



Standard Practice for Defining and Implementing Pharmacotherapy Information Services within the Electronic Health Record (EHR) Environment and Networked Architectures¹

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1. Scope

1.1 This practice applies to the process of defining and documenting the capabilities, logical data sources, and pathways of data exchange regarding pharmacotherapy information services within a given network architecture serving a set of healthcare constituents.

1.2 This practice is not a technical implementation standard but, rather, describes how the implementation methods and techniques can be used to coordinate pharmacotherapy services logically within an electronic health record (EHR) systems environment involving participating organizations and sites connected by a networked communication system.

1.3 This practice covers the content of the nodes and arcs of the resulting logical network involving EHR, pharmacy, and clinical laboratory-capable sites. This practice also considers the various purposes and organizational arrangements for coordinating pharmacotherapy services within the network boundaries and the considerations for connections among external networks.

1.4 This practice refers to other standards for conventions within various data domains, such as pharmacy systems, clinical laboratory information management systems (CLIMS), and EHR systems, and for messaging conventions.

1.5 This practice is intended to outline how integration of pharmacy, CLIMS, and EHR information systems can be undertaken to result in a transparent pharmacotherapy clinical decision support environment, regardless of the underlying implementation architecture, by describing the logical interoperability of information domains as facilitated by information and communications technology (ICT).

1.6 This practice is directed at pharmacists, clinical pharmacologists, clinical laboratorians, information system managers, and information systems vendors for use in planning and implementing coordinated pharmacotherapy services through effective dialog.

1.7 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the*

responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

2. Referenced Documents

2.1 ASTM Standards:²

E 1239 Practice for Description of Reservation/Registration-Admission, Discharge, Transfer (R-ADT) Systems for Electronic Health Record (EHR) Systems

E 1340 Guide for Rapid Prototyping of Information Systems

E 1384 Practice for Content and Structure of the Electronic Health Record (EHR)

E 1578 Guide for Laboratory Information Management Systems (LIMS)

E 1633 Specification for Coded Values Used in the Electronic Health Record

E 1714 Guide for Properties of a Universal Healthcare Identifier (UHID)

E 1715 Practice for An Object-Oriented Model for Registration, Admitting, Discharge, and Transfer (RADT) Functions in Computer-Based Patient Record Systems

E 1744 Practice for View of Emergency Medical Care in the Electronic Health Record

E 1762 Guide for Electronic Authentication of Health Care Information

E 1869 Guide for Confidentiality, Privacy, Access, and Data Security Principles for Health Information Including Electronic Health Records

E 1985 Guide for User Authentication and Authorization

E 1986 Guide for Information Access Privileges to Health Information

E 1987 Guide for Individual Rights Regarding Health Information

E 1988 Guide for Training of Persons who have Access to Health Information

E 2017 Guide for Amendments to Health Information

¹ This practice is under the jurisdiction of ASTM Committee E31 on Healthcare Informatics and is the direct responsibility of Subcommittee E31.25 on Healthcare Data Management, Security, Confidentiality, and Privacy.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

- E 2066** Guide for Validation of Laboratory Information Management Systems
- E 2084** Specification for Authentication of Healthcare Information Using Digital Signatures
- E 2085** Guide on Security Framework for Healthcare Information
- E 2086** Guide for Internet and Intranet Healthcare Security
- E 2145** Practice for Modeling in Health Informatics
- E 2147** Specification for Audit and Disclosure Logs for Use in Health Information Systems
- E 2171** Practice for Rating-Scale Measures Relevant to the Electronic Health Record
- E 2457** Terminology for Healthcare Informatics
- E 2473** Practice for the Occupational/Environmental Health View of the Electronic Health Record
- P 110** Proposed Guide to Assist in the Defining, Procuring, Installing, and Implementing of a Computerized Hospital Pharmacy System³
- 2.2 *ANSI/IEEE Standards*:⁴
- ANSI X3.172** American National Dictionary for Information Systems
- ANSI/IEEE 610.12™ 1990 (R2002)** Standard Glossary of Software Engineering Terminology
- ANSI/IEEE 830™ 1998** Software Requirements Specification
- ANSI/IEEE 1058™ 1998** Software Project Management Plans
- ANSI/IEEE 1062™ 1998 (R2002 includes 1062a)** Recommended Practice for Software Acquisition
- ANSI/IEEE 1063™ 2001** Software User Documentation
- ANSI/IEEE 1073™ 1996** Framework and Overview
- ANSI/IEEE 1073.3.1™ 2001/Amd1-2001** Transport Profile (redesignated 11073-3-1, Standard for Medical Device Communications-Transport Profile-Connection Mode)
- ANSI/IEEE 1073.4.1™ 2001** Physical Layer-Cable Connected (redesignated 11073-4-1, Standard for Medical Device Communications—Physical Layer Interface—Cable Connection)
- ANSI/IEEE 1074™ 2006** Standard for Developing Life Cycle Processes
- ANSI/IEEE 1074.1™ 1995** Guide for Developing Life Cycle Processes
- ANSI/IEEE 1220™ 2005** Standard for Application and Management of the System Engineering Process
- ANSI/IEEE 1233™ 1998 (R2002 includes 1233a)** Guide to Preparing System Requirements Specifications
- ANSI/IEEE 1320.1™ 1998 (R2004)** Standard for Conceptual Modeling Language—Syntax and Semantics for IDEF0
- ANSI/IEEE 1320.2™ 1998 (R2004)** Standard for Conceptual Modeling Language—Syntax and Semantics for IDEF1X97 (IDEF Object)
- ANSI/IEEE 1362™ 1998** Guide for Information Technology—System Definition—Concept of Operations Document
- ANSI/IEEE 1490™ 2003** IEEE Guide IEEE—Adoption of PMI Standard—A Guide to Project Management Body of Knowledge, 2000 Edition PMI
- ANSI/IEEE 12207.0™ 1996** Standard for Information Technology—Software Life Cycle Processes
- ANSI/IEEE 12207.1™ 1997** Guide for Information Technology—Software Life Cycle Processes—Life Cycle Data
- ANSI/IEEE 12207.2™ 1997** Guide for Information Technology—Software Life Cycle Processes—Implementation Considerations
- 2.3 *ANSI/HL7 Standards*:⁴
- ANSI/HL7** Interface Standard v2.4, v2.5, v3.0
- HL7** Message Development Framework v3.3, Dec. 1999
- 2.4 *ANSI/ADA Standards*:⁴
- ANSI/ADA TR 1039 2005** Clinical Content Data Model
- ANSI/ADA 1000.0** Introduction, Model Architecture, and Specification Framework
- ANSI/ADA 1000.1** Individual Identification
- ANSI/ADA 1000.2** Codes and Nomenclature
- ANSI/ADA 1000.3** Individual Characteristics
- ANSI/ADA 1000.4** Population Characteristics
- ANSI/ADA 1000.5** Organization
- ANSI/ADA 1000.6** Location
- ANSI/ADA 1000.7** Communication
- ANSI/ADA 1000.8** Healthcare Event
- ANSI/ADA 1000.9** Health Materiel
- ANSI/ADA 1000.10** Health Services
- ANSI/ADA 1000.11** Health Service Resources
- ANSI/ADA 1000.12** Population Health Facts
- ANSI/ADA 1000.13** Patient Health Facts
- ANSI/ADA 1000.14** Health Condition Diagnosis
- ANSI/ADA 1000.15** Health Service Plan
- ANSI/ADA 1000.16** Patient Health Service
- ANSI/ADA 1000.17** Clinical Investigation
- ANSI/ADA 1000.18** Comments Subject Area
- 2.5 *ISO Standards*:⁴
- ISO/IEC TR 9789** Information Technology—Guidelines for the Organization and Representation of Data Elements for Data Interchange-Coding Methods and Principles
- ISO 12200** Computer Applications in Terminology—Machine-Readable Terminology Interchange Format (MARTIF)—Negotiated Interchange
- ISO 12620** Computer Applications in Terminology—Data Categories
- ISO IS 12207** Information Technology—Software Life Cycle Processes
- ISO IS 15188** Project Management Guidelines for Terminology Standardization
- ISO 15189** Quality Management in the Clinical Laboratory
- ISO DIS 15193** Measurement of Quantities in Samples of Biologic Origin—Reference Methods
- ISO DIS 15194** Measurement of Quantities in Samples of Biologic Origin—Reference Materials

³ Withdrawn 1988.

⁴ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

ISO 15195 Requirements for Reference Measurement Laboratories

ISO WD 15288 System Life Cycle Processes

ISO 15440 Guide for Life Cycle Processes

ISO 17511 Traceability of Calibration and Control Materials

2.6 Other Standards:

AAMI SW68:2001 Medical Device Software-Software Life Cycle Processes⁵

ANSI X12⁴

CEN ENV 1613 Medical Informatics—Messages for the exchange of laboratory information⁶

CEN ENV 1614 Healthcare Informatics—Structure for nomenclature, classification and coding of properties in clinical laboratory sciences⁶

CEN EN 12017 Medical Informatics Vocabulary (MIVoc)⁶

CEN EN 12264 Categorical Structures of Systems of Concepts—Model for Representation of Semantics (MOSE)⁶

Internet RFC 1521 N. Borenstein, N Freed MIME [Multipurpose Internet Mail Extensions] Purpose: Mechanisms for Specifying and Designating the Format of Internet Message Bodies Bellcore Innosoft Sept. 1993⁵

ANSI/CLSI ASTP2 Point of Care In-vitro Diagnostic Testing⁴

CLSI AUTO1-A Laboratory Automation: Specimen Container/Specimen Carrier⁷

CLSI AUTO2-A Laboratory Automation: Bar codes for Specimen Container Identification⁷

CLSI AUTO3-A Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices and Information Systems⁷

CLSI AUTO4-A Laboratory Automation: Systems Operational Requirements, Characteristics and Information Elements⁷

CLSI AUTO5-A Laboratory Automation: Electromechanical Interfaces⁷

CLSI LIS-1A Specification for Low Level Protocol to Transfer Messages between Clinical Laboratory Instruments and Computer Systems⁷

CLSI LIS-2A Specification for Transferring Information between Clinical Instruments and Computer Systems⁷

CLSI LIS-3A Guide for Procurement of a Clinical Laboratory Information Management System (CLIMS)⁷

CLSI LIS-5A Specification for Transferring Clinical Observations between Independent Computer Systems⁷

CLSI LIS-7A Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory⁷

CLSI LIS-8A Guide for Functional Requirements of Clinical Laboratory Information Management Systems⁷

CLSI LIS-9A Guide for Coordination of Clinical Laboratory Services in an Electronic Health Record Environment

and Networked Architectures⁷

CLSI POCT1 Point of Care Connectivity⁷

DICOM Supplement 15 Visible Light Image, Anatomic Frame of Reference, Accession and Specimen for Endoscopy, Microscopy, and Photography⁸

EIA/IEEE J-Std-016 Standard for Information Technology, Software Life Cycle Processes, Software Development, Acquirer-Supplier Agreement⁹

IUPAC/IFCC Silver Book: Compendium of Terminology and Nomenclature of Properties in Clinical Laboratory Sciences¹⁰

IUPAC/IFCC Properties and Units in Clinical Laboratory Sciences X Properties and Units in General Clinical Chemistry¹⁰

IUPAC/IFCC Properties and Units in Clinical Laboratory Sciences XII Properties and Units in Clinical Pharmacology and Toxicology¹⁰

NCPDP SCRIPT v9.0¹¹

RxNorm¹²

3. Terminology

3.1 Definitions—Terminology related to general information systems appears in **ANSI X3.172** and **ANSI/IEEE 610.12**. Terminology relating generally to healthcare information appears in **CEN EN 12264** and **CEN EN 12017**, Terminology **E 2457**, and Unified Medical Language System (UMLS). The terms used frequently from these sources appear here, in addition to those terms specific to this practice.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 health information network, *n*—set of data domains (nodes) and communications pathways (arcs) serving a healthcare constituency with information management services.

3.2.2 identifier, *n*—symbol used to name, indicate, or locate.

ANSI/IEEE 610.12

3.2.2.1 Discussion—Identifiers may be associated with such things as data structures, data items, or program locations.

3.2.3 practitioner, licensed, *n*—individual at any level of professional specialization who requires a public license/certification to practice the delivery of care to patients.

E 1384

3.2.3.1 Discussion—A practitioner may also be a provider.

3.2.4 provider, *n*—business entity that furnishes healthcare to a consumer.

E 1384

3.2.4.1 Discussion—This term includes a professionally licensed practitioner who is authorized to operate a healthcare delivery facility.

3.3 Acronyms—The following acronyms are used in this practice and may also appear in other standards listed in Section 2.

⁸ Available from NEMA, Suite 1752, 1300 N. 17th St., Rosslyn, VA 22209.

⁹ Available from the Institute of Electrical and Electronics Engineers, Inc., 1828 L St., NW, Suite 1202, Washington, DC 20036-5104.

¹⁰ Available from the IUPAC Secretariat, PO Box 13757, Research Triangle Park, NC 27709-3757.

¹¹ Available from the National Council for Prescription Drug Programs, 9240 E. Raintree Dr., Scottsdale, AZ 85260-7518.

¹² Available from Reference and Web Services, National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894.

⁵ Available from the Association for Advancement of Medical Instrumentation, 1110 N. Glebe Rd., Suite 220, Arlington, VA 22201-4795.

⁶ Available from the European Committee for Standardization, 36 rue de Stassart, B-1050 Brussels, Belgium.

⁷ Available from the Clinical and Laboratory Standards Institute, 940 West Valley Rd., Suite 1400, Wayne, PA 19087-1898.

- 3.3.1 *CAP*—College of American Pathologists
- 3.3.2 *CDC*—Centers for Disease Control and Prevention, Department of Health and Human Services
- 3.3.3 *CDIM*—Common domain information model
- 3.3.4 *CDSS*—Clinical decision support systems
- 3.3.5 *CLIMS*—Clinical laboratory information management system
- 3.3.6 *CMS*—Centers for Medicare/Medicaid Services
- 3.3.7 *CPR*—Computer-based patient record
- 3.3.8 *DHHS*—Department of Health and Human Services
- 3.3.9 *DIM*—Domain information model
- 3.3.10 *EC*—Electronic commerce
- 3.3.11 *EDI*—Electronic data interchange
- 3.3.12 *EHR*—Electronic health record
- 3.3.13 *HIN*—Health information network
- 3.3.14 *ICT*—Information and communication technology
- 3.3.15 *IDS*—Integrated delivery systems
- 3.3.16 *ISA*—Information systems architecture
- 3.3.17 *LAS*—Laboratory automation system
- 3.3.18 *LIMS*—Laboratory information management system
- 3.3.19 *MDSS*—Management decision support system
- 3.3.20 *MCO*—Managed care organization
- 3.3.21 *MPI*—Master person/patient index
- 3.3.22 *NCPDP*—National Council for Prescription Drug Programs
- 3.3.23 *NCVHS*—National Committee on Vital and Health Statistics
- 3.3.24 *NPF*—National Provider File
- 3.3.25 *NPI*—National Provider Identifier
- 3.3.26 *NPS*—National Provider System
- 3.3.27 *NUCC*—National Uniform Claim Committee
- 3.3.28 *PIMS*—Pharmacy information management system
- 3.3.29 *POC*—Point of care
- 3.3.30 *POCT*—Point-of-care testing
- 3.3.31 *PPO*—Preferred Provider Organization
- 3.3.32 *SNOMED*—Systematized nomenclature of medicine
- 3.3.33 *SSAN*—Social security account number (also SSN)
- 3.3.34 *UMLS*—Unified medical language system
- 3.3.35 *WPC*—Washington Publishing Company

4. Significance and Use

4.1 Health information networks (HINs) have arisen in recent years as a way to share common information within organizational arrangements among those healthcare facilities that have been formed into large, more comprehensive integrated delivery systems (IDS) and managed care organizations (MCO) offering a full range of healthcare services, both inpatient and ambulatory.

4.2 The specific organizational structures to which the MCO term was originally applied most probably have evolved into something quite different. Furthermore, IDS organizations are contracting with other organizations that have a market larger than a single IDS itself and are buying such services for themselves rather than offering them internally.

4.3 These organizations will need a frame of reference for the global information needed to provide all of the services required during patient care. For a global Concept Model consult ADA Specification 1000.0–1000.18 and TR 1039.

4.3.1 Pharmacotherapy will require a number of these services, including those of the clinical laboratory for therapeutic drug monitoring as well as pharmacy services of both resident and nonresident care organizations and stand-alone pharmacies to ensure freedom from medication errors and conduct ongoing investigations of both the outcomes of care and the management of resources related to pharmacotherapy.

4.3.1.1 Pharmacotherapy functions include prescribing (clinical orders), dispensing, administering, and monitoring, which support “pharmaceutical care” defined as “provision of drug therapy to achieve desired therapeutic outcomes that improve a patient’s quality of life.” These functions address patients’ needs that require information support as noted in [Table 1](#).

4.4 Another aspect of the monitoring function is the development of instrumentation for testing at point of care (POCT) for high-value immediate-benefit services that support pharmacotherapy. POCT, however, needs supervision and training from skilled laboratorians for the actual performers, whether that supervision comes from within the IDS or outside of it. This range of operation is only achievable by distributed HIN structures that shall have the same quality of clinical and data services as offered by laboratories close at hand. Data management of POCT is documented separately (see CLSI POCT1, ASTP2), but such data management for support of pharmacotherapy shall be placed into the broader context of this practice and linked to [CLSI LIS-9A](#). Thus, this practice should be used to first organize the global domain and then the interconnected subdomains.

4.5 To provide common systematics for documenting coordination of pharmacotherapy services within the HIN structure, the problem has been broken down within this practice into identification and characterization of, first, the global domain and the business framework into which coordinated pharmacotherapy services will fit as a component. Then the constituent pharmacotherapy subdomains are addressed; these are represented as nodes (for example, see [Table 4](#)) in the network. Next, the characterization of the arcs in the network are treated, again focusing on the logical content and not the implementation. When the logical structure of the network is well understood in terms of its scope, purpose, and constituents, then enumeration of alternative implementation strategies and methods/techniques can be effectively considered, followed by selection of an alternative, or a set of compatible alternatives. Finally, selection of an evaluation methodology and its use in managing ongoing operation and evolution of pharmacotherapy services coordination as part of the overall evolution of

TABLE 1 Patient’s Needs

Patient Need	Drug Therapy Related Problem
Appropriate indication for therapy	Unnecessary drug therapy, duplicate drug of same class or different name
Effectiveness of therapy	Inadequate dose/duration, wrong drug ordered
Safety of therapy	Adverse drug reaction, excessive dose/duration
Ability to comply with therapy	Inadequate compliance
Treatment of all active conditions	Needs additional drug

TABLE 2 ISA Framework for Healthcare Informatics Standards

	Why	When	Who	What	How	Where
Vision [Guidelines]						
Scope (contextual)	Goals (motivation)	Events (time)	Stakeholders (People)	Values (content)	Processes (function)	Locations (Network)
	1. Personal/ PublicHealthcare delivery business case	2. Identification of significant care/care delivery events	3. Essential health Service Organizations and Functions	4. Description of important healthcare service and care delivery information	5. Important healthcare and care delivery services	6. Identification and description of organization and individual locations
Design [Standards]						
Enterprise Model (Conceptual)	Objectives	Timeline	Organization	E-R Data Model	Process Model	Interface Architecture
	7. Personal health benefit and care delivery business objectives	8. Sequence and timelines of healthcare services	9. Healthcare information workflow	10. Semantic description of healthcare processes	11. Conceptual activity model of healthcare delivery	12. Structure and interrelationship of healthcare facilities
System Model (Logical Design)	Requirements	Phases	Hierarchies	Logical Data Model	Data Flow	Network Model
	13. System Functional Requirements	14. Healthcare event phases and process components	15. Healthcare information system human-system interface architecture	16. Logical data model for healthcare information	17. Application architecture with function and user views	18. Connectivity and distributed system architecture
Implementation [Standards]						
Technology Model (Physical Design)	Knowledge Design	Control Structure	Human-Technology Architecture	PhysicalData Model	Structure Chart	System Architecture
	19. System Operational Requirements	20. Healthcare information system control structures	21. Healthcare information system human system interface description	22. Physical data model for healthcare information	23. System Design, language specification and structure charts	24. Health system information network detailed architecture
Components (Modules and Subsystems)	Knowledge Definition	Timing Definition	Security Architecture	Data Dictionary	Program Description	Network Architecture
	25. Technical Requirements	26. Healthcare Information System component timing descriptions	27. System Security Architecture and Operations	28. Healthcare Information Metadata and DBMS scripts	29. Code Statements, Control blocks, DBMS stored procedures	30. Physical data network components, addresses and communication protocols
Operation [Standards]						
Functioning System	Strategy	Schedule	Organization	Data	Function	Network
	31. Technology Operational Requirements	32. Healthcare information system operation Schedules	33. IS participant description	34. Functioning database, knowledgebase	35. User procedural system and documentation	36. Operating health system communication network

the HIN itself will be covered. Such an approach should then allow practitioners, pharmacists, clinical laboratorians, information system personnel, and any external suppliers who may be involved, to define, plan, implement, and use a networked architecture for coordination of the pharmacotherapy service component of an EHR environment to be implemented within a given enterprise-networked architecture. This development can be organized into the life-cycle processes defined in IS 12207 and **ISO WD 15288**, **ISO 15440**, AAMI SW68:2001 and **ANSI/IEEE 830**, 1058, 1062, 1063, 1233, 12207.0, 12207.1, 12207.2, 1074, 1074.1, 1220, 1490 and Guide **E 2066**.

5. Identification of the Network Domain

5.1 In order to encompass all of the aspects to be served by a networked architecture provided for coordinating all of the services serving pharmacotherapy by each specific care setting

and type, the global business objectives shall be stated, the roles of the various players in the care process outlined, and the increasingly specific content of the domain to be networked shall be established. This is usually done using a matrix model that defines all of the dimensions starting from the most general to the more technical. In healthcare, this technique is used as described in Guide **E 2145**. **Table 2** gives an example of such a matrix. The technique, detailed further in **5.2**, has been described by Zachman **(1)**¹³ as the information systems architecture (ISA) framework and has been implemented using several software tools **(2-5)**. From examination of this matrix format, further modeling of the business components, the

¹³ The boldface numbers in parentheses refer to the list of references at the end of this standard.

TABLE 3 ISA Framework for Pharmacotherapy Informatics Standards

Zachman	Why	When	Who	What	How	Where
Vision [Guidelines]						
Scope	Goals	Events	Stakeholders	Values	Processes	Locations
	Provide pharmacotherapy services Provide integrated Decision Support	24 Hr Service Just-in-time inventory Continuous Resource Mgt Immediate Claims processing	Pharmacy Clinical Laboratory Practitioner Clientele Suppliers Payers Patients	Services Requested Data Supplier Data	Services Request Data Work Mgt Resource Mgt Claims processing	Pharmacy Distributed Lab Practitioner Site of Care Network Domain
Generic [Standards]						
Enterprise Model	Objectives	Timeline	Organization	E-R Data Model	Process Model	Interface Architecture
	Request services Collect/transport Specimens	Milestone Chart PERT/CPA/Gantt	IDS MCO Reference Lab	High Level Data Model (IDEF1X)	Process Model UseCase/Actors (IDEF0)	Patterns of Service Utilization Health Benefits/ Objectives
System Model	Requirements	Phases	Hierarchies	Logical Data Model	Data Flow	Network Model
	Functional requirements Health Knowledge Architecture	IDEF3 Timeline Diagram	Organizational Hierarchies	Pharmacotherapy Data Model EHR Data Model IDEF1X/Objects		Information Architecture
Implementation [Standards]						
Technology Model	Knowledge Design	Control Structure	Human-Technology Architecture	PhysicalData Model	Structure Chart	System Architecture
			Interface Style Guide	Pharmacy System/ EHR Database Models		
Components	Knowledge Definition	Timing Definition	Security Architecture	Data Dictionary	Program Description	Network Architecture
	Populate Knowledge Databases			CLIMS/EHR Data Dictionaries	Structure Charts	
Utilization [Standards]						
Functioning System	Strategy	Schedule	Organization	Data	Function	Network

TABLE 4 Types of Information Domains (Nodes) in a Networked Architecture

Node Type	Relative Numbers
Pharmacotherapy workstation	5
Point-of-care settings	10
General EHR	50
Public health/reporting	2
Reference data	1
Commercial/administrative	20
Pharmaceutical dispensing services	7
Imaging services	5

processes, and the data structures and representations is sequentially undertaken to identify the nodes and arcs of the network that support the business case for the network. The detailed modeling of the data domains, using the business considerations given in 5.2, is then applied, as appropriate, using the approaches documented in Guide E 2145, to each node. This activity will identify both the data that are required for activities that are internal to the node and that may be exchanged with other domains for support of pharmacotherapy services. The business case for each node shall be understood

as part of the identification of the node and so a detailed internal business model should result that drives the process model for that node and may be independent of the models for a different node of the same type. Since the interactions of the nodes are known from identification of the arcs, those data needed by each arc can be generally identified and later characterized, as noted in Section 7. Following these steps, which identify the “requirements” of a network, effective delineation of implementation strategies that are consistent with the business case can be documented and a selection made of implementation tools and techniques that are appropriate to the selected life cycle.

5.2 Modeling of the Business Domain—A Zachman ISA framework matrix of the dimensions of the informatics standards applied to healthcare is given in Table 2. From this broad domain, standards dealing with those aspects relevant to coordination of pharmacotherapy services are shown in Table 3. The enterprise that is developing a networked architecture for coordinating pharmacotherapy services in an EHR environment shall refine this perspective to that embracing the interests of the enterprise. This refinement will begin by looking at each

of the cells in the upper left of the matrix dealing with scope and concept of operations; see [ANSI/IEEE 1362](#) (ISA matrix cells 1-6) and then moving to the right followed by moving down from content issues to implementation issues reflecting use of a particular technology and techniques. Once a refined framework is available, then more specific modeling of processes and data take place. (See Guides [E 1340](#) and [E 2145](#).) These will be focused first on the source and destination information domains (nodes) and then on the arcs.

5.2.1 A Representative Case—Most healthcare enterprises, and probably most care settings ([6.2](#)), will consist of both ambulatory and inpatient settings ([6.3](#)) in addition to appropriately located community pharmacies. The “concept of operations” ([ANSI/IEEE 1362](#)) should enumerate, for the healthcare enterprise offering pharmacotherapy interventions, the range of support that each care location will provide with respect to the identified care settings served, prepared as Cells 1-2 and 1-3 in [Table 2](#). The focus of Cell 1-6 in [Table 2](#) should be to document the service and patient referral patterns of the care sites (see [Appendix X1, Fig. X1.1](#)) and show the enterprise organizational network diagram. The pattern of intercommunication between nodes, the logical network, would be prepared as Cell 3-6. An example of this is shown in [Appendix X1, Fig. X1.2](#). These boundary conditions allow each pharmacy service node to identify its own business plan for internal management purposes as a complement to the enterprise business plan. The example in [Appendix X1](#) gives a basic documentation of this process phase for a community pharmacy serving both a family practice ambulatory care clinic and a general practice hospital. The initial ISA matrix is shown in [Table 3](#), which identifies the models for the enterprise and those for each service location needed to characterize the main information domains. Process models for the enterprise and each location are developed followed by data models for pharmacy, CLIMS, and EHR domains as guided, respectively, by [6.2](#) and [6.3](#). These models identify data elements and associated value sets required throughout the enterprise. When full characterization of nodes has been completed, additional node-specific data will next be identified.

5.3 Modeling of the Processes—Several techniques are available for the modeling of processes supporting pharmacotherapy, including IDEF0 (Ref ([3](#)) and IEEE 1320.1), use cases ([4](#)), and data flow diagrams ([5](#)). In each technique, both actions and the “actors” ([4](#)), or individuals/organizations, shall be identified and their activity described first globally and then in detail to identify scenarios involving pharmacotherapy services. An example of this technique is shown in [Fig. 1](#). Process models are generally hierarchical if using IDEF0 (but also using use cases) starting first at the global level and then increasingly refined to an appropriate level of detail needed to understand fully the activities within the defined domain. The purpose of these process models is to examine systematically and comprehensively all of the processes producing information within the healthcare enterprise that affect the defined business case noted in [5.2](#). They should be applied first to the enterprise and then to the nodal domains. [Fig. 1](#) shows a

representative use-case/actors model for a basic physician office pharmacotherapy scenario and setting (see [6.2](#)) in an enterprise view.

5.4 Modeling of the Data Domains—Data modeling, as noted in [5.2](#), involves systematically and comprehensively describing the data involved in processes detailed in [5.3](#). It includes identifying or constructing the terminologies needed to populate value sets for the defined data attributes. For example, this technology function shall draw on consensus vocabularies developed by professional specialty groups, public agencies, or other involved organizations with broad involvement in healthcare, if true interoperability is to be achieved. For measurement/observation names that may be involved in decisions about pharmacotherapy, see the LOINC vocabulary (<http://www.regenstrief.org>). The value sets may be selected from these more global vocabularies. To understand truly the data structures and data representations, an understanding of the processes is required. See Chen ([11](#)). Thus, process modeling should, but many times because of haste does not, precede data modeling. In the case in which data modeling shuns formal process modeling, an intuitive—and thus generally incomplete—process model drives the data modeling. The urge to omit the process modeling phase should be resisted. Rather, the modeling activities may be carried out iteratively first at a high level and then in increasing detail. [CLSI LIS-8A](#) and Practice [E 1715](#) delve into data modeling in constituent functional domains that relate to pharmacotherapy. A representative depiction of involved data objects is given in [Appendix X2](#). These activities, however, need to be placed in the context established by the business model ([5.2](#)) and the process models ([5.3](#)). (See also Ref ([9](#)).) This task is taken up in Section [6](#).

6. Characterization of the Network Nodes

6.1 One of the reasons that this standard is a practice and not a specification is that it is not possible to detail, in a global standard such as this, the specifics of the various factors that may need to be considered at the individual enterprise level. Likewise, for each of the node types, only a general guide to the issues that need to be considered is given here. The steps given in IS 12207 on Software Life Cycles and [ISO WD 15288](#) on System Life Cycles will need amplification and specification as part of the documentation for a specific enterprise and specific project. In considering the types of nodes that may be involved in coordination of pharmacotherapy services, a wide variety of activities become recognized that may not generally be included as separate data domains. Some of those included are shown in [Table 4](#). Because the view of pharmacotherapy services from the perspective of the performers of the services in each of these other domains may not be a realistic picture of the activity required to conduct its role at these other nodes, this section sets out to identify, and generally characterize, the business, processes, and data that may be involved in a representative real instance of each type of node in a working network so that network planners and designers have a comprehensive reference to these characteristics. While a real instance may contain one or more of these functions, but not necessarily all of those outlined here, it will allow planners/designers to identify the existing processes at that node and the

Basic Pharmacotherapy Scenario

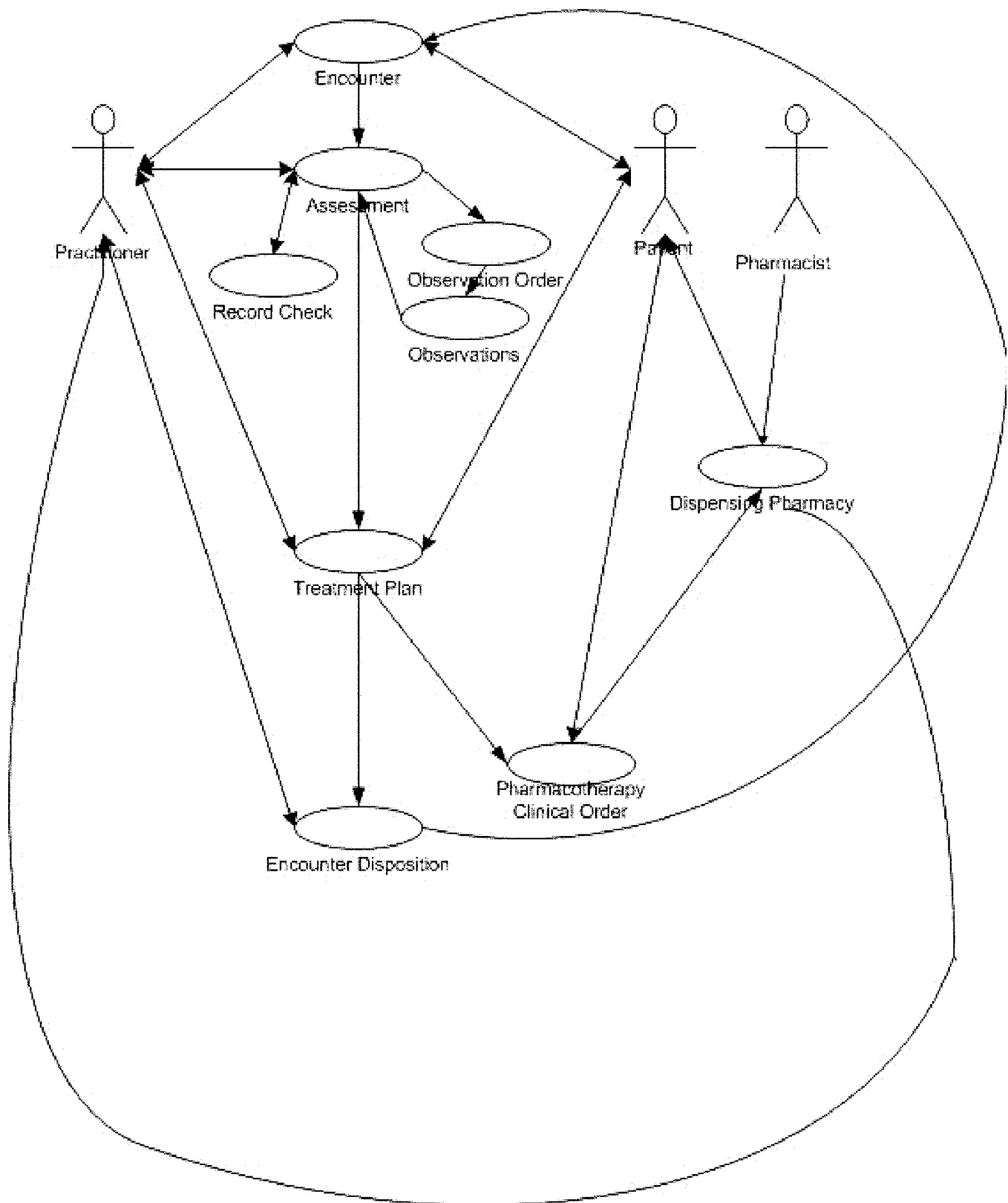


FIG. 1 Use-Case/Actor Model for a Physician Office Pharmacotherapy Situation

data needed to support them. Thus, the informaticians, pharmacists, practitioners, operators, and administrative staff can clearly document the functional and data components that are truly required for quality performance of their pharmacotherapy roles in their organization. The following subsections will probe the perspectives of the practitioners in some of the settings of care that will require pharmacotherapy information support. Privacy, Confidentiality and Security Concerns given in Guides E 1762, E 1869, E 1985, E 1986, E 1987, E 2084, E 2085, E 2086 and Specification E 2147 should be considered.

6.2 *Pharmacotherapy Service Domains*—Participating nodes for pharmacotherapy services in an enterprise network may be of a variety of types:

- (1) Office practices (service types/configurations)
- (2) Emergency services workstation (service types/configurations)
- (3) Large ambulatory clinic pharmacy
- (4) Hospital/inpatient-facility pharmacy
- (5) Commercial reference and healthcare enterprise laboratories
- (6) Stand-alone (community) pharmacies
- (7) Master patient index
- (8) National Provider File

6.2.1 Each node may have its own size and configuration of workstations that may interface with instrumentation and process, in a hierarchical fashion, the data relevant to its own operations. Each node may have a somewhat different process and data model depending upon the homogeneity of the organization of which it is a part or the function that it provides to the organization. These models should be identified within the business model. Guides E 1762, E 2017 and Specification E 2084 should be considered with respect to textual data.

6.2.2 *Office Practices*—The office practices are the predominate setting for initiating pharmacotherapy and yet are underserved by integrated information services supporting clinical decisions based on the type and nature of the decision behavior to be involved. Pharmacists are now becoming a part of such practices and have specific roles in ordering pharmaceutical interventions. For those therapeutic agents with low therapeutic range, prompts and guidance regarding dosage appear now in printed media. Support by, or communication with, pharmacotherapy expertise is not now consistent with the time frame of office visits. Nevertheless, the facts of pharmacotherapy must find their way expeditiously into the EHR (or paper records) serving the practice and into pharmacotherapy service records supporting quality control (see example in Fig. 1). Special information services may serve the information management requirements of the group practices and interface with the individual practice EHR domains of the group. Since the EHR configuration of each group member may not be identical to that for all members, the nodes that are different shall be separately described and clearly documented. If a group uses a common configuration accessed by each member, then a common description will suffice.

6.2.3 *Large Clinic Pharmacies*:

6.2.3.1 A pharmacy serving a large clinic offers a much larger range of services and this requires additional information

support capabilities and a detailed configuration of its PIMS. Either the PIMS itself and its linkages with CLIMS as part of clinical laboratory services serving pharmacotherapy, or at least some of the EHR nodes served, may require interoperability with either a CLIMS or a LIMS (see Guides E 1578 and E 2066) serving pharmaceutical support settings, such as in large clinical drug trials. Such may be the case if the patients served may have requested clinical laboratory services such as measurements directed at revealing toxic effects of the therapeutic agent. CLSI LIS-8A develops the CLIMS requirements for handling this responsibility.

6.2.3.2 The PIMS in such a setting may take on a structured clinical decision support capability and be responsible for organizing the data in the most effective way for decision support of the practitioner clients of the clinic for pharmacotherapy. The PIMS capability shall enumerate and document the sources of its knowledge, its representation, and its mode of use in supporting clinical decisions of its practitioners. In a networked architecture, referential data in other nodes may be used, but the process and the data nodes shall support the business model (see 5.2) of the clinic and its pharmacy with respect to how this is done.

6.2.4 *Hospital/Inpatient Facility Pharmacies*—Hospital inpatient enterprises will undoubtedly service many patient care nodes within the organization's architecture, and there will be a variety of specialty clinical decision support views needed. Consequently, the business case (see 5.2) and the informatics standards (see 5.2 and 5.3) shall be identified that are associated with each of the patient care nodes served to define the PIMS requirements for supporting these care sites and for those sites that are served outside the administrative boundaries of the enterprise (see 6.2.2 and 6.2.3). Forums shall also be arranged to depict the homogeneity or diversity of the sites served, their situation, and the possibility of agreeing on common conventions needed at each level of the pharmacotherapy information framework for each of these patient care-site nodes in the network.

6.2.5 *General Reference/Health Enterprise Laboratory*—General reference laboratories are separate enterprises serving many nodes that represent a wide variety of care settings (10) and may provide measurements needed in pharmacotherapy (See CLSI ASTP2, GP19, AUTO 1A–AUTO 5A, LIS 1A, LIS 7A, ISO 15189, ISO DIS 15193, ISO DIS 15194, ISO 15195, and ISO 17511). Each of these enterprises shall model its enterprise setting based upon its business case, but its domain information model (DIM) shall have commonality with that of its customers for the arcs of information flow to function optimally. Thus, a common model is an advantage that both customers and suppliers shall understand in designing an information architecture to meet its business needs. As common conventions (standards) for DIMs are agreed upon, these should form a starting point for documenting the enterprise information architecture for the clinical laboratory. Common therapeutic drug monitoring/toxicology laboratory services include:

- (1) Measurement of levels of low-therapeutic-range antimicrobials,
- (2) Measurement of levels of anticonvulsants,

- (3) Measurement of levels of anticoagulants, and
- (4) Measurement of levels of antiarrhythmics.

6.2.6 *Nonclinical/Analytical Database Domains*—

Nonclinical domains include clinical and health services research databases, for example, “Registries,” clinical trial databases, and so forth. Examples of nonclinical information domains that will draw on pharmacotherapy data and patient attributes are:

- (1) Trauma Registries
- (2) Tumor Registries
- (3) Disease (e. g. Diabetes) Registries
- (4) Immunization Registries
- (5) Drug Trial Registries

6.2.7 *Emergency Medical Facilities/Point-of-Care Workstations*—Point-of-care workstations constitute a special situation beyond that described in 6.2.2 concerning office practice above (see example in Fig. 1). This node shall be carefully characterized in terms of the “clinical view” served by the workstation and its broader role in the entire architecture. Examples of this kind of node include workstations in emergency departments (see Guide E 1744) and critical care settings. Others settings might include anesthesiology or operating suite settings in which major segments of the EHR may be needed to support the clinical view, in addition to any attached measuring instrumentation. A careful characterization of contributions of the clinical laboratory for toxicologic or therapeutic drug monitoring or other pharmaceutical care information domains needs to be made. These nodes carefully manage all contributed data in an integrated fashion to support the clinical decision setting and situation, leaving the attributes used stored in the nodes and information domains contributing to the clinical view. How this is done needs careful documentation of the “business,” the processes, and the data supporting the setting and the situation.

6.2.8 *MPI Functions in Pharmacotherapy*—An MPI capability would allow access to patient EHR information by practitioners in all settings of an enterprise and by those individuals in any contractual arrangement that the host enterprise might make for access to pharmacotherapy related information for any patient. Certain demographic data may be needed to interpret measurements made. In spite of this, only key individuals may need to know the individual patient and access these data. Privacy and confidentiality will be key in a networked architecture for the EHR environment. Guides E 1869, E 1986, E 1987, E 1988, E 2085, and E 2086 delve into the responsibilities of practices and pharmacies with supporting PIMS to meet these requirements that are mandated in PL 104-191 (Health Insurance Portability and Accountability Act – HIPAA). The unique identification of patients associated with prescriptions in the extended environment of the IDS will be conducted by the MPI function documented in Practice E 1239 to acquire that demographic data (see Practice E 1715) needed for providing its services to the practitioner. The MPI will also play a role in gathering, maintaining, and using those patient-specific data that support both patient safety and quality improvement that are likely to be separate case data structures from the EHR but with patient-specific data that support medication reconciliation and root cause analyses

leading to sentinel event reporting and on-sentinel event tracking. Either HL7 messages or CORBA Services (see 7.4.4) can provide the messaging/data transfer capability for both the MPI and the mediated MPI used and also for the RADT functions needed to provide this capability. Each PIMS site will need to document clearly the way that this component of the networked architecture will be integrated into the PIMS/EHR domains and how to deal unequivocally with the privacy/confidentiality aspects.

6.3 *EHR Domains*:

6.3.1 At the current time, there are few fully functional EHR systems and all have arisen from proprietary perspectives without the frame of reference of a common domain information model (CDIM) with which the EHR system should be conformant. Moreover, many systems are merely unique databases to capture data produced for claims processing or data reporting that stem from historically unique situations. The terms “data warehouses” or “data repositories” are used for many systems instead of the rather specific definition of a EHR as one that conforms in structure and representation to Practice E 1384. The process and data models of the existing systems at each node shall be documented and compared with the data and processes required at the other nodes with which each must communicate, as identified in the global network. This should be done using Practice E 1384 and Specification E 1633 as references, in addition to any working documentation of the embryonic CDIM. The specific clinical views, such as that for EMS defined in Practice E 1744 or Practice E 2473 for occupational/environmental health, should be identified to understand the clinical decisions being made at that node (see HL7). Additional nodes that support pharmacotherapy consultants or patient education, which includes pharmacotherapy, may also be involved. The EHR nodes shall be sufficiently broken down hierarchically in the family of models for the node that cost-effective implementation alternatives can subsequently be identified. For the therapeutic setting, the nature of the requesting dialog and the decision-support capabilities for clinical views shall be identified if those nodes are to be transparently integrated regardless of the location of the performing laboratory.

6.3.2 The following subcategories that focus on particular settings and “clinical views” should be considered:

- (1) National Provider File
- (2) Master patient indexes
- (3) EMS prehospital
- (4) EMS receiving hospital: initial care
- (5) EMS receiving hospital: trauma hospital
- (6) Inpatient care—general service
- (7) Inpatient care—specialty service
- (8) Ambulatory care facility—family practice
- (9) Ambulatory care—specialty practice
- (10) Ambulatory care—public health practice

6.3.2.1 Each of these categories needs to be considered from the point of view of integration of pharmacotherapy decisions into the decision-support dialog for practitioners in concert with the defined PIMS nodes. Some of these considerations will be dealt with in the following sections.

6.3.3 *National Provider File*:

6.3.3.1 The NPF was created to first (but not exclusively) serve CMS for Medicare patients. NUCC maintains the taxonomy and that website is supported by WPC. It has the capability of characterizing every “provider,” that is, every individual and organization involved in healthcare. It contains a taxonomy of providers that can categorize each entity to which an NPI is assigned. It will have the ability to be accessed, with appropriate security control, via telecommunications. Thus, it complements the MPI by being able to help validate the identity of “providers” and provide, under controlled conditions, certain attributes associated with that identity. It will be a resource for both the PIMS and EHR environments to populate, and keep up to date, those attributes needed regularly in information management within the pharmacotherapy domain. The way that it will evolve after its introduction remains to be seen. The electronic commerce community has organized a National Provider Identifier Outreach Initiative (NPIOI) with the Workgroup For Electronic Data Interchange (WEDI). See its website at <http://www.wedi.org/snip/> for evolving activities. Nevertheless, planning a networked architecture to take advantage of the potential capabilities should be envisioned. Administrative services messages, as described in 7.4.4, will be the primary vehicle for implementation of the services of this node.

6.3.3.2 The National Provider File (NPF) is a component in the National Provider System (NPS) that catalogs all practitioners and provider organizations who submit claims for Medicare and is administered by the Center for Medicare/Medicaid Services (CMS) of the U.S. Department of Health and Human Services (DHHS). Each practitioner and provider organization have unique identifiers that are intended to be part of the standards involved in healthcare as developed by the ANSI Health Informatics Standards Board (HISB)—now transitioning to the Health Information Technology Standards Panel (HITSP). As part of that standards program, CMS agreed to develop the NPI as part of their responsibilities in administering Medicare since it had a requirement under HIPAA to identify individual practitioner and organizations that could then become a central resource for that function throughout healthcare as the need evolved. Organizations and individuals will need to be identified within the structure and content of the EHR, as documented in Practice E 1384, and also in networked architectures nodes that will need this function for which the NPS will be the reference source. Proper authority will be required to query this file and extract required information for the enterprise domain, and this capability shall be recognized in the design of the network domain. CMS will be responsible for maintaining the currency of NPF and will contract to various SDOs for its components. The WPC (see: <http://www.wpc-edi.com/taxonomy/codes.html>) supports the taxonomy of providers website. Clinical laboratories, among other provider organizations that are identified with the NPI for each node, can be used in messaging traffic as well for operations within each node. This vocabulary has been incorporated into Specification E 1633.

6.3.4 *Master Patient Index and the EHR*—A number of organizations are now considering online MPIs that would allow online identification of patients and key attributes. Such

a capability would allow PIMS (see 6.2.8) to identify prescriptions sent either from outside the host facility or from other enterprise domains accessible from the MPI, depending upon how it is established, and to return dispensing results to the EHR. The characteristics of the MPI domain are described in Practice E 1239, but the use of MPI capabilities for pharmacotherapy is detailed in the documentation of the network architecture. The role of the unique identifiers given in Guide E 1714 should also be considered. That architecture documentation shall include the logical role of the MPI for pharmacotherapy in both the EHR and PIMS domains as well as its implementation aspects, which are discussed in Sections 8 and 9.

6.3.5 *EMS Pre-Hospital*—Each EMS mobile unit is an identifiable and characterized node in a networked architecture. To the extent that the identified EMS unit conducts pharmacotherapy services, its purposes and supporting data structure should be documented and, from that documentation, the needed arcs should be documented that characterize the data exchange requirements to and from that mobile EMS unit and from other nodes in the EMS system. While the component functions of an EMS mobile unit may be similar nationwide, each EMS system has its own requirements, and these need documentation as part of the definition and implementation process. For example, emergency pharmacotherapy needs to be recorded for the intended receiving node and, thus, requires system documentation to foster evolution of appropriate capabilities.

6.3.6 *EMS Receiving Hospital: Initial Care*—Depending upon the enterprise and role assigned to the facility in the EMS system, pharmacotherapy may be begun but not be completed before the patient is stabilized and sent on to a designated EMS trauma hospital. Even if the patient remains at the initial receiving facility, the details of pharmacotherapy need to be judiciously joined with the EHR. This may be the case if the services are POC in the Emergency Department (see Practice E 1744), but the data flow for these situations needs to be documented clearly to understand the information requirements of the node.

6.3.7 *EMS Receiving Hospital: Trauma Hospital*—Depending upon the structure of the regional trauma system, the EMS trauma hospital needs a DIM that shows how it can receive information about pharmacotherapy interventions that have originated either at the scene or in an initial receiving facility. Because of exigencies and distance, these destinations may change during transport, but the pharmacotherapy information needed is common at the receiving nodes and the data flow arcs in the regional system. There shall be documentation of how this information is collected, transmitted, and entered into the EHR and eventually used in support of care. Both data structures and data representation (vocabularies) are components of the DIM for this node.

6.3.8 *Inpatient Care—General Service*—In inpatient care, pharmacotherapy services involve a wide range of the attributes for clinical orders developed in Practice E 1384. The linkage of the attributes to messaging attributes is given in CLSI LIS-5A and ANSI/HL7 v2.4. The way that these attributes are used in the “business” of the enterprise shall be

defined in the concept of operations document (ANSI/IEEE 1362). The way that clinical decision support functions occur in the clinical order process shall be part of both the concept of operations and the requirement specifications documents for the architecture components. The way that the structure of the information architecture supports the pharmacotherapy services in the particular enterprise inpatient setting shall also be part of the concept of operations document and subsequently reflected in the requirements specification. This posture will then be the basis for stating specialty practice information requirements as clinical views as noted in 6.3.9.

6.3.9 Inpatient Care—Specialty Practice—Using the general information services requirements in 6.3.8, the clinical views of the supporting clinical decisions occurring in the specialty practice shall be carefully constructed so that they draw on the general attributes from the clinical order and treatment plans (Practice E 1384) used in requesting services from the pharmacy. These specialty practice views shall have consistency of content for the observations/measurements recorded to support optimally the sequence of steps in an intervention or treatment plan. For example, pharmacotherapy used in clinical views supporting a trauma setting shall be organized to show how this intervention is consistent with that used in subsequent stabilizing, reconstructive, and rehabilitative care such that the trajectory of patient health status (see Practice E 2171) can be clearly seen.

6.3.10 Ambulatory Care—Family Practice—Family practice is probably the most fundamental care setting in health-care, but each practice has a different profile of information needs and access requirements for patient records. As pharmacotherapy services are identified in the description of the practice (such as documented in ANSI/IEEE 1362 concept-of-operations-type document applying to the practice), the data flow arcs and the PIMS and EHR/CLIMS data models for the practice setting shall reflect the nature of the data needs by the practice from both internal and external sources. These steps will lead, in the requirements specification for the project, to the (implementation) technology independent data structures and representations needed by the practice. These requirements then allow selection of alternative implementing technologies. The project can then organize each step (see Section 8) in acquiring functional components for the practice enterprise architecture. Key functional components that will be part of any practice are: registration/admitting/discharge and transfer (RADT), master patient index (MPI), health condition problem list, clinical order entry, encounter recording, and treatment plan. These are developed in Practices E 1239 and E 1384.

6.3.11 Ambulatory Care Specialty Practice—Specialty practice information architectures build upon the fundamental capabilities noted for family practice in 6.3.10 but also shall relate to those inpatient aspects discussed in 6.3.9. The special decision support capabilities and modules supporting specialty data gathering for pharmacotherapy will require component functional modules that condition patient record and referential context-independent data from a variety of in-practice and external data sources. The use of these data-conditioning procedures and referential data (for example, practice guidelines and other knowledge bases: see Table 2 and Cells 4-1 and

5-1) all need description in the requirements specification if they are expected to interoperate with data from the EHR. Requirements to access patient data from other nodes (such as resident care facilities) to follow patient response to treatment in different settings will be needed particularly if the practitioner will be relying on pharmacotherapy specialists to aid in interpretation of observation/measurements made by the laboratory. Thus, the concept of operations and requirements documents will be more extensive than is the case in family practice settings.

6.3.12 Ambulatory Care Public Health Practice—Public health practice settings deal with a wide range of constituents, many of whom may not have an established family practitioner. Even in the best situations, the public health setting may deal with emergency, trauma, or infectious disease situations and could use access to the basic demographic data already gathered by the family practitioner. Even in the pharmacotherapy associated immunization activities supporting infectious disease management, the need for other pharmacotherapy may be needed, and the results will need communication to the regular practitioner to ensure follow up. In addition, communication of public-health-related pharmacotherapy information may also be involved. Thus, again, the basic concept of operations and requirements documents are required to understand clearly all of the information services and requirements for functional modules. Such documentation then allows the public health agency to plan the evolution of its information architecture as its services change in the context of the community health information network architecture. Thus, when new clinical services are offered, a project can be quickly organized to acquire just the needed product information services from suppliers in the market.

6.4 Public/Private Reporting Agency Domains:

6.4.1 The advent of networked architectures has elicited a recognition of the fact that reportable data needed for policy, research, or resource management can be derived from either the EHR or the PIMS nodes, depending upon satisfaction of defined criteria. The nature of the receiving node in a reporting system, and its privacy/confidentiality requirements, shall be documented as well as the process and data models that derive from its business model. These business models shall be obtained from each participating organization in the reporting network to proceed with modeling their uses. Either the process or the data models may be supplied by those organizations insofar as they characterize the nature of the arcs emanating from that node since these will be required by the nodes with whom they communicate, if the arc is to be optimally functional. Some of these public/private reporting agencies are:

- (1) Food and Drug Administration
- (2) Centers for Disease Control
- (3) Pharmaceutical company's drug trial organization
- (4) County/city Public Health Departments
- (5) National Center for Health Statistics
- (6) State Departments of Health
- (7) Universities/research centers
- (8) Private accrediting agencies

6.4.2 A variety of purposes cause reportable pharmacotherapy and adverse drug reaction data that is aggregated by the receiving agencies into research, resource management, or policy databases. The reported data may be used to form “registries” or other statistical or analytical database structures. Some of these are shown in [Table 5](#).

6.5 *Referential Information Domains*—Both pharmacists and clinical practices draw on data published in the scientific literature. The amount of this data has become so immense that any one individual cannot carry it around in his/her head but, rather, needs it quickly in the context of clinical decision-making and during dialog-supporting daily work actions. A networked architecture provides the capability for centralized collection of such referential data with subsequent distributed accesses to these data in an appropriate fashion. For coordination of pharmacotherapy services internally within an enterprise, the data items used by the pharmacy will be largely different from the items needed by the practitioner. Nevertheless, there is a common body of referential knowledge base data needed by both the pharmacy and the practitioner in guiding the requests for pharmacotherapy services. Some of these referential information data are:

- (1) Terminologies,
- (2) Drug product attribute databases,
- (3) Knowledge representations, and
- (4) Pharmaceutical product and logistic information.

6.5.1 Common conventions (standards) for the elements of these structures are critical to interoperability and are only just now being considered. Many reference data are terminological. These healthcare terminologies for pharmacotherapy classes are:

- (1) Procedure names,
- (2) Observation/measurement names,
- (3) Rule-based knowledge representations, and
- (4) Health condition/diagnosis names.

6.5.2 *Terminologies*—A terminology is a collection of terms in a specialty area. Names of measurement procedures and metrology related to the clinical laboratory (see [IUPAC/IFCC](#)) and pharmacotherapy will need to be compatible throughout an enterprise domain. The *LOINC Users’ Guide* ([6](#)) describes how to construct names to be used in these collections, but a clear understanding is needed of how they should be used in the EHR for documenting care and decision-support processes. Solutions, possibly involving knowledge bases (see [6.5.4](#)), will need to be clearly defined and documented so that both the

information domains and messaging use them in a consistent fashion. The Logical Observation Identifiers Names and Codes (LOINC®) terminology ([7](#)), now part of the NLM UMLS vocabulary, uses the rules stated in the *LOINC Users’ Guide*, and it contains the measurement names referring to pharmacogenomical concepts used in the pharmacotherapy training of practitioners that use these special terminologies. Terminologies may need to be developed for special aspects of either the EHR or PIMS information domains. If so, [ISO IS 15188](#), [ISO 12200](#), and [ISO 12620](#) should be used to conduct such projects.

6.5.3 *Drug Product Attribute Databases*—Probably the most important reference data structure for pharmacotherapy is that containing drug products used and the attributes associated with each product. Section [6.5.2](#) discusses the terminologies for the names of drug products, but these names have associated identifiers and links to a complex structure of attributes relating to that product that can guide its use in pharmacotherapy. [RxNorm](#) is one such recent effort. It will have a structure that reflects the simplicity or complexity of the enterprise’s needs. Payer’s needs for “medical necessity” attributes for pharmacotherapy involves a set of associated drug product attributes that details the health conditions/diagnoses for which that drug product provides an effective intervention in support of the treatment plan. Cost, price, and other resource attributes are also indicated. Each preferred name may have associated one or more trade, local or short names and one or more codes from defined coding schemes (such as SNOMED) that classify the drug product in various ways (see [ISO/IEC TR 9789](#)). The business case developed in [5.2](#) will help identify the attributes and standards relevant to the construction of a data model for this data structure.

6.5.4 *Knowledge Representations*—Each enterprise shall identify the context-independent knowledge structures needed to support its business case. One such structure now commonly mentioned is “practice guidelines.” Though few common conventions and collected data by these conventions currently exist, consensus efforts toward this end are underway, with directed interest by the FDA. These data structures provide organization of the concepts that depict their meaning to the practice of healthcare. For pharmacotherapy, concepts provide one means of guiding the request function for integrating the various services in a treatment plan that is consistent with best current understanding and recommended practices. To function in a concerted way, knowledge representations shall be keyed with the specific patient data to return the implications of that knowledge base for that individual. The analysis of the business case in [5.2](#) is the initial step in identifying the requirements for such knowledge representations and the role that such structures will play in the enterprise’s business.

6.5.5 *Commercial Products and the Logistic Chain*—A particular referential data structure for a pharmacy is one containing attributes of products and services involved in operating the pharmacy. These attributes should support the business case developed in [5.2](#) and aid in the resource management functions related to the volume and type of services requested by customer nodes in the enterprise environment. They should be used to develop electronic commerce

TABLE 5 Registries

Type	Purpose	Scope
Pharmaceutical product drug trials	product development	national
Tumor registries	epidemiology	national, regional, and state
Immunization registries	Public Health	national and state
Occupational health registries	research, policy	national
Product safety registries	research, policy	national and local
Practitioner profiling	education, policy	state and regional

(EC) capabilities in supplying the pharmacy node by means of electronic data interchange (EDI) capabilities according to the nature of the underlying platform and implementation strategy developed in Section 8. Considerations that include evolving technologies such as radio frequency identification (RFID) should be included. These attributes should aid in developing costs and pricing structures for service contracts involving nodes in the enterprise or among enterprises that may be customers of the particular enterprise offering services outside its immediate domain.

6.6 Commercial/Administrative Domains—As enterprise organizational structures evolve and healthcare financing arrangements change, the resource management sequelae of coordinated pharmacotherapy services shall also change to reflect correctly the legal requirements for reimbursement for pharmacotherapy services. Clear, simplified, understandable data structures will be needed within defined subdomains to reflect the explicit criteria for payments. Likewise, logistical support of the pharmacy will require gathering of data related to the estimated consumption of supplies, drug products, and maintenance of equipment, not to mention documentation of types and modes of utilization of pharmacy personnel, if effective cost accounting is to occur. Suppliers, to a large extent, now use EC and EDI for supply chain management and these capabilities reflect the ability to deliver just in time, obviating the large inventories needed to buffer changing logistical needs caused by changing patterns of services. The PIMS nodes will need to know how to use this capability internally as well as in messaging implementation (see 7.4.3) of the arcs connecting to supplier nodes.

6.7 Pharmaceutical Services—It is now clear that integration of professional services available within pharmacies with the patient care activities now documented in the EHR will shortly evolve in concert with the EHR evolution itself. The pharmaceutical care information available from pharmacists, whether active within the care or pharmacy settings, shall draw on the treatment plans and clinical medication orders written by practitioners (which may include pharmacy professionals) and shall emphasize compliance to those treatment plans and orders. Additionally, direct advice by pharmacists to the various practitioner specialties during the decision process leading to those clinical orders (see Fig. 1) will also most likely be part of the process. This decision process will also involve the clinical laboratory in monitoring functions when therapeutic drug monitoring may be involved. The nature of those interactions will be described in a (later) standard.

6.8 Imaging Services—Imaging services and pharmacotherapy relate to various contrast agents used in diagnostic studies. Use of the DICOM standard for storage of electronic copies, as well as for a communication format, is recommended for storing images since this provides the associated attributes in addition to the bitmap. These attributes allow identification of the originating sites so that the image archives can be accessed for later retrieval of images should they not be associated with the EHR, even if the imaging site itself may have been organizationally absorbed. Such capabilities shall be part of the enterprise DIM developed from the business case in 5.2.

7. Characterization of the Network Arcs

7.1 Pharmacotherapy interventions in patient care have numerous distributed activities that shall be coordinated if pharmacotherapy is to play its role in the treatment plan of which it is a part. Different activities may occur at different nodes so that information at one node shall be known at a coordinated node to achieve a defined clinical purpose and these activities shall appear as if they occurred in a unified domain. This use shall be designed to achieve this end. The nature of activities was dealt with in Section 6. This section characterizes the display that shall appear transparent.

7.2 Each information domain (node) captures, structures, stores, and manages data within its boundaries but shall create defined data constellations to communicate with other domains. “Messages” (arcs) are logically and structurally defined data constellations packaged for interchange. (See Internet RFC 1521) These constellations constitute the arcs of the network and are discussed here to elaborate a process for understanding what information needs to be exchanged in support of pharmacotherapy, why the interchange is required, and what alternatives exist for how it should be handled. Modeling is introduced as a mechanism for structuring this understanding. This modeling complements its use within the source and destination data domains.

7.3 Modeling for Definition of Arc Content:

7.3.1 Modeling is being used within healthcare informatics not only for definition of messaging by HL7, X12N, NCPDP, and DICOM SDOs within the United States but also by CEN TC 251 in Europe. Modeling is also being used within the ANSI HISB (now HITSP) SDOs as part of the standing committees on Standards Development Coordination to synchronize the models being used for definition of messages with those models being used for the source and destination data domains. CLSI, ADA, and DICOM are primarily involved in domain modeling, although several previous ASTM International laboratory messaging standards (now CLSI) are closely coordinated with HL7. The primary modeling methodology used is object oriented (see IEEE 1320.2 IDEF1X97-Objects) but the entity-relationship modeling conventions and tools are converging with those that are object oriented through the work of the IEEE IDEF effort that originated in the integrated computer-aided manufacturing (ICAM) efforts in the Department of Defense which began 25 years ago. For this section, reference to the use of object-oriented modeling by HL7 will be used.

7.3.2 The Message Development Framework (MDF) (8), now used by HL7, describes a process of sequentially developing four models: use case with actors (process scenario) model, information model, interaction model, and general message design model. The application of this process to messages is described in those standards and will not be detailed here, but rather, the compatibility of the process for messages with the use of these methods for characterizing source and destination domains will be considered in this practice. For coordinating pharmacotherapy, the role of the modeling techniques needs to be clearly defined within the structure of the Zachman Framework for the enterprise applied to pharmacotherapy (see 5.2 and 5.3) so that the role of these

steps is clearly understood in the global context. The use case model is consistent with the process models produced by the IDEF0 modeling convention. The use of the technique is carefully limited by **HL7** to the needs of message definition, but if an activity as pervasive as pharmacotherapy in healthcare is to be effectively coordinated, the use case/process models shall consistently reflect concepts over the global domains of the enterprise so that the definition of requirements for the enterprise, beginning with these models, shall reflect this consistency in the scope defined at the outset.

7.3.3 The data needs for messaging within an enterprise, assuming the enterprise can be bounded, may be less than that identified generally for messaging standards. Nevertheless, for those elements in common, the definitions of the data elements (object attributes) shall be identical, as shall the value sets. Moreover, the definitions within the source and destination data domains constituting the nodes shall be carefully harmonized even if, for the current time, data are not exchanged outside of the specific node because that requirement may rapidly change. Thus, the actors and use cases shall be carefully thought through for the long term, since the resulting requirements, and hierarchy of models, will proceed from the scenarios defined for these use cases and actors.

7.3.4 Modeling of the General Message Descriptions—Both the **CEN ENV 1613** and the **HL7** Message Development Framework standards describe a process for designing message syntax notations that serve a defined need. The process begins in these standards in defining scenarios, (messaging) DIMs, focused general message descriptions based on the domain models, and then hierarchical (general) message descriptions. Scenarios lead to use case (process models) and then interaction models with any associated state transition diagrams. These standards focus on the use of the processes for standard message development. But within the life cycle of systems contained in an enterprise architecture into which the particular components dealt with in a given project shall fit, the concepts of operations that were described in Sections 5 and 6 shall also be modeled and dealt with in a life-cycle context. Thus, the domain models used in this message development/selection process shall draw on all of the source and destination domain-related models and reflect the entire interoperation potential that will be reflected in a requirements specification tied to the project management plan for the introduction of the component into the enterprise architecture. The use of common model notation and broad models obviates the need to start from scratch but rather draws on professional consensus of the meaning of broad common concepts that will be part of the message DIM. The models also reflect the broad needs described in the business concept of operations for the enterprise. General message descriptions that are implementation independent set the stage for alternative implementable message specifications discussed in **7.3.5**.

7.3.5 Modeling and the Implementable Message Specifications—In a given enterprise environment, different message syntaxes may be required for exchanging similar information with different information domains within the enterprise architecture, but they may be based upon the same set of models. This part of the process translates the model into

the generally sequential organization of the attributes needed for messaging or other forms of information interchange. It is at this point that an existing standard message specification may be used as part of profiles of messages to achieve a particular purpose. The models allow understanding of the purpose and help identify where existing or new message specifications are needed in the context of the enterprise architecture and how the semantics inherent in these models will achieve the enterprise purpose. The **HL7**, **CEN**, **IEEE (ANSI/IEEE 1073, 1073.3.1, 1073.4.1)**, and **NCPDP** standards will be useful in selecting and documenting these alternatives within the life-cycle process context.

7.4 Identification of Purposes and Trigger Events for Data Interchange—One important aspect of characterizing network arcs, regardless of the level of decomposition, is to document the purpose (need for) exchange of data constellations between source and destination domains and to define explicitly the criteria for the “trigger event.” Such “trigger events” support scenarios defined by use cases with actions in process models. Automated pointers to referential objects and their associated context-insensitive attributes require only reference to the source data element at the context-sensitive level in whatever notation may be used in documenting the source and destination data domains. Certainly, as documented in **5.4** and Section **6**, consistent conventions that have been used for these data domains should be used for exchangeable data constellations. It is conceivable, for instance, that the business/administrative data related to patient encounters documented in a EHR domain might be structured into separate subdomains from the clinical EHR domain during the design of the overall EHR node. Likewise, in a pharmacotherapy domain, patient-specific data may be separated from workstation domains where it may not be needed for managing specimen and pharmaceutical product flow and workstation events. In some PIMS environments existing within a patient care setting, as differentiated from a geographically separated pharmacy environment, the patient attributes may reside in the EHR itself as a subdomain. In this situation, access to patient attributes needed for interpretation of observations may require a data interchange only of a narrowly defined data constellation from the EHR subdomain. This data constellation may be either the same or different in the case of a networked architecture that uses a reference laboratory or pharmacy for the data interpretation function. In differently implemented networks, the logical constellations may be the same even though the implementation techniques may be totally different. Thus, it is important to document clearly the purposes for, and the criteria activating, an exchange via a defined arc separately from the implementation approaches dealt with in Section **8**. The arcs dealing with continual process improvement (CPI) data for supporting the enterprise’s defined business processes also need documentation and a relationship to patient safety.

7.4.1 Requests for Pharmacotherapy Services—Arcs, which are requests for pharmacotherapy (medication clinical orders--prescriptions), originate in a practitioner’s source domain and terminate in a pharmacy services information domain. Depending upon the business model of the enterprise, pharmacy professionals may initiate requests for pharmacotherapy. In an

IDS enterprise in which a number of pharmacy service domains serve a number of practitioner settings, the variants of these requests must be composed of the same data elements and data representations throughout the enterprise, if the information about the pharmacotherapy services is to be consistent and informative, regardless of the view or viewer. In 7.3.4, the content of the arcs shall be carefully coordinated with the data content of the source and destination nodes, and all nodes shall consistently make use of the same concepts (data elements) in the same way. This will be particularly true for data elements that control trigger events in coordinating requests for pharmacotherapy services, since some data elements will have a contextual nature and some will involve context-insensitive attributes associated with referential data which may be part of central reference domains (nodes) as described in 6.5 and further noted in 7.4.6. The data model for the enterprise shall document these data relationships and how they are involved in the pharmacotherapy clinical decision support environment. CLSI LIS-8A develops the information requirements for the CLIMS domain, which may provide therapeutic drug-monitoring measurements or track potential adverse responses to pharmacotherapy, while Practice E 1384 and Specification E 1633 develop requirements for the EHR environment, particularly clinical orders. CLSI LIS-2A and HL-7 v2.4 map how these data requirements are used in common within the source and destination data domains with their use in messaging. See also Young et al (10) and CLSI standards LIS NCPDP SCRIPT standards deal with the payment-related functions.

7.4.2 *Reports of Requested Observations/Measurements*—Following internal laboratory processing of specimens associated with requested laboratory services (see CLSI LIS-8A) related to pharmacotherapy, measured/observed values shall be returned to the requester in a form enabling their display in a way best supporting clinical decision making by the requesting practitioner. The display process may be a node quite independent of the CLIMS such as a pharmacy or EHR. Standard message constellations of data are, therefore, the mechanism of interchange. CLSI-5A, LIS-2A, and ANSI/HL7 v2.4 define these message structures, as do CEN IN 1613 and 1614. These standards should be examined to ensure their ability to convey the required data values. The logical constellations of data for particular pharmacotherapy decision-support situations, such as either an emergency medical system or a chronic disease and its visual layout, are reported elsewhere.

7.4.3 *Requests and Reports for Logistic Services*—As a result of organizational arrangements that have now become part of the IDS enterprises, the pharmacy node shall also develop resource management information bases that allow it to order and manage the material and human resources used by the pharmacy in producing the requested services. Because different contractual arrangements may exist between the individual pharmacy site and the nodes serviced and because the supply nodes utilized will use EC, techniques using EDI will become common. The individual pharmacy data domain shall be organized to produce resource utilization data that is consistent with standard EDI data constellations and that is consistently and automatically converted into an on-time

supply delivery schedule adhering to established procurement agreements. The drug product catalog data (see 6.8) shall be accessible from the appropriate referential data, developed as described in 7.4.6. Some of the defined EDI messages are shown in Table 6 and further described in NCPDP (<http://www.ncdp.org>) and in X12 standards (see <http://www.disa.org>).

7.4.4 *Requests for, and Reports of, Administrative Services*—Most administrative services are related either to RADT (see Practice E 1239) or to HIPAA-mandated transactions (see X12 standards). The application of these transactions to pharmacotherapy will depend upon the business model and related enterprise architecture. These relationships should be spelled out in the ANSI/IEEE 1362 Concept of Operations document prepared for the system life cycle.

7.4.5 *Requests for, and Reports of, Reportable Data*—As the healthcare information domain evolves, the various public and private public health agencies that interact with healthcare enterprises will either request or require certain constellations of data, particularly that which includes clinical services. These data will be exchanged using common syntaxes and will likely be named structures. The information architecture for the enterprise shall identify those relating to the enterprise and the way that the available syntaxes can host these constellations.

7.4.6 *Access to Information Services*—One of the new capabilities that will influence pharmaceutical care services is the access to context-independent information, such as drug product attributes or drug-drug interaction data via telecommunications networks. The attributes of products and services, practice guidelines, knowledge structures of all kinds, and other information now produced and distributed as printed catalogs or compilations will be accessible via networking. The value of the content and its use in user interactions will influence whether local or remote networked information sources are developed. The maintenance of content and which attributes of the accessed records are used in the business during processing will be important.

TABLE 6 Common EDI Transaction Sets (x)

ASC X12.84	TS 834 Enrollment Benefit and Maintenance
ASC X12.85	TS 835 Healthcare Claim Payment/Advice
ASC X12.86	TS 837 Healthcare Claim
ASC X12.36	TS 848 Material Safety Data Sheet
ASC X12.374	TS 253 Data Reporting Requirements
ASC X12.281	TS 270 Healthcare Eligibility/Benefit Inquiry
ASC X12.282	TS 271 Healthcare Eligibility/Benefit Information
ASC X12.398	TS 274 Healthcare Provider Information
ASC X12.124	TS 148 Report of Injury or Illness
ASC X12.284	TS 186 Life and Annuity Laboratory Reporting
ASC X12.315	TS 275 Patient Information
ASC X12.316	TS 276 Healthcare Claim Status Request
ASC X12.317	TS 277 Healthcare Claim Status Notification
ASC X12.336	TS 278 Healthcare Claim Review Information
ASC X12.1	TS 850 Purchase Order
ASC X12.9	TS 855 Purchase Order Acknowledgment
ASC X12.18	TS 858 Shipping List
ASC X12.2	TS 810 Invoice
ASC X12.39	TS 811 Statement
ASC X12.40	TS 812 Debit/Credit Adjustment
ASC X12.284	TS 186 Insurance Underwriting Requirements Reporting

8. Description of Alternative Network Implementation Strategies

8.1 The documentation of implementation strategies shall rely on three life-cycle documents: **ANSI/IEEE 1362** Concept of Operations and, for each component of a defined architecture incorporated within a single project, a requirements specification document (IEEE 830 and 1233) and a project management plan (IEEE 1058) document pair for that project. This document triad will prompt the steps in the life cycle needed to consider the full range of potential items involved in including new components into an existing architecture in a fashion consistent with the conventions stated in the content health informatics standards that enable interoperability consistent with life-cycle concepts stated in **ISO 12207**, **ISO WD 15288**, **ANSI/IEEE 12207.0**, **ANSI/IEEE 12207.1**, and **ANSI/IEEE 12207.2**. In any enterprise, the evolution occurs over time. The content conventions and the vocabulary of the practitioner will change over time. For that reason, activities in Section 5, and their inclusion in the concept of operations document, are critical to identifying alternative strategies for implementation. The requirements specification and the project management plan provide a mechanism for documenting each potential alternative and noting the conventions (standards from the available list) to be used with that alternative in a fashion consistent with the life cycle. As the market perceives system components that incorporate a carefully documented common architectural function, suppliers modularize it such that architects can use those functions in producing capabilities in enterprise architectures that meet specialty identified common capabilities. Such modules can then be identified in the requirements specification.

9. Selection of an Implementation Strategy and Associated Methods and Techniques

9.1 **CLSI LIS-3A**, in concert with the documents noted in Section 8, provides a procedure by which procurement of a pharmacy information management system can be conducted consistently with best recommended practices. Proposed Guide **P 110**, which was derived from **CLSI LIS-3A**, appeared as a model for such a document. Recent IEEE standards should also be consulted about the acquisition process. In addition, **ANSI/IEEE 1062** and **EIA/IEEE J-Std-016** provide useful resources to each individual project.

10. Selection of an Evaluation Methodology and Followup

10.1 As each component is added to an information architecture supporting pharmacotherapy services, it should be evaluated with respect to the requirement specification and project management plan objectives, as well as with respect to the strategic plan and concept of operations document. Each evaluation is a learning experience and provides useful information for subsequent projects directed at adding additional components to the enterprise architecture. The basis for the evaluation shall be identified early on in the project management plan if the objective data to be used is to be gathered. The IEEE standards identified in Moore (9) should be used in selecting the appropriate measurements.

11. Keywords

11.1 EHR; electronic health record; information domain; network architecture; pharmacotherapy information services

APPENDIXES

(Nonmandatory Information)

X1. FIGURES

Example of Patient Referrals in Pharmacotherapy

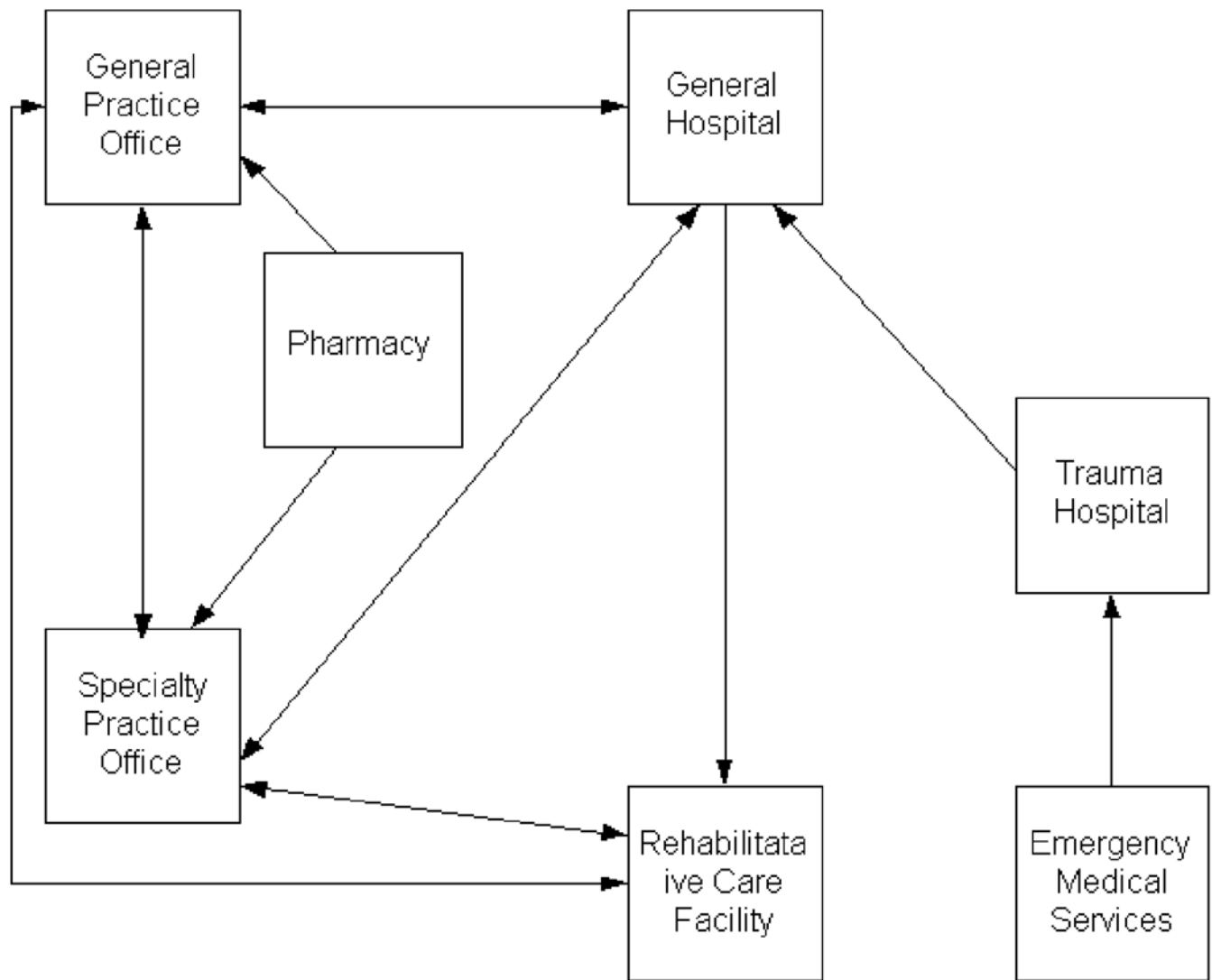


FIG. X1.1 Referral Patterns

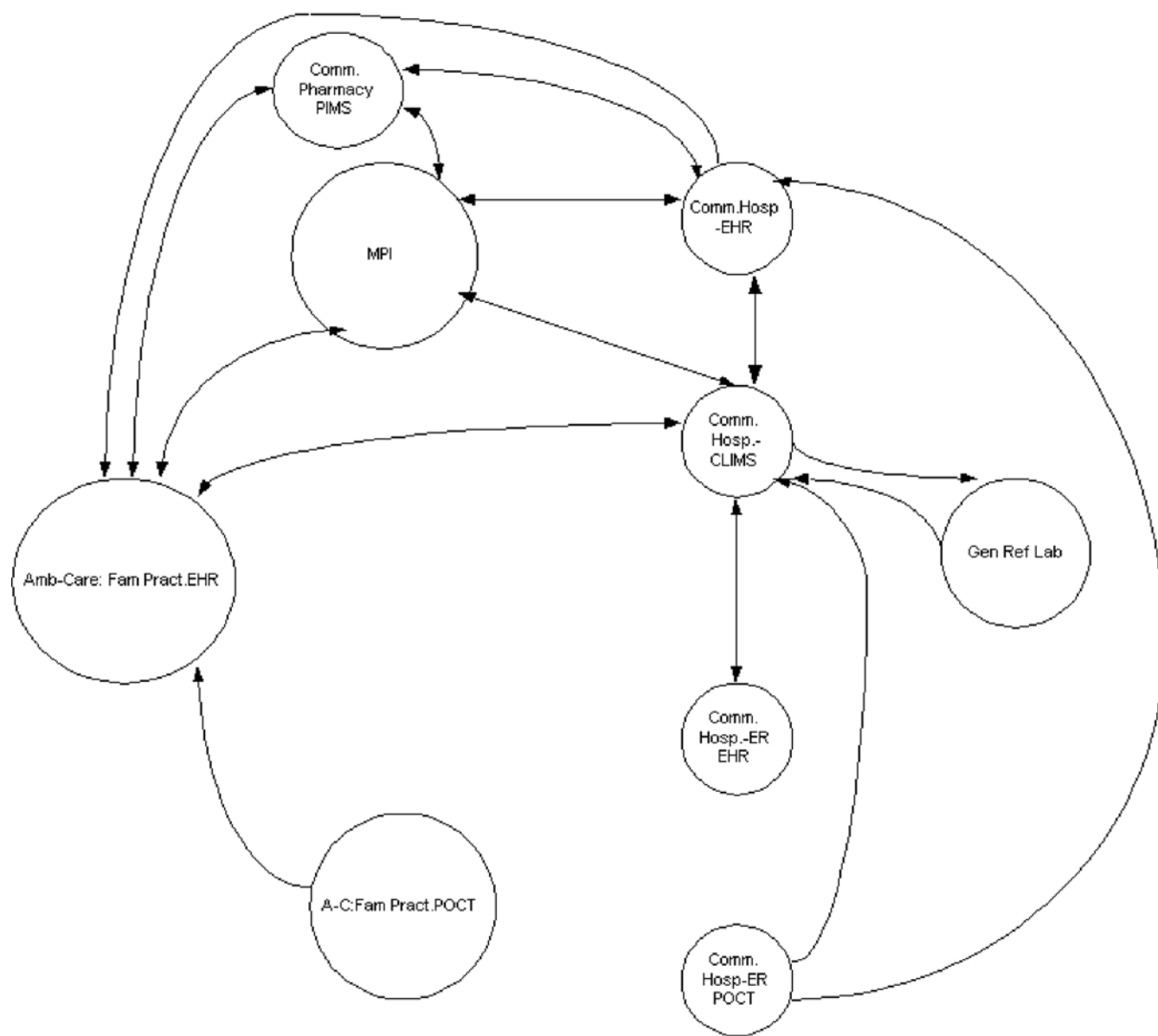
Pharmacotherapy Information Flow
Logical Network

FIG. X1.2 Logical Network

X2. PHARMACOTHERAPY DATA OBJECTS

X2.1 Data Objects—Data objects are entities about which data are gathered and have attributes that uniquely characterize the entity within the healthcare information domain. The relationships among entities, the constraints limiting attribute value sets, and the included methods in these entities are part

of the information services that are also documented. These attributes are documented in a representative logical data model (see also Fig. X2.1), which follows. The same objects could also be mapped to models given in ANSI X12N, NCPDP and HL7.

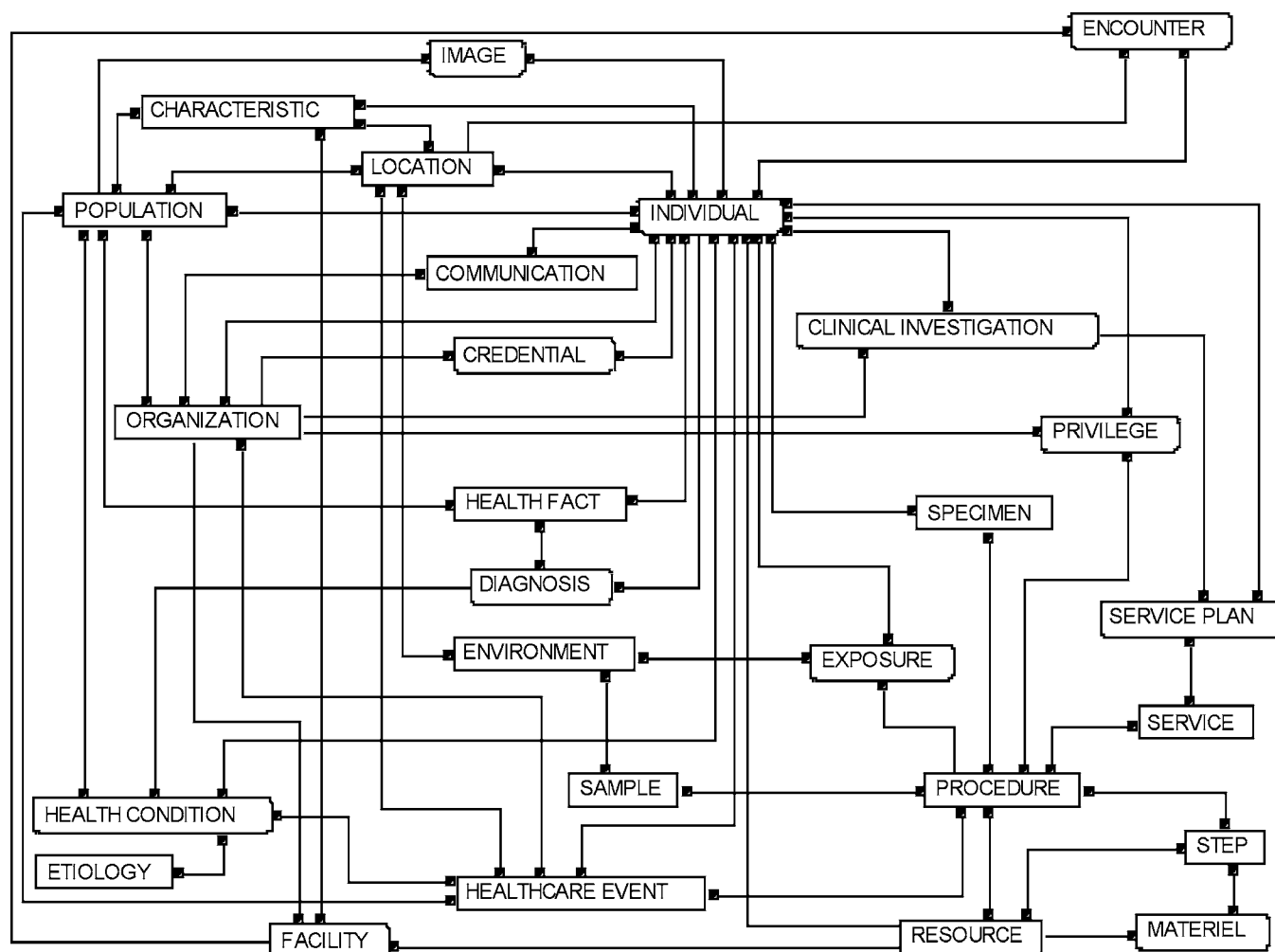


FIG. X2.1 ADA Clinical Concept Data Model (ADA 1039)

ORGANIZATION:

Organization
Healthcare Enterprise
Healthcare Provider
Employer
Customer
Vendor

FACILITY:

Healthcare Treatment Facility
Location
Work Location
Facility Bed
Facility Schedule
Pharmacy

CPR/EHR:

Patient
Family Member
Legal Agreement
Person Record Location
Record Release Instance
Organ/Tissue Donor Agreement
Research Study Agreement
Patient Subscriber Relationship
Release of Information Request
Guardian
Payment Source
Stakeholder
Stakeholder Role
Stakeholder Identifier
Episode
Healthcare Facility Encounter
Healthcare Facility Encounter Activities
Healthcare Facility Encounter Disposition
Healthcare Facility Encounter Receipt
Healthcare Registration
Healthcare Facility Practitioner
Practitioner Role
Pre-hospital Run
Emergency Room Activities
Emergency Room Admission
Emergency Room Disposition
Healthcare Visit

PIMS:

Pharmacy Organizational Service
Consumable Supplies
Customer Service Request
Employee Occupational health Training
Employee Work Schedule
Equipment
Pharmacy Admin Services
Pharmacy Customer Service Event
Maintenance Agreement
Maintenance Event Record
Pharmacy Workstation
Procedure
Protective Equipment
Stressor
Service Catalog
Service Requisition
Stock Item
Work Activity
Work Sheet

DEMOGRAPHIC:

Person
 Individual Identifier
 Alternate Individual Name
 Person Address
 Occupation
 Job
 Person Employment
 Employee/Worker
 Healthcare Worker
 Healthcare Practitioner
 Practitioner Role
 Laboratory Worker
 Pharmacy Worker

Healthcare Ambulatory Visit Receipt
 Healthcare Ambulatory Visit Activities
 Healthcare Ambulatory Visit Disposition
 Inpatient Admission
 Inpatient Activities
 Inpatient Transfer
 Inpatient Disposition
 Health History
 Examination
 Observation
 Result of Procedure/Observation
 Problem/Health Condition
 Diagnosis
 Clinical Order/Service Request
 Medication
 Procedure
 Service Catalog Entry
 Treatment Plan
 Patient Appointment Request
 Scheduled Patient Appointment
 Scheduled Practitioner Appointment
 Scheduled Equipment Appointment
 Scheduled Site Appointment

FISCAL:

Account
 Account Receivable
 Patient Account
 Guarantor (Subscriber)
 Healthcare Benefit Plan
 Insurer
 Insurance Coverage
 Other Account
 Invoice
 Bill for Services
 Billing Account
 Healthcare Claim
 Financial Transaction
 Account Payable
 Payroll
 Purchase Order
 Workers Compensation Claim

Data Object Detail
ORGANIZATION
Data Object

ORGANIZATION
 Organization Name
 Organization Address
 Region Identifier
 Organization Phone

HEALTHCARE ENTERPRISE ADA 1000.5

Healthcare Enterprise Identifier (NPI)
 Healthcare Enterprise Name

HEALTHCARE PROVIDER

Healthcare Enterprise Identifier ----->ORGANIZATION

Healthcare Identifier (NPI)

Healthcare Enterprise Name

Healthcare Category----->HEALTHCARE CATEGORY

HEALTHCARE PROVIDER ADA 1000.5

Provider/Practitioner Name

Provider Address

Provider Taxonomy Category

Provider ID

Provider Agency ID

EMPLOYER

Employer ID----->ORGANIZATION

Number of Employees

Commercial segment----->STANDARD INDUSTRIAL CODE

CUSTOMER

Customer ID

Organization----->ORGANIZATION

Individual Contact----->PERSON

VENDOR

Vendor ID

Organization----->ORGANIZATION

FACILITY
Data Object

HEALTHCARE TREATMENT FACILITY
 HEALTHCARE TREATMENT FACILITY ADA 1000.6

CCDM Object

ORGANIZATION

ORGANIZATION

ORGANIZATION

ORGANIZATION

ORGANIZATION

ORGANIZATION

CCDM Object

FACILITY

Healthcare Treatment Facility Name	
Mnemonic	
Organization Association----->ORGANIZATION	
Facility Identifier	
Location Identifier----->LOCATION	
LOCATION	LOCATION
LOCATION ADA 1000.6	
Location Name	
Location Identifier	
Facility Identifier-----> HEALTHCARE TREATMENT FACILITY	
Region	
Street Address	
Telephone No	
WORK LOCATION	LOCATION
Work Location ID	
Location ID----->LOCATION	
FACILITY BED	LOCATION
Bed ID	
Bed Location----->LOCATION	
FACILITY SCHEDULE	HEALTHCARE EVENT
Facility Location-----> LOCATION	
Event Datetime	
Event Name	
PHARMACY	ORGANIZATION
Pharmacy ID	
Facility ID----->ORGANIZATION	
Location ID-----> LOCATION	
DEMOGRAPHIC	
Data Object	CCDM Object
PERSON	
Person Name	INDIVIDUAL
Address	
Temporary address	
Temporary Phone	
Alias	
Business Phone	
Citizenship	
Date of Birth	
Birthplace Name	
Confidentiality Constraint Code	
Deceased Indicator	
Patient Disability Code	
Drivers License No	
Education Level	
Ethnic Group	
Employee Number	
Occupation	
Gender	
Home phone	
Job Code Class	
Job Title	
Language	
Marital Status Code	
Military Branch of Service Code	
Military rank	
Military Status Code	
Nationality	
Mothers Maiden Name	
Name	
Primary Name representation code	
Primary name type	
Primary Person Name	
Race	
Religion	
Student Indicator	
SSN	
INDIVIDUAL IDENTIFIER ADA 1000.1	INDIVIDUAL
<i>Individual Identifier (Multiple)</i>	

Person name----->PERSON	
Organization	
Type	
Start Date	
End Date	
Status	
 PERSON ALTERNATE NAME	 INDIVIDUAL
ALTERNATE INDIVIDUAL NAME ADA 1000.1	
Individual Alternate Name	
Usage	
Person----->PERSON	
Start Date	
End Date	
 PERSON ADDRESS	 INDIVIDUAL
Person----->PERSON	
<u>Patient Home Address</u>	
Patient Home Phone	
 PERSON OCCUPATION	 INDIVIDUAL
Person----->PERSON	
Individual Occupation----->OCCUPATION	
 PERSON JOB	 INDIVIDUAL
Person-----> PERSON	
Individual Job----->JOB	
Date Job Began	
Date Job Ended	
 PERSON EMPLOYMENT	 INDIVIDUAL
Person-----> PERSON	
Person Employment Date	
Person Employer----->EMPLOYER	
 EMPLOYEE/WORKER	 INDIVIDUAL
Employee Name----->PERSON	
Employee Identifier	
Employer----->EMPLOYER	
Functional Title	
Category	
Risk Code	
Pay Plan	
Job ID	
Job Title	
Hire date	
Occupation Code----->OCCUPATION	
Supervisor----->PERSON	
Primary Worksite----->WORK LOCATION	
Primary Work Operation----->WORK OPERATION	
Personal Protective Equipment----->STOCK ITEM	
Applicable Safety program (M)	
 HEALTHCARE WORKER	 INDIVIDUAL
Healthcare worker name----->EMPLOYEE	
Healthcare worker ID	
Healthcare worker discipline	
 HEALTHCARE PRACTITIONER ADA 1000.10	 INDIVIDUAL
<u>Practitioner Name</u> ----->PERSON	
<u>Practitioner National Provider ID</u>	
<u>Practitioner Profession, Occupation, Specialty</u> ----->OCCUPATION	
<u>Practitioner Address</u>	
<u>Practitioner Electronic Signature</u>	
 PRACTITIONER ROLE	 INDIVIDUAL
Practitioner Role Name	
Practitioner Role Identifier----->ROLE	
 LABORATORY WORKER	 INDIVIDUAL
Laboratory Worker name----->EMPLOYEE	
 PHARMACY WORKER	 INDIVIDUAL
Pharmacy Worker Name-----> EMPLOYEE	
 CPR/EHR	
 Data Object	 CCDM Object

PATIENT	INDIVIDUAL
Patient Name----->PERSON	
Date of Birth	
Birth Order	
Living arrangement	
Living Dependency Code	
Multiple Birth Indicator	
Classification Code	
Newborn Baby Indicator	
Organ Donor Indicator	
Preferred Pharmacy ID	
Triage Classification	
Disability Type code	
Employer Identification Number	
Employment Status Code	
Medical record Number	
Student Status Code	
Weight	
Alternate ID	
Ambulatory Status	
Diet Type	
Financial class	
Internal ID	
External ID	
Prior Alternate Patient ID	
Prior Patient ID	
Prior Patient external ID	
VIP Indicator	
 FAMILY MEMBER ADA 1000.3	 INDIVIDUAL
Patient Name----->PERSON	
Family Member Name----->PERSON	
<u>Family Member Relationship</u>	
Family Member SSAN	
Family Member Male Parent	
Family Member Female Parent	
Family Member Spouse	
Family Member Sex	
Family Member DOB	
Family Member Date of Death	
Family Member Head of Household Status	
Family Member Caregiver Status	
Family Member Location	
Family Member Occupation----->OCCUPATION	
Family Member Major Diagnosis (M)	
 LEGAL AGREEMENT	 INDIVIDUAL
Segment II: Legal Agreements	
<u>Patient Name----->PERSON</u>	
<u>Consent Signed/Admit Agreement</u>	
<u>Patient Rights Acknowledgement</u>	
<u>Directive to Physician</u>	
 PERSON RECORD LOCATION	 INDIVIDUAL
Person----->PERSON	
<u>Record Location ID</u>	
<u>Date of Earliest Entry</u>	
<u>Date of Latest Entry</u>	
 RECORD RELEASE INSTANCE	 INDIVIDUAL
<u>Release of Information Datetime</u>	
<u>Type of Information Released</u>	
<u>Person Releasing</u>	
 ORGAN/TISSUE DONOR AGREEMENT	 RESOURCE
Segment II: Legal Agreements	
<u>Patient Name----->PERSON</u>	
<u>Consent Signed/Admit Agreement</u>	
<u>Patient Rights Acknowledgement</u>	
<u>Directive to Physician</u>	
 RESEARCH STUDY AGREEMENT	 RESOURCE
<u>Patient Name----->PERSON</u>	
<u>Datetime of Agreement</u>	
<u>Text of Agreement</u>	

PATIENT SUBSCRIBER RELATIONSHIP	RESOURCE
<u>Patient Name</u> ----->PERSON	
RELEASE OF INFORMATION REQUEST	RESOURCE
<u>Patient Name</u> ----->PERSON	
Type of Action	
Type of Information	
RECORD RELEASE INSTANCE	RESOURCE
<u>Patient Name</u> ----->PERSON	
Release of Information Datetime	
Type of Action	
Type of Information Released	
Person Releasing	
Purpose of Release	
Released to	
Person Authorizing	
GUARDIAN	INDIVIDUAL
<u>Patient Name</u> ----->PERSON	
<u>Guardian Name</u> ----->PERSON	
Segment III: Financial	
PAYMENT SOURCE	RESOURCE
<u>Patient Name</u> ----->PERSON	
<u>Payment Source</u>	
<u>Payer Group No</u>	
<u>Payment Sponsor</u>	
<u>Address of Sponsor</u>	
STAKEHOLDER	INDIVIDUAL
<u>Stakeholder Name</u> ----->PERSON	
STAKEHOLDER ROLE	INDIVIDUAL
<u>Stakeholder</u> ----->STAKEHOLDER	
<u>Stakeholder Role ID</u> ----->ROLE	
STAKEHOLDER IDENTIFIER	INDIVIDUAL
<u>Stakeholder ID</u>	
<u>Stakeholder Name</u> ----->STAKEHOLDER	
EPISODE	ENCOUNTER
*EPISODE OF CARE: [ASTM: Healthcare Episode, RIM 0.87: EPISODE]	
<u>Patient Name</u> ----->PERSON	
(<u>Episode_Identifier_id</u>)	14001.A0031
Description	
<u>Episode_type_cd</u>	
<u>list_closed_in</u>	
<u>Outcome_txt</u>	
<u>Recurring_service_indicator</u>	
HEALTHCARE FACILITY ENCOUNTER ADA 1000.8	ENCOUNTER
<u>Datetime of Encounter</u>	
<u>Encounter Patient</u> ----->PATIENT	
<u>Name of Facility of Encounter</u> ----->HEALTHCARE ENTERPRISE	
<u>Encounter ID</u>	
<u>Encounter status</u>	
<u>Type of Encounter</u>	
<u>Reason for Visit</u>	
<u>Patient Chief Complaint</u>	
<u>Problem ID (M)</u>	
<u>Encounter status</u>	
<u>Comments</u>	
HEALTHCARE FACILITY ENCOUNTER RECEIPT	ENCOUNTER
<u>Encounter ID</u> -----> HEALTHCARE FACILITY ENCOUNTER	
<u>Facility Type</u>	
Type of Encounter	
Confidentiality Status	
<u>Episode ID</u>	
Mode of Injury	
Nature of Injury	
<u>Chief Complaint</u>	
<u>Health Condition/Problem ID (M)</u> ----->HEALTH CONDITION/PROBLEM	
Receipt Diagnosis	

Practitioner ID ----->HEALTHCARE FACILITY PRACTITIONER	
Practitioner Role----->PRACTITIONER ROLE	
HEALTHCARE FACILITY ENCOUNTER ACTIVITIES	ENCOUNTER
Encounter ID-----> HEALTHCARE FACILITY ENCOUNTER	
HEALTHCARE FACILITY ENCOUNTER DISPOSITION	ENCOUNTER
Encounter ID-----> HEALTHCARE FACILITY ENCOUNTER	
<u>Disposition</u>	
Disposition Date time	
<u>Disposition Destination</u>	
<u>Patient Instructions</u>	
<u>Disposition Note</u>	
<u>Disposition Note Signature</u>	
<u>Encounter Charges</u>	
Disposition Type	
Followup Action	
Followup target date	
DISPOSITION DIAGNOSIS	ENCOUNTER
Disposition Diagnosis Name ----->DIAGNOSIS	
<u>Diagnosis Type</u>	
DISPOSITION HEALTH STATUS	ENCOUNTER
Disposition Health Status Measure Name	
Disposition Health Status Measure Total Value	
HEALTHCARE REGISTRATION	ENCOUNTER
Encounter ID-----> HEALTHCARE FACILITY ENCOUNTER	
HEALTHCARE FACILITY PRACTITIONER	PRIVILEGE
HEALTHCARE PRACTITIONER ADA 1000.10	
Practitioner Name ----->PERSON	
Practitioner National Provider ID	
Practitioner Profession, Occupation, Specialty -----> OCCUPATION	
Practitioner Address	
<u>Practitioner Electronic Signature</u>	
PRACTITIONER ROLE	PRIVILEGE
Practitioner Role Name	
Practitioner Role Identifier----->ROLE	
PRE-HOSPITAL RUN	HEALTHCARE EVENT
Encounter ID----->HEALTHCARE FACILITY ENCOUNTER	
Run Number	
Datetime Call Received	
Datetime Run Dispatched	
Datetime Run Arrived at Scene	
Agency ID	
Vehicle ID	
Order Agency Arrived at Scene	
Datetime Patient Left Scene	
Datetime Patient Arrived at Treatment Facility	
Datetime Unit Returned to Duty	
Pre-Hospital Equipment/Procedures	
EMERGENCY ROOM ADMISSION	ENCOUNTER
Encounter ID----->HEALTHCARE FACILITY ENCOUNTER	
Pre-Hospital Run Number----->PRE-HOSPITAL RUN	
Datetime of Injury	
Encounter Nature of Injury	
Encounter Mode of Injury	
Encounter Location where injured	
Injury Circumstances	
Injury Severity Score	
E-R Admitting Physician	
Time of Triage	
Condition at Triage	
Datetime Surgeon Arrived	
Datetime Neurosurgeon Arrived	
EMERGENCY ROOM ACTIVITIES	ENCOUNTER
Encounter ID----->HEALTHCARE FACILITY ENCOUNTER	
EMERGENCY ROOM DISPOSITION	ENCOUNTER

Encounter ID----->HEALTHCARE FACILITY ENCOUNTER	
HEALTHCARE VISIT	ENCOUNTER
Encounter ID----->HEALTHCARE FACILITY ENCOUNTER	
HEALTHCARE AMBULATORY VISIT RECEIPT	ENCOUNTER
Encounter ID----->HEALTHCARE FACILITY ENCOUNTER	
HEALTHCARE AMBULATORY VISIT ACTIVITIES	ENCOUNTER
Encounter ID----->HEALTHCARE FACILITY ENCOUNTER	
HEALTHCARE AMBULATORY VISIT DISPOSITION	ENCOUNTER
Encounter ID----->HEALTHCARE FACILITY ENCOUNTER	
INPATIENT ADMISSION	ENCOUNTER
Encounter ID----->HEALTHCARE FACILITY ENCOUNTER	
Origin Facility ID	
Current Living arrangement	
Admission Authority	
Referral type	
Referring Provider	
Private Physician Name	
Private Physician Notified	
Admitting Hospital Type	
Admission Hospital Register Number	
Admitting Service	
Origin Service	
Enc/Attending Physician Name	
ER/Admitting Physician	
Admitting Room/Bed	
Admitting Type of Accommodation	
Primary Nursing Unit	
Admitting Floor	
Warnings	
Admitting Records Received	
Valuable Left	
Indicated Surgery	
Admission Custodian of Person Effects	
Police Hold	
Date-Time Notified Police	
INPATIENT ACTIVITIES	ENCOUNTER
Encounter ID----->HEALTHCARE FACILITY ENCOUNTER	
INPATIENT TRANSFER	ENCOUNTER
Encounter ID----->HEALTHCARE FACILITY ENCOUNTER	
Admission Intra-facility Transfer datetime	
Admission Intra-facility Transfer Type Clinical Service	
Admission Intra-facility Transfer Nursing Unit	
Admission Intra-facility Transfer Room/Bed	
Admission Intra-facility Transfer Diagnosis	
Admission Intra-facility Transfer Practitioner	
INPATIENT DISPOSITION	ENCOUNTER
Encounter ID----->HEALTHCARE FACILITY ENCOUNTER	
Datetime of death	
Release of Body to Morgue	
Discharge Datetime	
Time of Departure	
Condition on Discharge	
Reason for Discharge	
Person Accompanying Patient From Facility	
Disposition Transport Type	
Disposition Destination	
Discharge Summary Dictation Datetime	
Total Acute Care Length of Stay	
Length of Rehab services	
Total ICU Days	
Signature/Authenticator	
HEALTH HISTORY	HEALTH FACT
Segment VIII: Health History ADA 1000.13	
Patient Name----->PERSON	
Date of Health History	
History Source Contact Name	
History Source Relationship	
History Present Health Text	

Past History Social Text
Current Habits Text
 Health History Item (Multiple)

ENVIRONMENTAL STRESSOR EXPOSURE ENVIRONMENT
 Patient Name----->PERSON
 Environmental Stressor ID----->STRESSOR
 Datetime of Exposure measure
 Value of Exposure Measure
 Unit of Measure of Exposure Measure----->UNIT OF MEASURE

Patient Environmental Stressor
 STRESSOR EXPOSURE ADA CONCEPT MODEL: EXPOSURE HEALTH FACT
 Stressor Type (M)----->STRESSOR
 Stressor Total Lifetime Exposure
 Stressor Unit of Exposure
 Stressor Lifetime Milestone Date
 Stressor Exposure Period (M)----->STRESSOR EXPOSURE PERIOD

Patient Environmental Stressor Exposure
 STRESSOR EXPOSURE PERIOD HEALTH FACT
 Stressor Exposure begin date-time
 Stressor Exposure termination date
 Stressor Employer----->EMPLOYER
 Stressor Exposure Setting
 Stressor Route of Exposure
 Stressor Exposure Interval Dose
 Stressor Plant Process Code
 Stressor Plant Location Code
 Stressor Work Performed
 Stressor Personal Protection used (M)
 Stressor Measurement (M)----->STRESSOR MEASUREMENT

Patient Environmental Stressor Measurement
 STRESSOR MEASUREMENT HEALTH FACT
 Stressor Measurement Date
 Stressor ID----->STRESSOR
 Form of Measured Agent
 Environmental Specimen ID----->ENVIRONMENTAL SPECIMEN
 Units of Stressor Sample Collected
 Stressor Sample Unit of Measure----->UNIT OF MEASURE
 Stressor Sample Collection Datetime
 Stressor Sample Collection Device
 Stressor Test Sample Method
 Stressor Type of Determination
 Stressor Peak Measurement Value
 Stressor Peak Measurement Unit

Environmental Specimen
 ENVIRONMENTAL SPECIMEN HEALTH FACT
 Sample ID
 Sample Collection Datetime
 Sample Location----->ENVIRONMENTAL LOCATION
 Sample Subject
 Sample Collection Equipment ID----->INSTRUMENT
 Sample Collection Method
 Sample Period Duration
 Sample Size
 Sample Unit
 Sampling Conditions
 Analyzing Laboratory----->LABORATORY

EXAM HEALTH FACT

Segment IX: Examinations ADA 1000.12
 Patient Name----->PERSON
Date of Examination
Source of History Present Illness/status Present Health
Review of Systems
Exam Finding (Multiple)
Exam Finding Comment
Exam Health Status Total Measure Name
Exam Health Status Total Measure Value
Exam Summary

OBSERVATION HEALTH FACT
 Segment XI: Diagnostic Tests ADA 1000.13 ADA CONCEPT MODEL: HEALTH FACT
 Patient Name----->PERSON

<u>Datetime of Test (Multiple)</u>	
<u>Clinical Order ID</u> ----->CLINICAL ORDER/SERVICE REQUEST	
<u>Name of Requested Test</u> ----->MEASUREMENT	
<u>Test Ordering Facility</u> -----> HEALTHCARE TREATMENT FACILITY	
<u>Test Ordering Practitioner</u> -----> HEALTHCARE PRACTITIONER	
<u>Test Performing Facility</u> -----> WORK LOCATION	
<u>Test Performer</u> -----> LABORATORY WORKER	
<u>Datetime Result Reported</u>	
<u>Test Report Text (for Textual Reports)</u>	
<u>Interpretation</u>	
<u>Microorganism Requested (M)</u>	
<u>Microorganism Attribute (M)</u>	
<u>Microorganism Comments</u>	
<u>Test Comments</u>	
 RESULT OF PROCEDURE/OBSERVATION	HEALTH FACT
<u>Patient Name</u> ----->PERSON	
<u>Datetime of Test (Multiple)</u>	
<u>Clinical Order ID</u> ----->CLINICAL ORDER/SERVICE REQUEST	
<u>Name of Requested Test</u> ----->MEASUREMENT	
<u>Analyte/Measurement/Observation Name (M)</u> ----->MEASUREMENT	
<u>Analyte/Measurement/Observation Value</u>	
<u>Analyte/Measurement/Observation Unit of Measure</u> ----->UNIT OF MEASURE	
 Health Condition	
 PROBLEM/HEALTH CONDITION	HEALTH CON- DITION
 Segment V: Health Condition/Problem ADA 1000.14	HEALTH CON- DITION
<u>Patient ID</u> ----->PATIENT	
<u>Health Condition/Problem ID</u>	
<u>Health Condition/Problem Name</u> ----->HEALTH CONDITION	
<u>Health Condition/Problem Time of Onset</u>	
<u>Health Condition/Status</u>	
<u>Etiology</u> ----->ETIOLOGY	
 DIAGNOSIS	DIAGNOSIS
RECEIPT DIAGNOSIS	
<u>Patient ID</u> ----->PATIENT	
<u>Encounter ID</u> ----->HEALTHCARE FACILITY ENCOUNTER	
<u>Health Condition/Problem ID</u> ----->PROBLEM/HEALTH CONDITION	
<u>Encounter Receipt Diagnosis</u> ----->DIAGNOSIS	
<u>Encounter Receipt Health Status</u>	
 Segment X: Clinical Orders ADA CONCEPT MODEL: COMMUNICATION	
 CLINICAL ORDER/SERVICE REQUEST	SERVICE PLAN
<u>Patient ID</u> ----->PATIENT	
<u>Clinical Order ID</u>	
<u>Encounter ID</u> ----->HEALTHCARE FACILITY ENCOUNTER	
<u>Clinical Order Datetime</u>	
<u>Clinical Order Full Text</u>	
 MEDICATION	SERVICE
Segment XII Medications	
<u>Patient ID</u> ----->PATIENT	
<u>Datetime of Medication Clinical Order/Prescription</u>	
<u>Encounter ID</u> ----->HEALTHCARE FACILITY ENCOUNTER	
<u>Medication Name</u> ----->DRUGPRODUCT	
<u>Prescription Number</u>	
<u>Prescriber ID</u> ----->HEALTHCARE PRACTITIONER	
<u>Prescriber Location</u> ----->LOCATION	
<u>Problem ID</u> ----->HEALTH CONDITION	
<u>Reason for Administration</u>	
<u>Status of Prescription/Order</u>	
<u>Dose</u>	
<u>Unit</u>	
<u>Form</u>	
<u>Route</u>	
<u>Frequency</u>	
<u>Medication Administration Device</u>	
<u>Medication Administration Method</u>	
<u>Interval/Frequency</u>	
<u>Instructions for Use</u>	
<u>Total doses prescribed/refill</u>	
<u>Number of Refills</u>	
<u>Date of Refill (M)</u>	

Refill dispensing facility
Medication Start Time
Medication Stop Time
Medication Notes

DRUG PRODUCT

MATERIEL

Manufactured Drug ID
Manufactured Drug Trade Name
Mfr Code Number
Therapeutic Class-----> THERAPEUTIC CLASS
Clinical Drug Component (M)----->CLINICAL DRUG
Color Description----->DRUG PRODUCT COLOR
Shape Description----->DRUG PRODUCT SHAPE
Flavor Description-----> DRUG PRODUCT FLAVOR
Coating Description-----> DRUG PRODUCT COATING
Scoring Description-----> DRUG PRODUCT SCORING
Markings Description
Image----->IMAGE FILE
Composite Type----->COMPOSITE TYPE

CLINICAL DRUG

MATERIEL

Clinical Drug Name
International Nonproprietary Name
US Adopted Name
British Adopted Name
Japanese Adopted Name
Clinical Drug ID
Conventional Dose Qty
Conventional Dose Unit of Measure----->UNIT OF MEASURE
Ingredient (M)----->INGREDIENT
Dose Form (M)----->DOSE FORM
Route of Administration (M)----->ROUTE OF ADMINISTRATION
Site of Administration----->SITE OF ADMINISTRATION
Method of Administration----->METHOD OF ADMINISTRATION
Rate of Absorption
Percent Absorbed
Pharmacokinetic Model
Distribution rate constant
Elimination rate constant
Volume of Distribution
Loading Dose
Maintenance Dose
Level of Toxic Metabolites as Percent of Dose
Protein----->PROTEIN
Enzyme----->ENZYME
Contraindications
Indications
Pathophysiologic effect(M) ----->PHARMACOTHERAPY PATHOLOGY EFFECT

INGREDIENT

MATERIEL

Ingredient Name
Ingredient ID
Chemical Name
CAS Number
InChI
Molecular Variation of ingredient----->INGREDIENT
Ingredient AHFS Code
Ingredient ATC Code
Ingredient BNF Code
Assay Measurement (M)----->ASSAY
Metabolizing Enzyme (M)----->METAB-ENZYME
Therapeutic Action Code----->THERAPEUTIC ACTION
Inert Ingredient Code----->INGREDIENT
Trace code
Organ of Metabolism----->D-A FOUNDATIONAL MODEL
Percent of Conventional Dose
Upper Therapeutic Level
Lower Therapeutic level
Percent Serum Protein Binding

ASSAY

MATERIEL

Assay Measurement (M)----->LOINC
Assay Sample Type
Sample Handling Conditions

METAB-ENZYME

MATERIEL

Metabolizing Enzyme (M)----->ENZYME
Induction/Repression code----->INDUCTION/REPRESSION

Metabolism Gene Allele (M)----->GENE	
Percent effect	
Agent	
PROCEDURE	PROCEDURE
PROCEDURE [ADA 1000.10]	
Procedure Identifier----->SERVICE CATALOG ENTRY	
Procedure Term	
Procedure Type	
Procedure mnemonic	
ADA Procedure code	
Base value	
Procedure Description	
SERVICE CATALOG ENTRY	RESOURCE
Service ID	
Service Name	
Treatment Plan	
TREATMENT PLAN	SERVICE PLAN
Segment X: Treatment Plans ADA 1000.15 ADA CONCEPT MODEL: TREATMENT PLAN	
Patient ID----->PATIENT	
<u>Treatment Plan ID</u>	
<u>Treatment Plan Description</u>	
<u>Health Condition/Problem ID</u> ----->HEALTH CONDITION/PROBLEM	
<u>Treatment Plan Phase (M)</u>	
Treatment Plan Procedure----->PROCEDURE	
PATIENT APPOINTMENT REQUEST	HEALTHCARE EVENT
Appointments Segment XIII: Appointments ADA 1000.15	
Patient ID----->PATIENT	
Date-time (M)	
Treatment Facility	
Expected Duration 00868	
Clinic Name	
Previous Encounter datetime----->ENCOUNTER	
Provider ID----->PRACTITIONER	
Requestor----->PRACTITIONER	
Purpose/Chief Complaint 00866	
Remarks	
Appointment Status	
Expected Services (M)	
Type 00867	
Urgency	
Cancellation Reason	
Cancellation Datetime	
Overbook status	
Encounter Disposition	
SCHEDULED PATIENT APPOINTMENT	HEALTHCARE EVENT
Patient ID----->PATIENT	
Date-time (M)	
Treatment Facility	
Practitioner ID----->PRACTITIONER	
Duration	
SCHEDULED PRACTITIONER APPOINTMENT	HEALTHCARE EVENT
Practitioner ID----->PRACTITIONER	
Date-time (M)	
Treatment Facility	
Location----->LOCATION	
Patient ID----->PATIENT	
Duration	
SCHEDULED EQUIPMENT APPOINTMENT	HEALTHCARE EVENT
Equipment ID----->EQUIPMENT	
Date-time (M)	
Treatment Facility	
Location ID----->LOCATION	
SCHEDULED SITE APPOINTMENT	HEALTHCARE EVENT
Location ID----->LOCATION	
Date-time (M)	

Treatment Facility
 Practitioner ID----->PRACTITIONER
 Duration

PIMS

Data Object	CCDM Object
PHARMACY ORGANIZATIONAL SERVICE Pharmacy Organizational Service ID Pharmacy Organizational Service Name Location ID----->LOCATION	SERVICE
CONSUMBLE SUPPLIES Stock Item ID----->STOCK ITEM	MATERIEL
CUSTOMER SERVICE REQUEST Customer ID----->CUSTOMER Requested Service----->	RESOURCE
EMPLOYEE OCCUPATIONAL HEALTH TRAINING Employee ID----->EMPLOYEE	RESOURCE
EMPLOYEE WORK SCHEDULE Employee ID----->EMPLOYEE- Work date Work Period Work Duration	HEALTHCARE EVENT
EQUIPMENT Equipment ID Equipment Name Manufacturer ID----->MANUFACTURER	RESOURCE
PHARMACY ADMIN SERVICES	RESOURCE
PHARMACY CUSTOMER SERVICE EVENT Pharmacy Customer Service Datetime Service Customer----->CUSTOMER Associated Service----->SERVICE	HEALTHCARE EVENT
MAINTENANCE AGREEMENT Equipment ID----->EQUIPMENT	RESOURCE
MAINTENANCE EVENT RECORD Equipment ID----->EQUIPMENT	RESOURCE
Manufacturer MANUFACTURER Manufacturer ID----->ORGANIZATION Manufacturer Name Product ID (M)	ORGANIZATION
PHARMACY WORKSTATION	LOCATION
PROTECTIVE EQUIPMENT Protective Equipment ID Protective Equipment Name Stressors protected Against----->STRESSOR	MATERIEL
Environmental Stressor STRESSOR Environmental Stressor ID	ENVIRONMENT
SERVICE CATALOG SERVICE [ADA 1000.16] Service Identifier Service Term Service Type Service Description	RESOURCE
SERVICE REQUISITION	RESOURCE
Stock Item STOCK ITEM Stock Item Product ID	MATERIEL

Stock Item Name

Manufacturer

Manufacturer ID----->MANUFACTURER

Manufacturer Name

Product ID (M)

Public Health Agency

Public Health Agency Organizational ID---->ORGANIZATION

ORGANIZATION

WORK ACTIVITY

Work Activity ID

Work Activity Name

Protective Equipment Name

Stressor ID----->STRESSOR

Work Activity/Operation

WORK OPERATION

Work Operation Name

Exposure Protection Code

Operation Risk Assessment Code

Associated Stressor (M)----->STRESSOR

Engineering Control (M)

Operation Description

Work Location

WORK LOCATION

Work Location ID Code----->LOCATION

Work Location Name

Worker Type (M)

Contact Name

Supervisor

Worksite (M)----->WORK LOCATION

Work Operation (M)----->WORK OPERATION

Building

Floor

Phone

LOCATION

WORK SHEET

HEALTHCARE
EVENT

FISCAL

Data Object

ACCOUNT

Account ID

CCDM Object
RESOURCE

ACCOUNT RECEIVABLE

Billing Account ID

RESOURCE

PATIENT ACCOUNT

Billing Account ID

Medicare Number

Medicare A effective Data

Medicare B effective dat

Medicaid Number

RESOURCE

GUARANTOR

*GUARANTOR Role:[ASTM/RIM 0.87;GUARANTOR; X12N SUBSCRIBER]

financial_class-id

household_annual_income_amt

household_size_qty

I Contract Amount

I Contract Code

I Contract Effective Date

I Contract Period

I Interest Code

I Household_size_qty

I Household_record_amt

INDIVIDUAL

00778

00779

00156

00154

00155

00157

00158

HEALTHCARE BENEFIT PLAN

HEALTHCARE_BENEFIT_COVERAGE [RIM 0.87; X12N: BENEFIT]

annual_limit_amt

benefit_desc

benefit_product_nm

dependent_coverage_limit_amt

effective_dttm

lifetime_limit_amt

RESOURCE

termination_dttm

INSURER
 Insurer ID
 Insurer Name----->ORGANIZATION

ORGANIZATION

INSURANCE COVERAGE
 Insurance Type
 Primary payment Source ----->PAYMENT SOURCE
 Primary payment Class
 Insurance group Number
 Insurance ID Number
 Principle payment sponsor
 Address of principle sponsor
 Payor priority

RESOURCE

ACCOUNT PAYABLE
 Account_id----->ACCOUNT

RESOURCE
 00236

BILL FOR SERVICES
 BILLING_INFORMATION_ITEM [RIM 0.87]
 Bill Id
 Vendor ID----->VENDOR
 Purchase Order ID----->PURCHASE ORDER
 Condition_cd

RESOURCE

Occurance_cd
 occurrence_dt
 occurrence_span_cd

 occurrence_span_from_dt

 occurrence_span_through_dt

00563/00541/
 00555
 0545/00559
 00559
 00542/00546/
 00560
 0543/00547/
 00560
 00544/00548/
 00560
 00532

Quantity_amt
 Quantity_type_cd
 Value_amt
 Value_cd

00539/00558
 00539/00558

BILLING ACCOUNT
 PATIENT_BILLING_ACCOUNT [RIM 0.87]
 account_id----->ACCOUNT
 Patient ID----->PATIENT
 adjustment_cd
 authorization_information
 billing_status_cd
 certification-required_ind
 current_unpaid_balance_amt
 delete_dt
 deleted_account_reason_cd
 expected_insurance_plan_qty
 expected_payment_source_cd
 notice_of_admission_dt
 notice_of_admission_ind
 patient_financial_caps_cd
 price_schedule_class
 purge_status_cd
 purge_status_dt
 report_of_eligibility_dt
 retention_ind
 signature_on_file_dt
 special_progr_cd
 stoploss_limit_ind
 suspend_charges_ind
 total_adjustment_amt
 total_charge_amt
 total_payment_amt

RESOURCE

00236

 00731
 00439
 00457/00171
 00505
 00176
 00165
 00164

 00449
 00448

 00151
 00717
 00718

 00729
 00719
 00808
 00806
 00178
 00177
 00179

HEALTHCARE CLAIM
 CLAIM: [X12N]
 Claim Id
 Patient ID----->PATIENT
 datetime type code
 diagnosis_related_group_code
 discharge_percent
 frequency_code
 from_datetime
 identification_number

RESOURCE
 RESOURCE

institutional quantity
 patient_release_of_information_code
 patient_signature_source_code
 provider_assignment_of_concept_code
 provider_signature_on_file_indicator
 special_program_code
 submitter_identification_number
 thru_datetime
 total quantity

FINANCIAL TRANSACTION

RESOURCE

INVOICE

Invoice ID
 Invoice Date
 Invoice Vendor ID----->VENDOR
 Stock Item Ordered----->STOCK ITEM

INVENTORY

RESOURCE

Stock Item ID----->STOCK ITEM
 Number in Stock

PAYROLL

RESOURCE

Employee ID----->EMPLOYEE
 Pay Class
 Time Unit Worked
 Time Unit

PURCHASE ORDER

RESOURCE

Purchase Order ID
 Purchase Order Date
 Purchase Order Vendor ----->VENDOR

Stock Item Ordered
 Number Ordered

STOCK ITEM

RESOURCE

Stock Item ID
 Stock Item Name
 Stock Item Class
 Stock Item Price

WORKER'S COMPENSATION CLAIM

RESOURCE

Patient ID----->PATIENT
 Worker's Comp Claim Date
 Worker's Comp Claim ID

LEGAL AGREEMENTS

Segment II: Legal Agreements
 Patient ID----->PATIENT
Consent Signed/Admit Agreement
Patient Rights Acknowledgement
Directive to Physician

RECORD RELEASE INSTANCE

Patient ID----->PATIENT
Release of Information Datetime
Type of Information Released
Person Releasing

PAYMENT SOURCE

RESOURCE

Payment Source
Payer Group No
Payment Sponsor
Address of Sponsor

VOCABULARIES and REFERENTIAL CONTEXT-INSENSITIVE DATA: ADA 100.2

Measurement Name

MEASUREMENT NAME
 Measurement Name
 Measurement LOINC ID----->LOINC
 Measurement Payment Code

Observation

OBSERVATION
 Observation Identifier
 Observation Name

Unit of Measure

UNIT OF MEASURE [ADA 1000.14]
 Unit of Measure ID
 Unit of Measure Name/Unit of Measure Term
 Unit of Measure Abbreviation
 Unit of Measure Code
 Unit of Measure System

Occupation

OCCUPATION [ASTM/ADA]
 Occupation ID
 Occupation Name
 Occupation Identifier

Race

RACE
 Race/Biologic Population ID
 Race/Biologic Population Name

Religion

RELIGION [ADA 1000.3]
 Religion ID
 Religion Name
 Religion Code
 Sect Name

Sex Characteristic

SEX CHARACTERISTIC [ADA 1000.3]
 Sex Characteristic Code
 Sex Characteristic description

SEX

Sex ID
 Sex Name

Ethnic Group

ETHNIC GROUP
 Ethnic Group ID
 Ethnic Group Name

Language

LANGUAGE [ADA 1000.3]
 Language Code
 Language Name
 Dialect Name

Marital (Pair-Bond) Status

MARITAL STATUS [ADA]
 Marital Status Code
 Marital Status description

HEALTHCARE CATEGORY

Healthcare Category ID
 Healthcare Category Name

Health Condition

HEALTH CONDITION/PROBLEM [ADA 1000.10]
 Health Condition/Problem Identifier
 Health Condition/Problem Name

Diagnosis

DIAGNOSIS [ADA 1000.10]
 Diagnosis Identifier
 Diagnosis Term

Procedure

PROCEDURE [ADA 1000.10]
 Procedure Identifier
 Procedure Term
 Procedure Type
 Procedure mnemonic
 ADA Procedure code
 Base value
 Procedure Description

Role

ROLE
Role Identifier
Role Name

Materiel

MATERIEL [ADA 1000.9] ADA CONCEPT MODEL: MATERIEL
Materiel Identifier
Materiel Name

Outcome

OUTCOME [ADA 1000.10]
Outcome Identifier
Outcome Term code
Outcome description

Population

POPULATION [ADA 1000.12]
Population Identifier
Population Name

Quantitative Measure

QUANTITATIVE MEASURE [ADA 1000.14]
Quantitative Measure Term
Quantitative Measure Description

Stressor

STRESSOR
Stressor ID
Stressor Name
Trade Name (M)
CAS No
RTECS Code
Description
MSDS Availability Code
STEL
STL Sampling Duration
Hazard Class

Taxonomy

TAXONOMY [ADA 1000.3]
Taxonomy Identifier
Taxonomy Name

Etiology ADA CONCEPT MODEL: ETIOLOGY

ETIOLOGY [ADA 1000.14]
Etiology Code
Etiology type

Service ADA CONCEPT MODEL: TREATMENT

SERVICE [ADA 1000.16]
Service Identifier
Service Term
Service Type
Service Description

Location

LOCATION [ADA 1000.6]
Location Identifier
Location Name

Anatomic Location ADA CONCEPT MODEL: ANATOMIC LOCATION

ANATOMIC LOCATION [ADA]
Anatomic Code
Anatomic Location Type

Laboratory Procedure

LABORATORY PROCEDURE [ASTM]
Laboratory Procedure Identifier
Laboratory Procedure Name
ICD-10 PCS Code

DOSE FORM

Dose Form Name
Dose Form Abbrev/Code

ROUTE OF ADMINISTRATION

Route of Administration Name

Route of Administration Abbrev/Code

SITE OF ADMINISTRATION

Site of Administration Name

Site of Administration Abbrev/Code

METHOD OF ADMINISTRATION

Method of Administration Name

Method of Administration Abbrev/Code

DRUG PRODUCT COLOR

Drug Product Color Name

Drug Product Color Abbrev/Code

SHAPE

Drug Product Shape Name

Drug Product Shape Abbrev/Code

FLAVOR

Drug Product Flavor Name

Drug Product Flavor Abbrev/Code

COATING

Drug Product Coating Name

Drug Product Coating Abbrev/Code

SCORING

Drug Product Scoring Name

Drug Product Scoring Abbrev/Code

THERAPEUTIC CLASS

Therapeutic Class Name

Therapeutic Class Code

THERAPEUTIC ACTION

Therapeutic Action Name

Therapeutic Action Code

COMPOSITE TYPE

Composite Type Name

Composite Type Abbrev/Code

GENE

Gene Name

Gene ID

Gene Abbrev/Code

PROTEIN

Protein Name

Protein Identifier

LOINC

LOINC Measurement/Observation Name

LOINC Code

IVD Measurement Product----->PRODUCT

PRODUCT

Product ID

Product Name

Product Type

ENZYME

Enzyme Name

Enzyme Abbrev/Code

Protein ID----->PROTEIN

PHARMACOTHERAPY PATHOLOGY EFFECT

Pharmacotherapy Pathology Effect Name

Pharmacotherapy Pathology Effect Abbrev/Code

Pharmacotherapy Pathology Effect Description

INDUCTION/REPRESSION

Induction/Repression Effect Name

Induction/Repression Code

Digital-Anatomist FOUNDATIONAL MODEL

Anatomic Term

Location ID

REFERENCES

- (1) Zachman, J. A., *IBM Systems Journal*, Vol 26, No. 3, 1987.
- (2) O'Docherty, M., *Object Oriented Analysis and Design: Understanding System Development with UML*, Wiley 2005.
- (3) Integration Definitions for Functional Modeling (IDEF0) Federal Information Processing Standard 183, Gaithersburg, MD: National Institute of Standards and Technology, 1993.
- (4) Jacobsen, I., *Object Oriented Software Engineering: A Use Case Driven Approach*, Addison-Wesley, Reading MA, 1992.
- (5) DeMarco, T., *Structured Analysis and System Specification*, Prentice Hall, 1978.
- (6) *LOINC Users' Guide*, Regenstrief Institute, Inc., Indianapolis, IN.
- (7) Forrey, A. W., McDonald, C. J., et al, *Clinical Chemistry*, Vol 42, 1996, pp. 81-90.
- (8) HL7 Framework for Message Development, Health Level Seven Inc., Ann arbor MI.
- (9) Moore, J. W., *Software Engineering Standards: a Users Road Map*, IEEE, Washington, DC, 1998.
- (10) Young, D. C., Nipper, H., and Hicks, J., and Uddin, D., *Clinician and Chemist: The Relationship of the Laboratory and the Physician*, AACC, 1979.
- (11) Chen, P., *ACM Transactions in Database Systems Research*, 1976.

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