

# **NCVHS Testimony on PMRI Standards**

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**Experts in the  
Business of Healthcare**

# NCVHS Objective

- **To “study the issues related to the adoption of uniform data standards for patient medical record information (PMRI) and the electronic exchange of that information...”**

# Essential Criteria for Selection of Standards

## ■ ANSI accredited Standards Development Organization (SDO)

- Open to all participants: inclusive, not exclusive
- No undue financial barrier to participation
- Balanced: producers, consumers, government, academia, others
- Open, consensus process
- Ballot: full resolution of negative comments

(Consortia tend to constrain membership, balance, due process and may impose financial barriers to participation.)



# Essential Criteria for Selection of Standards (con't)

- **Technology independence**
- **Completeness of coverage**
- **Validation, proof in practice**
- **Market acceptance**

# Quick Assessment of Suggested Standards

## ■ **HL7 v2.x Data Interchange**

- + ANSI accredited, open, consensus, balanced
- + Widespread industry acceptance
- Deficiencies remain with regard to enabling a robust EHR (detail follows...)
- For additional discussion of deficiencies, reference HL7 v2.4 Standard, Section 1.8

## ■ **ASTM XML Specifications**

- + ANSI accredited, open, consensus, balanced
- Lacks validation, industry acceptance



# Quick Assessment of Suggested Standards (con't)

## ■ DICOM v3 Imaging

- Consortia, not ANSI accredited
- Unbalanced: dominated by producers
- Not fully open or consensus based
- + Widespread industry acceptance

## ■ NCPDP SCRIPT v4.0

- + ANSI accredited, open, consensus, balanced
- ? Industry acceptance

# Quick Assessment of Suggested Standards (con't)

## ■ IEEE Medical Device Communications

- + ANSI accredited, open, consensus, balanced
- Lack validation, industry acceptance

## ■ OMG CORBAmed

- Consortia, not ANSI accredited
- Substantial financial barrier to participation
- Technology dependent
- Minimal industry acceptance

# Per-Sé Software Family

## ■ Patient1™

- Full clinical support: inpatient, ambulatory, emergent, short stay, long-term care, home care
- Electronic health record
- (Overview of design and trust objectives follow...)

## ■ Business1™

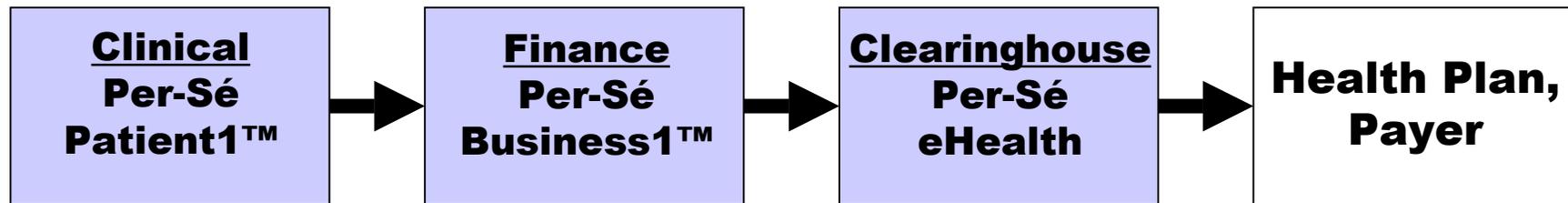
- Patient accounting, billing, claims

## ■ Resource1™

- Patient scheduling: OR, radiology, clinic, ambulatory care
- Staff scheduling



# Per-Sé Enabled HIPAA Chain of Trust



## ■ Trusted End-to-End Information Flow:

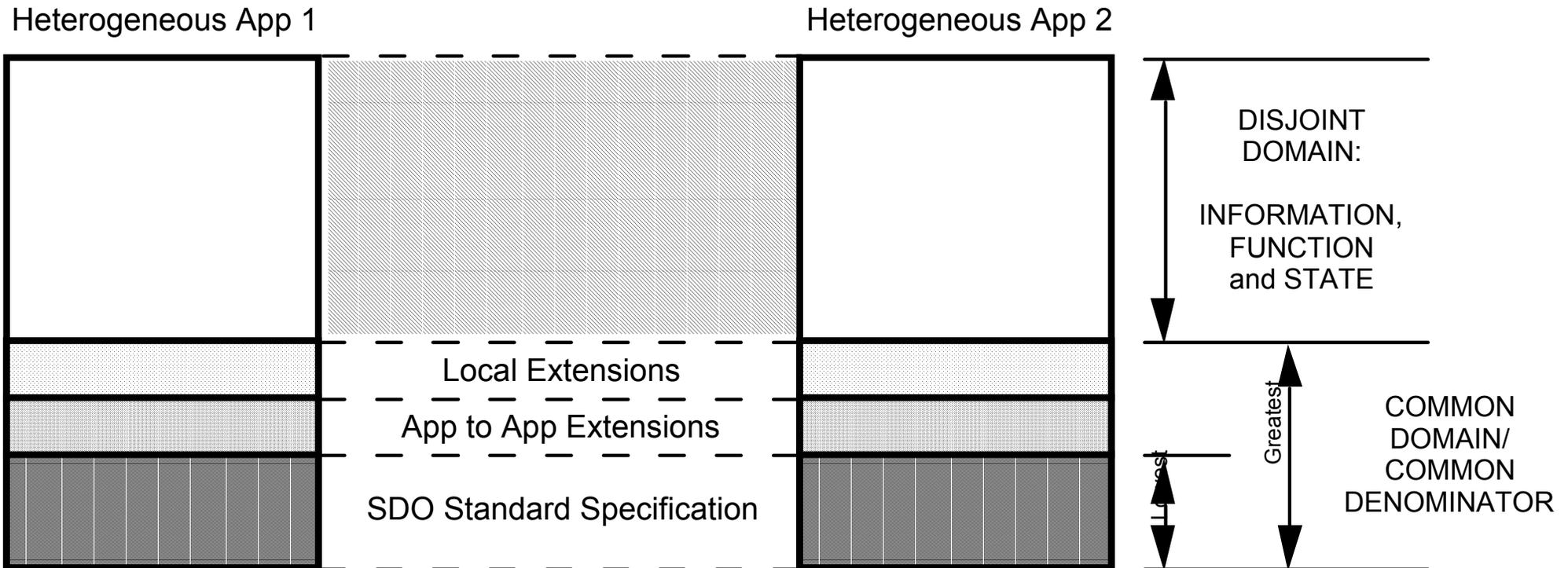
- From Clinical Front-End, Point of Service/Care:
  - Per-Sé Patient1™
- To Financial System
  - Per-Sé Business1™
- To Clearinghouse
  - Per-Sé eHealth
- To Health Plan, Payer



# Applicability and Market Demand for Standards

- **Domain applicable, major market demand:**
  - HL7 v2.x
- **Domain applicable, no market demand:**
  - ASTM
  - OMG
- **Domain not applicable:**
  - DICOM
  - NCPDP
  - IEEE

# The Constraint of Heterogeneity



- ↑ Heterogeneity
- ↑ Disparity (mismatched info/process)
- ↓ Common Denominator

# HL7 v2.x

## Scope of Coverage

### ■ In Scope

- Interchange directly enabled by the HL7 v2.x specification
- HL7 v2.x “Common Denominator” (CD)
  - v2.x trigger events
  - v2.x message segments, data attributes, data types
  - v2.x vocabulary: code sets, classification schemes

### ■ Beyond Scope

- If implemented using HL7 v2.x z-extensions:
  - z-trigger events
  - z-segments, attributes
  - z-vocabulary



## HL7 v2.x

# Application Coupling

### ■ **Per-Sé Patient1™ application software**

- Homogeneous architecture
- Full EHR integration by design
- Tightly coupled application interchange, no HL7 messaging

### ■ **Foreign application software**

- Heterogeneous architecture
- Typically loosely coupled interchange, utilizing HL7 v2.x
- Based on HL7 v2.x CD, extended by z-extensions
- To achieve full EHR integration (and tight coupling), certain impediments may be difficult to overcome:
  - Critical disparities in software architectures
  - Lack of will, budget or attendant resources



## HL7 v2.x

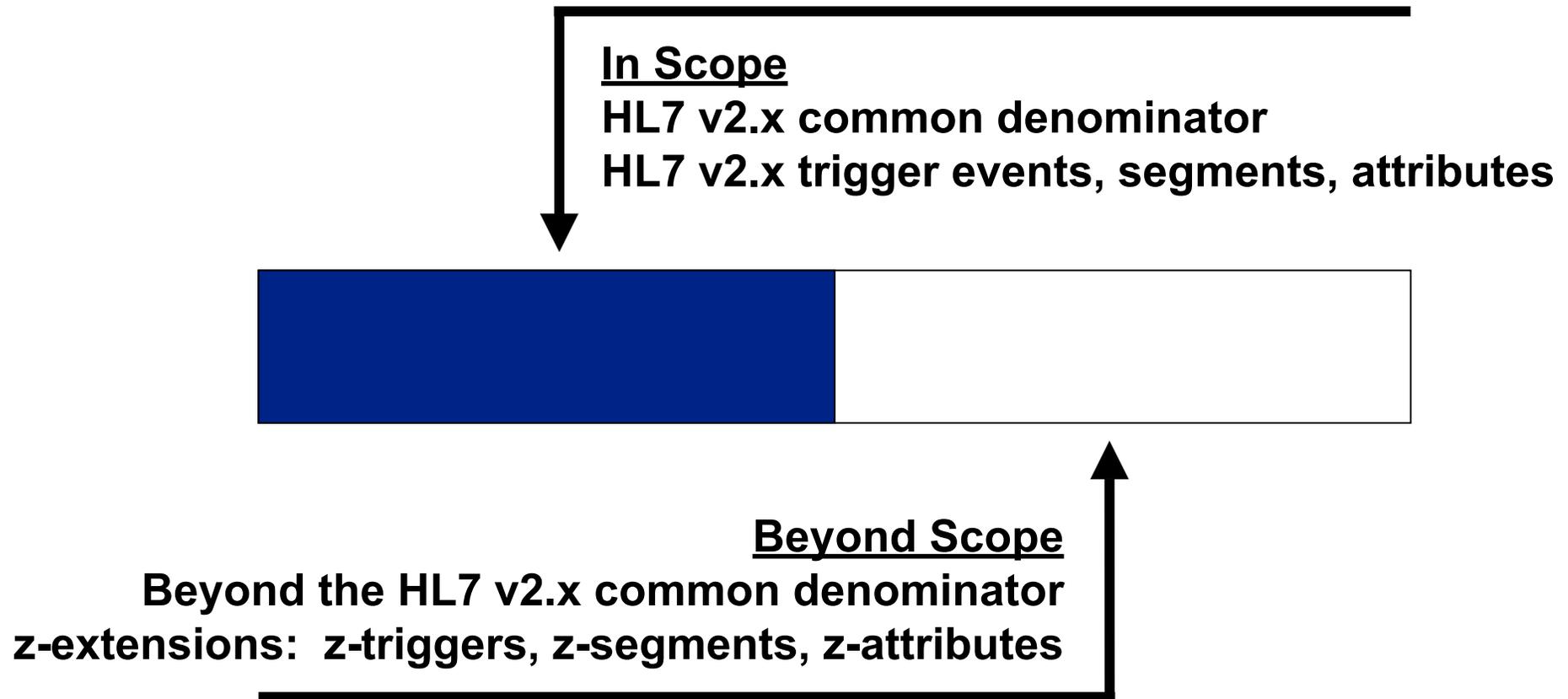
# EHR Coverage Assessment

- **HL7 v2.x scope vs. EHR (PMRI) problem space**
- **Presented in the context of**
  - Design objectives for Per-Sé Patient1™
  - Trust objectives
- **Based on substantial experience**
  - Interfacing Patient1™ with numerous foreign applications
  - Utilizing HL7 v2.x data interchange standards



# HL7 v2.x

## Scope of Coverage - Illustration



**Illustration only** - actual scope of coverage is detailed in following slides

# Patient1™ EHR

## Key Design Objectives

### ■ Medical/legal health record



### ■ Care continuum

- Inpatient, ambulatory, emergent, short stay, long term care, home care



### ■ Timeline continuum

- Prospective: events/actions to be done
- Concurrent: events/actions in progress
- Retrospective: events/actions complete, in terminus state



# Patient1™ EHR

## Key Design Objectives (con't)

### ■ Health record continuum

- Individual health record
- Organizational business (operations) record
- Practitioner service record



### ■ Multi-media record

- Text, audio, video, image/graphic, waveform

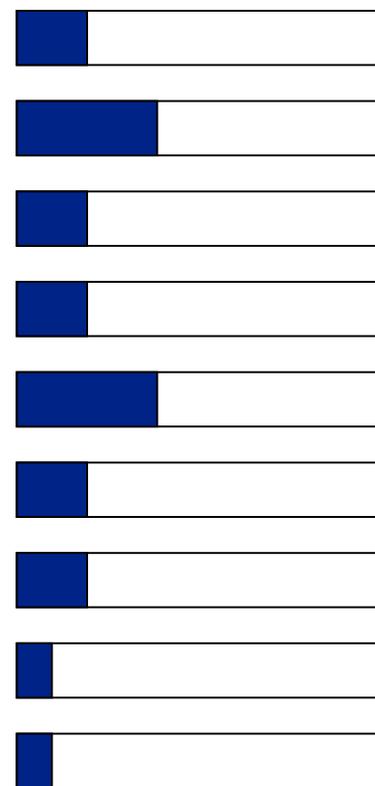


## Key Design Objectives (con't)

### ■ Health(care) delivery

#### Clinical work flow management

- Assigned responsibility, work list
- Integrated scheduling
- Allocation, staging
- Routing, deployment
- Performance, completion
- Alerts, prompts, reminders
- Problem list, episode management
- Clinical pathways, care plans
- Costs, resources: projected vs. actual



# Patient1™ EHR

## Key Design Objectives (con't)

### ■ Functional (business) integration

- Inter-disciplinary
  - Among practitioners
  - Across departments, services, specialties
- Intra-organizational
  - Across the IDN
  - Across sites, facilities, business units



### ■ Continuity, completeness

- Health(care) delivery process
- Health record



## Key Design Objectives (con't)

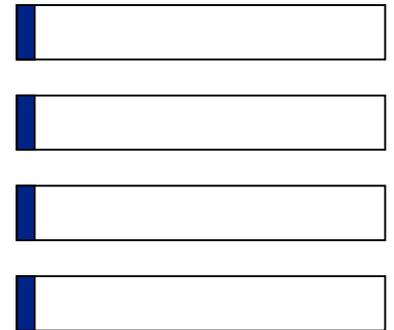
### ■ Clinical decision support

- Real-time, concurrent
- Retrospective



### ■ Clinical knowledge bases

- Facilities, resources, services
- Diagnostic, treatment, medication guidelines
- Standards of care
- Medical literature



# Patient1™ EHR

## Key Design Objectives (con't)

### ■ Availability

- 24 x 7 x 365
- Fault tolerance, redundancy

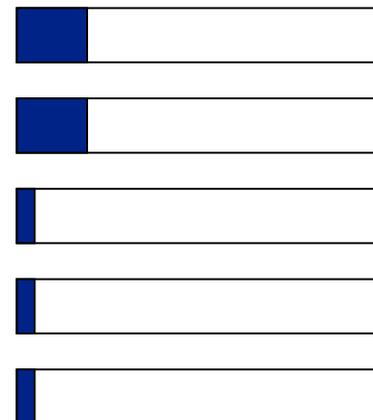
N/A

### ■ Scalability

N/A

### ■ Localization

- Master files
- Data definition, identifiers
- Vocabulary, terminology
- Work flow
- Clinical decision support

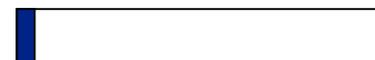
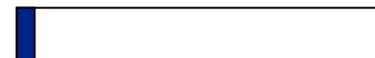


# Patient1™ EHR

## Key Design Objectives (con't)

### ■ Synchrony

- Database: two phase commits
- Time: clock concurrency



### ■ Version Control

- Application
- Vocabulary
- Messaging standard



# Patient1™ EHR

## Key Trust Objectives

- **Uniform privacy and security infrastructure**
- **Accountability, traceability**
  - **Accountable Parties**
    - Organizations, Business Units, Individuals
  - **Accountable Agents**
    - Software, Devices
  - **Accountable Actions: e.g.,**
    - Provision, performance, completion of health (care) services
    - Origination, retention, use, disclosure of protected health information



## Key Trust Objectives (con't)

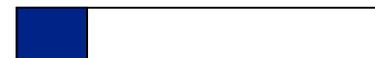
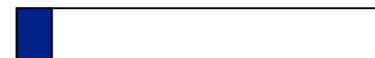
### ■ Access control

- What you have: physical token  
What you know: password
- User-based
- Role-based
- Context-based



### ■ Authentication

- Entity: evidence of identity
- Data: evidence of origin and authorship
- Message: evidence of transmittal, receipt



## Key Trust Objectives (con't)

### ■ Discrete privacy, security policy domains

- Per organization, facility, business unit

### ■ Single point of administration, configuration

- Master entity registries

- Parties: organizations, business units, individuals
- Agents: application software, devices

- Security classifications

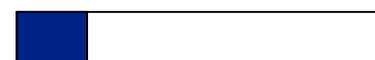
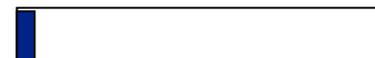
- Data groups, data attributes
- Functions, resources

- Security clearances for users, roles

## Key Trust Objectives (con't)

### ■ Audit trails, audit inspection

- Security incident, system management events
- Health(care) delivery, work flow events
- Access events
  - System resources, functions
  - Data
- Record chain of trust events
  - Point of origination to point of access/use
- Record integrity/continuity
  - Preservation of successive data states (initial and with each amendment)



## Key Trust Objectives (con't)

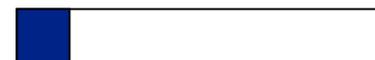
### ■ Data integrity

- Uniform data definition, vocabulary
  - Data groups: e.g., datasets
  - Data attributes: e.g., data elements
  - Data types
  - Code sets, classification schemes
- Accuracy, consistency, completeness
  - Measurable (per JCAHO definition)
- Persistence, permanence, indelibility
  - Update by amendment only, preserving previous content
  - Measurable (per HIPAA definition)



## Key Trust Objectives (con't)

### ■ Health record “chain of trust”

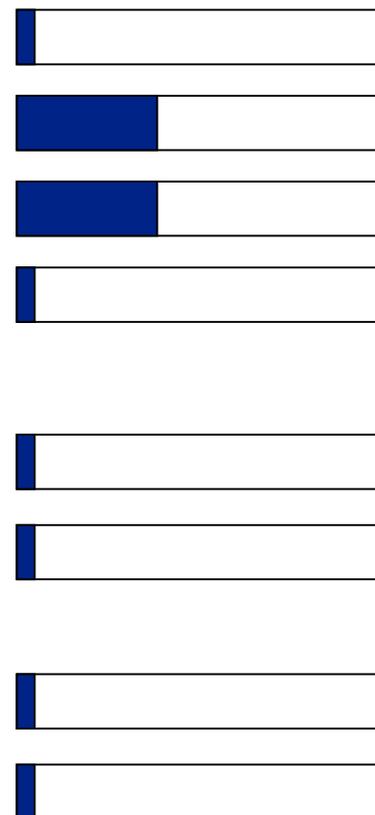


- From point of origination
  - e.g., point of service, point of care
- To point of access/use
  - e.g., point of review, point of report

## Key Trust Objectives (con't)

### ■ “Chain of trust” audit events

- Record/data access, use
- Record/data origination, amendment
- Record/data verification
- Record/data translation:
  - e.g., code sets, one to another
- Record disclosure, transmittal, receipt
- Record de-identification, aliasing, re-identification
- Record archival
- Physical record check-out/in
  - e.g., paper, film, magnetic media



# References

- **ISO 18307**

“Healthcare Informatics - Key Characteristics for Interoperability and Compatibility in Messaging and Communications Standards”, 2001

- **ASTM E1769**

“Standard Guide for the Properties of Electronic Health Records and Record Systems”, 1996

- **Health Level Seven v2.4, Section 1.8**

“The Scope of HL7”, 2000

