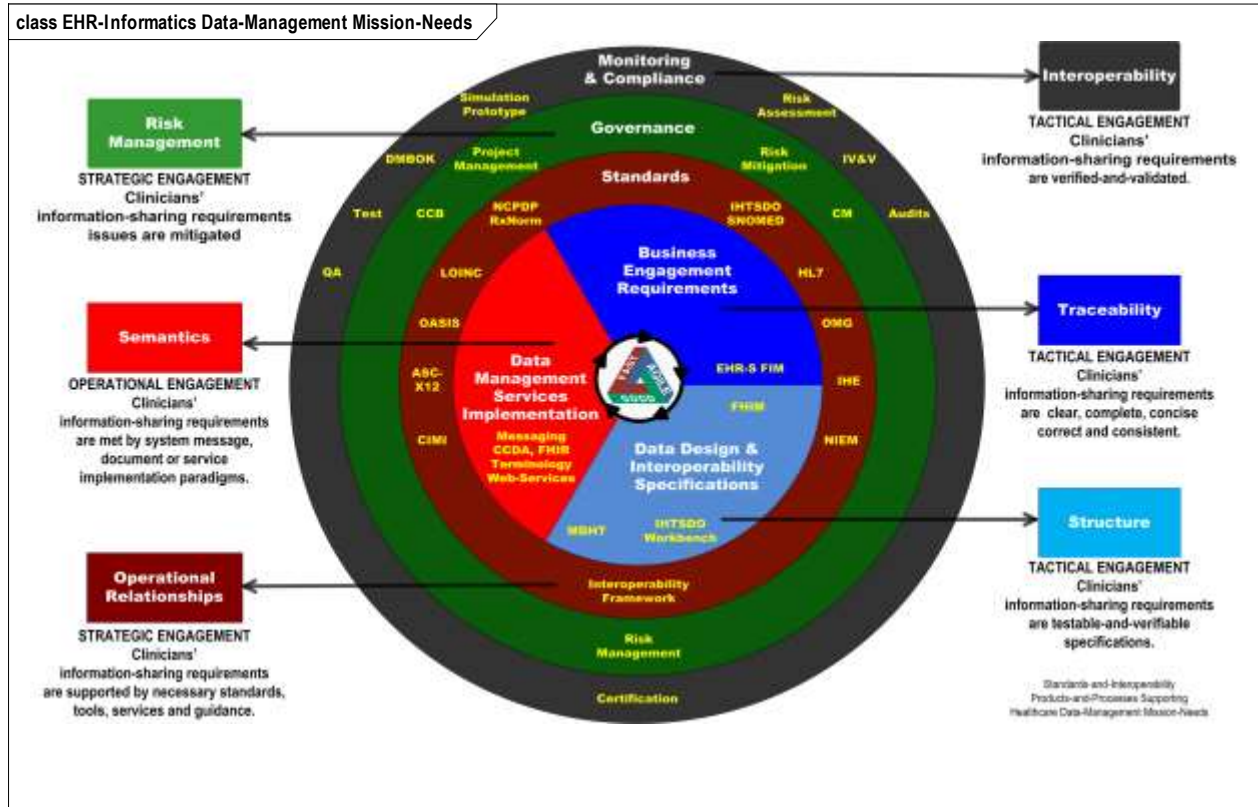


Figure: 1 EHR-Informatics Data-Management Mission-Needs

INTRODUCTION: HL7 EHR-S FIM (Function-and-Information Model) release-3 PSS (Project Scope Statement) #688 was approved in January 2012; where, EHR-S and PHR-S FIM release-3 (r3) follows an agile-process to

- formally-structure EHR functional-requirements, based upon a reference model (**RM**), to address the structural issues identified by the release-2 ballot and
- add UML data requirements-specifications, based on release-2 functions and their conformance criteria.
- create a clear, complete, concise, correct and consistent EHR-S FIM r3.0 from EHR-S FM r2.0, which is HL7 ballot-publishable from Sparx Systems Enterprise Architect (**EA**) tool.
- interoperate-with Fast Healthcare Interoperability Resource (**FHIR**)
- interoperate-with US-realm Federal Health Information Model (**FHIM**)
- Harmonize with **ISO/EN 13606 Health informatics - Electronic Health Record Communication** standard
- Harmonize with ISO/EN 13940 "**Health Informatics - System of Concepts to Support Continuity-of-Care (CONTsys)** standard

Subject Specification	Enterprise Viewpoint "Why" Policy	Information Viewpoint "What" Content	Computational Viewpoint "How" Behavior	Engineering Viewpoint "Where" Implementation
Computational Independent Model - CIM (Conceptual)	<ul style="list-style-type: none"> ✓ Inventory of <ul style="list-style-type: none"> ○ Use Cases, Contracts ○ Capabilities-Services ○ Stakeholders ○ Non-Functional Rqmts. ○ Methodologies/Processes ✓ Business Vision, Scope ✓ Business Objectives ✓ Policy & Regulations 	<ul style="list-style-type: none"> ✓ Inventory of <ul style="list-style-type: none"> ○ Domain Entities ○ Stakeholders, Roles ○ Activities ○ Associations ○ Information Rqmts. ○ Information Models <ul style="list-style-type: none"> • Conceptual • Domain 	<ul style="list-style-type: none"> ✓ Inventories of <ul style="list-style-type: none"> ○ Capabilities-Components ○ Functions-Services ✓ Requirements <ul style="list-style-type: none"> ○ Accountability, Roles ○ Functional Rqmts. Profiles, Behaviors, Interactions ○ Interfaces, Contracts ✓ Conceptual Functional Service Specifications 	<ul style="list-style-type: none"> ✓ Inventory of <ul style="list-style-type: none"> ○ Platforms, Layers ○ Environments ○ Components ○ Services ○ Technical Rqmts. ○ Enterprise Service Bus <p style="font-size: small; text-align: center;">Topic Maps among viewpoints and their architectural artifacts can define Traceability</p>
Platform Independent Model - PIM (Logical)	<ul style="list-style-type: none"> ✓ Applicable Rules ✓ Use Case Specs ✓ Governance ✓ Implementation Guides ✓ Technology Neutral Standards ✓ Wireframes of <ul style="list-style-type: none"> ○ Architectural Layers ○ Components and Associations ✓ Contracts 	<ul style="list-style-type: none"> ✓ State Variables ✓ Information Models <ul style="list-style-type: none"> ○ Localized ○ Constrained ○ Project ✓ Vocabularies ✓ Value Sets ✓ Content Specifications <ul style="list-style-type: none"> ○ Messages ○ Documents ○ Services 	<ul style="list-style-type: none"> ✓ State Machines ✓ Specifications <ul style="list-style-type: none"> ○ Use Cases, Interactions ○ Components, Interfaces ✓ Collaboration Participations ✓ Collaboration Types ✓ Function Types ✓ Interface Types ✓ Collaboration Scripts ✓ Service Contracts 	<ul style="list-style-type: none"> ✓ Versioned Specs. for <ul style="list-style-type: none"> ○ Platforms ○ Capabilities ○ Libraries ○ Services ○ Transports <p style="font-size: small; text-align: center;">RACI Charts for each viewpoint can define stakeholder roles and responsibilities "Who does What When" "Who needs What When"</p>
Platform Specific Model - PSM (Implementable)	<ul style="list-style-type: none"> ✓ Business Nodes ✓ Business Rules ✓ Business Procedures ✓ Business Workflows ✓ Technology Specific Standards 	<ul style="list-style-type: none"> ✓ Schemas for <ul style="list-style-type: none"> ○ Databases ○ Messages ○ Documents ○ Services ○ Transformations 	<ul style="list-style-type: none"> ✓ Automation Units ✓ Technical Interfaces ✓ Technical Operations ✓ Orchestration Scripts 	<ul style="list-style-type: none"> ✓ Application Specs. ✓ GUI Specifications ✓ Component Designs ✓ Deployment Topologies ✓ Platform Bindings
Potential Architectural Artifacts				

Figure: 2 HL7 Service Aware Interoperability Framework (SAIF)

HL7 SAIF IG: This report demonstrates the HL7 EHR-S FIM Release-3 "Easy Button" Knowledge Reuse Approach (KRA) Architecture Development Methodology (ADM) to generate Interoperability Specifications (ISs) Implementation Guides (IGs) conformant with the HL7 Service Aware Interoperability Framework (SAIF); where, SAIF organizes Interoperability Specifications (ISs) into a matrix of Computationally Independent Models (conceptual CIMs), Platform Independent Models (logical PIMs) and Platform Specific Models (implementable PSMs) views for the following SAIF (aka RM-ODP) perspectives:

1. **Enterprise/Business** (WHY - policy & business rules))
2. **Information** (WHAT - content)
3. **Computational** (HOW - behavioral)
4. **Engineering** (WHERE - engineering)
5. **Technology** (WHERE - technology)

EHR-S and PHR-S Reference Model

Type: **Package**
Package: EHR-S FIM r3 CP.6.2 Immunization Management Report
Detail: Created on 11/4/2013, Last modified on 12/31/2013

Release-3 work is based-on the OASIS RM definition; where, the RM

- Structures significant-relationships among system entities defined-by system Action-and-Information Conceptual-Models.
- is based-on a functional-use-case constrained hierarchical-lexicon of
 - nouns (Data-Entities) and noun qualifiers (Data-hierarchy or Sub-Types),
 - verbs (System-Actions) and verb qualifiers (Action-hierarchy or Sub-Types) with
 - conditions {Business Rules based on laws, policies, preferences}
- Defines Conformance-Criteria syntax-and-semantics; where,
 - Conformance Criteria (CC) are scenario-threads through the reference use-case.
 - Functions constrain the Verb sub-types, Noun sub-types and Conditions
 - Functions can-be linked-to Information Exchanges (IEs),
 - IEs can-be linked-to implementation standards and patterns.

OASIS RM Definition: 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."

System Function (SF) Conformance Criteria (CC) SYNTAX

SF CC Invariant-condition (context)

- System Identifier (EHR or PHR) <followed-by>
- System Function (SF) Identifier <followed-by>
- Profile Identifier <followed-by>
- SF CC Identifier (number) <followed-by>
EXAMPLE: CP.6.2#01

Pre-condition (verb-clause)

- SF CC Pre-condition (trigger) <followed-by>
EXAMPLE: During an encounter,

SF CC Invariant-condition

- <After a Human-Action or System-Action> the System SHALL, SHOULD or MAY provide-the-ability-to manage Record Entries; where, it can
- <OR> the system SHALL, SHOULD or MAY *manage* Record Entries; where, it can

SF CC System-Action Bindings

- Operation linked-to Data-Type; where, conditionally,
 - the System-Actions depends-on other-SF
 - Data-Type are associated-with other Data-Types
 - Information Exchange(s) are linked-to implementation specifications (e.g., FHIR, FHIM, CDA, IHE, DURSA, SLA)

SF CC Post-Condition (expected-outcome)

- Post-condition is a subordinate-clause.
EXAMPLE: according-to scope-of practice, organizational-policy and jurisdictional-law.

SF CC See Also

- Supporting or related SFs (e.g., Infrastructure)

Name: EHR-S & PHR-S Reference CONOPS Model
 Author: EHR Interoperability WG
 Version: 2013 Release-3 Prototype
 Created: 12/14/2013 1:18:17 PM
 Updated: 12/30/2013 6:04:59 AM

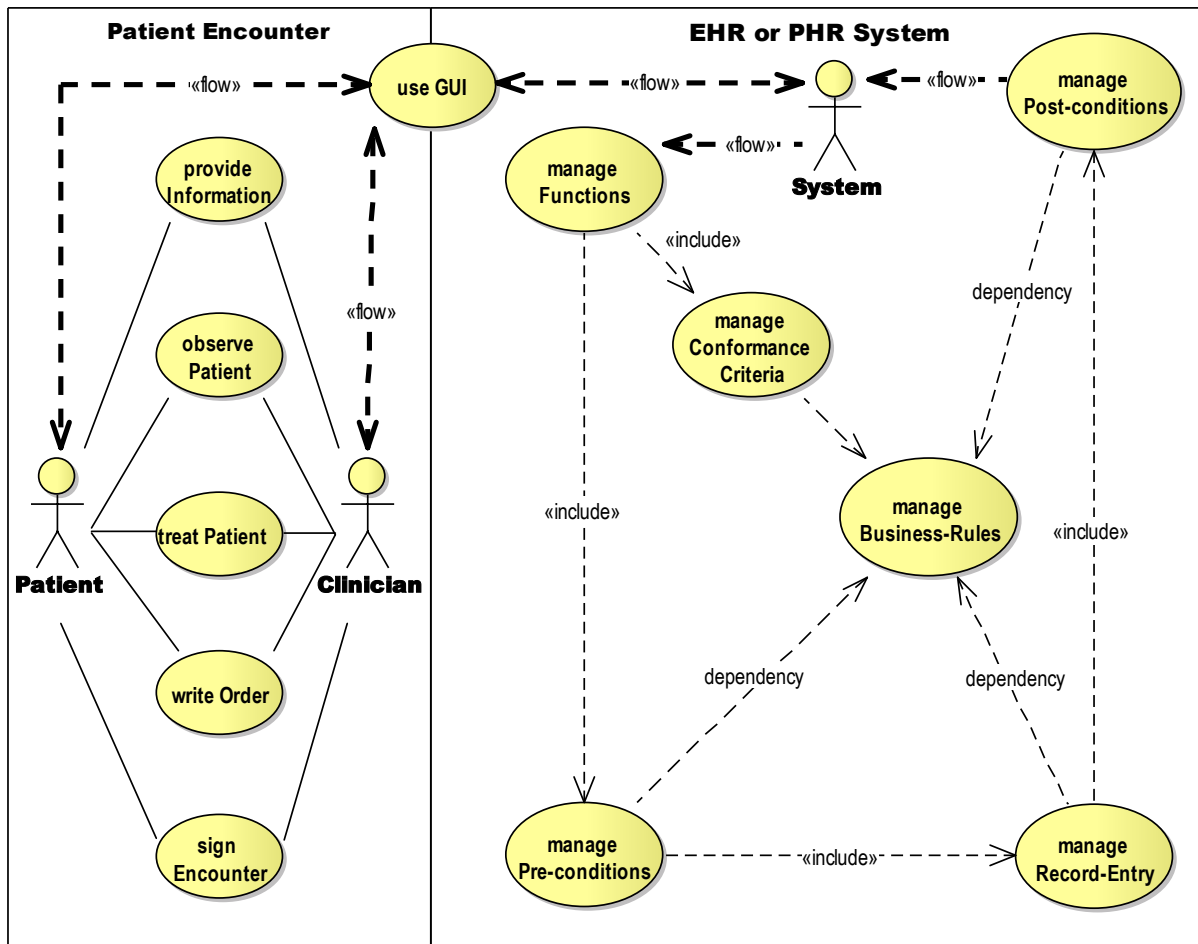
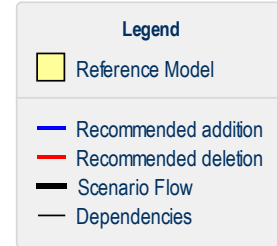


Figure: 3 EHR-S & PHR-S Reference CONOPS Model

Methodology: We represent each function as a use case (aka Data Flow Diagram (DFD)); where, data sources, data destinations and Information Exchanges (IEs) are shown. In this way, an entire function can be simply visualized; where, this representation is independent of implementation constraints. Next, each function’s conformance criteria are analyzed as scenario execution-threads through its DFD.

But, first we present the **EHR concept-of-operations (CONOPS)**; where, the CONOPS defines the operational-context used to communicate quantitative and qualitative system characteristics to stakeholders of EHR system functions and associated information models (EHR-S FIM); where, the EHR and PHR system CONOPS describes the set of high-level operational-concepts to be refine by the set of system functions and their conformance-criteria needed to achieve a desired set of EHR system management objectives.

In the EHR-S and PHR-S CONOPS,

- Patient, Clinician and EHR-S interactions are through the EHR-S GUI
- Record Entries can be an order, treatment or observation; where, Record Entries depend on the Clinician to observe the patient, write orders, treat the Patient or manage the EMR.
- Electronic Medical Record (EMR) management depends on the Patient, Clinician or their representatives to create, retrieve or update Patient data, according to scope-of-practice, organizational-policy, jurisdictional-law, patient preference-or-consent.
- Conformance Criteria (CC) bind Reference Model (RM) verbs (UML class operations) to RM nouns (UML classes or entities); where, applicable System operations on applicable System data are defined by CCs (e.g., CP.6.2 Immunization Management's CCs).
- RM Adjectives are defined as UML type (generalization element) to the core RM nouns (e.g., Observation, Order, Treatment or their descendents)
- Histories are defined as lists of Observations, Treatments or Orders of various types.
- Care Plans are defined as lists of Orders

Functions are modeled-as "manage Record-Entry" sub-type Use-Cases.

Conformance Criteria are modeled-as (subject, verb, object) Scenarios; where,

- subjects-and-objects are Record-Entry sub-types
- verbs are manage sub-types

Business Rules are "*according to scope of practice, organizational policy, jurisdictional law, patient preference or consent.*"

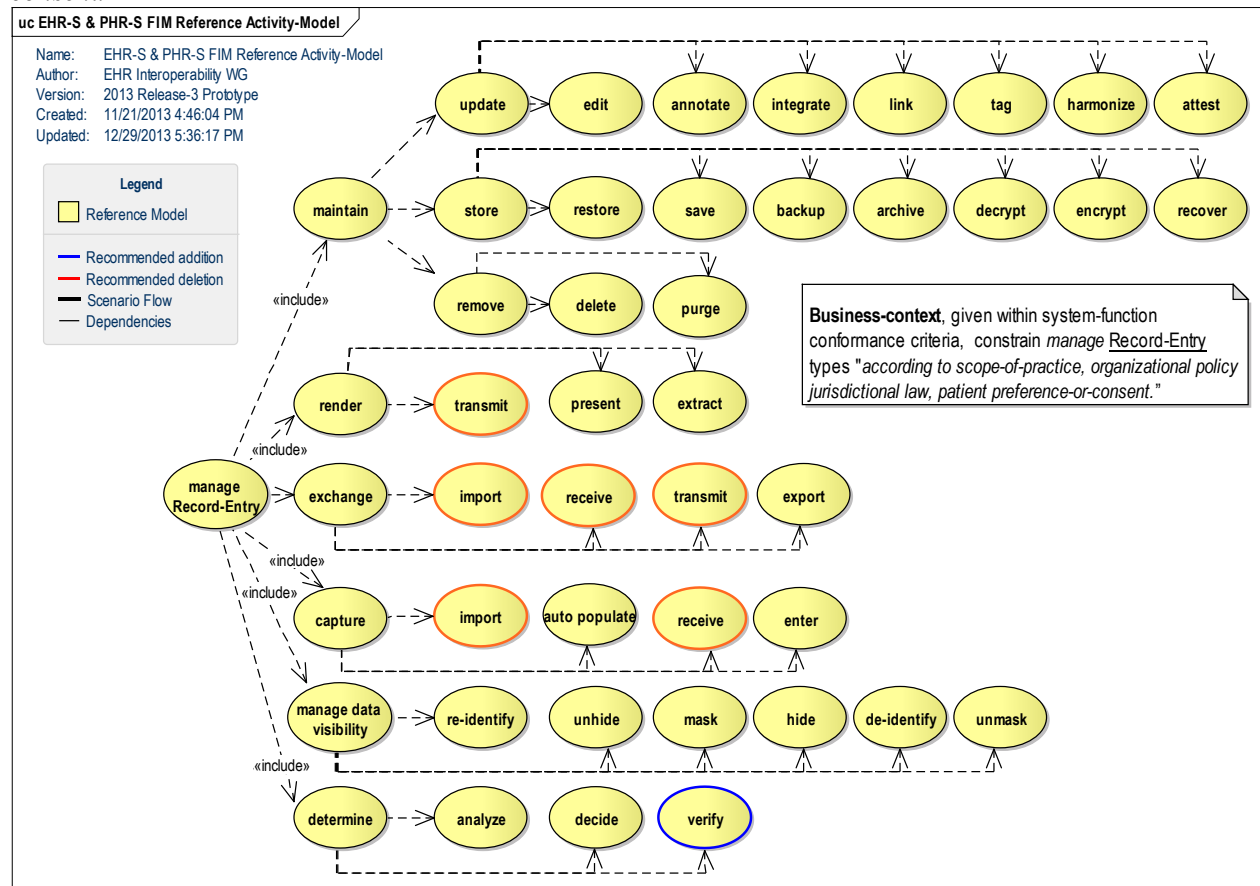


Figure: 4 EHR-S & PHR-S FIM Reference Activity-Model

The EHR-S FIM Reference Activity-Model includes the key System-Action types, which are universally used in clinical medicine; where in the EHR-S FIM, they are <<Stereotypes>> to *manage*; and, they are also known as the

Release-2 EHR- FM Verb Hierarchy.

How do we distinguish duplicate activities within Conformance Criteria scenarios? Does it matter? Should "include relationship" be replaced with "generalization relationship"?

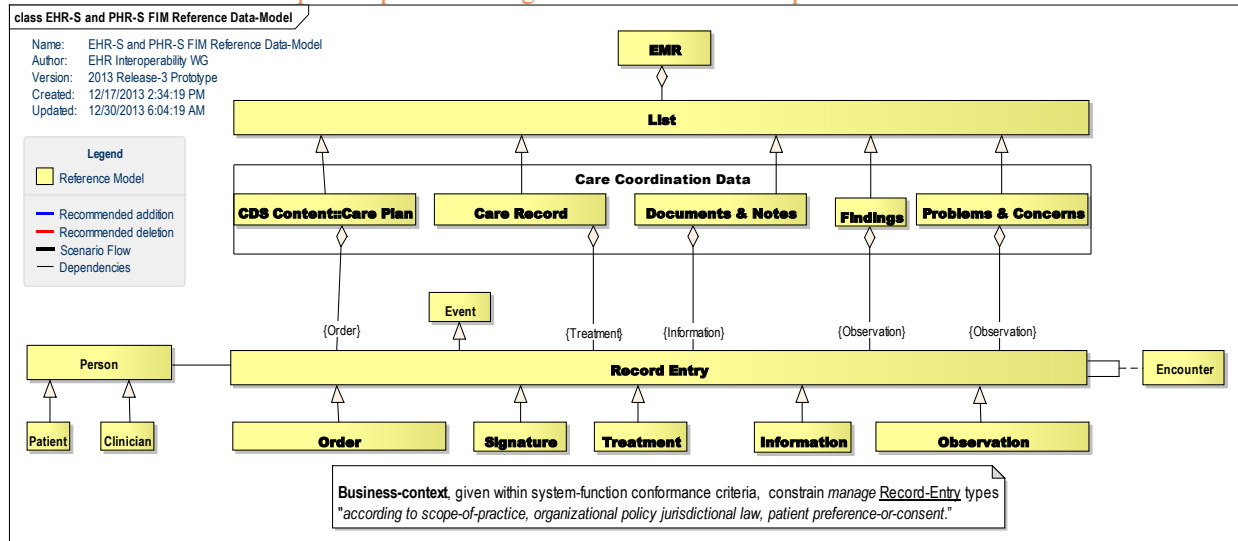


Figure: 5 EHR-S and PHR-S FIM Reference Data-Model

The EHR-S FIM Reference Data-Model includes the key-concepts, which are universally used in clinical medicine; where in the EHR-S FIM, they are the EHR Record-Entry <<Stereotypes>>.

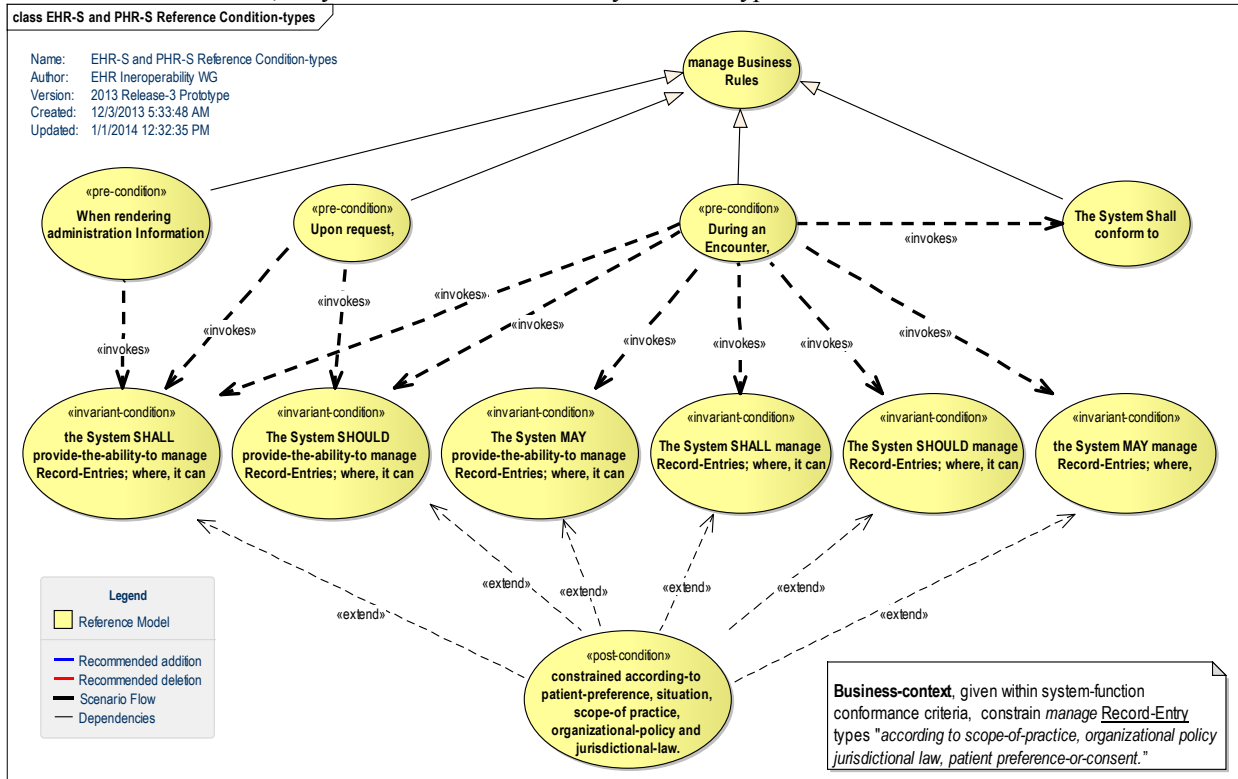


Figure: 6 EHR-S and PHR-S Reference Condition-types

The EHR-S FIM Reference Conditions-Model includes the key pre, invariant and post conditions, which are universally used in clinical medicine; where in the EHR-S FIM, they are modeled as <<Stereotypes>>.

EHR-S FIM CP.6.2 Requirements, Use-Cases, Information Models & Scenarios

Type: **Package**
Package: EHR-S FIM r3 CP.6.2 Immunization Management Report
Detail: Created on 11/3/2013, Last modified on 1/1/2014

NOTE: **Interoperability Specifications (IS)** for specific implementation paradigms (e.g., specific messages, services, document exchanges) and behavioral profiles (e.g., IHE) are generated separately, due to their large volume of information; where, Interoperability Specifications are defined for each Information-Exchanges (IEs) defined-by EHR-S FIM Functions' scenarios; where, IEs can be bound-to implementation-paradigms, such as

- a) HL7 V2 and V3 message, RIM and CDA, SOA RLUS standards and related DAMS
- b) FHIR (Fast Healthcare Interoperability Resource) specifications, for the International-Realm, profiled-with
- c) FHIM (Federal Health Information Model) specifications, for the US-Realm, bound to
 - Terminology value-sets,
- d) IHE information-exchange behavioral-protocols refined by,
 - SLA and DURSA (Service-level-agreement and Data-Use and Reciprocal-Support Agreement) and
 - KPPs (Key Performance Parameters).
 - Cost estimation factors

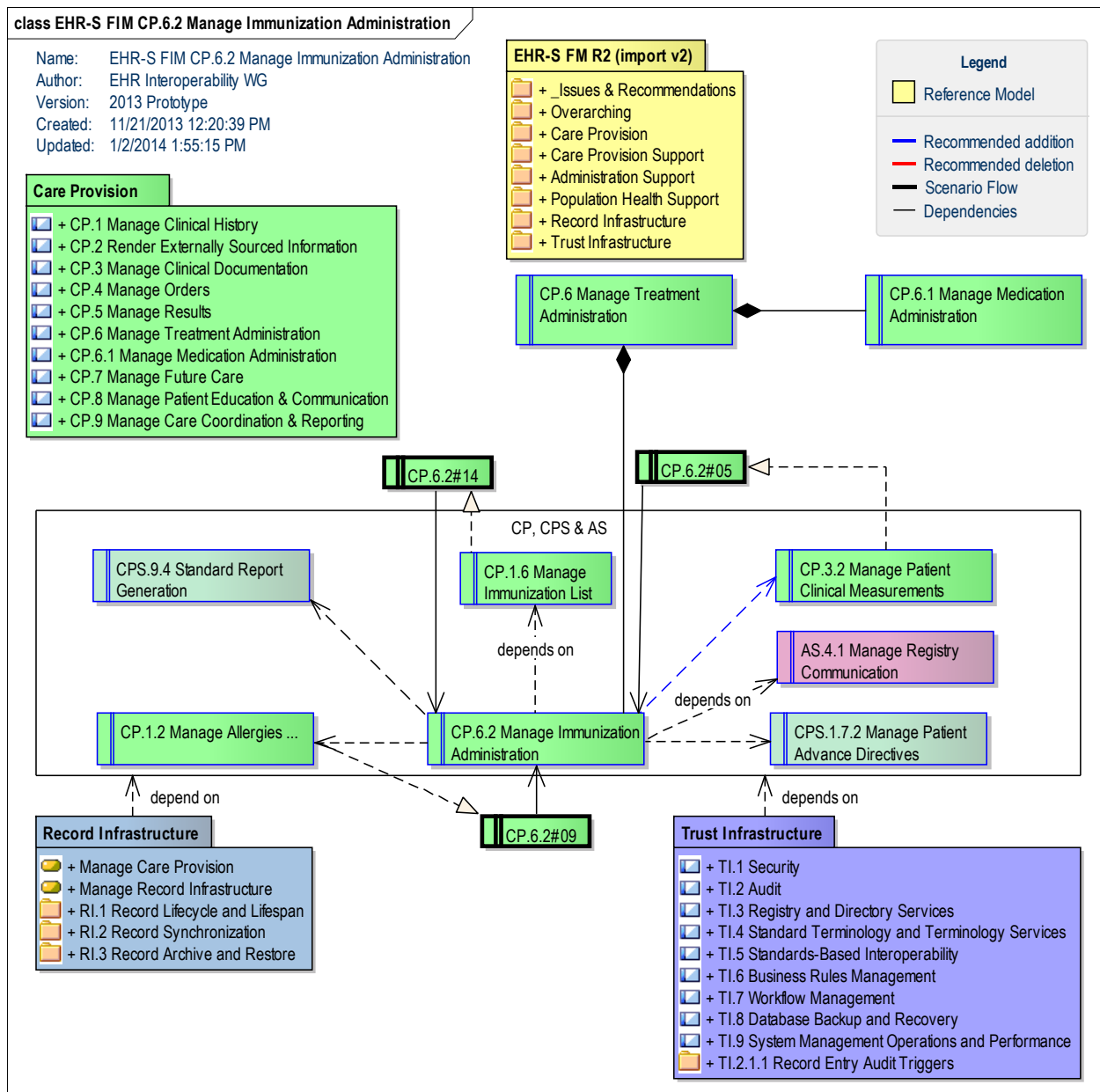


Figure: 7 EHR-S FIM CP.6.2 Manage Immunization Administration

Statement: Capture and maintain discrete data concerning immunizations given to a patient including date administered, type, manufacturer, lot number, and any allergic or adverse reactions. Facilitate the interaction with an immunization registry to allow maintenance of a patient's immunization history.

Description: During an encounter, recommendations based on accepted immunization schedules are presented to the provider. Allergen and adverse reaction histories are checked prior to giving the immunization. If an immunization is administered, discrete data elements associated with the immunization including date, type, manufacturer and lot number are recorded. Any new adverse or allergic reactions are noted. If required, a report is made to the public health immunization registry or other organization (e.g. military unit commander, refugee program leadership).

Example: Use-Case Description

1. A Clinician reviews the patient's EMR for Allergies and Intolerance, reviews the Patient's Immunization-Schedule, treats (immunizes) the Patient with a Vaccine and observes Adverse-Reactions.
2. The Immunization related managers can
 Capture, Auto-populate, Maintain, Render, Transmit, Exchange, Harmonize, Update, or Determine

1. The following data-modules:

Immunization-Administrations, Allergies, Intolerance, Adverse-Events Events, Schedules, Plans and Educational Materials

Where,

- Patient, Clinician and EHR-S interactions are through the EHR-S GUI
- Record Entries can be an order, treatment or observation; where, Record Entries depend on the Clinician to observe the patient, write orders, treat the Patient or manage the EMR.
- Electronic Medical Record (EMR) management depends on the Patient, Clinician or their representatives to create, retrieve or update Patient data, according to scope-of-practice, organizational-policy, jurisdictional-law, patient preference-or-consent.
- Conformance Criteria (CC) bind Reference Model (RM) verbs (UML class operations) to RM nouns (UML classes or entities); where, applicable System operations on applicable System data are defined by CCs (e.g., CP.6.2 Immunization Management's CCs).
- RM Adjectives are defined as UML type (generalization element) to the core RM nouns (e.g., Observation, Order, Treatment or their descendents)
- Histories are defined as lists of Observations, Treatments or Orders of various types.
- Care Plans are defined as lists of Orders

Release-2 EHR-S FM CP.6.2 Conformance Criteria are:

- **CP.6.2#01** The system **SHALL** provide the ability to *capture, maintain and render* immunization administration details as discrete data, including:(1) the immunization name/type, strength and dose;(2) date and time of administration;(3) manufacturer, lot number, expiration date,(4) route and site of administration;(5) administering provider;(6) observations, reactions and complications;(7) reason immunization not given and/or immunization related activity not performed; according to scope of practice, organizational policy and/or jurisdictional law."
- **CP.6.2#02** The system **MAY** *auto-populate* the immunization administration record as a by-product of verification of administering provider, patient, medication, dose, route and time according to scope of practice, organizational policy and/or jurisdictional law.
- **CP.6.2#03** The system **SHALL** provide the ability to *determine and render* required immunizations, and when they are due, based on widely accepted immunization schedules, when rendering encounter information.
- **CP.6.2#04** The system **SHOULD** provide the ability to *capture*, in a discrete field, an allergy/adverse reaction to a specific immunization.
- **CP.6.2#05** The system **SHALL** conform to function CP.3.2 (Manage Patient Clinical Measurements) to capture other clinical data pertinent to the immunization administration (e.g., vital signs).
- **CP.6.2#06** The system **SHOULD** provide the ability to *link* standard codes (e.g. NDC, LOINC, SNOMED or CPT) with discrete data elements associated with an immunization.
- **CP.6.2#07** The system **SHALL** provide the ability to *maintain* the immunization schedule.
- **CP.6.2#08** The system **SHALL** provide the ability to *render* a patient's immunization history upon request for appropriate authorities such as schools or day-care centers.
- **CP.6.2#09** The system **SHALL** conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List).
- **CP.6.2#10** The system **SHOULD** *transmit* required immunization administration information to a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law.
- **CP.6.2#11** The system **SHOULD** *exchange* immunization histories with public health immunization registries according to scope of practice, organizational policy and/or jurisdictional law.
- **CP.6.2#12** The system **SHOULD** *harmonize* Immunization histories with a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law.
- **CP.6.2#13** The system **SHOULD** *capture and render* immunization histories from a public health immunization registry.
- **CP.6.2#14** The system **SHALL** conform to function CP.1.6 (Manage Immunization List).
- **CP.6.2#15** The system **SHOULD** provide the ability to *update* immunization histories at the time of capturing an immunization administration.

-
- **CP.6.2#16** The system **SHALL** provide the ability to *render* the immunization order as written (i.e., exact clinician order language) when rendering administration information.
 - **CP.6.2#17** The system **SHALL** provide the ability to *determine* due and overdue ordered immunizations and *render* a notification.
 - **CP.6.2#18** The system **SHALL** provide the ability to *render* a patient educational information regarding the administration (e.g., Vaccine Information Statement (VIS)).
 - **CP.6.2#19** The system **SHALL** provide the ability to *capture* that patient educational information (e.g., VIS) was provided at the time of immunization administration.
 - **CP.6.2#20** The system **SHALL** provide the ability to *capture* documentation that patient educational information (e.g., VIS) was provided at the time of immunization administration.
 - **CP.6.2#21** The system **SHALL** provide the ability to *capture* the receiving entity (e.g., patient, representative, organization) when patient education information is provided at the time of immunization administration.
 - **CP.6.2#22** The system **SHOULD** provide the ability to *capture* and *maintain* immunization refusal reasons as discrete data.
 - **CP.6.2#23** The system **SHOULD** provide the ability to *capture* patient preferences regarding receipt of immunization (e.g. refusal of certain vaccine types) at time of immunization administration.

ISSUE:

From: Noam H Arzt, PhD [mailto:arzt@hln.com]

Sent: Sunday, December 29, 2013 1:25 PM

Subject: Re: REQUEST FOR FEEDBACK: Release-3 EHR-S Function and Information Model Immunization Management Prototype Use Cases, Information Models and Scenarios

Steve,

I have not been following this closely, and am not familiar with this methodology, but I do know a little about the content. I have a few suggestions for clarifying some of the information in the conformance criteria in the basic use case (p. 9 and following):

- I'm not sure if the items listed in item 1 are exhaustive or complete. At minimum, we know that public health agencies require the capture of insurance eligibility information (in particular eligibility for public vaccine programs like Vaccines for Children) at the time of encounter relative to *every* dose. I don't see that among the topics listed.
- With respect to immunization schedule (item 7), there are several models for doing this, including access by and EHR-S to an *external* clinical decision support system that would be maintained *external* to the EHR-S. I'm not sure I would include this type of setup in my understanding of "maintain."
- Along a similar vein, EHR-S often do more than just exchange immunization *histories* with a public health registry, or IIS (items 11-13). They often exchange the *forecast* as well. I don't see this variation captured in the conformance criteria.

There may be other things I am missing but those were the obvious ones to me.

Thanks, Noam

From: owner-ehrinterop@lists.hl7.org [mailto:owner-ehrinterop@lists.hl7.org] **On Behalf Of** William Grossen

Sent: Sunday, December 29, 2013 2:28 PM

Dear Noam,

I can support your comments. However would like to suggest some adjustments.

1. All children in the Netherlands are getting the vaccines by government order. So we could change insurance into source of payment, with a vocabulary set including government, insurance, private and perhaps more.
2. Beside the external DSS there is also an external national record system from Dutch rijks Institute for Healthcare and Environmental Care RIVM which stores for every child basic personal data, vaccines history, vaccines orders and administration, side effects and as addition to the DSS the future plan for follow up vaccines according the national guideline.

3 the plan for a certain vaccine will soon be send from RIVM via HL7 v3 message to the local EHR system and after administration that will be reported back.

The local EHR will have the history and complications etc as well. Any local care profession decision can be stored, including changes in the plan.

From: Rob Savage [mailto:rob.savage50@gmail.com]
 Sent: Thursday, January 02, 2014 12:06 PM

I agree with Noam's comments. I would clarify one.

In the US, we record the eligibility of a person and immunization event for vaccines funded by various programs. The most wide spread is the Vaccines for Children (VFC) program. An event is eligible if certain characteristics of the person are true AND if the vaccine type is eligible. For example, if the person is < 19 years old and on Medicaid, they are eligible. If they receive a vaccine eligible for VFC program (like MMR), then the event is eligible. We track the reason (Medicaid recipient). If they received a vaccine not eligible for VFC (like Yellow fever vaccine), the event is not VFC eligible. Some states also have special programs for vaccine funding when VFC does not cover them.

Funding source for a given vaccine refers to who actually paid for a given immunization. It is possible that the vaccine given was privately funded, while the recipient was VFC eligible. If funding source is important, it is captured separately from eligibility

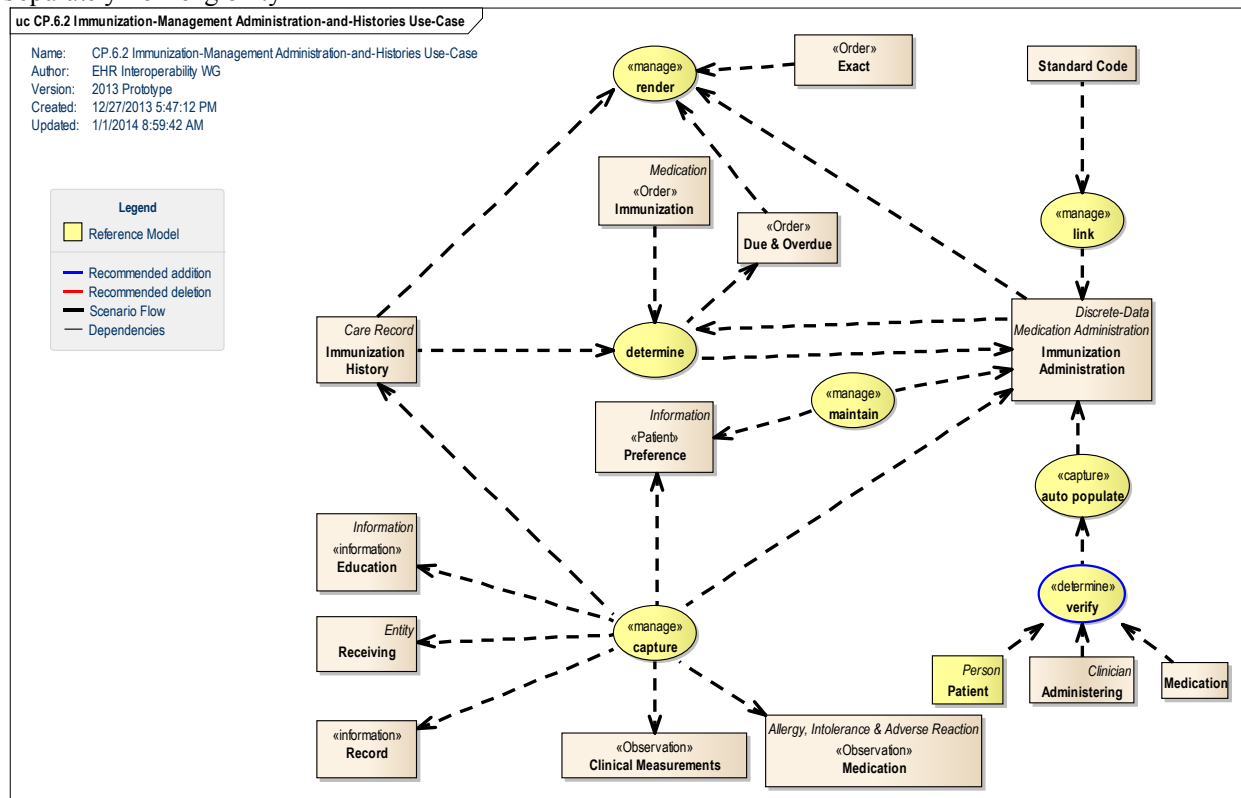


Figure: 8 CP.6.2 Immunization-Management Administration-and-Histories Use-Case

In this view, we represent a use case as a Data Flow Diagram (DFD); where, we focus on data flows, sources and destinations. An entire function can be described from the viewpoint of the data it processes and moves around; where, DFDs are powerful enough to show parallel activities independent of how it is actually implemented; that is, they show what takes place, rather than how an activity is accomplished. These DFDs are the basis of our detailed analyses; where each function's conformance criteria can be considered as a scenario execution-thread through the DFD.

Use-Case Description

1. A Clinician reviews the patient's EMR for Allergies and Intolerance, reviews the Patient's Immunization-Schedule, treats (immunizes) the Patient with a Vaccine and observes Adverse-Reactions.

-
2. The EHR-S Immunization related managers can
Capture, Auto-populate, Maintain, Render, Transmit, Exchange,
Harmonize, Update, or Determine
 1. The following data-modules:
Immunization-Administrations, Allergies, Intolerance, Adverse-Events Events, Schedules, Plans and Educational
Materials;
where,
 - Patient, Clinician and EHR-S interactions are through the EHR-S GUI
 - Record Entries can be an order, treatment or observation; where, Record Entries depend on the Clinician to observe the patient, write orders, treat the Patient or manage the EMR.
 - Electronic Medical Record (EMR) management depends on the Patient, Clinician or their representatives to create, retrieve or update Patient data, according to scope-of-practice, organizational-policy, jurisdictional-law, patient preference-or-consent.
 - Conformance Criteria (CC) bind Reference Model (RM) verbs (UML class operations) to RM nouns (UML classes or entities); where, applicable System operations on applicable System data are defined by CCs (e.g., CP.6.2 Immunization Management's CCs).
 - RM Adjectives are defined as UML type (generalization element) to the core RM nouns (e.g., Observation, Order, Treatment or their descendents)
 - Histories are defined as lists of Observations, Treatments or Orders of various types.
 - Care Plans are defined as lists of Orders

uc CP.6.2 Immunization-Management Public-Health Use-Case

Name: CP.6.2 Immunization-Management Public-Health Use-Case
 Author: EHR Interoperability WG
 Version: 2013 Prototype
 Created: 12/27/2013 7:03:07 PM
 Updated: 1/2/2014 1:54:34 PM

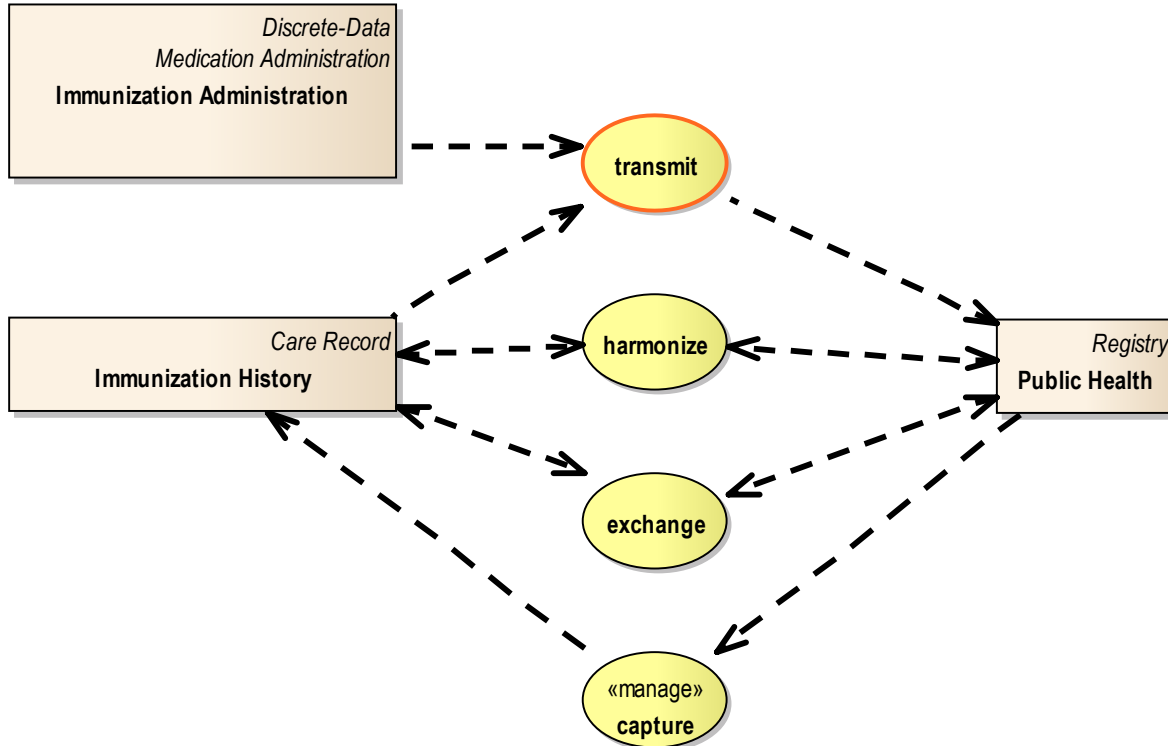
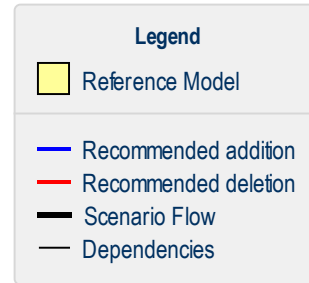


Figure: 9 CP.6.2 Immunization-Management Public-Health Use-Case

Public-Health Immunization-Management Use-Case

Release-2 EHR-S FM CP.6.2 Conformance Criteria are:

- **CP.6.2#10** The system SHOULD *transmit* required immunization administration information to a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law.
- **CP.6.2#11** The system SHOULD *exchange* immunization histories with public health immunization registries according to scope of practice, organizational policy and/or jurisdictional law.
- **CP.6.2#12** The system SHOULD *harmonize* Immunization histories with a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law.
- **CP.6.2#13** The system SHOULD *capture and render* immunization histories from a public health immunization registry.

uc CP.6.2 Immunization-Management Immunization-Schedule Use-Case

Name: CP.6.2 Immunization-Management Immunization-Schedule Use-Case
 Author: Interoperability WG
 Version: 2013 Prototype
 Created: 12/27/2013 7:12:07 PM
 Updated: 1/2/2014 1:40:33 PM

Legend

- Reference Model
- Recommended addition
- Recommended deletion
- Scenario Flow
- Dependencies

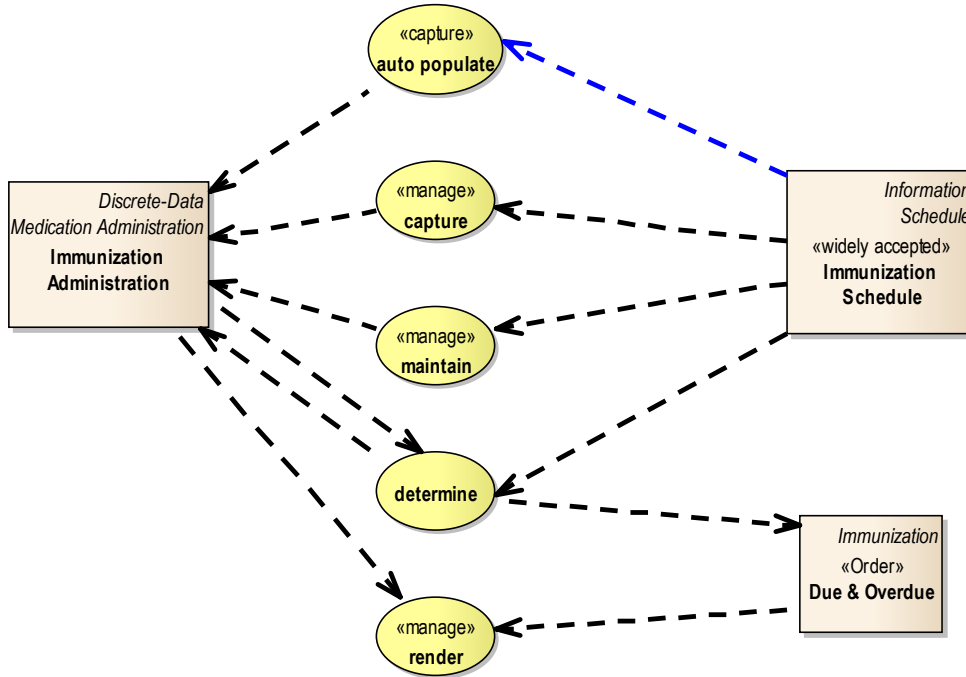


Figure: 10 CP.6.2 Immunization-Management Immunization-Schedule Use-Case

Immunization-Schedule Use-Case

Release-2 EHR-S FM CP.6.2 Conformance Criteria are:

- CP.6.2#03 The system **SHALL** provide the ability to *determine and render* required immunizations, and when they are due, based on widely accepted immunization schedules, when rendering encounter information.
- CP.6.2#07 The system **SHALL** provide the ability to *maintain* the immunization schedule.

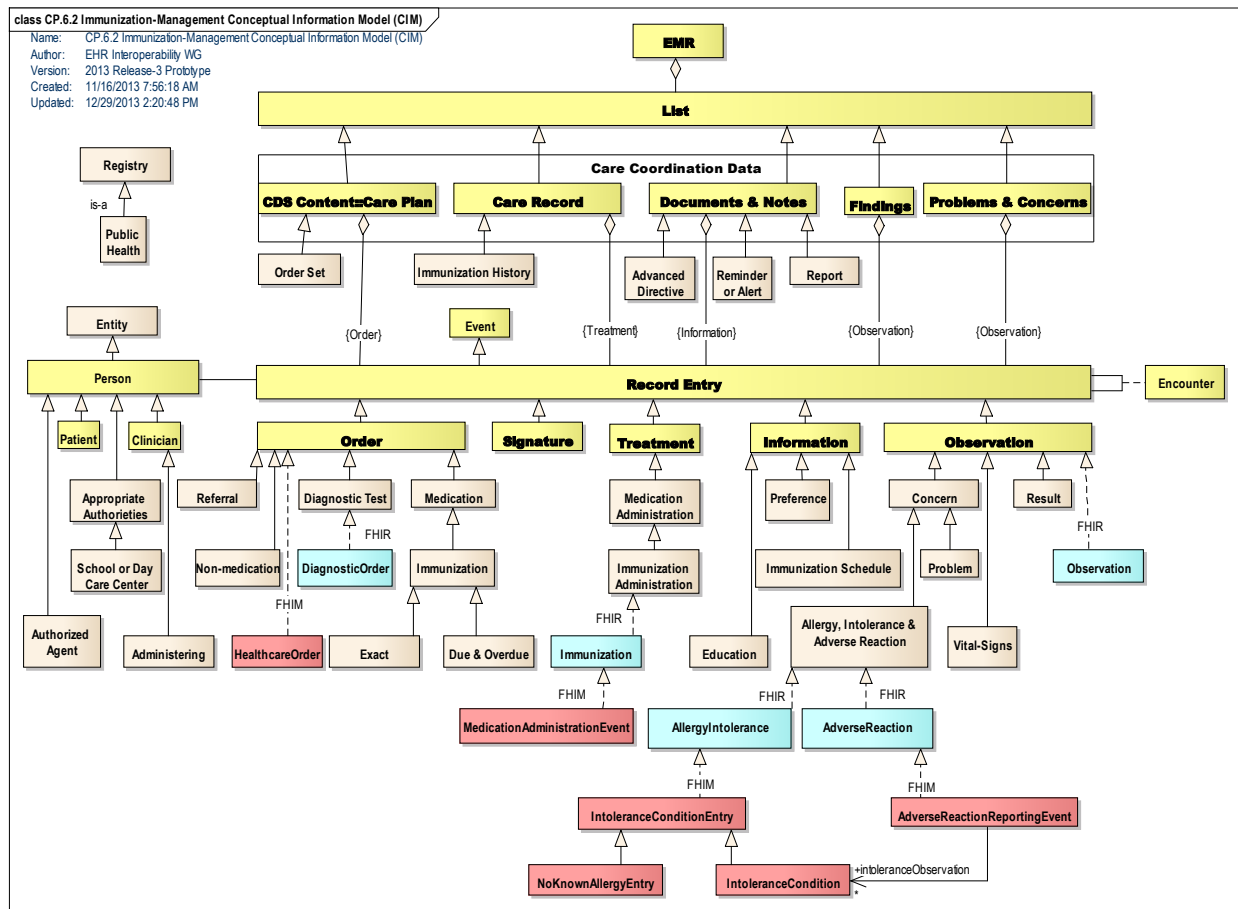


Figure: 11 CP.6.2 Immunization-Management Conceptual Information Model (CIM)

An objective of the EHR Interoperability WG team, under the System Function and Information Model (EHR-S FIM r3.0) HL7-project, is to create a clear, complete, concise, correct and consistent EHR-S FIM r3.0 from EHR-S FM r2.0, which is HL7 ballot-publishable from Sparx Systems Enterprise Architect tool. EHR-S FIM r3 is 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 VA negative ballot.

- integrate Fast Healthcare Interoperability Resource (FHIR)
- integrate Federal Health Information Model (FHIM)
- Harmonize with ISO/EN 13606 Health informatics - Electronic Health Record Communication standard
- Harmonize with ISO/EN 13940 "Health Informatics - System of Concepts to Support Continuity-of-Care (CONTsys) standard

INTERIM CONCLUSION

FHIR implementation-specifications complement EHR-S FIM requirements.

- EHR-S FIM and FHIR complement each other
- EHR-S FIM needs data element specifications and Data Dictionary
FHIR provides data element specifications and Data Dictionary
But, Configuration Management is essential to keep the models consistent
- Maybe, EHR WG should CM the FHIR UML model.

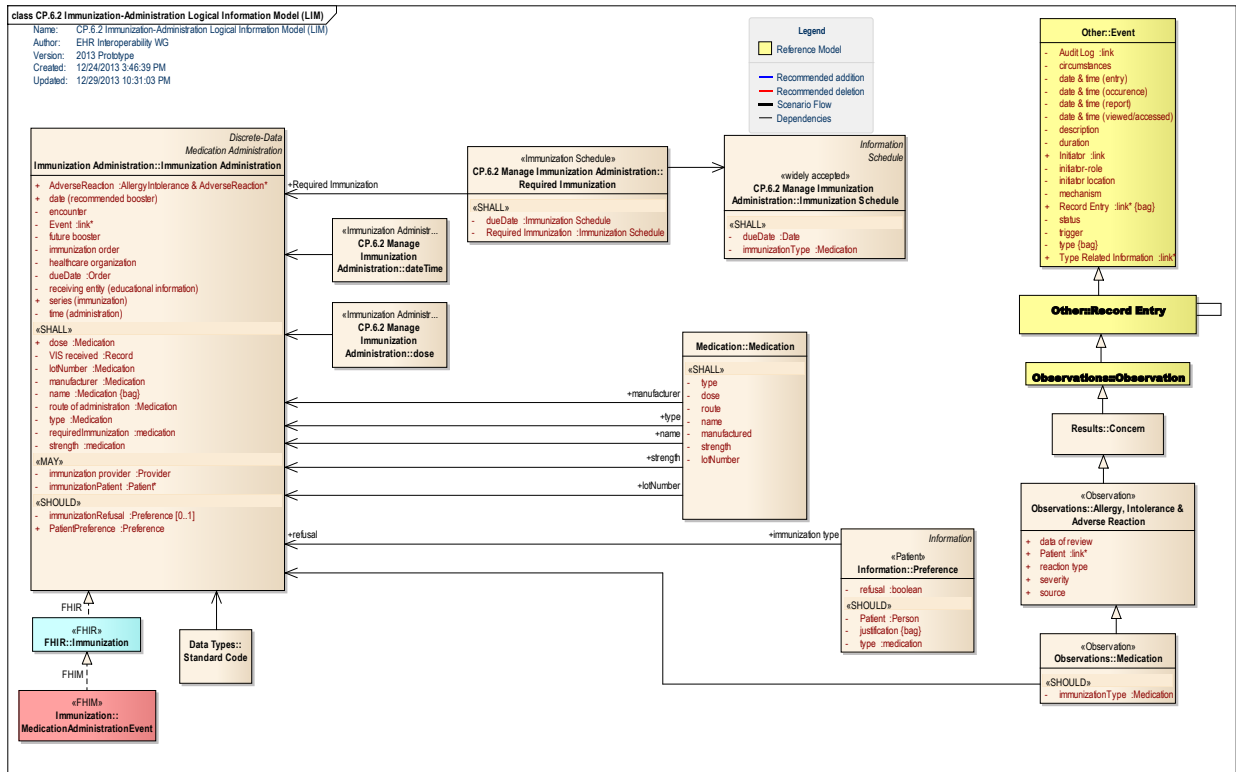


Figure: 12 CP.6.2 Immunization-Administration Logical Information Model (LIM)

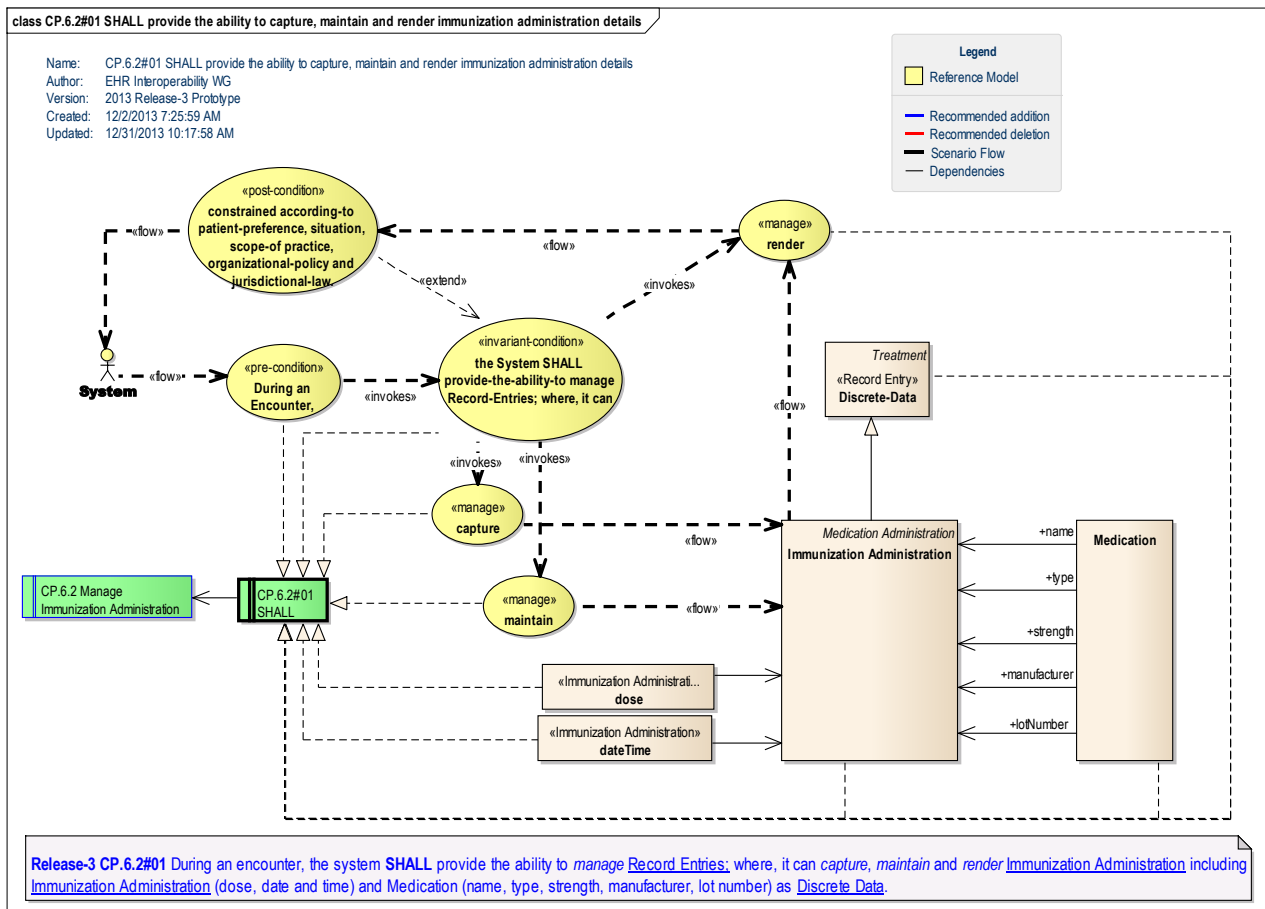


Figure: 13 CP.6.2#01 SHALL provide the ability to capture, maintain and render immunization administration details

Release-2 CP.6.2#01 The system SHALL provide the ability to capture, maintain and render immunization administration details as discrete data, including: (1) the immunization name/type, strength and dose; (2) date and time of administration; (3) manufacturer, lot number.

Overarching post-condition: System-Actions are according to scope-of practice, organizational-policy and jurisdictional-law.

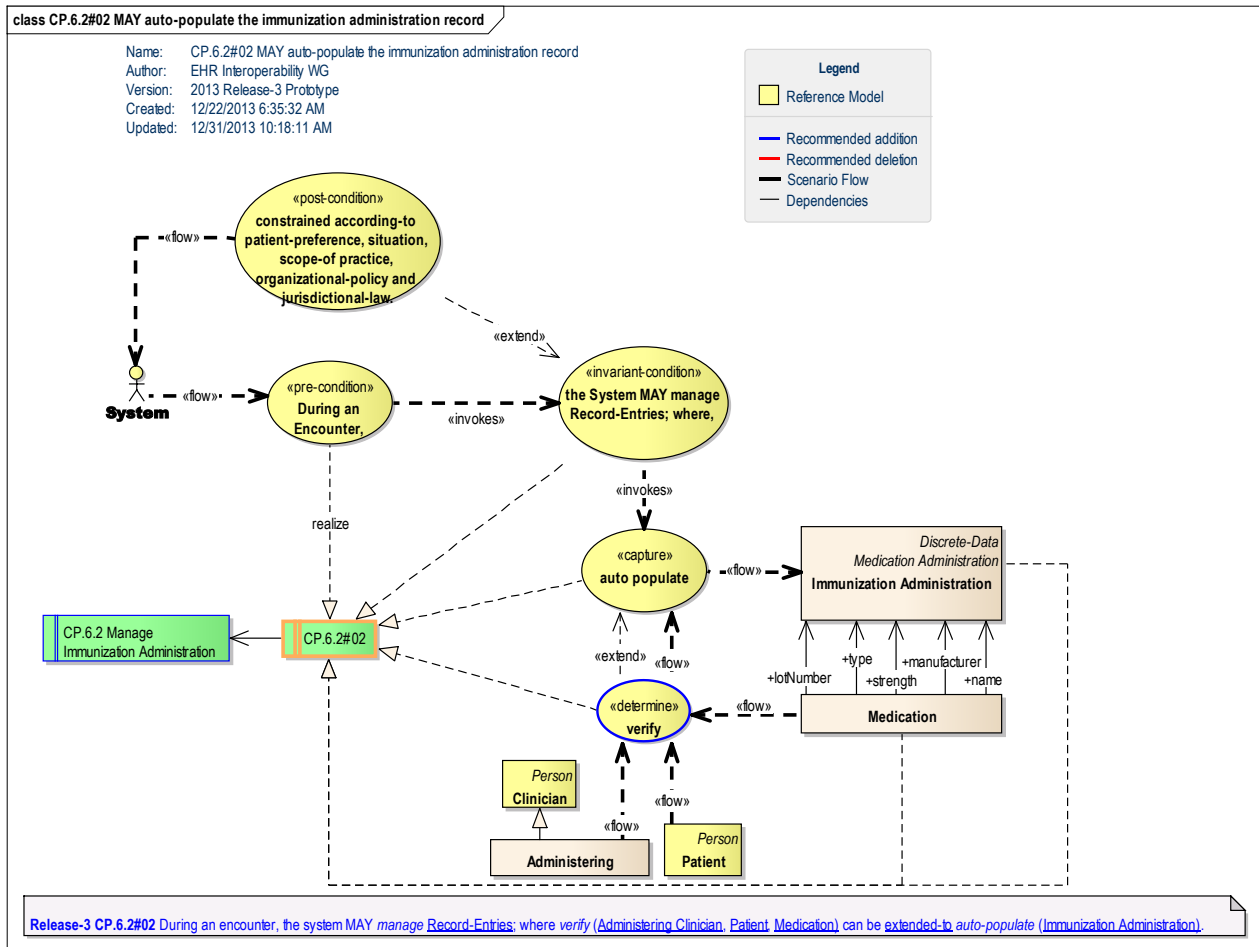


Figure: 14 CP.6.2#02 MAY auto-populate the immunization administration record

Release-2 CP.6.2#02 The system MAY auto-populate the immunization administration record as a by-product of verification of administering provider, patient, medication, dose, route and time according to scope of practice, organizational policy and/or jurisdictional law.

Overarching post-condition: System-Actions are according to scope-of-practice, organizational-policy and jurisdictional-law.

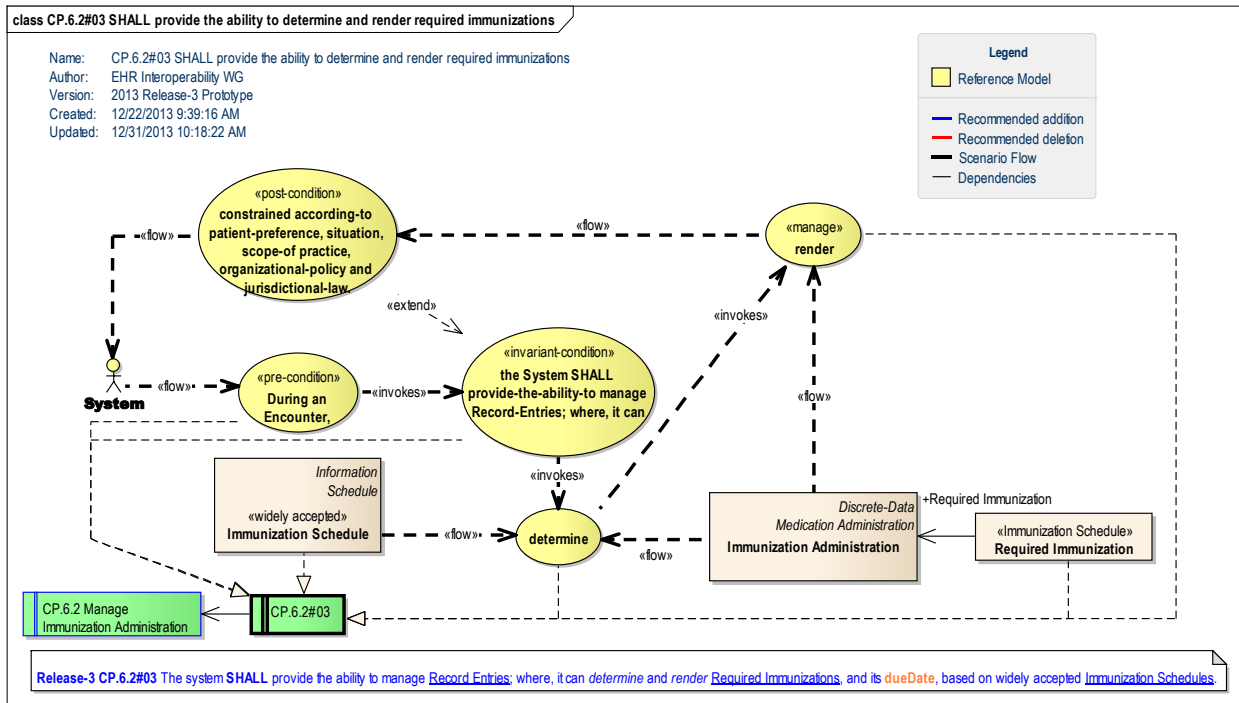


Figure: 15 CP.6.2#03 SHALL provide the ability to determine and render required immunizations

Release 2 CP.6.2#03 The system SHALL provide the ability to determine and render required immunizations, and when they are due, based on widely accepted immunization schedules, when rendering encounter information.

Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

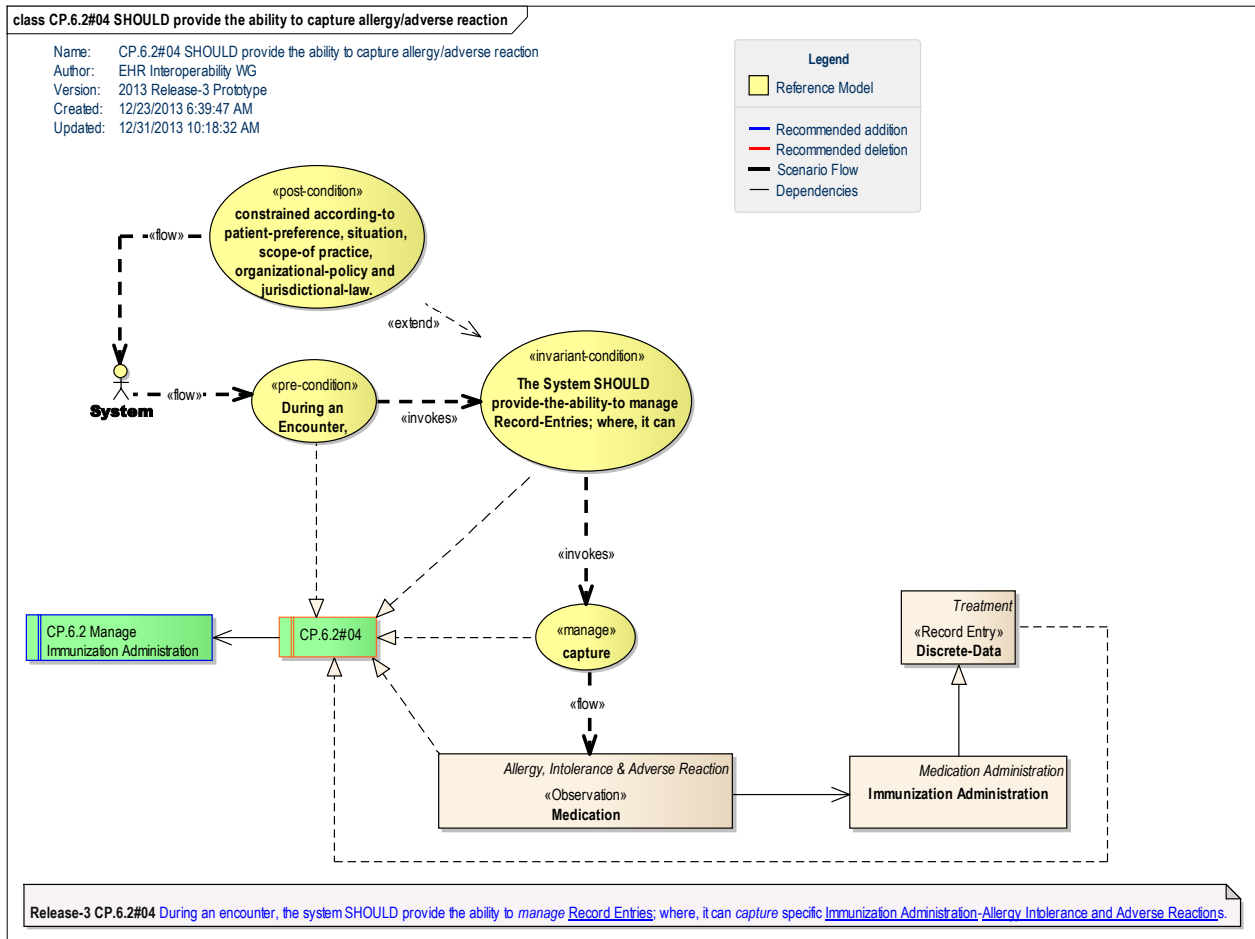


Figure: 16 CP.6.2#04 SHOULD provide the ability to capture allergy/adverse reaction

Release-3 CP.6.2#04 The system SHOULD provide the ability to *capture*, in a discrete field, an allergy/adverse reaction to a specific immunization.

Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

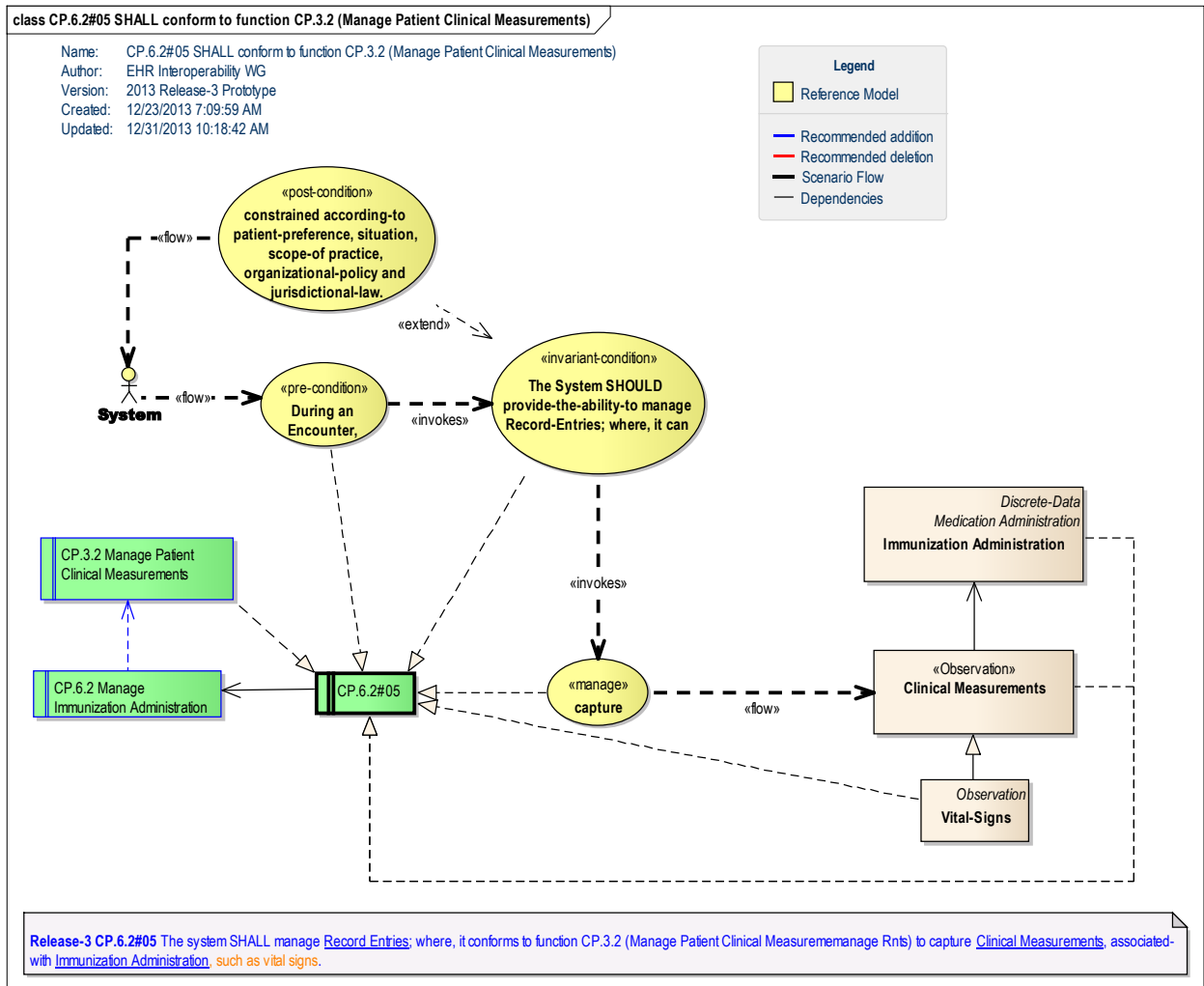


Figure: 17 CP.6.2#05 SHALL conform to function CP.3.2 (Manage Patient Clinical Measurements)

Release-2 CP.6.2#05 The system SHALL conform to function CP.3.2 (Manage Patient Clinical Measurements) to capture other clinical data pertinent to the immunization administration (e.g., vital signs).

Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

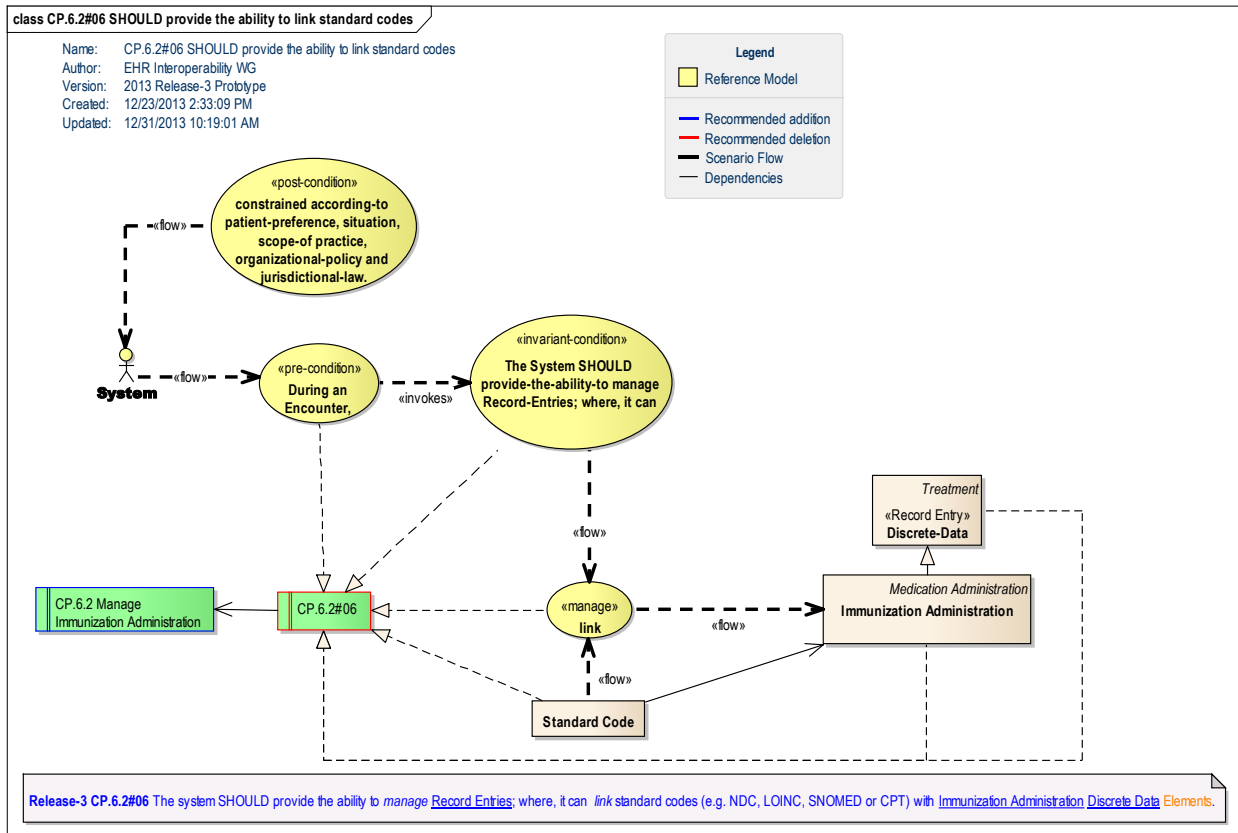


Figure: 18 CP.6.2#06 SHOULD provide the ability to link standard codes

Release-2 CP.6.2#06 The system SHOULD provide the ability to link standard codes (e.g. NDC, LOINC, SNOMED or CPT) with discrete data elements associated with an immunization.

Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

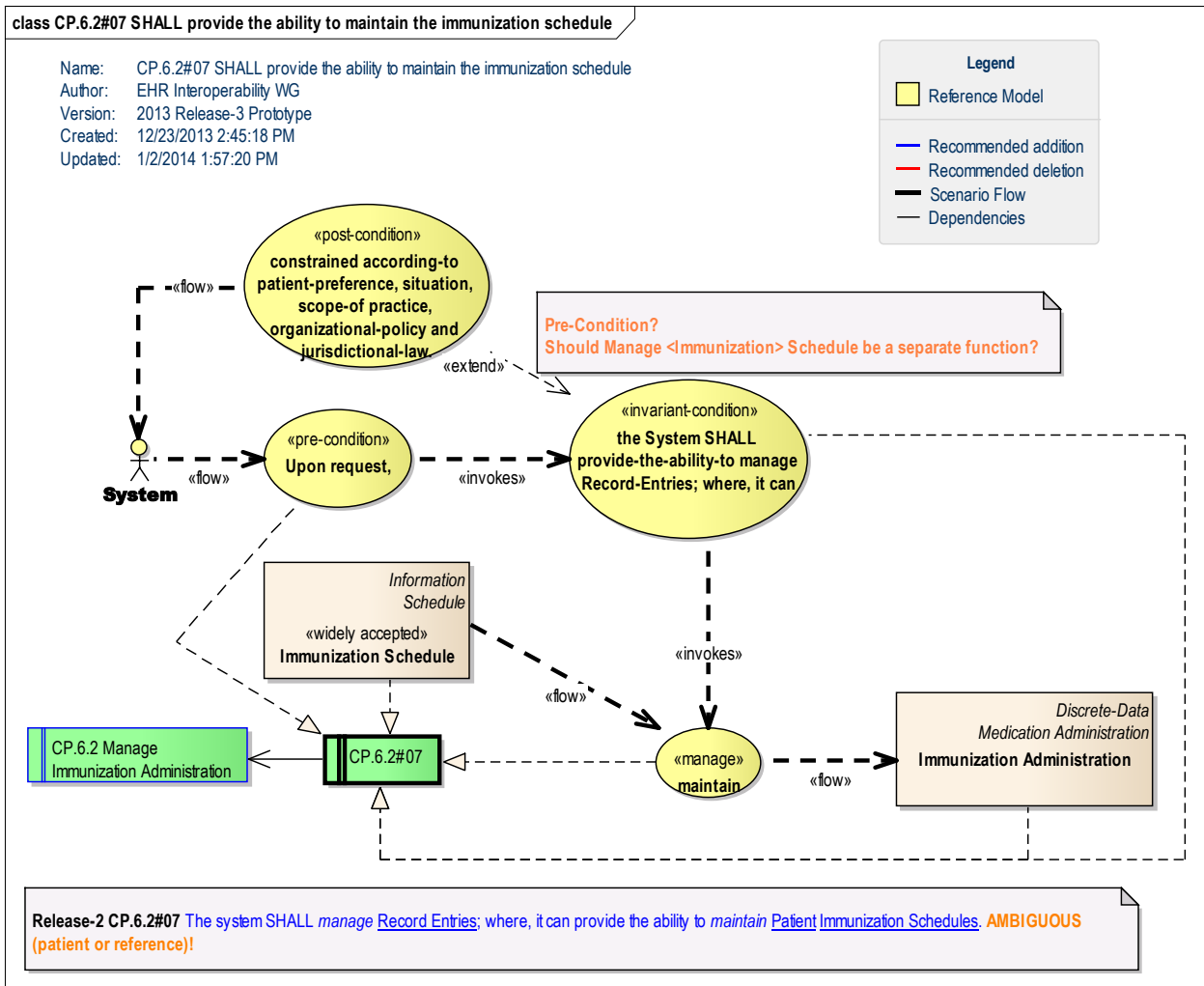


Figure: 19 CP.6.2#07 SHALL provide the ability to maintain the immunization schedule

Release-2 CP.6.2#07 The system SHALL provide the ability to maintain the immunization schedule.
Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

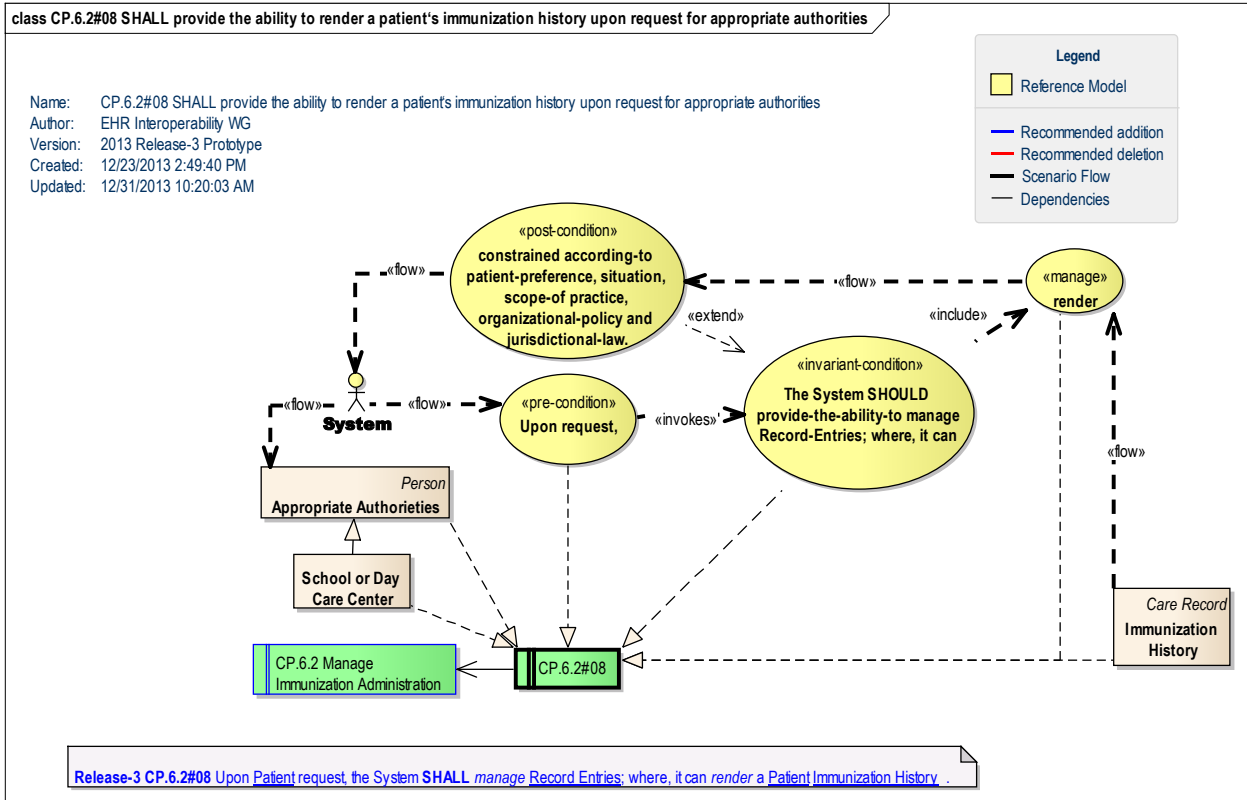


Figure: 20 CP.6.2#08 SHALL provide the ability to render a patient's immunization history upon request for appropriate authorities

Release-2 CP.6.2#08 The system SHALL provide the ability to render a patient's immunization history upon request for appropriate authorities such as schools or day-care centers.

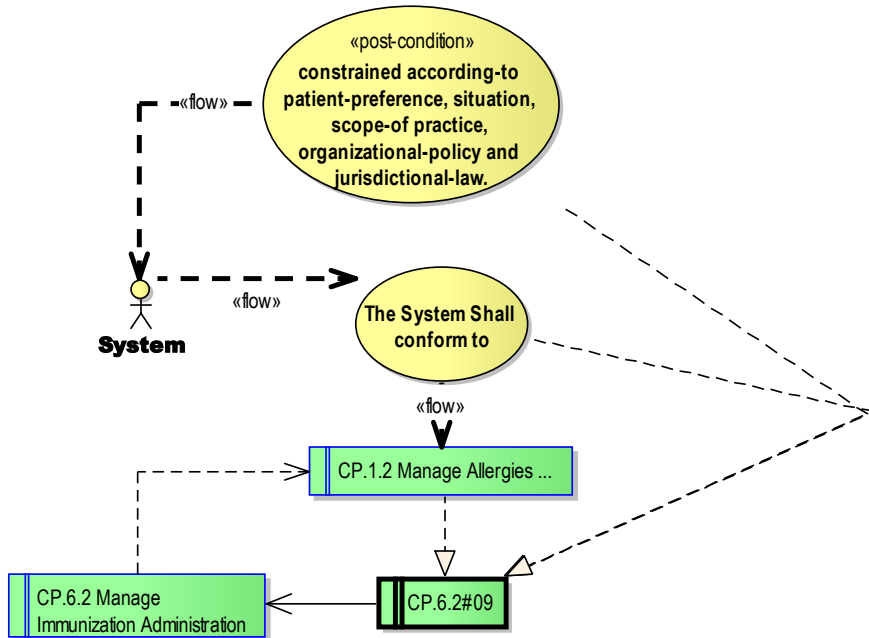
Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

class CP.6.2#09 SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List)

Name: CP.6.2#09 SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List)
 Author: EHR Interoperability WG
 Version: 2013 Release-3 Prototype
 Created: 12/23/2013 2:56:35 PM
 Updated: 12/31/2013 10:20:13 AM

Legend

- Reference Model
- Recommended addition
- Recommended deletion
- Scenario Flow
- Dependencies



Release-3 CP.6.2#09 The system SHALL manage Record Entries; where, it SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List).

Figure: 21 CP.6.2#09 SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List)

Release-2 CP.6.2#09 The system SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List).

Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

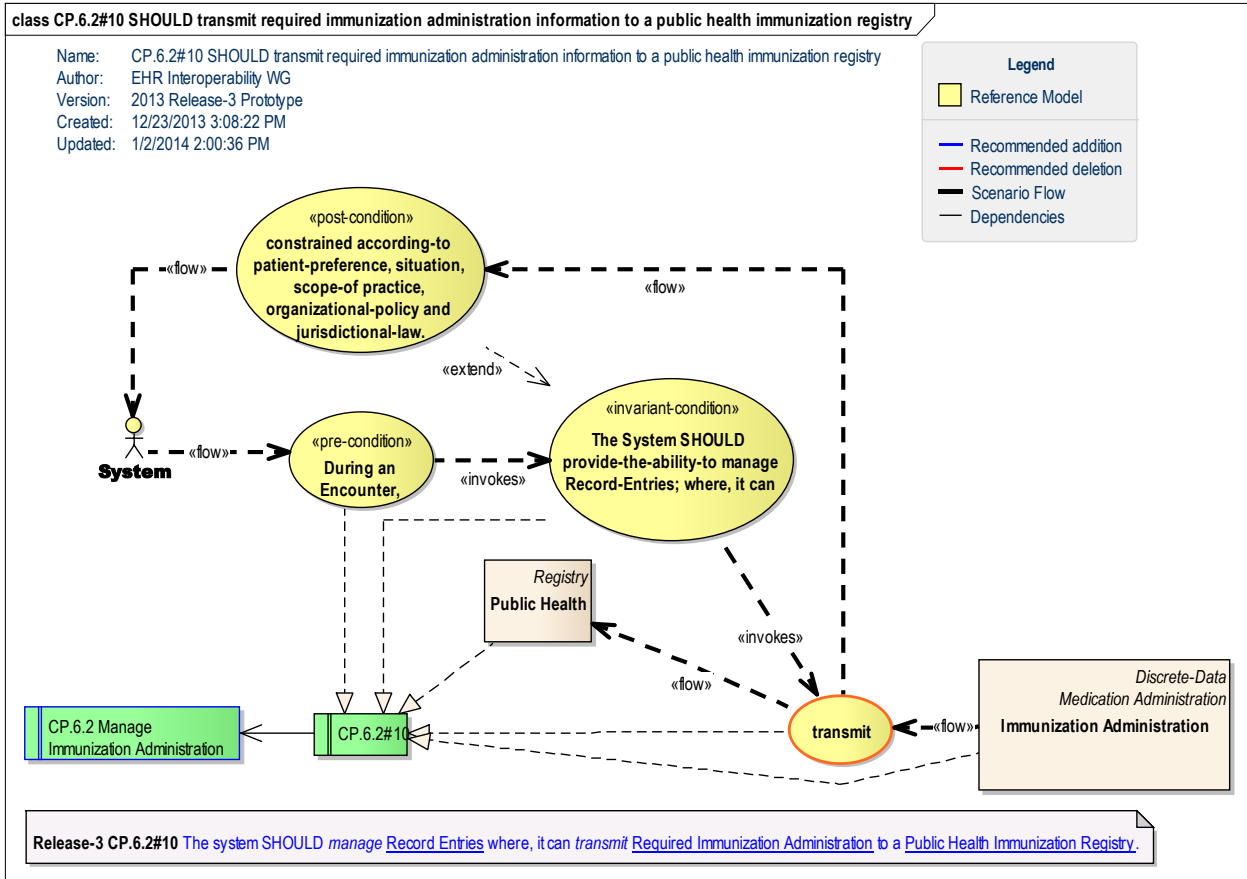


Figure: 22 CP.6.2#10 SHOULD transmit required immunization registry administration information to a public health immunization registry

Release-2 CP.6.2#10 The system SHOULD transmit required immunization administration information to a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law.

Overarching post-condition: System-Actions are according-to scope-of-practice, organizational-policy and jurisdictional-law.

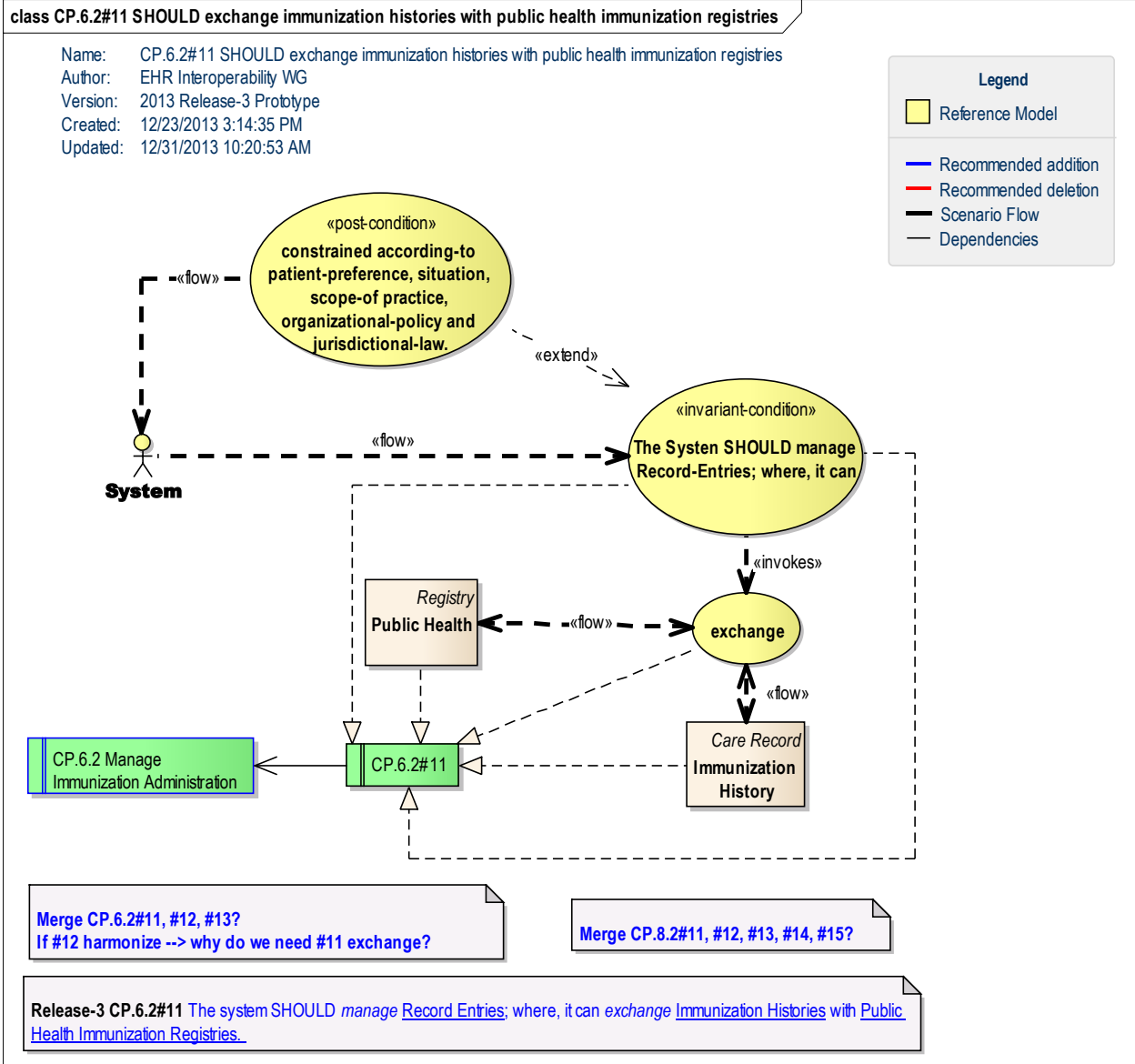


Figure: 23 CP.6.2#11 SHOULD exchange immunization histories with public health immunization registries

Release-2 CP.6.2#11 The system SHOULD exchange immunization histories with public health immunization registries according to scope of practice, organizational policy and/or jurisdictional law.

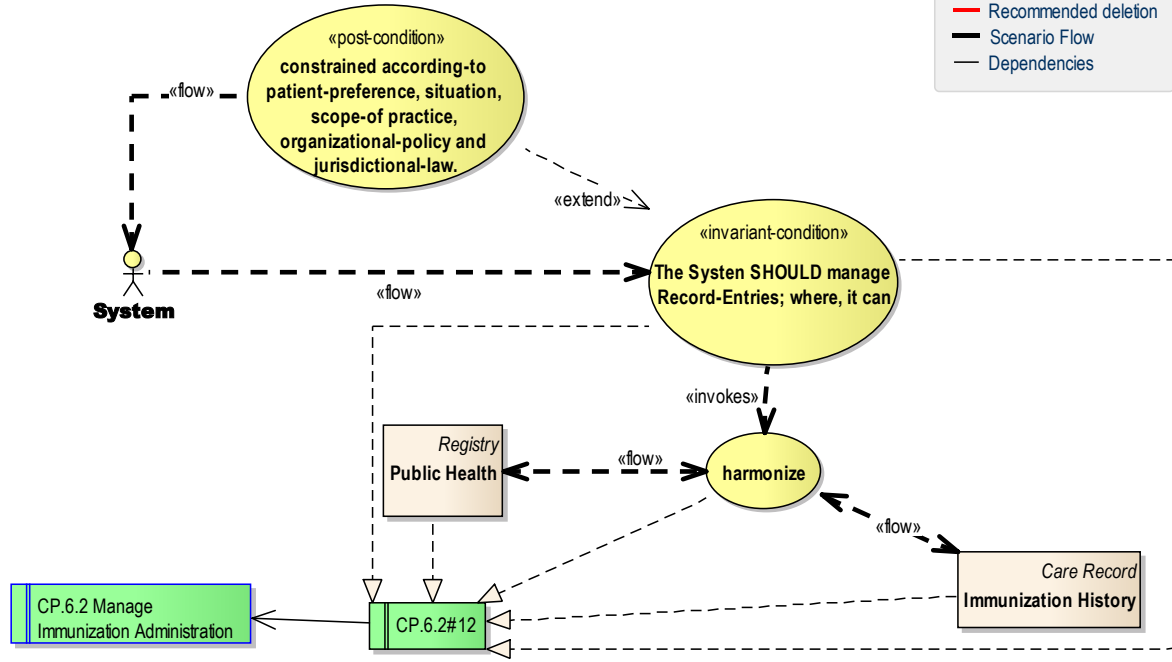
Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

class CP.6.2#12 SHOULD exchange immunization histories with public health immunization registries

Name: CP.6.2#12 SHOULD exchange immunization histories with public health immunization registries
 Author: EHR Interoperability WG
 Version: 2013 Release-3 Prototype
 Created: 12/23/2013 4:18:29 PM
 Updated: 12/31/2013 10:21:09 AM

Legend

- Reference Model
- Recommended addition
- Recommended deletion
- Scenario Flow
- Dependencies



Merge CP.6.2#11, #12, #13?
 If #12 harmonize --> why do we need #11 exchange?

Release-3 CP.6.2#12 The system SHOULD *manage Record Entries; where, it can* *harmonize Immunization Histories* with a *Public-Health Immunization-Registry*.

Figure: 24 CP.6.2#12 SHOULD exchange immunization histories with public health immunization registries

Release-2 CP.6.2#12 The system SHOULD harmonize Immunization histories with a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law.

Overarching post-condition: System-Actions are according-to scope-of-practice, organizational-policy and jurisdictional-law.

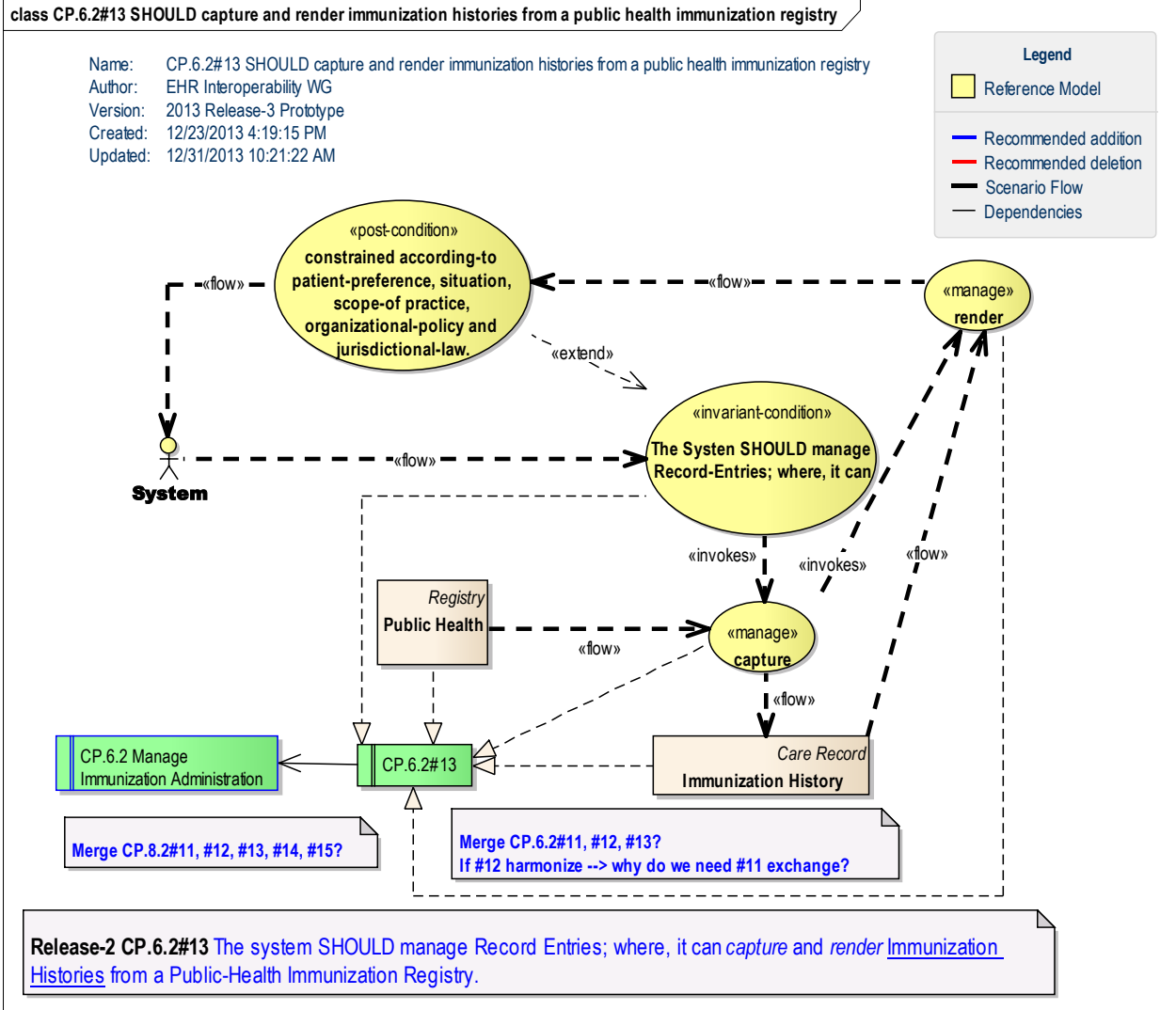


Figure: 25 CP.6.2#13 SHOULD capture and render immunization histories from a public health immunization registry

Release-2 CP.6.2#13 The system SHOULD capture and render immunization histories from a public health immunization registry.

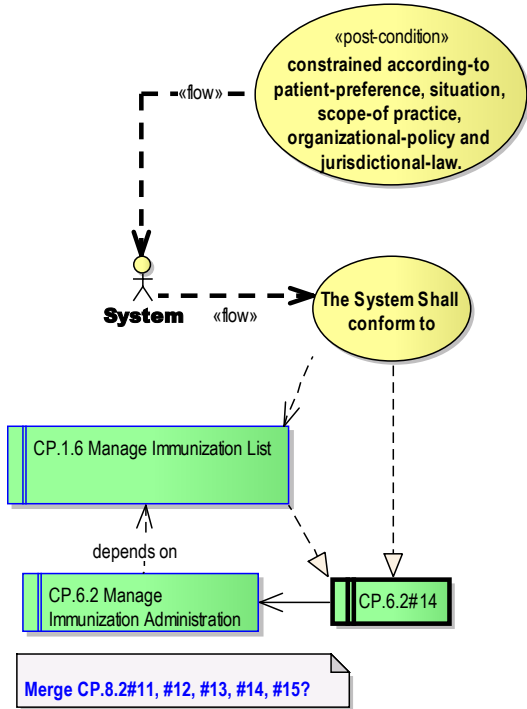
Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

class CP.6.2#14 SHALL conform to function CP.1.6 (Manage Immunization List)

Name: CP.6.2#14 SHALL conform to function CP.1.6 (Manage Immunization List)
 Author: EHR Interoperability WG
 Version: 2013 Release-3 Prototype
 Created: 12/23/2013 4:41:02 PM
 Updated: 12/31/2013 10:21:32 AM

Legend

- Reference Model
- Recommended addition
- Recommended deletion
- Scenario Flow
- Dependencies



Merge CP.8.2#11, #12, #13, #14, #15?

Release-3 CP.6.2#14 The system SHALL conform to function CP.1.6 (Manage Immunization List).

Figure: 26 CP.6.2#14 SHALL conform to function CP.1.6 (Manage Immunization List)

Release-2 CP.6.2#14 The system SHALL conform to function CP.1.6 (Manage Immunization List).

Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

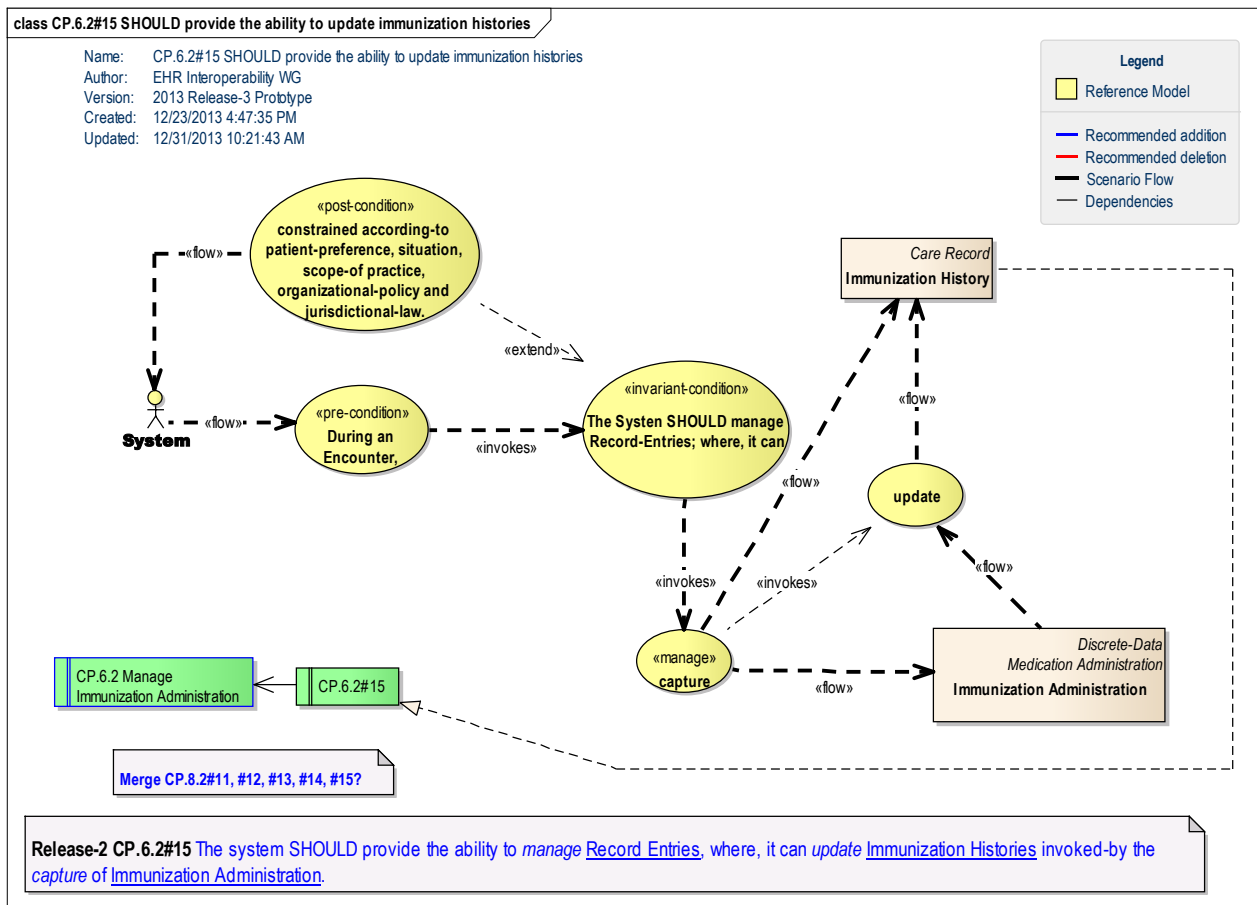
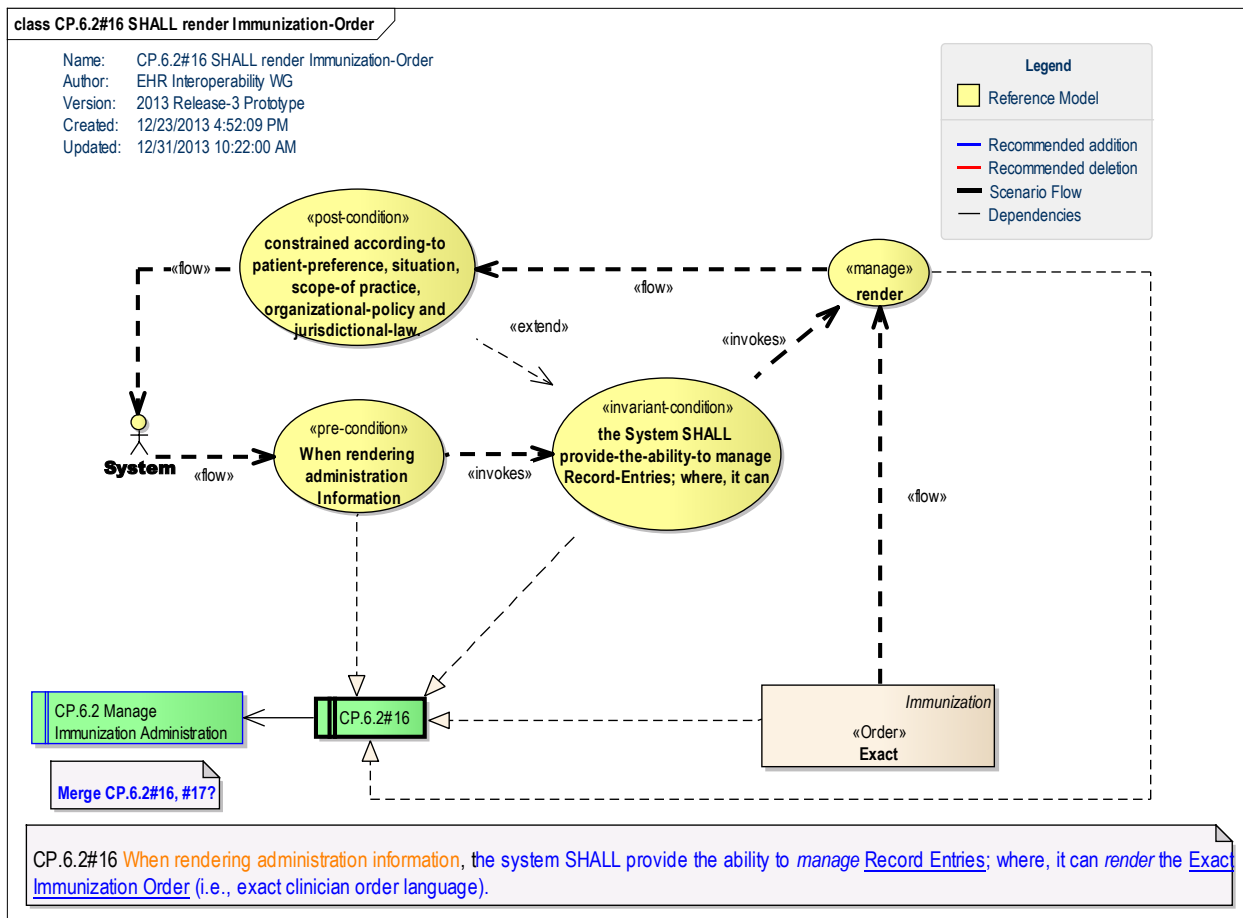


Figure: 27 CP.6.2#15 SHOULD provide the ability to update immunization histories

Release-2 CP.6.2#15 The system SHOULD provide the ability to update immunization histories at the time of capturing an immunization administration.

Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.



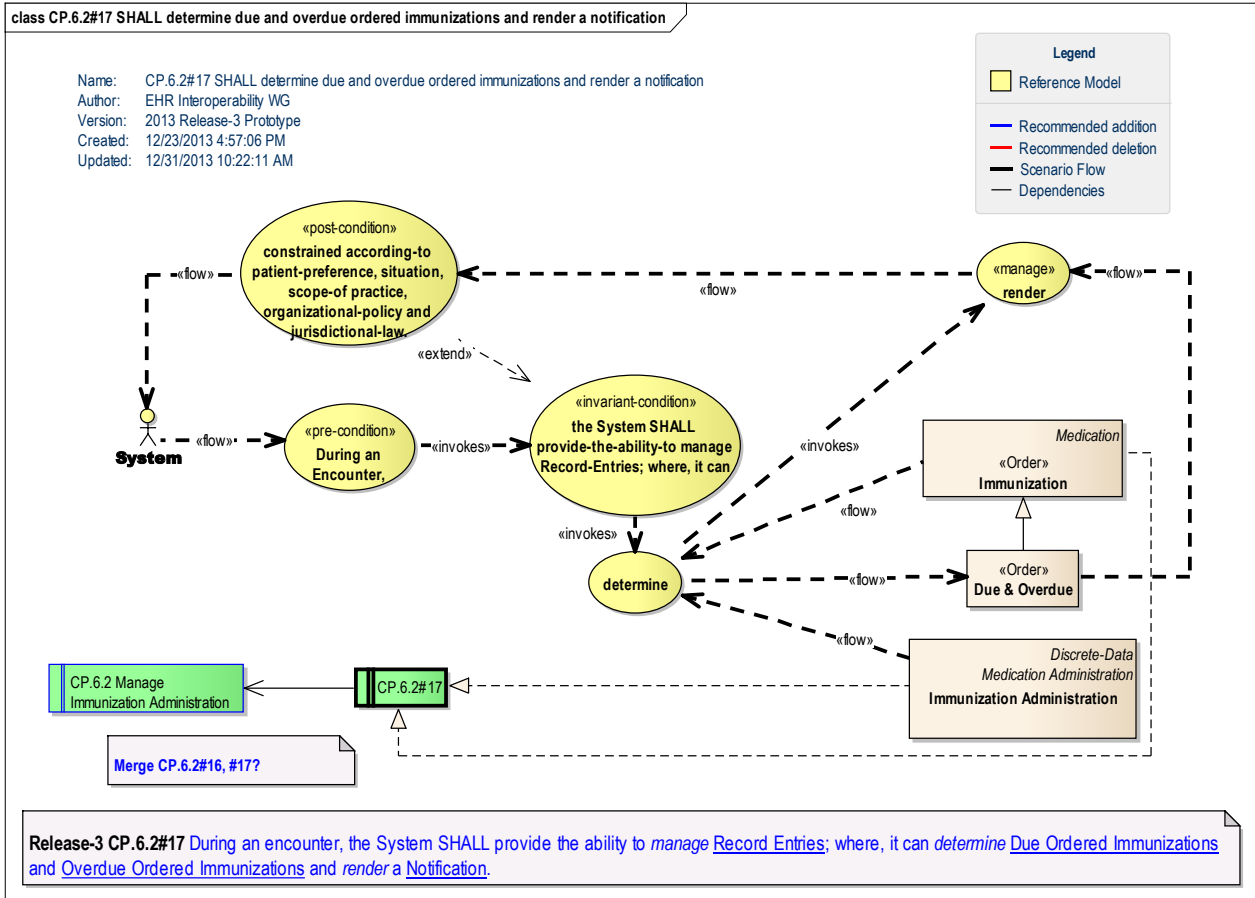


Figure: 29 CP.6.2#17 SHALL determine due and overdue ordered immunizations and render a notification

Release-2 CP.6.2#17 The system SHALL provide the ability to determine due and overdue ordered immunizations and render a notification.

Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

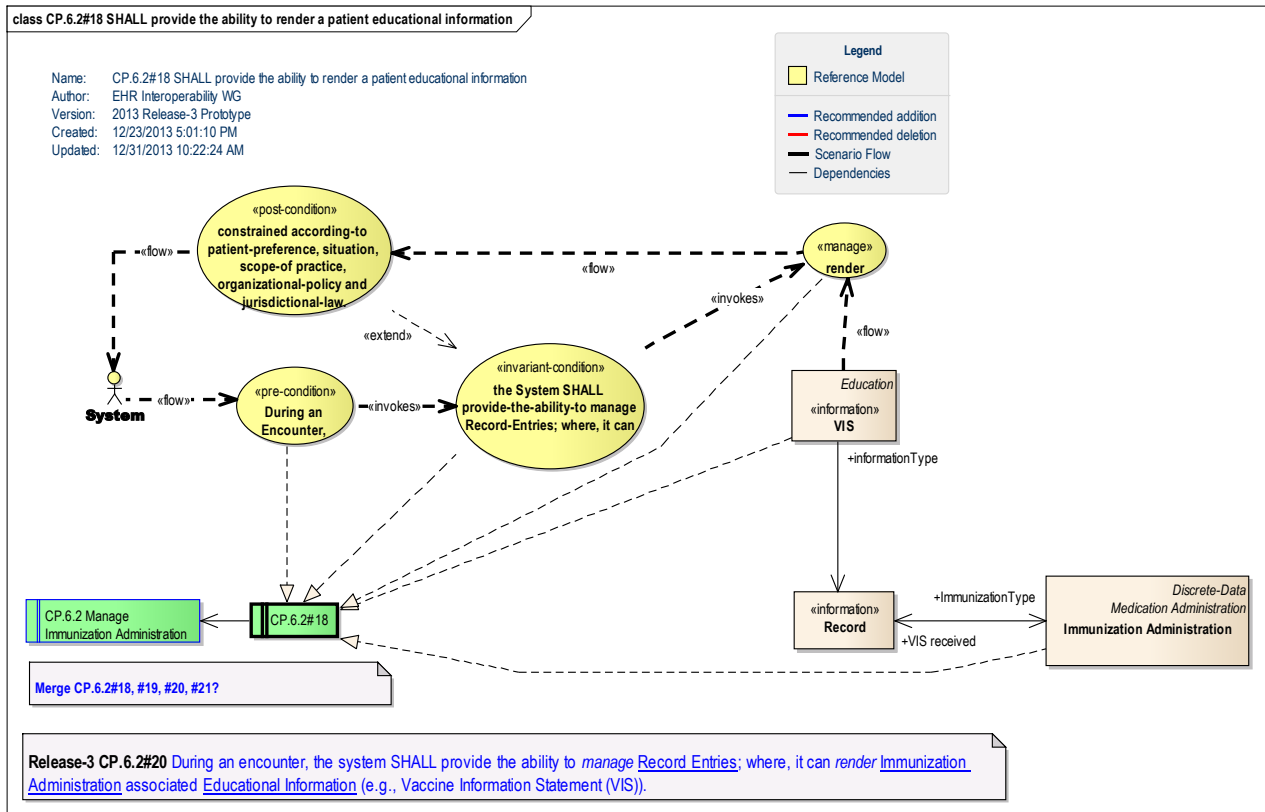


Figure: 30 CP.6.2#18 SHALL provide the ability to render a patient educational information

Release-2 CP.6.2#18 The system SHALL provide the ability to render a patient educational information regarding the administration (e.g., Vaccine Information Statement (VIS)).

Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

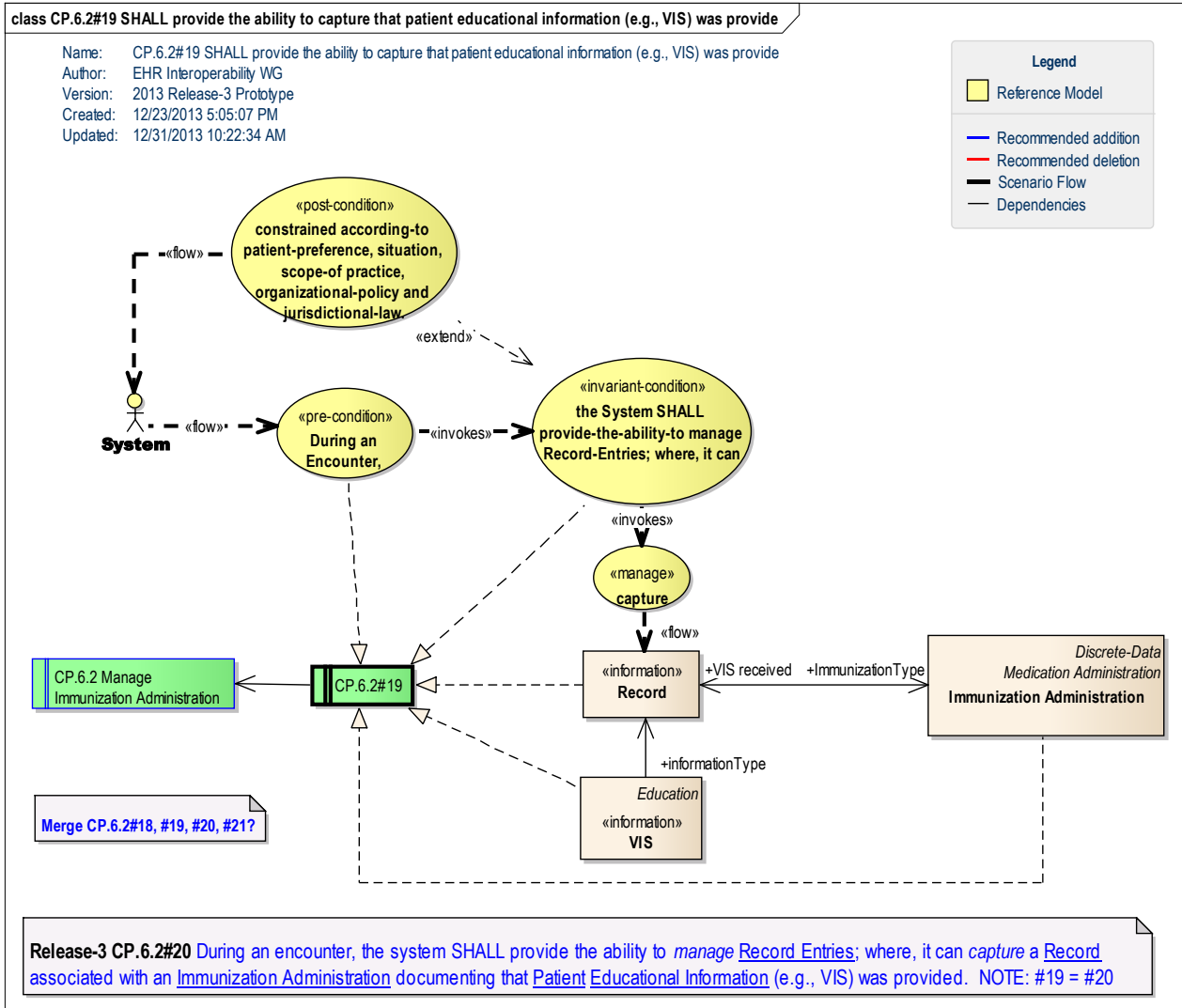


Figure: 31 CP.6.2#19 SHALL provide the ability to capture that patient educational information (e.g., VIS) was provide

Release-2 CP.6.2#19 The system SHALL provide the ability to capture that patient educational information (e.g., VIS) was provided at the time of immunization administration.

Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

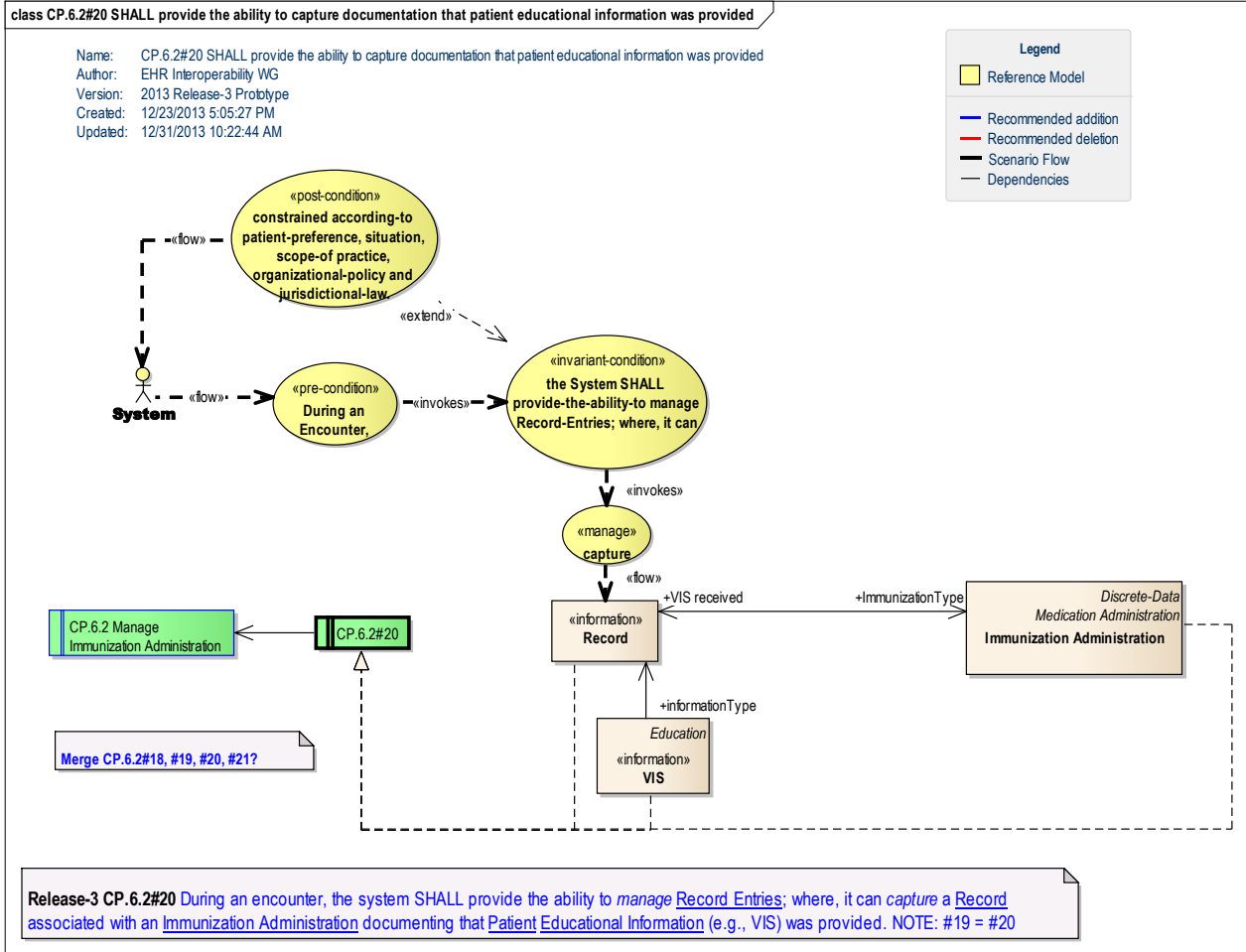


Figure: 32 CP.6.2#20 SHALL provide the ability to capture documentation that patient educational information was provided

Release-2 CP.6.2#20 The system SHALL provide the ability to capture documentation that patient educational information (e.g., VIS) was provided at the time of immunization administration.

Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

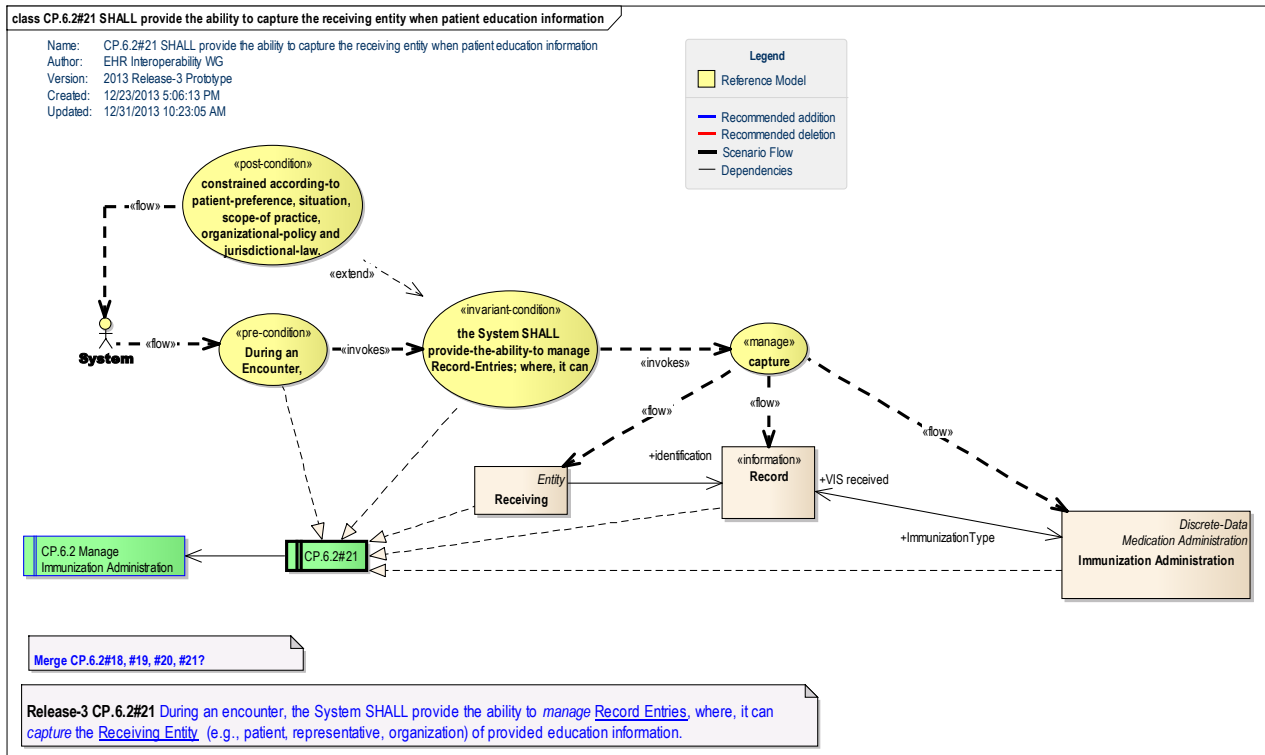


Figure: 33 CP.6.2#21 SHALL provide the ability to capture the receiving entity when patient education information

Release-2 CP.6.2#21 The system SHALL provide the ability to capture the receiving entity (e.g., patient, representative, organization) when patient education information is provided at the time of immunization administration.

Overarching post-condition: System-Actions are according-to scope-of-practice, organizational-policy and jurisdictional-law.

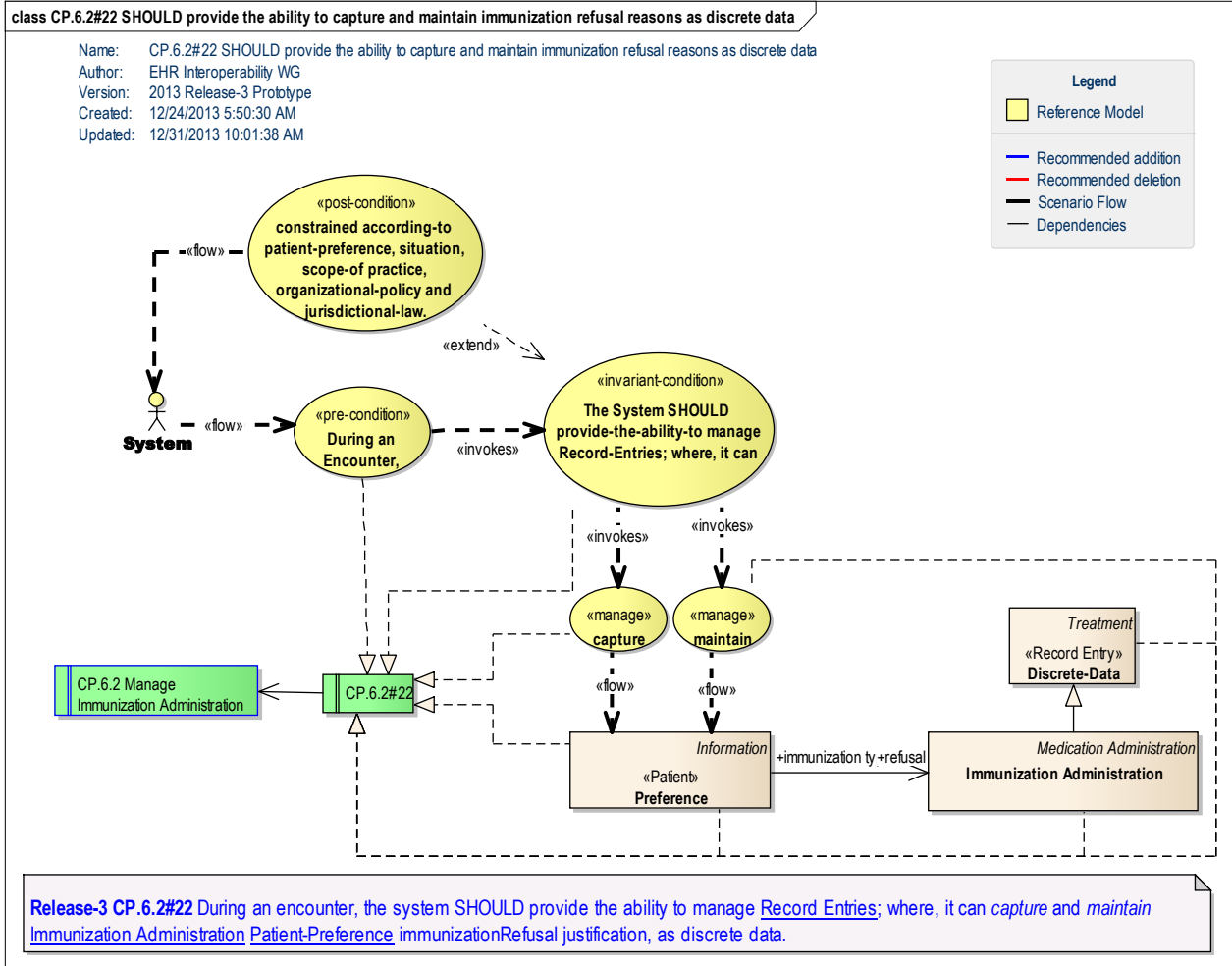


Figure: 34 CP.6.2#22 SHOULD provide the ability to capture and maintain immunization refusal reasons as discrete data

Release-2 CP.6.2#22 The system SHOULD provide the ability to capture and maintain immunization refusal reasons as discrete data.

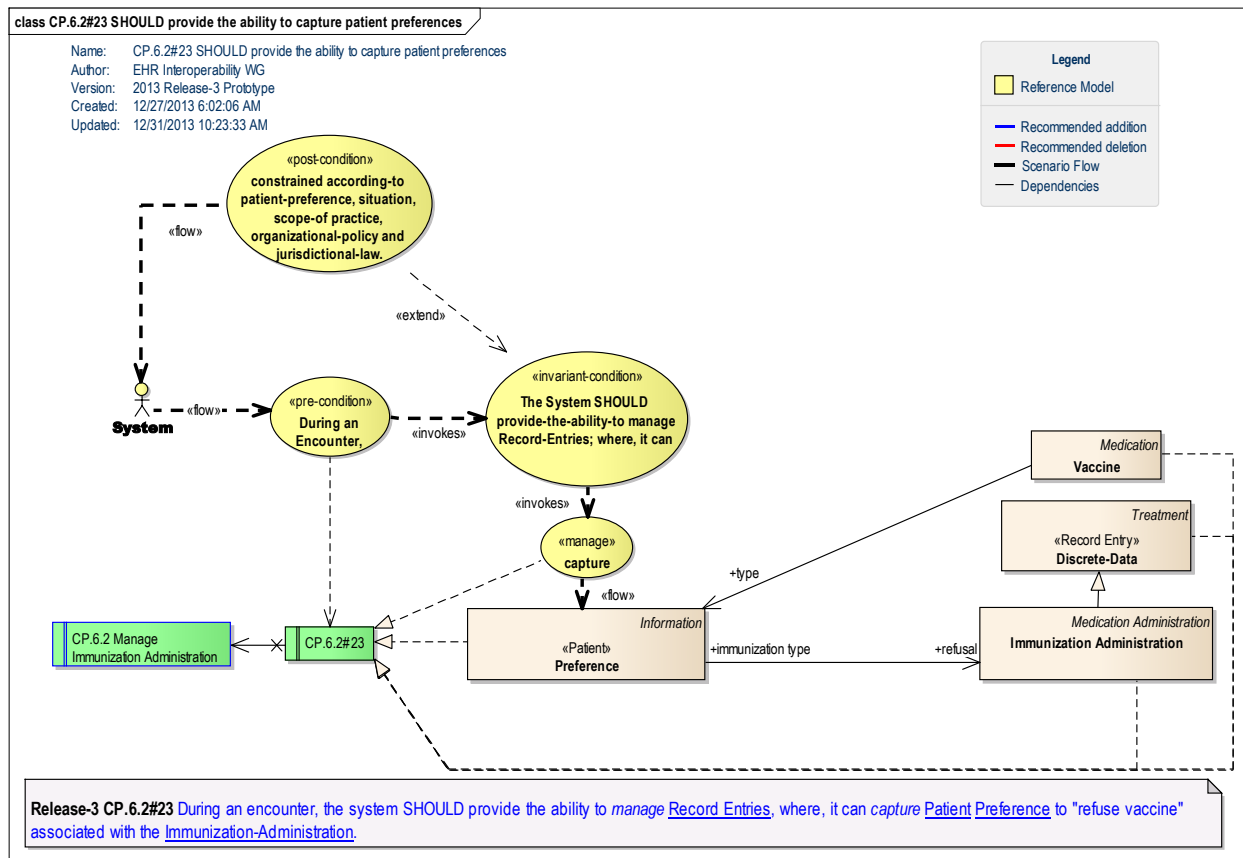


Figure: 35 CP.6.2#23 SHOULD provide the ability to capture patient preferences

Release-2 CP.6.2#23 The system SHOULD provide the ability to capture patient preferences regarding receipt of Immunization (e.g. refusal of certain vaccine types) at time of immunization administration.

ISSUE: Should CP.6.2#22 and #23 be combined?

During an encounter, the system SHOULD provide the ability to capture and maintain patient "refused vaccine types" preferences and justification associated with the Immunization-Administration; where, the data is discrete.

Overarching post-condition: System-Actions are according to scope-of-practice, organizational-policy and jurisdictional-law.

EHR-S FIM-FHIR Interoperability Example

Type: **Package**
 Package: EHR-S FIM r3 CP.6.2 Immunization Management Report
 Detail: Created on 12/28/2013, Last modified on 12/31/2013

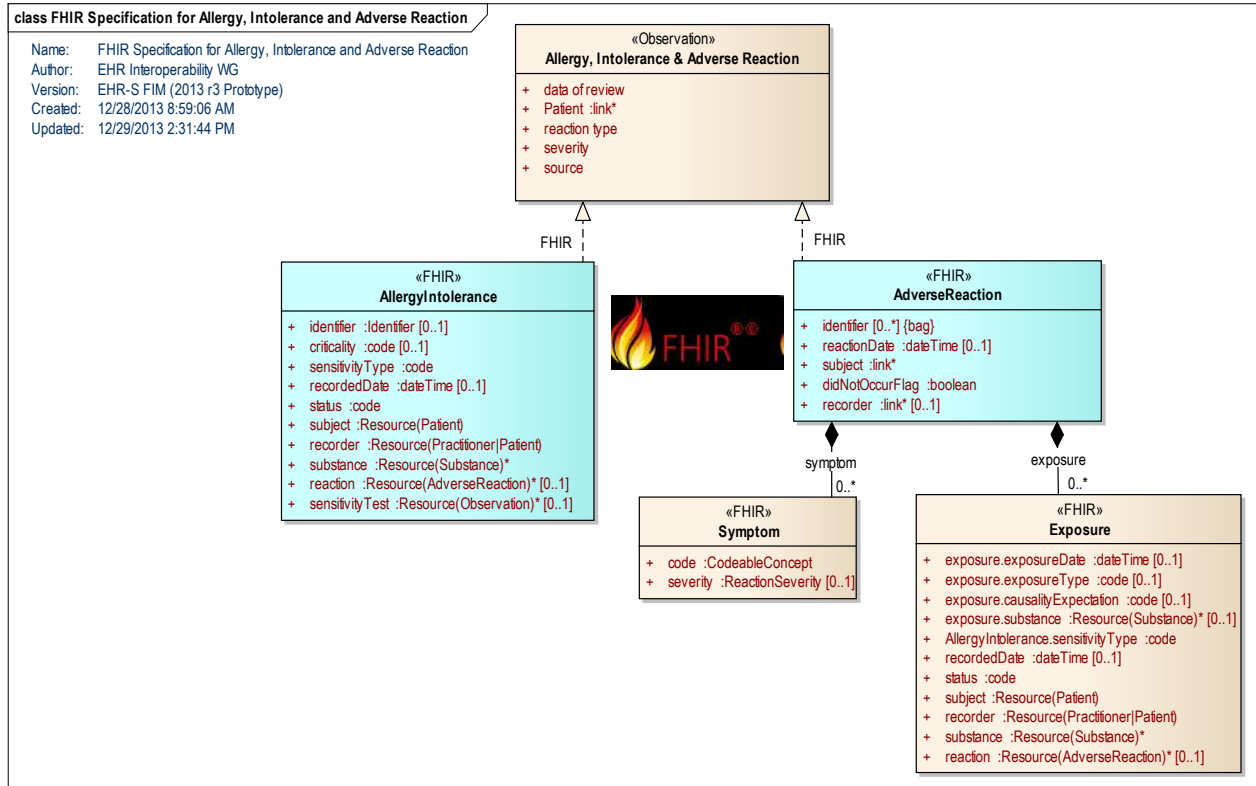


Figure: 36 FHIR Specification for Allergy, Intolerance and Adverse Reaction

This diagram illustrates how FHIR can be used to add implementation design-specification fidelity to the EHR-S FIM data-requirements conformance criteria (CC) for Allergy, Intolerance and Adverse Reaction.

Fast Healthcare Interoperability Resources (FHIR, pronounced "Fire") defines a set of "Resources" that represent granular clinical concepts. The resources can be managed in isolation, or aggregated into complex documents. This flexibility offers coherent solutions for a range of interoperability problems. The simple direct definitions of the resources are based on thorough requirements gathering, formal analysis and extensive cross-mapping to other relevant standards. A workflow management layer provides support for designing, procuring, and integrating solutions. 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. Where possible, open internet standards are used for data representation.

EHR-S FIM-FHIR-FHIM Interoperability Example

Type: **Package**
 Package: EHR-S FIM r3 CP.6.2 Immunization Management Report
 Detail: Created on 12/28/2013, Last modified on 12/30/2013

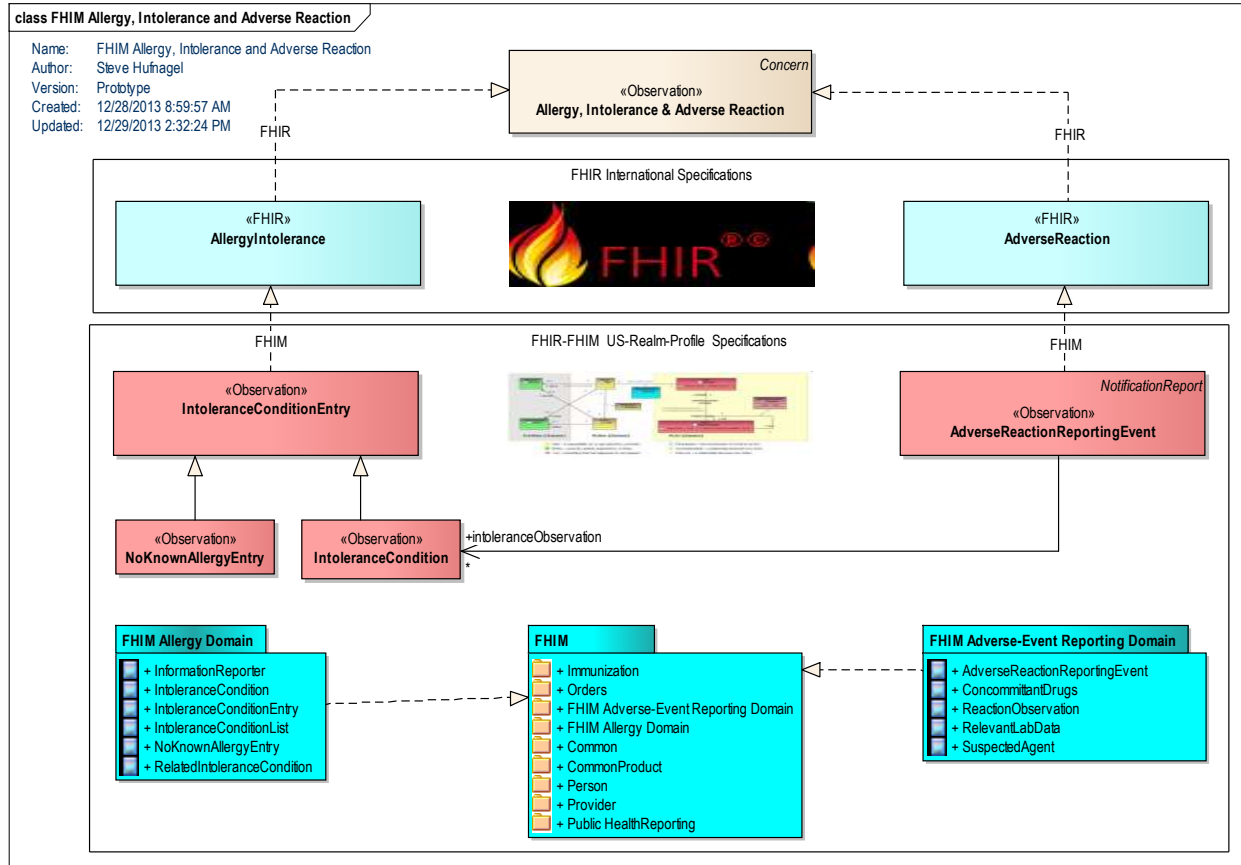


Figure: 37 FHIM Allergy, Intolerance and Adverse Reaction

[Federal Health Information Model](http://www.fhims.org/) <http://www.fhims.org/>

The FHA, together with its federal partners, addresses Executive Order 13410 to achieve secure, interoperable health information exchanges within the federal government and its consortia. FHA serves a coordinating and convening role across the federal agencies to support alignment of health information technology (IT) investments. This has led to the Federal Health Interoperability Modeling (FHIM) Initiative, Federal Health Information Planning and Reporting (FHIPR), and other projects aimed at coordinating across federal agencies. The FHIM is a model of healthcare data developed for the FHA partner agencies. The FHIM project seeks to develop a common Logical Information Model or Computationally Independent Model (CIM).

The Federal Health Information Model is a project under a larger program called Federal Health Interoperability Modeling and Standards (FHIMS), which is an initiative of the Federal Health Architecture (FHA). Briefly, the United States federal government has established a Federal Enterprise Architecture (FEA), which provides guidance to federal agencies on how they should develop their enterprise architectures. The methodology used by FEA, the Federal Segment Architecture Methodology (FSAM) recognizes that some "lines of businesses" in which the federal government is engaged cross agency boundaries. The healthcare line of business is one such case. As a result, the FHA was established as a partnership of over 20 departments and agencies to coordinate Healthcare Information Technology (sometimes called Healthcare IT, or HIT) activities among those partners. The FHA is managed by the Office of the National Coordinator for Health IT (ONC). The FHA has served as a forum by which the partner agencies have collaborated on several important initiatives, including the Nationwide Health Information Network.

Acts, Roles, and Entities The FHIMS program is intended to coordinate the efforts of the partner agencies with respect to information and terminology standards, including the coordination of agency efforts at relevant Standards Development Organizations (SDOs) such as Health Level Seven (HL7), the National Council for Prescription Drug Programs (NCPDP), Integrating the Healthcare Enterprise (IHE), and others. Many of the partner agencies are already active in some of these SDOs, in which case the FHIMS program can help agencies speak with a single voice at the SDOs while also reducing redundant participation. For those agencies that do not yet have a presence in a particular SDO, this program provides a mechanism for agencies to delegate issues to another agency. For example, if the Department of Veterans Affairs (VA) is active in the Organization for the Advancement of Structured Information Standards (OASIS), and the Indian Health Service (IHS) is not, the FHIMS program provides an opportunity for IHS to learn of relevant OASIS activities, and for IHS to request the VA representatives to OASIS to champion a particular issue.

Another FHIMS initiative is the Federal Health Terminology Model project, which coordinates partner agency efforts to develop healthcare terminology models (i.e., new content), and to enumerate "value sets" that can be associated with the Information Model. The Terminology Model is closely related to the Information Model, as they are each describing the same real-world concepts from two different angles. The Information Modeling team will work very closely with the Terminology Modeling team to identify those concepts which should be enumerated in a value set, to define that value set, and to define the members of the value set.

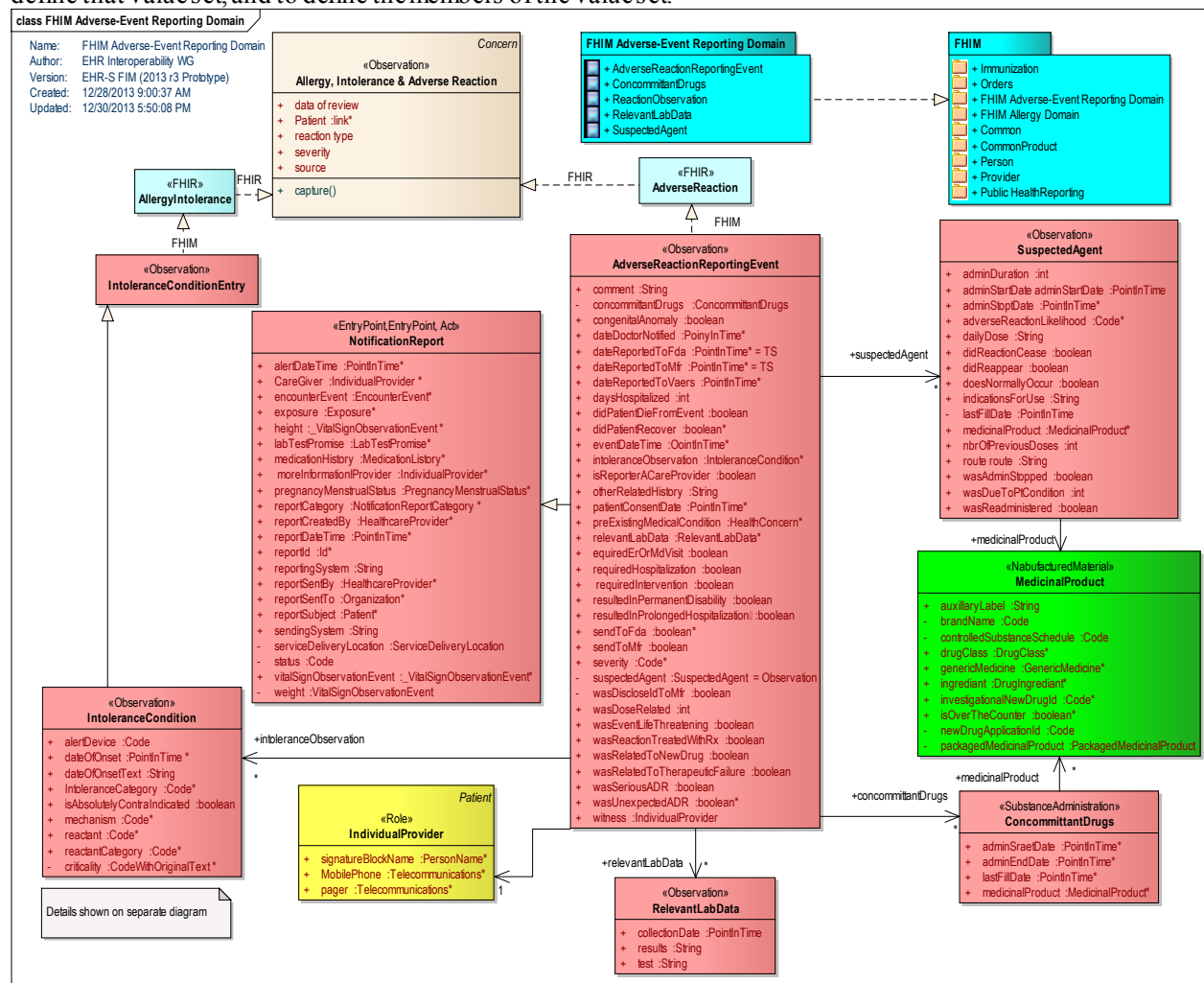


Figure: 38 FHIM Adverse-Event Reporting Domain
 Federal Health Information Model <http://www.fhims.org/>

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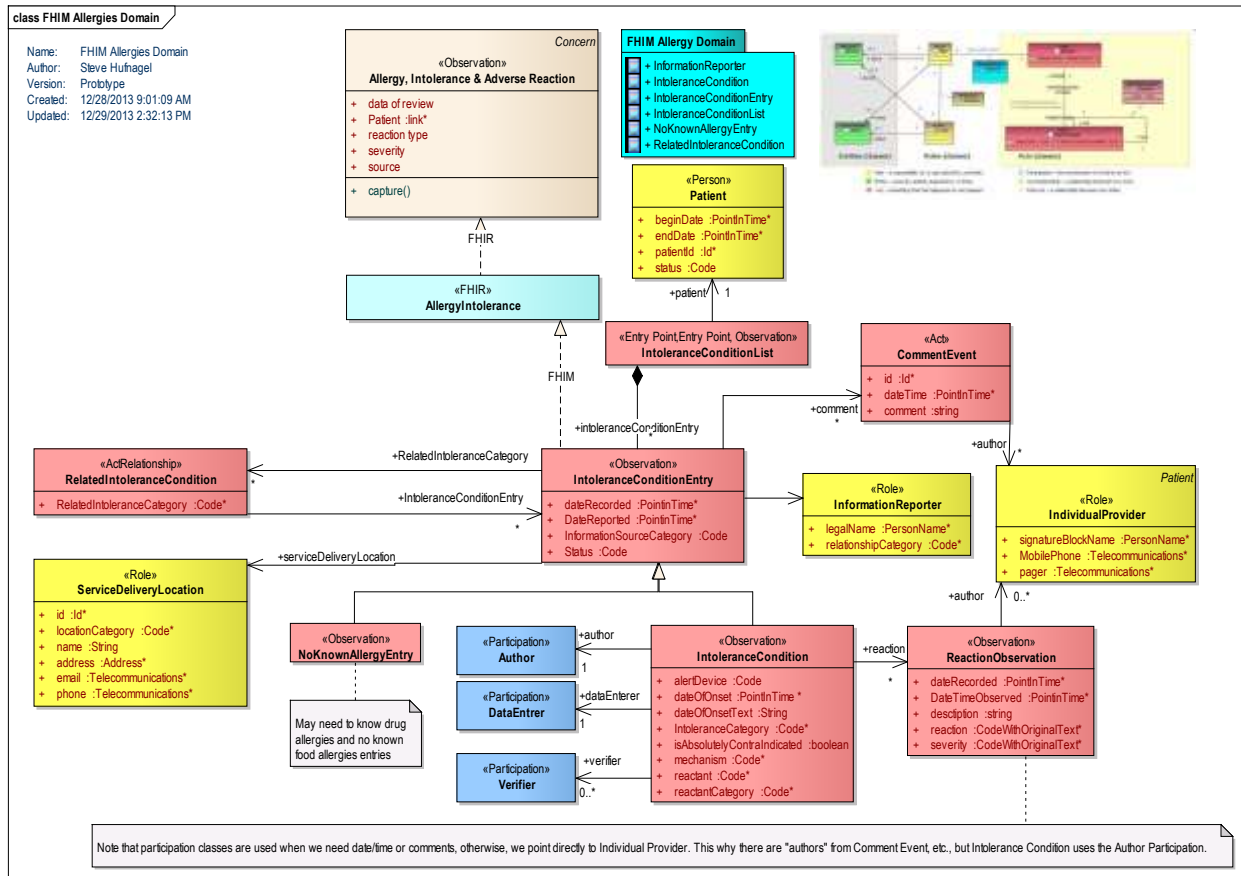


Figure: 39 FHIM Allergies Domain

Federal Health Information Model <http://www.fhims.org/>

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EHR-S FIM r3 Easy-Button Tool Overview

Type: **Package**
Package: EHR-S FIM r3 CP.6.2 Immunization Management Report
Detail: Created on 12/28/2013, Last modified on 12/31/2013

The EHR-S FIM “Easy-Button” is resident in SparxEnterprise Architect Tool; where, an EHR-S

1. Concept-of-Operation (**CONOPS**) is defined-and-refined into a
2. SystemReference-Model (**RM**); where,
3. SystemFunctions are defined-by Use-Cases; where,
 - a. System-operations are verbs refined into a “manage verb-hierarchy” aka operation-type model,
 - b. System-entities are subjects-and-objects refined into a Record-Entry data-type model
 - c. Terminology value-sets are bound-to discrete-data-elements within each Record-Entry.
4. Requirements Conformance-Criteria are defined-by use-case scenarios; where,
5. Scenarios define business-context and subject-verb-object-terminology bindings; where,
6. Business-Context defines pre, post and invariant conditions; where,
 - a. pre-condition are triggers, followed by
 - b. applicability; where,
 - 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 manage-hierarchy verb applies and
 2. a use-case constrained data-model noun applies; where,
 - c. post-condition Business-Rules are
 - d. “according-to scope-of-practice, organizational-policy, jurisdictional-law, and patient-preferences.”
7. Information-Exchanges are defined-by scenarios interoperable-with implementation-paradigms, such as
 - a. HL7 International V2 and V3 message, RIM and CDA, SOA RLUS standards and related DAMS
 - b. HL7 International FHIR (Fast Healthcare Interoperability Resource) profiled-with
 - c. FHA US-Realm FHIM (Federal Health Information Model) bound to
 - i. Terminology value-sets,
 - d. IHE information-exchange behavioral-protocols refined by,
 - i. SLA and DURSA (Service-level-agreement and Data-Use-and-Reciprocal-Support-Agreement) and
 - ii. KPPs (Key Performance Parameters).
 - iii. Cost estimation factors
8. EHR-S & PHR-S Profiles are defined-by constrained Use-Cases and scenario
9. Applicability, business-context and subject-verb-object-terminology bindings.
10. Interoperability-Specifications are generated with the EHR-S FIM r3 “Easy-Button” reporting-tool.
 - a. Functional Use Cases
 - b. Conformance Criteria Scenarios
 - c. Information Exchange Interoperability Specifications, Test-Cases and Simulations
 - i. Conformant-with HL7 Service Aware Interoperability Framework (**SAIF**)
 - ii. Interoperable-with HL7 International Fast Interoperability Healthcare Resources (FHIR)
 - iii. Interoperable-with FHA US-Realm Federal Health Information Model (FHIM)
 - iv. Interoperable-with Integrating the Healthcare Enterprise (**IHE**) profiles
 - v. Interoperable-with HL7 V2 and V3 message, RIM and CDA,
 - vi. Interoperable-with HL7 SOA RLUS standards and related DAMS

The benefit of this formally-specified Concept-of-Operation (CONOPS) and Reference Model (RM) approach is a clear, complete, concise, correct and consistent EHR-S and PHR-S Function-and-Information Model (FIM), profiles and resultant Interoperability-Specifications (ISs); where, ISs include appropriate implementation-paradigm specifications (V2 or V3 messaging, CDA, FHIR profiles, RLUS Data Services).

class EHR-S FIM Tool is an “Easy-Button” to Reuse EHR-Informatics ...



Figure: 40 EHR-S FIM Tool is an “Easy-Button” to Reuse EHR-Informatics Knowledge